COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: August 1, 2024 Notification Posted: June 17, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for August 1, 2024

POLICIES REVISED

• Program Summary: Androgens and Anabolic Steroids

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
231000300020		testosterone td soln	30 MG/ACT	2	Bottles	30	DAYS				
231000300085	Androderm	testosterone td patch	2 MG/24HR ; 4 MG/24HR	30	Patches	30	DAYS				
23100030004044	Androgel	Testosterone TD Gel 20.25 MG/1.25GM (1.62%)	20.25 MG/1.25GM	30	Packets	30	DAYS				
23100030004025	Androgel	Testosterone TD Gel 25 MG/2.5GM (1%)	25 MG/2.5GM	60	Packets	30	DAYS				
23100030004047	Androgel	Testosterone TD Gel 40.5 MG/2.5GM (1.62%)	40.5 MG/2.5GM	60	Packets	30	DAYS				
23100030004030	Androgel ; Testim ; Vogelxo	Testosterone TD Gel 50 MG/5GM (1%)	1 % ; 50 MG/5GM	60	Tubes	30	DAYS				
23100030004030	Androgel ; Testim ; Vogelxo	Testosterone TD Gel 50 MG/5GM (1%)	1 % ; 50 MG/5GM	60	Packets	30	DAYS				
23100030004050	Androgel pump	Testosterone TD Gel 20.25 MG/ACT (1.62%)	1.62 %	2	Bottles	30	DAYS				
23100030004070	Fortesta	Testosterone TD Gel 10MG/ACT (2%)	10 MG/ACT	2		30	DAYS				
23100030004080	Natesto	Testosterone Nasal Gel 5.5 MG/ACT	5.5 MG/ACT	3		30	DAYS				
23100030004040	Vogelxo pump	Testosterone TD Gel 12.5 MG/ACT (1%)	1 %	4	Bottles	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Prior Authorization with Quantity Limit	**TARGET AGENT(S)** **Topical Androgen Agents:** **Androderm®** (testosterone transdermal system) **AndroGel®** (testosterone gel)* **Fortesta®** (testosterone gel)* **Natesto®** (testosterone nasal gel) **Testim®** (testosterone gel)*

Module	Clinical Criteria for Approval
	Testosterone solution **Vogelxo®** (testosterone gel)* * – Generic available and included in prior authorization and quantity limit programs. **Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. If the request is for Androderm, Androgel, Testosterone gel, testosterone solution, Fortesta, Natesto, Testim, or Vogelxo, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. AIDS/HIV-associated wasting syndroms **OR** 3. Gender identity disorder (GID), gender dysphoria, or gender incongruence **OR** B. If the request is for Depo-Testosterone, testosterone enanthate, or Xyosted, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. AIDS/HIV-associated wasting syndrome **OR** 3. Delayed puberty in an adolescent **OR** 4. Metastatic/inoperable breast cancer **OR** 5. Gender identity disorder (GID), gender dysphoria, or gender incongruence **OR** C. If the request is for Testopel, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. Delayed puberty in an adolescent **OR** 3. Gender identity disorder (GID), gender dysphoria, or gender incongruence **OR** D. If the request is for danazol, the patient has a diagnosis of ONE of the following: 1. Endometriosis amenable to hormone management **OR** 2. Angioedema and will be taking for the prevention of attacks **OR** 3. Myeloproliferative neoplasms **OR** 4. Fibrocystic breast disease **OR** E. If the request is for Jatenzo, the patient has a diagnosis of primary or secondary (hypogonadotropic) hypogonadism **OR** F. If the request is for Aveed, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. Gender identity disorder (GID), gender dysphoria, or gender incongruence **OR** G. If the request is for methyltestosterone or Methitest, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. Metastatic/inoperable breast cancer **OR** 3. Delayed puberty in an adolescent **AND** 2. ONE of the following: A. If the request is for primary or secondary hypogonadism, then ONE of the following: 1. The patient is NOT currently receiving testosterone replacement therapy AND meets BOTH of the following: A. The patient has a sign or symptom of hypogonadism **AND** B. The patient has ONE of the following pretreatment levels: 1. Total serum testosterone level that is below the testing laboratory's normal range or is less than 300 ng/dL **OR** 2. Free serum testosterone level that is below the testing laboratory's normal range **OR** 2. The patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels:

Module	Clinical Criteria for Approval
	A. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR** B. Free serum testosterone level that is within OR below the testing laboratory's normal range **OR** B. If the request is for AIDS/HIV-associated wasting syndrome, BOTH of the following: 1. ONE of the following: A. The patient has had an unintentional weight loss that meets ONE of the following: 1. 10% within 12 months **OR** 2. 7.5% within 6 months **OR** B. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months **OR** C. The patient's sex is male and has BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/m2 **OR** D. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m2 **OR** E. There is support that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/m2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex **OR** F. The patient's BMI is less than 20 kg/m2 **AND** 2. All other causes of weight loss have been ruled out **OR** C. If the request is for gender identity disorder (GID), gender dysphoria, or gender incongruence, ONE of the following: 1. The patient is an adolescent and ONE of the following: A. The patient is initiating sex hormone treatment AND ALL of the following: 1. A persistent diagnosis was confirmed by a mental health professional and/or trained physician who is trained in child and adolescent developmental psychopathology **AND** 2. The patient's indication for sex hormone treatment has been confirmed by an endocrinologist OR clinician experienced in pubertal sex hormone induction **AND** 3. The patient does not have any medical contraindications to sex hormone treatment as confirmed by an endocrinologist OR clinician experienced in pubertal sex hormone induction **AND** 4. The patient has been informed and counseled regarding effects and side effects of sex hormone treatment including those which are irreversible, and regarding loss of fertility and options to preserve fertility **AND** 5. ONE of the following: A. The patient is 16 years of age or over **OR** B. There is support for initiating therapy prior to 16 years of age **AND** 6. The patient has sufficient mental capacity to give consent **AND** 7. The patient has provided consent AND, as applicable, the parents or other caretakers or guardians have provided consent to therapy **AND** 8. The patient's coexisting psychological, medical, or social problems that could interfere with treatment have been addressed and the patient's functioning is stable enough to start sex hormone therapy **OR** B. The patient is continuing therapy with sex hormone treatment AND the patient is being monitored at least once per year **OR** 2. The patient is an adult AND ONE of the following: A. The patient is initiating sex hormone treatment AND ALL of the following: 1. A persistent diagnosis has been confirmed by a mental health professional **AND** 2. The patient has sufficient mental capacity to give consent **AND**

Module	Clinical Criteria for Approval

3. The patient's coexisting mental health concerns, if present, are reasonably well controlled **AND**
4. The patient's medical conditions that can be exacerbated by treatment with sex hormones have been evaluated and addressed **OR**

B. The patient is currently on sex hormone treatment and BOTH of the following:
1. ONE of the following:
A. The patient's current testosterone level is ONE of the following:
1. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR**
2. Free serum testosterone level that is within OR below the testing laboratory's normal range **OR**
B. There is support for continuing therapy with the patient's current testosterone level **AND**
2. The patient is being monitored at least once per year **OR**

D. If the request is for delayed puberty in an adolescent, then ONE of the following:
1. The patient's sex is male **OR**
2. There is support that the requested agent is medically appropriate for the patient's sex **OR**

E. If the request is for metastatic/inoperable breast cancer, then ONE of the following:
1. The patient's sex is female **OR**
2. There is support that the requested agent is medically appropriate for the patient's sex **OR**

F. The request is for fibrocystic breast disease **OR**

G. The request is for endometriosis amenable to hormone management **OR**

H. The request is for the prevention of attacks of angioedema **OR**

I. If the request is for myeloproliferative neoplasms, ONE of the following:
1. Patient has a serum EPO greater than or equal to 500 mU/mL **OR**
2. Patient has a serum EPO less than 500 mU/mL and no response or loss of response to erythropoietic stimulating agents **OR**

J. The request is for bone pain frequently accompanying osteoporosis **OR**

K. If the request is to promote weight gain, the patient has ONE of the following:
1. weight loss following extensive surgery **OR**
2. chronic infections **OR**
3. severe trauma **OR**
4. failure to gain or maintain normal weight without definite pathophysiologic reasons **OR**
5. a prolonged administration of corticosteroids **AND**

3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
4. If the request is for one of the following brand agents, then ONE of the following:

Brand Agent(s)
Androderm
Androgel
Fortesta
Natesto
Testim
Testosterone gel
Vogelxo

A. The patient has tried and had an inadequate response to a generic androgen or anabolic steroid agent that is supported for use for the requested indication **OR**

Module	Clinical Criteria for Approval
	B. The patient has an intolerance or hypersensitivity to a generic androgen or anabolic steroid agent that is supported for use for the requested indication that is not expected to occur with the brand agent **OR** C. The patient has an FDA labeled contraindication to ALL generic androgen or anabolic steroid agents that is supported for use for the requested indication that is not expected to occur with the brand agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL generic androgen or anabolic steroid agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with another androgen or anabolic steroid agent for the requested indication **OR** B. There is support for therapy with more than one androgen or anabolic steroid agent **Length of Approval:** 6 months (delayed puberty only); 12 months (all other indications) NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** Target Agent(s) will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. ONE of the following: A. The patient has a diagnosis of primary or secondary hypogonadism and the patient's current testosterone level is ONE of the following: 1. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR** 2. Free serum testosterone level that is within OR below the testing laboratory's normal range **OR** B. The patient has a diagnosis of gender identity disorder (GID), gender dysphoria, or gender incongruence AND ONE of the following: 1. If the patient is an adult, BOTH of the following: A. The patient is being monitored at least once per year **AND** B. ONE of the following: 1. The patient's current testosterone level is ONE of the following: A. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR** B. Free serum testosterone level that is within OR below the testing laboratory's normal range **OR** 2. There is support for continuing therapy with the patient's current testosterone level **OR**

Module	Clinical Criteria for Approval
	2. If the patient is an adolescent, the patient is being monitored at least once per year **OR** C. The patient has a diagnosis other than primary or secondary hypogonadism, gender identity disorder (GID), gender dysphoria, or gender incongruence **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. If the request is for one of the following brand agents, then ONE of the following: **Brand Agent(s)** Androderm Androgel Fortesta Natesto Testim Testosterone gel Vogelxo A. The patient has tried and had an inadequate response to a generic androgen or anabolic steroid agent that is supported for use for the requested indication **OR** B. The patient has an intolerance or hypersensitivity to a generic androgen or anabolic steroid agent that is supported for use for the requested indication that is not expected to occur with the brand agent **OR** C. The patient has an FDA labeled contraindication to ALL generic androgen or anabolic steroid agents that is supported for use for the requested indication that is not expected to occur with the brand agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL generic androgen or anabolic steroid agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with another androgen or anabolic steroid agent for the requested indication **OR** B. There is support for therapy with more than one androgen or anabolic steroid agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested agent does NOT have a program quantity limit **OR** 2. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND**

Module	Clinical Criteria for Approval
	B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 4. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support of therapy with a higher dose for the requested indication **Length of Approval:** Initial: up to 6 months (delayed puberty only), up to 12 months (all other indications). Renewal: up to 12 months

● Program Summary: Anti-COVID19

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
12700046000120	Lagevrio	Molnupiravir Cap	200 MG	40	Capsules	30	DAYS				
1299000255B710	Paxlovid	Nirmatrelvir Tab	10 x 150 MG & 10 x 100MG	20	Tablets	30	DAYS				
1299000255B720	Paxlovid	Nirmatrelvir Tab	20 x 150 MG & 10 x 100MG	30	Tablets	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when **ALL** of the following are met: 1. The patient is using the requested agent for a COVID-19 reinfection **AND** 2. The patient's age is within FDA labeling OR Emergency Use Authorization (EUA) for the requested indication for the requested agent **AND** 3. The requested agent is NOT being used to extend treatment beyond the maximum FDA labeling OR EUA treatment regimen for the requested indication **AND** 4. The patient will NOT be using the requested agent in combination with another agent in this program for the requested indication **AND** 5. The requested quantity (dose) does NOT exceed the maximum FDA labeling OR EUA dosing for the requested indication **Length of Approval:** 1 additional course of therapy for 1 month

• Program Summary: Biologic Immunomodulators

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001507F810	Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001507F820	Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001507F520	Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	4	Syringes	28	DAYS				
6650007000D5	Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9ML	4	Pens	28	DAYS				
6627001510D517	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001510D537	Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS				
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E508	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E517	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
9025051800D520	Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	2	Pens	56	DAYS				
9025051800E520	Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	2	Syringes	56	DAYS				
525050201064	Cimzia	certolizumab pegol for inj kit	200 MG	2	Kits	28	DAYS				
5250502010F840	Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	2	Kits	28	DAYS				
5250502010F860	Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	1	Kit	180	DAYS				
9025057500E530	Cosentyx	Secukinumab Subcutaneous Pref	150 MG/ML	2	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Syr 150 MG/ML (300 MG Dose)									
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	1	Syringe	28	DAYS				
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS				
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS				
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS				
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00597037597 ; 00597054522 ; 82009014822			
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037516 ; 00597054566			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037523 ; 00597054544			
662900300021	Enbrel	etanercept for subcutaneous inj	25 MG	8	Vials	28	DAYS				
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	8	Vials	28	DAYS				
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	4	Syringes	28	DAYS				
6629003000E530	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS				
6629003000E2	Enbrel mini	etanercept subcutaneous solution cartridge	50 MG/ML	4	Cartridges	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6629003000D5	Enbrel sureclick	etanercept subcutaneous solution auto-injector	50 MG/ML	4	Pens	28	DAYS				
5250308000D220	Entyvio	vedolizumab soln pen-injector	108 MG/0.68ML	2	Pens	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1ML	2	Syringes	28	DAYS				
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F840	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8ML	1	Kit	180	DAYS				
6627001500F880	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	00074012402 ; 83457012402			
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS				
6627001500F440	Humira pen-cd/uc/hs start	adalimumab pen-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012403			
6627001500F420	Humira pen-cd/uc/hs start	Adalimumab Pen-injector Kit ;	40 MG/0.8ML	1	Kit	180	DAYS	00074433906			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		adalimumab pen-injector kit									
6627001500F440	Humira pen-pediatric uc s	adalimumab pen-injector kit	80 MG/0.8ML	4	Pens	180	DAYS	00074012404			
6627001500F420	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433907			
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001504D540	Hyrimoz ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS	61314045420 ; 83457010701			
6627001504D540	Hyrimoz crohn's disease a ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	1	Starter Kit	180	DAYS	61314045436 ; 83457011301			
6627001504E560	Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4ML	2	Syringes	180	DAYS				
6627001504E540	Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8ML	3	Syringes	180	DAYS				
6627001504D560	Hyrimoz plaque psoriasis	adalimumab-adaz soln auto-injector	80 MG/0.8ML & 40MG/0.4ML	1.6	Starter Kit	180	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001502F540	Idacio (2 pen)	adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219055408 ; 65219061299			
6627001502F840	Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	1	Kit	28	DAYS				
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055438			
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055428			
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML ; 200 MG/1.14ML	2	Syringes	28	DAYS				
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML ; 200 MG/1.14ML	2	Pens	28	DAYS				
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	28	Syringes	28	DAYS				
90731060100120	Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS				
666030100003	Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	30	Tablets	30	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS				
6640001000D5	Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	4	Syringes	28	DAYS				
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS				
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS				
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	2	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001540F520	Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS				
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
9025057070F8	Skyrizi	risankizumab-rzaa sol prefilled syringe	75 MG/0.83ML	1	Box	84	DAYS				
9025057070E5	Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	1	Injection Device	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridges	56	DAY				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridges	56	DAYS				
9025057070D5	Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	1	Pen	84	DAYS				
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS				
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS				
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	1	Syringe	84	DAYS				
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS				
9025055400D5	Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	1	Syringe	28	DAYS				
9025055400E5	Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	1	Syringe	28	DAYS				
9025054200D2	Tremfya	guselkumab soln pen-injector	100 MG/ML	1	Pen	56	DAYS				
9025054200E5	Tremfya	guselkumab soln prefilled syringe	100 MG/ML	1	Syringe	56	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
52504525100350	Velsipity	etrasimod arginine tab	2 MG	30	Tablets	30	DAYS				
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS				
66603065100330	Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS				
66603065100320	Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS				
66603065107530	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS				
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS				
6627001503F530	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002209 ; 72606003009			
6627001503F560	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	72606002304 ; 72606004004			
6627001503F530	Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002210 ; 72606003010			
6627001503F820	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001503F830	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4ML	1	Kit	28	DAYS				
6627001503F560	Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	72606002307			
6627001509D240	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8ML	2	Pens	28	DAYS				
5250504020F530	Zymfentra 1-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002501			
5250504020F530	Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002502			
5250504020F830	Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	2	Syringes	28	DAYS				

PREFERRED AGENTS

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Option A - FlexRx, GenRx, BasicRx, and KeyRx	**Step Table**

Disease State	Step 1		Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO step 1 agents)	Step 3b (Directed to TWO agents from step 1	Step 3c (Directed to THREE step 1 agents)
	Step 1a	Step 1b (Directed to ONE TNF				

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			inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors			**and/or step 2)**	
	Rheumatoid Disorders						
	Ankylosing Spondylitis (AS)	SQ: Cosentyx, Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz	SQ: Actemra (Hadlima, or Humira is a required Step 1 agent)	N/A	SQ: Orencia	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Psoriatic Arthritis (PsA)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Rheumatoid Arthritis	SQ: Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Hadlima, or Humira is a required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Dermatological Disorder						

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	Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Psoriasis (PS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	Oral: Sotyktu	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Amjevita**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Simlandi**, Taltz, Yuflyma**, Yusimry**
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Hadlima, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Hadlima, or Humira is a required Step 1 agent)	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**, Zymfentra
	Ulcerative Colitis	SQ: Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Had lima, or Humira is a required Step 1 agent)	N/A	SQ: Entyvio Oral: Zeposia (Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz/Xelj anz XR are required Step agents)	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Omvoh, Simlandi**, Yuflyma**, Yusimry**, Zymfentra Oral Velsipity

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	Other						
	Uveitis	SQ: Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	N/A	N/A	N/A	N/A	N/A	N/A
	*Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product **Note: Hadlima and Humira are required Step 1 agents						

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Note: Branded generic available for Cyltezo, Idacio, Hulio, Hyrimoz, and Yuflyma and are included as a target at same step level in this program

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. ONE of the following:
    A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy: Abrilada Amjevita Cyltezo, Adalimumab-adbm Hulio, Adalimumab-fkjp Hyrimoz, Adalimumab-adaz Idacio, Adalimumab-aacf Omvoh Simlandi Yuflyma, Adalimumab-aaty Yusimry Zymfentra

        1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
        2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

    B. ALL of the following:
        1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following:
            A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following:
                1. ONE of the following:
                    A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **OR**
                    B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy **OR**
                    C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR**

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	D. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the request is for Simponi, ONE of the following: A. The patient will be taking the requested agent in combination with methotrexate **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR** B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

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	B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR** 4. The patient has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 5. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PS **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone,

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	budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR** 2. The patient has severely active ulcerative colitis **OR** 3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** 5. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR** 6. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 7. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to

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	achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 2-week duration of therapy **OR** 2. The patient has tried and had an inadequate response to periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an intolerance or hypersensitivity to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that BOTH oral corticosteroids and periocular/intravitreal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-

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	infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA after at least a 7-10 day duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR** 3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of GCA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of AS after at least a 4-week total trial **OR**

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	2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of AS **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of nr-axSpA after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of nr-axSpA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of nr-axSpA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of nr-axSpA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PJIA **OR**

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	3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PJIA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** K. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction,

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	decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** L. BOTH of the following: 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR** M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of ERA after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **OR** D. The patient has an Investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD after at least a 4-week duration of therapy **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy **OR** B. The patient has an intolerance or hypersensitivity to at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**

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	C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 4. BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND** B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** O. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR after at least an 8-week duration of therapy **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain

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	reasonable functional ability in performing daily activities or cause physical or mental harm **OR** Q. The patient has a diagnosis of juvenile psoriatic arthritis (JPsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of JPsA **OR** 3. The patient has an FDA labeled contraindication to methotrexate **OR** 4. The patient has severe active JPsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to JPsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of JPsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** R. The patient has a diagnosis not mentioned previously **AND** 2. ONE of the following (reference Step Table): A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR** B. The requested agent is a Step 1a agent for the requested indication **OR** C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested indication after at least a 3-month duration of therapy (See Step 1a for preferred TNF inhibitors) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR** 4. BOTH of the following: A. ALL TNF inhibitors are not clinically appropriate for the patient **AND**

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	B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL TNF inhibitors for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE of the required Step 1 agents for the requested indication after at least a 3-month duration of therapy (See Step 2) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the required Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the required Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3a) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration or hypersensitivity to TWO of the Step 1 agents for the requested indication **OR**

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	3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication after at least a 3-month trial per agent (See Step 3b) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO agents from Step 1 and/or Step 2 for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (chart notes required):

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	1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3c) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If Cosentyx 300 mg is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 4. If Omvoh is requested for the treatment of ulcerative colitis, ONE of the following: A. the patient has received Omvoh IV for induction therapy **OR** B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND** 5. If Entyvio is requested for the treatment of ulcerative colitis, ONE of the following: A. The patient has received at least 2 doses of Entyvio IV therapy **OR** B. The patient is new to therapy and will receive 2 doses of Entyvio IV therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease, ONE of the following A. The patient received Skyrizi IV for induction therapy **OR** B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND** 7. If an ustekinumab product is requested for the treatment of Crohn's disease or ulcerative colitis, ONE of the following: A. The patient received an ustekinumab IV product for induction therapy **OR** B. The patient is new to therapy and will receive an ustekinumab IV product for induction therapy **AND**

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	8. If Zymfentra is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following: A. The patient received an infliximab IV product for induction therapy **OR** B. The patient is new to therapy and will receive an infliximab IV product for induction therapy **AND** 9. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. If an ustekinumab 90 mg product is requested, then ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

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	1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note ustekinumab product renewal must be for the same strength as the initial approval) [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 4. ONE of the following: A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): 1. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** 2. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 7. If Cosentyx 300 mg is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy AND
8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) AND
9. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Length of Approval: 12 months

**NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</td></tr>
<tr><td>Option B - Focus Rx</td><td>Step Table
<table>
<tr><th rowspan="2">Disease State</th><th colspan="2">Step 1</th><th rowspan="2">Step 2 (Directed to ONE step 1 agent)</th><th rowspan="2">Step 3a (Directed to TWO step 1 agents)</th><th rowspan="2">Step 3b (Directed to TWO agents from step 1 and/or step 2)</th><th rowspan="2">Step 3c (Directed to THREE step 1 agents)</th></tr>
<tr><th>Step 1a</th><th>Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors</th></tr>
<tr><td colspan="7">Rheumatoid Disorders</td></tr>
<tr><td>Ankylosing Spondylitis (AS)</td><td>SQ: Cosentyx, Cyltezo, Enbrel, Humira</td><td>Oral: Rinvoq, Xeljanz, Xeljanz XR</td><td>N/A</td><td>SQ: Cimzia, Simponi, Taltz</td><td>N/A</td><td>SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**</td></tr>
<tr><td>Nonradiographic Axial Spondyloarthritis (nr-axSpA)</td><td>SQ: Cimzia, Cosentyx</td><td>Oral: Rinvoq</td><td>N/A</td><td>SQ: Taltz</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Polyarticular Juvenile Idiopathic Arthritis (PJIA)</td><td>SQ: Cyltezo, Enbrel, Humira</td><td>Oral: Rinvoq, Xeljanz</td><td>SQ: Actemra (Cyltezo or Humira a is required Step 1 agent)</td><td>N/A</td><td>SQ: Orencia</td><td>SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**</td></tr>
</table></td></tr>
</table>

Module	Clinical Criteria for Approval						
	Psoriatic Arthritis (PsA)	SQ: Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita*, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Rheumatoid Arthritis	SQ: Cyltezo, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Cyltezo or Humira is a required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Psoriasis (PS)	SQ: Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	Oral: Sotyktu	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Amjevita**, Bimzelx, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Siliq, Simlandi**, Taltz, Yuflyma**, Yusimry**
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Cyltezo, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Cyltezo, or Humira is a required	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**,

Module	Clinical Criteria for Approval						
					Step 1 agent)		Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**, Zymfentra
	Ulcerative Colitis	SQ: Cyltezo, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Cyltezo , or Humira is required Step 1 agent)	N/A	SQ: Entyvio Oral: Zeposia (Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Omvoh, Simlandi**, Yuflyma**, Yusimry**, Zymfentra Oral: Velsipity
	Other						
	Uveitis	SQ: Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA)	N/A	N/A	N/A	N/A	N/A	N/A

Module	Clinical Criteria for Approval

Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

*Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product
**Note: Cyltezo and Humira are required Step 1 agents
Note: Branded generic available for Cyltezo, Idacio, Hulio, Hyrimoz, and Yuflyma and are included as a target at same step level in this program

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. ONE of the following:
    A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy: Abrilada Amjevita Hadlima Hulio, Adalimumab-fkjp Hyrimoz, Adalimumab-adaz Idacio, Adalimumab-aacf Omvoh

Module	Clinical Criteria for Approval
	Simlandi Yuflyma, Adalimumab-aaty Yusimry Zymfentra 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following: A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **OR** B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy **OR** C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** D. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the request is for Simponi, ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient will be taking the requested agent in combination with methotrexate **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR** B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR** 4. The patient has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR**

Module	Clinical Criteria for Approval
	5. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PS **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

Module	Clinical Criteria for Approval
	E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR** 2. The patient has severely active ulcerative colitis **OR** 3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** 5. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR** 6. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 7. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 2-week duration of therapy **OR** 2. The patient has tried and had an inadequate response to periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an intolerance or hypersensitivity to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval
	B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that BOTH oral corticosteroids and periocular/intravitreal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA after at least a 7-10 day duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR** 3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of GCA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of AS after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of AS **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of nr-axSpA after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of nr-axSpA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of nr-axSpA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of nr-axSpA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PJIA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PJIA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** K. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following:

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	1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** L. BOTH of the following: 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR** M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of ERA after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

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	B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **OR** D. The patient has an Investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD after at least a 4-week duration of therapy **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy **OR** B. The patient has an intolerance or hypersensitivity to at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND**

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	4. BOTH of the following: 1. The patient is currently treated with topical emollients and practicing good skin care **AND** 2. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** O. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR after at least an 8-week duration of therapy **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** Q. The patient has a diagnosis of juvenile psoriatic arthritis (JPsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of JPsA **OR** 3. The patient has an FDA labeled contraindication to methotrexate **OR** 4. The patient has severe active JPsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to JPsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of JPsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents used in the treatment of JPsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** R. The patient has a diagnosis not mentioned previously **AND** 2. ONE of the following (reference Step Table): A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR** B. The requested agent is a Step 1a agent for the requested indication **OR** C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested indication after at least a 3-month duration of therapy (See Step 1a for preferred TNF inhibitors) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR** 4. BOTH of the following: A. ALL TNF inhibitors are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL TNF inhibitors for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE of the required Step 1 agents for the requested indication after at least a 3-month duration of therapy (See Step 2) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the required Step 1 agents for the requested indication **OR**

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	3. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the required Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3a) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration or hypersensitivity to TWO of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (chart notes required):

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	1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication after at least a 3-month trial per agent (See Step 3b) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO agents from Step 1 and/or Step 2 for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3c) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical

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	condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If Cosentyx 300 mg is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 4. If Omvoh is requested for the treatment of ulcerative colitis, ONE of the following: A. The patient has received Omvoh IV for induction therapy **OR** B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND** 5. If Entyvio is requested for the treatment of ulcerative colitis, ONE of the following: A. The patient has received at least 2 doses of Entyvio IV therapy **OR** B. The patient is new to therapy and will receive at least 2 doses of Entyvio IV therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease, ONE of the following: A. The patient received Skyrizi IV for induction therapy **OR** B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND** 7. If an ustekinumab product is requested for the treatment of Crohn's disease or ulcerative colitis, ONE of the following: A. The patient received an ustekinumab IV product for induction therapy **OR** B. The patient is new to therapy and will receive an ustekinumab IV product for induction therapy **AND** 8. If Zymfentra is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following: A. The patient received an infliximab IV product for induction therapy **OR** B. The patient is new to therapy and will receive an infliximab IV product for induction therapy **AND** 9. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. If an ustekinumab 90 mg product is requested, then ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):

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	A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note ustekinumab product renewal must be for the same strength as the initial approval) [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 4. ONE of the following: A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND**

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	2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): 1. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** 2. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 7. If Cosentyx 300 mg is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL All Program Type	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:

Module	Clinical Criteria for Approval
	A. The requested agent is Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis, AND BOTH of the following: 1. There is support for therapy for the dose exceeding the quantity limit [e.g., patient has lost response to the FDA labeled maintenance dose (i.e., 5 mg twice daily or 11 mg once daily) during maintenance treatment; requires restart of induction therapy] (medical records required) **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR** B. The requested agent is Xeljanz oral solution for a diagnosis of polyarticular course juvenile idiopathic arthritis, AND ONE of the following: 1. BOTH of the following: A. The requested quantity (dose) does not exceed the maximum FDA labeled dose (i.e., 5 mg twice daily) NOR the maximum compendia supported dose **AND** B. There is support why the patient cannot take Xeljanz 5 mg tablets **OR** 2. The requested quantity (dose) exceeds the maximum FDA labeled dose but does NOT exceed the maximum compendia supported dose for the requested indication **OR** 3. BOTH of the following: A. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** B. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** C. The requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, AND ONE of the following: 1. The patient has an FDA labeled indication for the requested agent, AND ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does NOT exceed the program quantity limit **OR** B. ALL of the following: 1. The requested quantity (dose) exceeds the FDA maximum labeled dose **AND** 2. The patient has tried and had an inadequate response to at least a 3 month duration of therapy at the maximum FDA labeled dose (medical records required) **AND** 3. ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** 2. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR**

Module	Clinical Criteria for Approval
	2. The patient has a compendia supported indication for the requested agent, AND ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication **AND** 2. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 3. The patient does NOT have an FDA labeled indication NOR a compendia supported indication for the requested agent AND BOTH of the following: A. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **AND** B. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** **Initial Approval with PA**: up to 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for up to 12 weeks, Rinvoq for AD may be approved for up to 6 months, Siliq for PS may be approved for up to 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for up to 16 weeks. **Renewal Approval with PA:** up to 12 months **Standalone QL approval:** up to 12 months or through the remainder of an existing authorization, whichever is shorter **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.

Contraindication Agents

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab)

Contraindicated as Concomitant Therapy
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)

Contraindicated as Concomitant Therapy
Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Calcitonin Gene-Related Peptide (CGRP)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
67701060707220	Nurtec	Rimegepant Sulfate Tab Disint 75 MG	75 MG	16	Tablets	30	DAYS				
67701010000310	Qulipta	Atogepant Tab	10 MG	30	Tablets	30	DAYS				
67701010000320	Qulipta	Atogepant Tab	30 MG	30	Tablets	30	DAYS				
67701010000330	Qulipta	Atogepant Tab	60 MG	30	Tablets	30	DAYS				
67701080000340	Ubrelvy	Ubrogepant Tab 100 MG	100 MG	16	Tablets	30	DAYS				
67701080000320	Ubrelvy	Ubrogepant Tab 50 MG	50 MG	16	Tablets	30	DAYS				
6770202010D540	Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 140 MG/ML	140 MG/ML	1	Injection Device	28	DAYS				
6770202010D520	Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 70 MG/ML	70 MG/ML	1	Injection Device	28	DAYS				
6770203530D520	Emgality	Galcanezumab-gnlm Subcutaneous Soln Auto-Injector 120 MG/ML	120 MG/ML	1	Injection Device	28	DAYS				
6770203530E515	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 100 MG/ML	100 MG/ML	9	Syringes	180	DAYS				
6770203530E520	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 120 MG/ML	120 MG/ML	1	Syringe	28	DAYS				
6770203020D520	Ajovy	Fremanezumab-vfrm Subcutaneous Soln Auto-inj 225 MG/1.5ML	225 MG/1.5ML	3	Injection Devices	84	DAYS				
6770203020E520	Ajovy	Fremanezumab-vfrm Subcutaneous Soln Pref Syr 225 MG/1.5ML	225 MG/1.5ML	3	Syringes	84	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Indication	Preferred Agent(s)	Non-Preferred Agent(s)	Stand Alone Target Agent(s)
	Preferred and non-preferred target agents - to be determined by client	Preferred and non-preferred target agents - to be determined by client	
Chronic Migraine Prophylaxis	Aimovig, AJOVY, Emgality, QULIPTA		
Episodic Migraine Prophylaxis	Aimovig, AJOVY, Emgality, Nurtec, QULIPTA		
Episodic Cluster Headaches	Emgality		
Acute Migraine Treatment	Nurtec, UBRELVY		Zavzpret

Initial Evaluation
Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
    A. The requested agent is being used for migraine prophylaxis AND ALL of the following:
        1. ONE of the following:
            A. The patient has at least 15 migraine headache days per month of migraine-like or tension-like headache for a minimum of 3 months (chronic migraine) AND ALL of the following:
                1. The patient has at least 8 migraine headache days per month for a minimum of 3 months **AND**
                2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP **AND**
                3. The requested agent and strength are FDA labeled for chronic migraine prophylaxis **OR**
            B. The patient has 4-14 monthly migraine headache days (episodic migraine) AND ALL of the following:
                1. The patient has experienced at least moderate disability due to migraines as indicated by ONE of the following:
                    A. Migraine Disability Assessment (MIDAS) score greater than or equal to 11 **OR**
                    B. Headache Impact Test (HIT-6) greater than 50 **AND**
                2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP agent **AND**
                3. The requested agent and strength are FDA labeled for episodic migraine prophylaxis **AND**
        2. ONE of the following:
            A. The patient has tried and had an inadequate response to at least one migraine prophylaxis class [i.e., anticonvulsants (divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] **OR**
            B. The patient has an intolerance or hypersensitivity to therapy with at least one migraine prophylaxis class listed above **OR**
            C. The patient has an FDA labeled contraindication to ALL migraine prophylaxis agents listed above **OR**

Module	Clinical Criteria for Approval
	D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL migraine prophylaxis class (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If the client has a preferred agent, then ONE of the following: A. The requested agent is a preferred agent or a stand-alone agent for the requested indication **OR** B. The requested agent is a non-preferred agent and ONE of the following: 1. The patient has tried and had an inadequate response to ONE preferred agent for the requested indication **OR** 2. The patient has tried has an intolerance or hypersensitivity to ONE preferred agent for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the requested indication **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL preferred agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. Medication overuse headache has been ruled out **OR** B. The requested agent is being used for the treatment of episodic cluster headache AND ALL of the following: 1. The patient has had at least 5 cluster headache attacks **AND** 2. The patient has at least two cluster period lasting 7-365 days **AND** 3. The patient's cluster periods are separated by a pain-free remission period of greater than or equal to 3 months **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to verapamil, melatonin, corticosteroids, topiramate, OR lithium **OR** B. The patient has an intolerance or hypersensitivity to verapamil, melatonin, corticosteroid, topiramate, OR lithium **OR** C. The patient has an FDA labeled contraindication to verapamil, melatonin, corticosteroid, topiramate, AND lithium **OR**

Module	Clinical Criteria for Approval
	D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that verapamil, melatonin, corticosteroids, topiramate, OR lithium cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. Medication overuse headache has been ruled out **AND** 6. The requested agent and strength are FDA labeled for episodic cluster headache treatment **OR** C. The requested agent is being used for acute migraine treatment AND ALL of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to at least one triptan agent **OR** B. The patient has an intolerance or hypersensitivity to a triptan agent **OR** C. The patient has an FDA labeled contraindication to ALL triptan agents **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL triptan agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, triptan, ergotamine) **AND** 3. If the client has a preferred agent, then ONE of the following: A. The requested agent is a preferred agent or a stand-alone agent for the requested indication **OR** B. The requested agent is a non-preferred agent and ONE of the following: 1. The patient has tried and had an inadequate response to ONE preferred agent for the requested indication **OR** 2. The patient has tried has an intolerance or hypersensitivity to ONE preferred agent for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the requested indication **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval
	5. The prescriber has provided documentation that ALL preferred agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. Medication overuse headache has been ruled out **AND** 5. The requested agent and strength are FDA labeled for acute migraine treatment **OR** D. The patient has another FDA labeled indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The patient does not have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** Cluster headache treatment - 6 months; migraine prophylaxis - 6 months; all other indications - 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been approved for the requested agent previously through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The requested agent is being used for migraine prophylaxis AND ALL of the following: 1. The patient has had improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication) with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP for the requested indication **AND** 3. ONE of the following: A. BOTH of the following: 1. The patient has at least 15 migraine headache days per month (chronic migraine) **AND** 2. The requested agent and strength are FDA labeled for chronic migraine **OR** B. BOTH of the following: 1. The patient has 4-14 monthly migraine days (episodic migraine) **AND** 2. The requested agent and strength are FDA labeled for episodic migraine **OR** B. The requested agent is being used for episodic cluster headache treatment AND BOTH of the following: 1. The patient has had improvement in cluster headaches management with the requested agent **AND**

Module	Clinical Criteria for Approval
	2. The requested agent and strength are FDA labeled for episodic cluster headache treatment **OR** C. The requested agent is being used for acute migraine treatment AND ALL of the following: 1. The patient has had improvement in acute migraine management with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, triptan, ergotamine) for the requested indication **AND** 3. The requested agent and strength are FDA labeled for acute migraine treatment **AND** 2. Medication overuse headache has been ruled out **OR** B. The requested agent is being used for an indication other than migraine prophylaxis, episodic cluster headache treatment, or acute migraine treatment AND has had clinical benefit with the requested agent **AND** 3. The patient does not have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity limit for Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. ALL of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. If the requested agent is being used for treatment of acute migraine, then ONE of the following: A. The patient is currently being treated with a migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], onabotulinum toxin A [Botox]) **OR** B. The patient has an intolerance or hypersensitivity to therapy with migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP

Module	Clinical Criteria for Approval
	[e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], OR onabotulinum toxin A [Botox]) **OR** C. The patient has an FDA labeled contraindication to ALL migraine prophylactic medications (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], AND onabotulinum toxin A [Botox]) **OR** D. There is support that the patient's migraine is manageable with acute therapy alone **AND** 3. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of approval up to 12 months.

• Program Summary: Cannabidiol

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	726000170020	Epidiolex	cannabidiol soln	100 MG/ML	M ; N ; O ; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of seizures associated with ONE of the following: A. Lennox-Gastaut syndrome (LGS) **OR** B. Dravet syndrome (DS) **OR** C. Tuberous sclerosis complex (TSC) **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The requested agent will NOT be used as monotherapy for seizure management **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The requested agent will NOT be used as monotherapy for seizure management **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months

• Program Summary: Cibinqo (abrocitinib)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
90272005000320	Cibinqo	Abrocitinib Tab	50 MG	30	Tablets	30	DAYS			09-01-2022	
90272005000325	Cibinqo	Abrocitinib Tab	100 MG	30	Tablets	30	DAYS			09-01-2022	
90272005000330	Cibinqo	Abrocitinib Tab	200 MG	30	Tablets	30	DAYS			09-01-2022	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

Module	Clinical Criteria for Approval
	B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **OR** D. The patient has an investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to at least a mid-potency topical steroid used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**

3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

E. The prescriber has provided documentation that ALL topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

4. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND**

5. BOTH of the following:

A. The patient is currently treated with topical emollients and practicing good skin care **AND**

B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR**

B. The patient has another FDA labeled indication for the requested agent and route of administration **AND**

2. If the patient has an FDA labeled indication, then ONE of the following:

A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

B. There is support for using the requested agent for the patient's age for the requested indication **OR**

C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

2. The patient has been tested for latent tuberculosis (TB) AND if positive the patient has begun therapy for latent TB **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):

A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**

B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:

1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND**

5. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Length of Approval: 6 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

	1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis other than moderate-to-severe atopic dermatitis AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed**: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval**: Initial - up to 6 months, Renewal - up to 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)

Contraindicated as Concomitant Therapy
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Coverage Exception with Quantity Limit – Commercial

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☑ Coverage / Formulary Exception

This program should not be used as formulary exception criteria. Ascensia products are the preferred glucose test strip products.

Weight loss agents must use the Saxenda Wegovy Zepbound Coverage Exception and Formulary Exception criteria.

Weight loss agents on coverage delay must use the Saxenda Wegovy Zepbound Coverage Exception and Formulary Exception criteria for FlexRx Closed, FlexRx Open, GenRx Closed, and GenRx Open.

This criterion does not apply to FocusRx or KeyRx (see appropriate program).

Objective

These criteria apply to any request for agents that are included in the clients Lockout/Excluded Agents list and is not otherwise excluded from coverage under the member's pharmacy benefit.

EXCEPTION CRITERIA FOR APPROVAL

A coverage exception will be granted when ALL of the following are met:

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

Examples of Agents Restricted to Coverage on the Medical Benefit
Insulin Pumps and Insulin Pump Supplies
Route of Administration which is excluded from coverage under the pharmacy benefit

   AND
2. ONE of the following:
   - A. ALL of the following:
     - i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
       AND
     - ii. The member's benefit includes ACA Preventive Care for the category requested
       AND
     - iii. ONE of the following:
       - a. The requested agent is a contraception agent **AND** BOTH of the following:

1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
   AND
2. The requested agent is being used for contraception

OR

b. BOTH of the following:
   1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
      A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
         OR
      B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
         OR
      C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

      AND
   2. ONE of the following:
      A. The requested agent is an aspirin agent **AND** ALL of the following:
         i. The requested agent is the 81 mg strength aspirin
            AND
         ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
            AND
         iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

      OR

      B. The requested agent is a bowel prep agent **AND** ALL of the following:
         i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
            AND
         ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
            AND
         iii. The patient is 45 years of age or over

      OR

      C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
         i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
            AND
         ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
            AND
         iii. The patient is 35 years of age or over
            AND
         iv. The agent is requested for the primary prevention of breast cancer

      OR

      D. The requested agent is a fluoride supplement **AND** BOTH of the following:
         i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
            AND
         ii. The patient is 6 months to 16 years of age

OR

E. The requested agent is a folic acid agent **AND** ALL of the following:
    i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
    AND
    ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
    AND
    iii. The requested folic acid supplement is to be used in support of pregnancy

OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PrEP **AND** ALL of the following:
    i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
    AND
    ii. ONE of the following:
        a. The requested PrEP agent is ONE of the following:
            1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
            OR
            2. Tenofovir alafenamide and emtricitabine combination ingredient agent
            OR
            3. Cabotegravir
        OR
        b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir alafenamide and emtricitabine combination ingredient agent, or cabotegravir is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
    AND
    iii. The patient is at high risk of HIV infection
    AND
    iv. The patient has recently tested negative for HIV

OR

G. The requested agent is an infant eye ointment **AND** ALL of the following:
    i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary
    AND
    ii. The patient is 3 months of age or younger
    AND
    iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

OR

H. The requested agent is an iron supplement **AND** ALL of the following:
    i. The prescriber has provided information stating that the requested iron supplement is medically necessary
    AND
    ii. The patient is under 12 months of age
    AND
    iii. The patient is at increased risk for iron deficiency anemia

OR

I. The requested agent is a statin **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested statin is medically necessary
   AND
   ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
      a. Atorvastatin 10-20 mg per day (20 mg tablet)
      OR
      b. Fluvastatin 20-80 mg per day (40 mg capsule)
      OR
      c. Fluvastatin ER 80 mg per day (80 mg tablet)
      OR
      d. Lovastatin 20-40 mg per day (40 mg tablet)
      OR
      e. Lovastatin ER 20-40 mg per day (40 mg tablet)
      OR
      f. Pitavastatin 1-4 mg per day (4 mg tablet)
      OR
      g. Pravastatin 10-80 mg per day (80 mg tablet)
      OR
      h. Rosuvastatin 5-10 mg per day (10 mg tablet)
      OR
      i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)
   AND
   iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)
   AND
   iv. The patient is 40-75 years of age (inclusive)
   AND
   v. The patient has at least one of the following risk factors:
      a. Dyslipidemia
      OR
      b. Diabetes
      OR
      c. Hypertension
      OR
      d. Smoking
   AND
   vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent **AND** BOTH of the following:
   i. The patient is a non-pregnant adult
   AND
   ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

OR

K. The requested agent is a vaccine **AND** BOTH of the following:

i. The prescriber has provided information stating that the requested vaccine is medically necessary
AND
ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
   i. ONE of the following:
      a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
      OR
      b. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventive Care category
            OR
            B. The member's benefit does NOT include ACA Preventive Care for the category requested
         AND
         2. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
Brand for Generic*   Agents with the following reject message: #NDC NOT COVERED, USE XXX#
Bulk Powders*   (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs*   (Y in the Clinic Pack field)
Cosmetic Alteration*   (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Infertility Agents*   (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility)
Institutional Packs*   Those that contain any one of the following modifier codes in the product file in RXClaims   i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK   ii. MODIFIER BBAD9A INSTITUTIONAL   iii. MODIFIER TTAAJQ INSTITUTIONAL   iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY   v. MODIFIER AAAB9A HOSPITAL PACK   vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE)   vii. MODIFER AAAD6T HOSPITAL USE ONLY
Non-FDA Approved Agents*   (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Repackagers (not including Veterans Administration and Department of Defense Claims)*   (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes)   (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)
Sexual Dysfunction Agents*   (Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction))

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
Weight Loss Agents* (Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss)
Other

*Category specific denial reasons apply

AND

ii. ONE of the following:

a. The requested agent is a CGM/Sensor/Transmitter/Receiver **AND** ONE of the following:

1. Patient has a visual impairment
   OR
2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
   OR
3. Patient has a physical or a mental disability

OR

b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system **AND** ONE of the following:

1. Patient has visual impairment
   OR
2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
   OR
3. Patient has a physical or a mental disability

OR

c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent **AND** ONE of the following:

1. BOTH of the following:
   A. The requested agent is a rapid insulin
      AND
   B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

   OR
2. The request is for Humalog Mix 50/50 **AND** ONE of the following:
   A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
      OR
   B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

   OR
3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent
   OR
4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent
   OR
5. The patient is pregnant

OR

d. The requested agent is a long-acting insulin agent and the following:

1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Semglee, Insulin glargine-yfgn) of the same type (long-acting) that is not expected to occur with the requested agent

OR

e. The requested agent is Cialis/tadalafil 2.5 and 5 mg **AND** BOTH of the following:
    1. The requested agent is be used for a diagnosis of benign prostatic hyperplasia
    AND
    2. The requested quantity is equal to or less than 30 tablets per month

OR

f. The requested agent is a Self-Administered Contraceptive Agent **AND** the agent is being prescribed for an allowable diagnosis

Allowable Diagnoses
Acne vulgaris
Amenorrhea
Dysfunctional uterine bleeding
Dysmenorrhea
Endometriosis
Fibroid Uterus
Hyperandrogenism
Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea)
Menstrual migraine
Perimenopausal symptoms
Polycystic ovarian syndrome
Premenstrual dysphoric disorder (PMDD)
Premenstrual syndrome
Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders

OR

g. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)

OR

h. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP **AND** ALL of the following:
    1. ONE of the following:
        A. The patient has a Fully Insured plan
        OR
        B. The patient has a Self Insured plan AND the patient's plan covers HIV PEP at $0 member cost-share

    AND

    2. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents
    AND
    3. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
            OR
            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
            OR
            iii. Emtricitabine 200 mg single ingredient agent (Emtriva)
            OR
            iv. Raltegravir 400 mg single ingredient agent (Isentress)
            OR
            v. Dolutegravir 50 mg single ingredient agent (Tivicay)

OR

vi. Darunavir 800 mg single ingredient agent (Prezista)

OR

vii. Ritonavir 100 mg single ingredient agent (Norvir)

OR

B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

AND

4. The patient is at high risk of HIV infection

AND

5. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

i. BOTH of the following:

1. The requested agent is for ONE of the following:
   A. Weight loss agent that will not be used for weight loss
   OR
   B. Infertility agent that will not be used for infertility
   OR
   C. Coverage Delay Agent

AND

2. BOTH of the following:
   A. ONE of the following:
      i. The patient has an FDA labeled indication for the requested agent
      OR
      ii. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
      OR
      iii. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

   AND

   B. ONE of the following:
      i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent **AND** BOTH of the following:
         a. If the requested agent is a brand product with an available formulary generic equivalent **AND** ONE of the following:
            1. The patient has tried and failed one or more available formulary generic equivalents to the requested agent
            OR
            2. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or

will cause an adverse reaction or other harm for the patient

AND

b. ONE of the following:
    1. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
    OR
    2. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

ii. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent

OR

iii. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

AND

3. ONE of the following:
    A. The requested agent is not subject to an existing quantity limit program
    OR
    B. The requested agent is subject to an existing quantity limit program and ONE of the following:
        i. The requested quantity (dose) does NOT exceed the program quantity limit
        OR
        ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
        OR
        iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
            a. BOTH of the following:
                1. The requested agent does not have a maximum FDA labeled dose for the requested indication
                AND
                2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

            OR

            b. BOTH of the following:
                1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
                AND
                2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

            OR

            c. BOTH of the following:
                1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the

requested indication
AND

2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

ACA Length of Approval:

- Aspirin 81 mg: 9 months
- Infant eye ointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if HIV PEP criteria met

Coverage Exception Length of Approval: 12 months

• Program Summary: Coverage Exception with Quantity Limit – Health Insurance Marketplace

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☑ Coverage / Formulary Exception

This program applies to individual and small group plans, on- and off-Exchange, that are fully insured and non-grandfathered.

Please note, this program applies to clinical appropriateness. Please see the Clinical Review process flows for determination of exigency as defined per the regulation.

These criteria apply to any request for medication that is not included on the Essential Health Benefit covered drug list.

Weight loss agents must use the Saxenda Wegovy Zepbound Coverage Exception and Formulary Exception criteria.

Objective

These criteria apply to any request for agents that are included on the covered agents list and can be used to treat a medical condition/disease state that is not otherwise excluded from coverage under the pharmacy benefit.

EXCEPTION CRITERIA FOR APPROVAL

A coverage exception will be granted when ALL of the following are met:

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

Examples of Agents Restricted to Coverage on the Medical Benefit
Insulin Pumps and Insulin Pump Supplies
Route of Administration which is excluded from coverage under the pharmacy benefit

AND

2. ONE of the following:
   - A. ALL of the following:
     - i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
       AND
     - ii. The member's benefit includes ACA Preventive Care for the category requested
       AND
     - iii. ONE of the following:
       - a. The requested agent is a contraception agent **AND** BOTH of the following:
         1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary

AND

2. The requested agent is being used for contraception

OR

b. BOTH of the following:
    1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
        A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
        OR
        B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
        OR
        C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

    AND

    2. ONE of the following:
        A. The requested agent is an aspirin agent **AND** ALL of the following:
            i. The requested agent is the 81 mg strength aspirin
            AND
            ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
            AND
            iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

        OR

        B. The requested agent is a bowel prep agent **AND** ALL of the following:
            i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
            AND
            ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
            AND
            iii. The patient is 45 years of age or over

        OR

        C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
            i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
            AND
            ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
            AND
            iii. The patient is 35 years of age or over
            AND
            iv. The agent is requested for the primary prevention of breast cancer

        OR

        D. The requested agent is a fluoride supplement **AND** BOTH of the following:
            i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
            AND
            ii. The patient is 6 months to 16 years of age

        OR

E. The requested agent is a folic acid agent **AND** ALL of the following:
    i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
    AND
    ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
    AND
    iii. The requested folic acid supplement is to be used in support of pregnancy

OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PREP **AND** ALL of the following:
    i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
    AND
    ii. ONE of the following:
        a. The requested PrEP agent is ONE of the following:
            1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
            OR
            2. Tenofovir alafenamide and emtricitabine combination ingredient agent
            OR
            3. Cabotegravir

        OR

        b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir alafenamide and emtricitabine combination ingredient agent, or cabotegravir is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

    AND

iii. The patient is at high risk of HIV infection
AND
iv. The patient has recently tested negative for HIV

OR

G. The requested agent is an infant eye ointment **AND** ALL of the following:
i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary
AND
ii. The patient is 3 months of age or younger
AND
iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

OR

H. The requested agent is an iron supplement **AND** ALL of the following:
i. The prescriber has provided information stating that the requested iron supplement is medically necessary
AND
ii. The patient is under 12 months of age
AND
iii. The patient is at increased risk for iron deficiency anemia

OR

I. The requested agent is a statin **AND** ALL of the following:
i. The prescriber has provided information stating that the requested statin is medically necessary
AND
ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
a. Atorvastatin 10-20 mg per day (20 mg tablet)
OR
b. Fluvastatin 20-80 mg per day (40 mg capsule)
OR
c. Fluvastatin ER 80 mg per day (80 mg tablet)
OR
d. Lovastatin 20-40 mg per day (40 mg tablet)
OR
e. Lovastatin ER 20-40 mg per day (40 mg tablet)
OR
f. Pitavastatin 1-4 mg per day (4 mg tablet)
OR
g. Pravastatin 10-80 mg per day (80 mg tablet)
OR
h. Rosuvastatin 5-10 mg per day (10 mg tablet)
OR
i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)
AND
iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)
AND
iv. The patient is 40-75 years of age (inclusive)
AND
v. The patient has at least one of the following risk factors:

a. Dyslipidemia
OR
b. Diabetes
OR
c. Hypertension
OR
d. Smoking

AND

vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent **AND** BOTH of the following:
   i. The patient is a non-pregnant adult
   AND
   ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

OR

K. The requested agent is a vaccine **AND** BOTH of the following:
   i. The prescriber has provided information stating that the requested vaccine is medically necessary
   AND
   ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
   i. ONE of the following:
      a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
      OR
      b. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventive Care category
            OR
            B. The member's benefit does NOT include ACA Preventive Care for the category requested

         AND

         2. ONE of the following:
            A. The request is for a drug that is on BCBS MN's "CE Formulary Alternative Supplement List" AND BOTH of the following:
               i. The patient has an FDA labeled indication for the requested agent or an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
               AND
               ii. The patient has tried and failed ALL formulary alternatives for the diagnosis being treated with the requested agent

            OR

            B. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

Excluded from Coverage on the Pharmacy Benefit
Alcohol Swabs
Blood Component (not including Hemophilia Factor)
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration*
Diagnostic Agents (not including glucose test strips)
Dietary and Herbal Supplements
General Anesthetic
Infertility Agents* For the treatment of infertility
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RXClaims i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK ii. MODIFIER BBAD9A INSTITUTIONAL iii. MODIFIER TTAAJQ INSTITUTIONAL iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY v. MODIFIER AAAB9A HOSPITAL PACK vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) vii. MODIFER AAAD6T HOSPITAL USE ONLY
Investigative, experimental, or not medically necessary
Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined by GPI 97**********)
Medical devices approved through a different FDA-approval process than drugs (Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)
Non-FDA Approved Agents* (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Over-The-Counter Medications* (specific OTC medications are covered if group purchases OTC benefit) (not including glucose test strips, insulin, or ACA required drugs)
Repackagers (not including Veterans Administration and Department of Defense Claims)* (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
Self-Administered Contraceptives* (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)
Sexual Dysfunction Agents* (Addyi, Viagra, Cialis, Levitra, Staxyn, Caverject, Edex, Muse) for treatment of sexual dysfunction
Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)
Syringes other than insulin syringes
Weight Loss Agents* (GPI: 6120**********, 6125**********) for the treatment of weight loss

*Category specific denial reasons apply

AND

ii. ONE of the following:
   a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:
      1. Patient has a visual impairment
         OR
      2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
         OR
      3. Patient has a physical or a mental disability

   OR

   b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:
      1. Patient has visual impairment
         OR
      2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
         OR
      3. Patient has a physical or a mental disability

   OR

   c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:
      1. BOTH of the following:
         A. The requested agent is a rapid insulin
            AND
         B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

      OR

      2. The request is for Humalog Mix 50/50 AND ONE of the following:
         A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
            OR
         B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

      OR

      3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent
         OR
      4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent
         OR
      5. The patient is pregnant

   OR

   d. The requested agent is a long-acting insulin agent and the following:
      1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents of the same type (long-acting) that is not expected to occur with the requested agent

   OR

   e. The requested agent is part of the Brand for Generic strategy (i.e., Agents with the following reject message: #NDC NOT COVERED, USE XXX#) AND BOTH of the following:
      1. The prescriber has provided information stating that the available formulary (any formulary tier) brand equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient
         AND
      2. ONE of the following:

A. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
OR
B. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
OR
C. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

OR

f. The requested agent is Procysbi AND the patient has tried and had an inadequate response to therapy with Cystagon in combination with a GI protectant (e.g., proton pump inhibitor, histamine-2 receptor antagonists)
OR

g. The requested agent is a Self-Administered Contraceptive Agent (e.g., 2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) AND the agent is being prescribed for an allowable diagnosis

Allowable Diagnoses
Acne vulgaris
Amenorrhea
Dysfunctional uterine bleeding
Dysmenorrhea
Endometriosis
Fibroid Uterus
Hyperandrogenism
Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea)
Menstrual migraine
Perimenopausal symptoms
Polycystic ovarian syndrome
Premenstrual dysphoric disorder (PMDD)
Premenstrual syndrome
Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders

OR

h. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)
OR

i. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP and ALL of the following:
1. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents
AND
2. ONE of the following:
A. The requested PEP agent is ONE of the following (agent AND strength must match):
i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
OR
ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
OR

iii. Emtricitabine 200 mg single ingredient agent (Emtriva)
OR
iv. Raltegravir 400 mg single ingredient agent (Isentress)
OR
v. Dolutegravir 50 mg single ingredient agent (Tivicay)
OR
vi. Darunavir 800 mg single ingredient agent (Prezista)
OR
vii. Ritonavir 100 mg single ingredient agent (Norvir)

OR

B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

AND

3. The patient is at high risk of HIV infection
AND
4. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

j. ONE of the following:
1. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
A. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and they have determined that the medication prescribed will best treat the patient's condition

OR

2. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria
OR
3. BOTH of the following:
A. ONE of the following:
i. The patient has an FDA labeled indication for the requested agent
OR
ii. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
OR
iii. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

AND

B. ONE of the following:
i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:

1. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
OR
2. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

b. ONE of the following:
1. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
OR
2. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

ii. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent
OR
iii. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

ii. If the request is for Restasis or Xiidra and the patient has met the additional clinical review criteria
AND
iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

AND

3. ONE of the following:
A. The requested agent is not subject to an existing quantity limit program
OR
B. The requested agent is subject to an existing quantity limit program and ONE of the following:
i. The requested quantity (dose) does NOT exceed the program quantity limit
OR
ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
OR
iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
a. BOTH of the following:
1. The requested agent does not have a maximum FDA labeled dose for the requested indication
AND
2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

b. BOTH of the following:
    1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
    AND
    2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

c. BOTH of the following:
    1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
    AND
    2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

ACA Length of Approval:

- Aspirin 81 mg: 9 months
- Infant eye ointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if HIV PEP criteria is met

Coverage Exception Length of Approval: 12 months

• Program Summary: Coverage Exception with Quantity Limit – NetResults (KeyRx and FocusRx)

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☑ Coverage / Formulary Exception

Weight loss agents must use the Saxenda Wegovy Zepbound Coverage Exception and Formulary Exception criteria.

Objective

These criteria apply to any request for agents that are included on the covered agents list and can be used to treat a medical condition/disease state that is not otherwise excluded from coverage under the pharmacy benefit.

EXCEPTION CRITERIA FOR APPROVAL

A coverage exception will be granted when ALL of the following are met:

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

Examples of Agents Restricted to Coverage on the Medical Benefit
Insulin Pumps and Insulin Pump Supplies
Route of Administration which is excluded from coverage under the pharmacy benefit (Injectable drugs included on Tier 40 of FID 33102 that reject "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION" [Excluding drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx])

AND

2. ONE of the following:
    A. ALL of the following:
        i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
        AND
        ii. The member's benefit includes ACA Preventive Care for the category requested
        AND

iii. ONE of the following:
   a. The requested agent is a contraception agent **AND** BOTH of the following:
      1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
         AND
      2. The requested agent is being used for contraception

   OR

   b. BOTH of the following:
      1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
         A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
            OR
         B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
            OR
         C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

      AND

      2. ONE of the following:
         A. The requested agent is an aspirin agent **AND** ALL of the following:
            i. The requested agent is the 81 mg strength aspirin
               AND
            ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
               AND
            iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

         OR

         B. The requested agent is a bowel prep agent **AND** ALL of the following:
            i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
               AND
            ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
               AND
            iii. The patient is 45 years of age or over

         OR

         C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
            i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
               AND
            ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
               AND
            iii. The patient is 35 years of age or over
               AND
            iv. The agent is requested for the primary prevention of breast cancer

         OR

         D. The requested agent is a fluoride supplement **AND** BOTH of the following:
            i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary

AND

ii. The patient is 6 months to 16 years of age

OR

E. The requested agent is a folic acid agent **AND** ALL of the following:

i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary

AND

ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid

AND

iii. The requested folic acid supplement is to be used in support of pregnancy

OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PrEP **AND** ALL of the following:

i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents

AND

ii. ONE of the following:

a. The requested PrEP agent is ONE of the following:

1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent

OR

2. Tenofovir alafenamide and emtricitabine combination ingredient agent

OR

3. Cabotegravir

OR

b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir alafenamide and emtricitabine combination ingredient agent, or cabotegravir is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

AND

iii. The patient is at high risk of HIV infection

AND

iv. The patient has recently tested negative for HIV

OR

G. The requested agent is an infant eye ointment **AND** ALL of the following:

i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary

AND

ii. The patient is 3 months of age or younger

AND

iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

OR

H. The requested agent is an iron supplement **AND** ALL of the following:

i. The prescriber has provided information stating that the requested iron supplement is medically necessary

AND

ii. The patient is under 12 months of age

AND

iii. The patient is at increased risk for iron deficiency anemia

OR

I. The requested agent is a statin **AND** ALL of the following:

i. The prescriber has provided information stating that the requested statin is medically necessary

AND

ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):

a. Atorvastatin 10-20 mg per day (20 mg tablet)

OR

b. Fluvastatin 20-80 mg per day (40 mg capsule)

OR

c. Fluvastatin ER 80 mg per day (80 mg tablet)

OR

d. Lovastatin 20-40 mg per day (40 mg tablet)

OR

e. Lovastatin ER 20-40 mg per day (40 mg tablet)

OR

f. Pitavastatin 1-4 mg per day (4 mg tablet)

OR

g. Pravastatin 10-80 mg per day (80 mg tablet)

OR

h. Rosuvastatin 5-10 mg per day (10 mg tablet)

OR

i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)

AND

iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)

AND

iv. The patient is 40-75 years of age (inclusive)

AND

v. The patient has at least one of the following risk factors:

a. Dyslipidemia

OR

b. Diabetes

OR

c. Hypertension

OR

d. Smoking

AND

vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent **AND** BOTH of the following:

i. The patient is a non-pregnant adult

AND

ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

OR

K. The requested agent is a vaccine **AND** BOTH of the following:
    i. The prescriber has provided information stating that the requested vaccine is medically necessary
    AND
    ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
    i. ONE of the following:
        a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
        OR
        b. BOTH of the following:
            1. ONE of the following:
                A. The requested agent is NOT in an ACA Preventive Care category
                OR
                B. The member's benefit does NOT include ACA Preventive Care for the category requested
            AND
            2. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

Excluded from Coverage on the Pharmacy Benefit
AHFS (devices and pharmaceutical aids, not including needles, syringes, lancets, CGM/sensor/transmitter/receiver) (Defined as those products containing the AHFS code 940000000 (DEVICES) and/ or 960000000 (PHARMACEUTICAL AIDS) in the product file in RxClaim)
Brand for Generic* Agents with the following reject message: #NDC NOT COVERED, USE XXX#
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration* (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Diagnostic Agents (not including glucose test strips) (Defined as those products containing the third-party restriction code of 5 (DIAGNOSTIC AGENT) in the product file in RxClaim)
Drugs That Are Not Covered Exclusion (not including glucose test strips, insulin, AuviQ 0.1 mg, ACA required drugs, lancets, syringes, CGM/sensor/transmitter/receiver) [See MN NDC Lock Out List NetResults]
General Anesthetics (Defined as those products containing the third-party restriction code of 6 (GENERAL ANESTHETIC) in the product file in RxClaim)
Infertility Agents* (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility)
Injectable drugs not on covered drug list, not including the drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx (Defined as those products included on Tier 40 of FID 33102 with any reject message other than "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION".)
Institutional Packs*

Excluded from Coverage on the Pharmacy Benefit
Those that contain any one of the following modifier codes in the product file in RXClaims 3. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK ii. MODIFIER BBAD9A INSTITUTIONAL iii. MODIFIER TTAAJQ INSTITUTIONAL iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY 4. MODIFIER AAAB9A HOSPITAL PACK vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) vii. MODIFER AAAD6T HOSPITAL USE ONLY
Investigative, experimental, or not medically necessary
Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined by GPI 97**********)
Medical devices approved through a different FDA-approval process than drugs (Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)
Non-FDA Approved Agents* (Refer all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes) (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)
Repackagers (not including Veterans Administration and Department of Defense Claims)* (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
RX drugs with OTC Equivalents (Excluded categories listed below) (Defined by an RX NDC (Rx-OTC indicator R or S) with an OTC NDC (RX-OTC indicator O or P) within the same GPI 14 in the product file in RxClaim. Rx drugs with OTC alternatives where the Rx drug category will be excluded: 1. Omega-3 Fatty Acids (GPI 395000********) 2. Non-Sedating Antihistamines (GPI 415500********) 3. Topical Antivirals (GPI 903500********))
Self-Administered Contraceptives* (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)
Sexual Dysfunction Agents* (Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction)
Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)
Universal Product Code (UPC), Health Related Item Code (HRI) (not including glucose test strips) (UPCs will be defined as those products designated as product type 1 in the product file in RxClaim. HRIs will be defined as those products designated as product type 2 in the product file in RxClaim.)
Weight Loss Agents* (Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss)

*Category specific denial reasons apply

AND

ii. ONE of the following:

a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:

1. Patient has a visual impairment

OR

2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
   OR
3. Patient has a physical or a mental disability

OR

b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:
   1. Patient has visual impairment
      OR
   2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
      OR
   3. Patient has a physical or a mental disability

   OR

c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:
   1. BOTH of the following:
      A. The requested agent is a rapid insulin
         AND
      B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

      OR
   2. The request is for Humalog Mix 50/50 AND ONE of the following:
      A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
         OR
      B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

      OR
   3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent
      OR
   4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent
      OR
   5. The patient is pregnant

   OR

d. The requested agent is a long-acting insulin agent and the following:
   1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents of the same type (long-acting) that is not expected to occur with the requested agent

   OR

e. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria

   OR

f. The requested agent is a Self-Administered Contraceptive Agent (e.g., 2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) AND the agent is being prescribed for an allowable diagnosis

Allowable Diagnoses
Acne vulgaris
Amenorrhea
Dysfunctional uterine bleeding

OR

g. The

Dysmenorrhea
Endometriosis
Fibroid Uterus
Hyperandrogenism
Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea)
Menstrual migraine
Perimenopausal symptoms
Polycystic ovarian syndrome
Premenstrual dysphoric disorder (PMDD)
Premenstrual syndrome
Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders

requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)

OR

h. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP **AND** ALL of the following:
    1. ONE of the following:
        A. The patient has a Fully Insured plan
        OR
        B. The patient has a Self Insured plan AND the patient's plan covers HIV PEP at $0 member cost-share

        AND
    2. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents

        AND
    3. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
            OR
            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
            OR
            iii. Emtricitabine 200 mg single ingredient agent (Emtriva)
            OR
            iv. Raltegravir 400 mg single ingredient agent (Isentress)
            OR
            v. Dolutegravir 50 mg single ingredient agent (Tivicay)
            OR
            vi. Darunavir 800 mg single ingredient agent (Prezista)
            OR
            vii. Ritonavir 100 mg single ingredient agent (Norvir)

        OR
        B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

        AND
    4. The patient is at high risk of HIV infection

AND

5. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

i. BOTH of the following:

1. If the requested agent is part of a drug class listed below then ONE of the following:

Prescription drugs with OTC alternatives (partial category lockout)

- Artificial Tears/Dry Eye Therapy (GPI 8672**********, 8673**********)
- Topical Acne (GPI 9005**********)
- Topical Antifungals; Combination products (GPI 901599********)
- Ophthalmic Antiallergic Agents (GPI 868020********)
- Prenatal vitamins (GPI 7851**********)
- Ulcer drugs/H2 Antagonists/Proton Pump Inhibitors (GPI 4920**********, 4927**********)
- Nasal steroids (GPI 4220**********)

A. The patient has tried and failed the OTC alternative for the requested diagnosis

OR

B. The prescriber has provided information stating that OTC equivalents are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

2. ONE of the following:

A. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:

i. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and they have determined that the medication prescribed will best treat the patient's condition

OR

B. BOTH of the following:

i. ONE of the following:

a. The patient has an FDA labeled indication for the requested agent

OR

b. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent

OR

c. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

AND

ii. ONE of the following:

a. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:

1. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:

A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
OR
B. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

2. ONE of the following:
   A. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
   OR
   B. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

b. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent
OR
c. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

AND

5. ONE of the following:
   A. The requested agent is not subject to an existing quantity limit program
   OR
   B. The requested agent is subject to an existing quantity limit program and ONE of the following:
      ii. The requested quantity (dose) does NOT exceed the program quantity limit
      OR
      iii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
      OR
      iv. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
         a. BOTH of the following:
            1. The requested agent does not have a maximum FDA labeled dose for the requested indication
            AND
            2. The prescriber has provided information in support of therapy with a higher dose for the

requested indication

OR

b. BOTH of the following:
   1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
   2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

c. BOTH of the following:
   1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      AND
   2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

ACA Length of Approval:

- Aspirin 81 mg: 9 months
- Infant eye ointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if HIV PEP criteria is met

Coverage Exception Length of Approval: 12 months

• Program Summary: Erectile Dysfunction – Phosphodiesterase Type 5 Inhibitors, Topical Prostaglandin

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

The prior authorization with quantity limit program applies to Health Insurance Marketplace formularies and targets Cialis/tadalafil 2.5 mg and 5 mg only.

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
40304090107230		Vardenafil HCl Orally Disintegrating Tab 10 MG	10 MG	6	Tablets	30	DAYS				
40304090100310		Vardenafil HCl Tab 2.5 MG	2.5 MG	6	Tablets	30	DAYS				
40304090100320		Vardenafil HCl Tab 5 MG	5 MG	6	Tablets	30	DAYS				
40304080000310	Cialis	Tadalafil Tab 10 MG	10 MG	6	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
40304080000302	Cialis	Tadalafil Tab 2.5 MG	2.5 MG	30	Tablets	30	DAYS				
40304080000320	Cialis	Tadalafil Tab 20 MG	20 MG	6	Tablets	30	DAYS				
40304080000305	Cialis	Tadalafil Tab 5 MG	5 MG	30	Tablets	30	DAYS				
40304090100330	Levitra	Vardenafil HCl Tab 10 MG	10 MG	6	Tablets	30	DAYS				
40304090100340	Levitra	Vardenafil HCl Tab 20 MG	20 MG	6	Tablets	30	DAYS				
403040150003	Stendra	avanafil tab	100 MG ; 200 MG ; 50 MG	6	Tablets	30	DAYS				
40304070100330	Viagra	Sildenafil Citrate Tab 100 MG	100 ; 100 MG	6	Tablets	30	DAYS				
40304070100310	Viagra	Sildenafil Citrate Tab 25 MG	25 MG	6	Tablets	30	DAYS				
40304070100320	Viagra	Sildenafil Citrate Tab 50 MG	50 MG	6	Tablets	30	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
40304090107230		Vardenafil HCl Orally Disintegrating Tab 10 MG	10 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304090100310		Vardenafil HCl Tab 2.5 MG	2.5 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304090100320		Vardenafil HCl Tab 5 MG	5 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304080000310	Cialis	Tadalafil Tab 10 MG	10 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304080000302	Cialis	Tadalafil Tab 2.5 MG	2.5 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304080000320	Cialis	Tadalafil Tab 20 MG	20 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304080000305	Cialis	Tadalafil Tab 5 MG	5 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg)			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
				are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304090100330	Levitra	Vardenafil HCl Tab 10 MG	10 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304090100340	Levitra	Vardenafil HCl Tab 20 MG	20 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304070100330	Viagra	Sildenafil Citrate Tab 100 MG	100 ; 100 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304070100310	Viagra	Sildenafil Citrate Tab 25 MG	25 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			
40304070100320	Viagra	Sildenafil Citrate Tab 50 MG	50 MG	Quantity of 30 tablets per month is cumulative for Cialis/tadalafil 2.5 mg and 5 mg. All agents (except for Cialis/tadalafil 2.5 mg and 5 mg) are limited to 6 doses per month. The quantity of 6 doses per month is cumulative.			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Target Agent(s)** will be approved when ONE of the following is met: 1. The patient's diagnosis is erectile dysfunction (ED) and ALL of the following: A. The patient's benefit plan covers agents for treatment of erectile dysfunction **AND** B. The patient is 18 years of age or over **AND** C. The patient will NOT be using the requested agent in combination with a nitrate or nitric oxide **AND** D. The patient will NOT be using the requested agent in combination with another ED agent (e.g., oral, injectable, or suppository) **AND** E. ONE of the following: 1. The requested agent is a generic phosphodiesterase type 5 inhibitor **OR** 2. The requested agent is for one of the following phosphodiesterase type 5 inhibitor brand agents with an available generic equivalent (listed below), then ONE of the following: A. The patient has tried and had an inadequate response to the required generic equivalent **OR** B. The patient has an intolerance or hypersensitivity to the required generic equivalent **OR** C. The patient has an FDA labeled contraindication to the required generic equivalent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval

2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

E. The prescriber has provided documentation that the required generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

Brand	Generic Equivalent
Cialis	tadalafil tablets
Levitra	vardenafil tablets
Staxyn	vardenafil orally disintegrating tablets
Viagra	sildenafil tablets

3. The requested agent is Stendra and ONE of the following:
   A. The patient has tried and had an inadequate response to ONE generic phosphodiesterase type 5 inhibitor **OR**
   B. The patient has an intolerance or hypersensitivity to ONE generic phosphodiesterase type 5 inhibitor **OR**
   C. The patient has an FDA labeled contraindication to ALL generic phosphodiesterase type 5 inhibitor **OR**
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   E. The prescriber has provided documentation that ALL generic phosphodiesterase type 5 inhibitor cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

F. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
G. The requested quantity does NOT exceed the program quantity limit **OR**

2. The patient's diagnosis is benign prostatic hyperplasia (BPH) and ALL of the following:
   A. The requested agent is Cialis or tadalafil 2.5 mg or 5 mg **AND**
   B. The patient will NOT be using the requested agent in combination with a nitrate or nitric oxide **AND**
   C. ONE of the following:
      1. The patient has tried and had an inadequate response to ONE generic alpha blocker **OR**
      2. The patient has an intolerance or hypersensitivity to ONE generic alpha blocker **OR**
      3. The patient has an FDA labeled contraindication to ALL generic alpha blockers **OR**
      4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval

B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

5. The prescriber has provided documentation that ALL generic alpha blockers cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

D. The patient will NOT be using the requested agent in combination with an alpha blocker for the requested indication **AND**
E. ONE of the following:
1. The requested agent is generic tadalafil 2.5 mg or 5 mg **OR**
2. If the request is for one of the following phosphodiesterase type 5 inhibitor brand agents with an available generic equivalent (listed below), then ONE of the following:
A. The patient has tried and had an inadequate response to the generic equivalent **OR**
B. The patient has an intolerance or hypersensitivity to the generic equivalent **OR**
C. The patient has an FDA labeled contraindication to the generic equivalent **OR**
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
E. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

Brand	Generic Equivalent
Cialis	tadalafil tablets

F. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
G. The requested quantity does NOT exceed the program quantity limit **OR**

3. The patient's indication of use is for preservation of erectile function following a radical retropubic prostatectomy AND ALL of the following:
A. The patient will NOT be using the requested agent in combination with a nitrate or nitric oxide **AND**
B. ONE of the following:
1. The requested agent is a generic phosphodiesterase type 5 inhibitor **OR**
2. If the request is for one of the following phosphodiesterase type 5 inhibitor brand agents with an available generic equivalent (listed below), then ONE of the following:
A. The patient has tried and had an inadequate response to the required generic equivalent **OR**
B. The patient has an intolerance or hypersensitivity to the required generic equivalent **OR**
C. The patient has an FDA labeled contraindication to the required generic equivalent **OR**
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval

1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

E. The prescriber has provided documentation that the required generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

Brand	Generic Equivalent
Cialis	tadalafil tablets
Levitra	vardenafil tablets
Staxyn	vardenafil orally disintegrating tablets
Viagra	sildenafil tablets

3. The requested agent is Stendra and ONE of the following:
   A. The patient has tried and had an inadequate response to ONE generic phosphodiesterase type 5 inhibitor **OR**
   B. The patient has an intolerance or hypersensitivity to ONE generic phosphodiesterase type 5 inhibitor **OR**
   C. The patient has an FDA labeled contraindication to ALL generic phosphodiesterase type 5 inhibitor **OR**
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   E. The prescriber has provided documentation that ALL generic phosphodiesterase type 5 inhibitor cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

C. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
D. The requested quantity does NOT exceed 30 tablets per month

Length of Approval:

Erectile dysfunction (ED) or benign prostatic hyperplasia (BPH) - 12 months

Preservation of erectile function following radical retropubic prostatectomy – 30 tablets per month for 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ALL the following are met: 1. The patient will NOT be using the requested agent in combination with another phosphodiesterase type 5 (PDE5) inhibitor for the requested indication **AND** 2. The requested agent has been prescribed for preservation of erectile function following radical retropubic prostatectomy **AND** 3. The quantity requested is less than or equal to 30 tablets per month **Length of Approval:** Preservation of erectile function following a radical retropubic prostatectomy – 30 tablets per month for 12 months

• Program Summary: Ergotamine

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
67991002100310	Cafergot	Ergotamine w/ Caffeine Tab 1-100 MG	1-100 MG	40	Tablets	28	DAYS				
67991002100310	Cafergot	Ergotamine w/ Caffeine Tab 1-100 MG	1-100 MG	40	Tablets	28	DAYS				
67000030102005	D.h.e. 45	Dihydroergotamine Mesylate Inj 1 MG/ML	1 MG/ML	24	Ampules	28	DAYS				
67000030102005	D.h.e. 45	Dihydroergotamine Mesylate Inj 1 MG/ML	1 MG/ML	24	Ampules	28	DAYS				
67000020100705	Ergomar	Ergotamine Tartrate SL Tab 2 MG	2 MG	20	Tablets	28	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Formulary Exception with Quantity Limit for FlexRx and GenRx

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☑ Coverage / Formulary Exception

APPLICATION
These criteria apply only to FDA approved legend drugs which are covered under the member's current benefit plan. Medications which are investigational or otherwise not a covered benefit should be forwarded for review under the appropriate process.

This criteria only applies to FlexRx Closed and GenRx Closed products which are non-formulary.

FORMULARY EXCEPTION CRITERIA FOR APPROVAL
A formulary exception will be granted when BOTH of the following are met:

1. ONE of the following:
    A. ALL of the following:
        i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
        AND
        ii. The member's benefit includes ACA Preventive Care for the category requested
        AND
        iii. ONE of the following:
            a. The requested agent is a contraception agent AND BOTH of the following:
                1. There is support that the requested contraceptive agent is medically necessary
                AND
                2. The requested agent is being used for contraception
            OR
            b. BOTH of the following:
                1. If the requested agent is a brand product with an available formulary generic equivalent ONE of the following:
                    A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
                    OR
                    B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
                    OR
                    C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent
                AND
                2. ONE of the following:
                    A. The requested agent is an aspirin agent AND ALL of the following:
                        i. The requested agent is the 81 mg strength aspirin
                        AND

ii. There is support that the requested aspirin agent is medically necessary

AND

iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

OR

B. The requested agent is a bowel prep agent AND ALL of the following:

i. There is support that the requested bowel prep agent is medically necessary

AND

ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy

AND

iii. The patient is 45 years of age or over

OR

C. The requested agent is a breast cancer primary prevention agent AND ALL of the following:

i. There is support that the requested breast cancer primary prevention agent is medically necessary

AND

ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)

AND

iii. The patient is 35 years of age or over

AND

iv. The agent is requested for the primary prevention of breast cancer

OR

D. The requested agent is a fluoride supplement AND BOTH of the following:

i. There is support that the requested fluoride supplement is medically necessary

AND

ii. The patient is 6 months to 16 years of age

OR

E. The requested agent is a folic acid agent AND ALL of the following:

i. There is support that the requested folic acid supplement is medically necessary

AND

ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid

AND

iii. The requested folic acid supplement is to be used in support of pregnancy

OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PrEP AND ALL of the following:

i. There is support that the requested PrEP agent is medically necessary

AND

ii. The requested agent is being used for PrEP

AND

iii. The requested PrEP agent is ONE of the following:

a. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent

OR

b. Tenofovir alafenamide and emtricitabine combination ingredient agent

OR

c. Cabotegravir

AND

iv. The patient has increased risk for HIV infection

AND

v. The patient has recently tested negative for HIV

OR

G. The requested agent is an infant eye ointment AND ALL of the following:

i. There is support that the requested infant eye ointment is medically necessary

AND

ii. The patient is 3 months of age or younger

AND

iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

OR

H. The requested agent is an iron supplement AND ALL of the following:

i. There is support that the requested iron supplement is medically necessary

AND

ii. The patient is under 12 months of age

AND

iii. The patient is at increased risk for iron deficiency anemia

OR

I. The requested agent is a statin AND ALL of the following:

i. There is support that the requested statin is medically necessary

AND

ii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)

AND

iii. The patient is 40-75 years of age (inclusive)

AND

iv. The patient has at least one of the following risk factors:

a. Dyslipidemia

OR

b. Diabetes

OR

c. Hypertension

OR

d. Smoking

AND

v. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent AND BOTH of the following:

i. The patient is a non-pregnant adult

AND

ii. There is support that the requested tobacco cessation agent is medically necessary

OR

K. The requested agent is a vaccine AND BOTH of the following:
    i. There is support that the requested vaccine is medically necessary
    AND
    ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
    i. ONE of the following:
        a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
        OR
        b. BOTH of the following:
            1. ONE of the following:
                A. The requested agent is NOT in an ACA Preventive Care category
                OR
                B. The member's benefit does NOT include ACA Preventive Care for the category requested
            AND
            2. The requested agent is not excluded from coverage under the pharmacy benefit

    AND

    ii. ONE of the following:
        a. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria AND the following:
            1. The patient's current benefit plan covers agents for use in the management for GID or gender dysphoria

        OR

        b. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
            1. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and he/she has determined that the medication prescribed will best treat the patient's condition

        OR

        c. The requested agent is Omnipod DASH or Omnipod 5
        OR
        d. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP AND ALL of the following:
            1. ONE of the following:
                A. The patient has a Fully Insured plan
                OR
                B. The patient has a Self Insured plan AND the patient's plan covers HIV PEP at $0 member cost-share
            AND
            2. There is support that the requested PEP agent is medically necessary
            AND
            3. The requested PEP agent is ONE of the following (agent AND strength must match):
                A. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
                OR
                B. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
                OR
                C. Emtricitabine 200 mg single ingredient agent (Emtriva)
                OR

D. Raltegravir 400 mg single ingredient agent (Isentress)
OR
E. Dolutegravir 50 mg single ingredient agent (Tivicay)
OR
F. Darunavir 800 mg single ingredient agent (Prezista)
OR
G. Ritonavir 100 mg single ingredient agent (Norvir)

AND

4. The patient is at high risk of HIV infection
AND
5. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

e. BOTH of the following:
1. The patient has an FDA labeled indication or an indication supported in AHFS, DrugDex with 1 or 2A level of evidence, or NCCN with 1 or 2A level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
AND
2. ONE of the following:
A. The requested agent has formulary alternatives that can be prescribed in a dose to fit the patient's needs AND ONE of the following:
i. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives, if available, for the diagnosis being treated with the requested agent
OR
ii. There is support that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

B. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent
OR
C. The prescriber states that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

AND

2. ONE of the following:
A. The requested agent is not subject to an existing quantity limit program
OR
B. The requested agent is subject to an existing quantity limit program and ONE of the following:
i. The requested quantity (dose) does NOT exceed the program quantity limit
OR
ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
OR
iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
a. BOTH of the following:
1. The requested agent does not have a maximum FDA labeled dose for the requested indication
AND

2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

b. BOTH of the following:
   1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
   2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

c. BOTH of the following:
   1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      AND
   2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

ACA Length of Approval:

- Aspirin 81 mg: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if ACA criteria met

Formulary Exception Length of Approval: 12 months

• Program Summary: Homozygous Familial Hypercholesterolemia Agents (HoFH)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
39480050200130	Juxtapid	Lomitapide Mesylate Cap 10 MG (Base Equiv)	10 MG	30	Capsules	30	DAYS				
39480050200140	Juxtapid	Lomitapide Mesylate Cap 20 MG (Base Equiv)	20 MG	60	Capsules	30	DAYS				
39480050200150	Juxtapid	Lomitapide Mesylate Cap 30 MG (Base Equiv)	30 MG	60	Capsules	30	DAYS				
39480050200120	Juxtapid	Lomitapide Mesylate Cap 5 MG (Base Equiv)	5 MG	30	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation**

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient has the diagnosis of homozygous familial hypercholesterolemia (HoFH) and ALL of the following: 1. ONE of the following: A. Genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the *LDLR, Apo-B, PCSK9,* or *LDLRAP1* genes, or greater than or equal to 2 such variants at different loci **OR** B. History of untreated LDL-C greater than 400 mg/dL (greater than 10 mmol/L) AND ONE of the following: 1. The patient had cutaneous or tendon xanthomas before age of 10 years **OR** 2. Untreated elevated LDL-C levels consistent with heterozygous FH in both parents, (or in digenic form, one parent may have normal LDL-C levels and the other may have LDL-C levels consistent with HoFH) **AND** 2. ONE of the following: A. The patient has tried a combination of a high-intensity statin (e.g., atorvastatin 40-80 mg, rosuvastatin 20-40 mg daily) and ezetimibe and had an inadequate response **OR** B. The patient has an intolerance or hypersensitivity to ALL combinations of a high-intensity statin and ezetimibe **OR** C. The patient has an FDA labeled contraindication to ALL combinations of a high-intensity statin and ezetimibe **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL combinations of a high-intensity statin and ezetimibe cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to a PCSK9 inhibitor **OR** B. The patient has an intolerance or hypersensitivity to ALL PCSK9 inhibitors **OR** C. The patient has an FDA labeled contraindication to ALL PCSK9 inhibitors **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL PCSK9 inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

Module	Clinical Criteria for Approval
	4. The patient will be using with a low-fat diet and/or other lipid-lowering therapy (e.g., statin, PCSK9 inhibitor, lipoprotein apheresis, evinacumab) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, endocrinologist, lipid specialist, geneticist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR** B. The patient has another FDA labeled indication for the requested agent and route of administration **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved for renewal when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. If the patient has a diagnosis of HoFH, BOTH of the following: A. The patient will continue to use with a low fat diet and/or other lipid-lowering therapy (e.g., statin, PCSK9 inhibitor, lipoprotein apheresis, evinacumab) **AND** B. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, endocrinologist, lipid specialist, geneticist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** up to 12 months

• Program Summary: Imcivree

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
61253860102020	Imcivree	Setmelanotide Acetate Subcutaneous Soln	10 MG/ML	10	Vials	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient's benefit plan covers the requested agent **AND** 2. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of monogenic obesity due to pro-opiomelanocortin (POMC) deficiency, proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency, or leptin receptor (LEPR) deficiency **AND** 2. Genetic testing with an FDA-approved test has confirmed variants in POMC, PCSK1, or LEPR genes (medical records required) **AND** 3. The patient's genetic status is bi-allelic, homozygous, or compound heterozygous (NOT double heterozygous) **AND** 4. The patient's genetic variant is interpreted as pathogenic, likely pathogenic, OR of uncertain significance (VUS) **AND** 5. The patient's genetic variant is NOT classified as benign or likely benign **OR** B. BOTH of the following: 1. The patient has a diagnosis of syndromic obesity due to Bardet-Biedl syndrome (BBS) **AND** 2. The patient's diagnosis has been clinically confirmed by four primary features OR three primary and two secondary features (medical records required) (i.e., primary features [rod-cone dystrophy, polydactyly, obesity, genital anomalies, renal anomalies, learning difficulties]; secondary features [speech delay, developmental delay, diabetes mellitus, dental anomalies, congenital heart disease, bracydactyly/syndactyly, ataxia/poor coordination, anosmia/hyposmia]) **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. ONE of the following: A. For adult patients, the body mass index (BMI) is greater than or equal to 30 kg/m^2 **OR**

Module	Clinical Criteria for Approval
	B. For pediatric patients, weight is greater than or equal to 95th percentile (for POMC, PCSK1, or LEPR) or 97th percentile (for BBS) using growth chart assessments **AND** 5. ONE of the following: A. The patient is newly starting therapy **OR** B. ONE of the following: 1. For patients with obesity due to POMC, PCSK1, or LEPR deficiency, ONE of the following: A. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR** B. The patient has received at least 16 weeks of therapy, and has achieved a weight loss of ONE of the following: 1. Weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) **OR** 2. For patients with continued growth potential, weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **OR** 2. For patients with obesity due to BBS, ONE of the following: A. The patient is currently being treated and has received less than one year of therapy **OR** B. The patient has received at least one year of therapy, and has achieved a weight loss of ONE of the following: 1. Weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) **OR** 2. For patients aged less than 18 years, weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 4 months for POMC, PCSK1, or LEPR deficiency; 12 months for BBS NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient's benefit plan covers the requested agent **AND** 3. ONE of the following: A. For adult patients, the patient has achieved and maintained weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) **OR** B. ONE of the following: 1. For patients with POMC, PCSK1, or LEPR deficiency AND continued growth potential, the patient has achieved and maintained weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **OR** 2. For patients with BBS AND are aged less than 18 years, the patient has achieved and maintained weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **AND**

Module	Clinical Criteria for Approval
	4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** Initial - up to 4 months for POMC, PCSK1, or LEPR deficiency; up to 12 months for BBS Renewal - up to 12 months

• Program Summary: Interleukin (IL-1) Inhibitors

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
664500600021	Arcalyst	rilonacept for inj	220 MG	8	Vials	28	DAYS				
664600200020	Ilaris	canakinumab subcutaneous inj	150 MG/ML	2	Vials	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Arcalyst	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** No target agents are eligible for continuation of therapy

Module	Clinical Criteria for Approval
	1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. BOTH of the following: 1. The patient has ONE of the following indications: A. Cryopyrin Associated Periodic Syndrome (CAPS) **OR** B. Familial Cold Auto-Inflammatory Syndrome (FCAS) **OR** C. Muckle-Wells Syndrome (MWS) **AND** 2. BOTH of the following: A. The patient has elevated pretreatment serum inflammatory markers (C-reactive protein/serum amyloid A) **AND** B. The patient has at least TWO symptoms typical for CAPS (i.e., urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms of arthralgia/arthritis/myalgia, chronic aseptic meningitis, skeletal abnormalities of epiphyseal overgrowth/frontal bossing) **OR** B. BOTH of the following: 1. The patient has a diagnosis of deficiency of interleukin-1 receptor antagonist **AND** 2. The requested agent is being used for maintenance of remission **OR** C. The patient has a diagnosis of recurrent pericarditis AND ONE of the following 1. BOTH of the following: A. The patient has tried and had an inadequate response to at least a 6-month trial of colchicine **AND** B. ONE of the following: 1. Colchicine was used concomitantly with at least a 1 week trial of a non-steroidal anti-inflammatory drug (NSAID) AND a corticosteroid **OR** 2. The patient has an intolerance or hypersensitivity to BOTH an NSAID AND a corticosteroid **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs AND ALL corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to colchicine **OR** 3. The patient has an FDA labeled contraindication to colchicine **OR** 4. The patient has tried and had an inadequate response to an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) used in the treatment of recurrent pericarditis **OR** 5. The patient has an intolerance or hypersensitivity to oral immunosuppressants used in the treatment of recurrent pericarditis **OR** 6. The patient has an FDA labeled contraindication to oral immunosuppressants used in the treatment of recurrent pericarditis **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that colchicine AND oral immunosuppressants cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **OR** C. The patient has another indication that is supported in compendia for the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**

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	2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Ilaris	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. BOTH of the following: 1. The patient has ONE of the following indications: A. Cryopyrin Associated Periodic Syndrome (CAPS) **OR** B. Familial Cold Auto-Inflammatory Syndrome (FCAS) **OR** C. Muckle-Wells Syndrome (MWS) **AND** 2. BOTH of the following: A. The patient has elevated pretreatment serum inflammatory markers (C-reactive protein/serum amyloid A) **AND** B. The patient has at least TWO symptoms typical for CAPS (i.e., urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms of arthralgia/arthritis/myalgia, chronic aseptic meningitis, skeletal abnormalities of epiphyseal overgrowth/frontal bossing) **OR** B. The patient has a diagnosis of Familial Mediterranean Fever (FMF) AND ONE of the following: 1. The patient has tried and had an inadequate response to colchicine for at least 6 months **OR** 2. The patient has an intolerance or hypersensitivity to colchicine **OR** 3. The patient has an FDA labeled contraindication to colchicine **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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	5. The prescriber has provided documentation that colchicine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. BOTH of the following: 1. The patient has a diagnosis of Hyperimmunoglobulin D Syndrome (HIDS) or Mevalonate Kinase Deficiency (MKD) **AND** 2. The patient's diagnosis was confirmed via genetic testing for mutations in the mevalonate kinase (MVK) gene **OR** D. BOTH of the following: 1. The patient has a diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) **AND** 2. The patient's diagnosis was confirmed via genetic testing for mutations in the TNFR1 gene **OR** E. The patient has a diagnosis of active systemic juvenile idiopathic arthritis (SJIA) AND ALL of the following: 1. The patient has ongoing fever for at least 2 weeks **AND** 2. The patient has arthritis in greater than or equal to 1 joint **AND** 3. The patient has ONE or more of the following: A. Evanescent erythematous rash B. Generalized lymphadenopathy C. Hepatomegaly or splenomegaly D. Pericarditis, pleuritis and/or peritonitis **OR** F. The patient has a diagnosis of adult-onset Still's disease and BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to at least ONE corticosteroid or ONE non-steroidal anti-inflammatory drug (NSAID) **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid or ONE non-steroidal anti-inflammatory drug (NSAID) **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids AND non-steroidal anti-inflammatory drugs (NSAIDs) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL corticosteroids and non-steroidal anti-inflammatory drug (NSAIDs) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following

Module	Clinical Criteria for Approval
	A. The patient has tried and had an inadequate response to ONE immunosuppressant used in the treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** B. The patient has an intolerance or hypersensitivity to ONE immunosuppressant used in the treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** C. The patient has an FDA labeled contraindication to ALL immunosuppressants used in the treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL immunosuppressants used in treatment of AOSD (i.e., methotrexate, cyclosporine, AND azathioprine) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** G. The patient has a diagnosis of gout flares AND ALL of the following: 1. The patient has experienced greater than or equal to 3 flares in the past 12 months **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to ONE non-steroidal anti-inflammatory drug (NSAID) **OR** B. The patient has an intolerance or hypersensitivity to ONE non-steroidal anti-inflammatory drug (NSAID) **OR** C. The patient has an FDA labeled contraindication to ALL non-steroidal anti-inflammatory drugs (NSAIDs) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL non-steroidal anti-inflammatory drug (NSAIDs) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following**:**

Module	Clinical Criteria for Approval
	A. The patient has tried and had an inadequate response to colchicine for at least 6 months **OR** B. The patient has an intolerance or hypersensitivity to colchicine **OR** C. The patient has an FDA labeled contraindication to colchicine **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that colchicine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. Repeated courses of corticosteroids are not appropriate for the patient **OR** H. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **OR** C. The patient has another indication that is supported in compendia for the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 weeks for gout flares; 12 months for all other diagnoses NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
	1. The patient has been previously approved for the requested agent through plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab)

Contraindicated as Concomitant Therapy
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)

Contraindicated as Concomitant Therapy
Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tysabri (natalizumab) Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Interleukin-4 (IL-4) Inhibitor

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9027302000D215	Dupixent	Dupilumab Subcutaneous Soln Pen-injector	200 MG/1.14ML	2	Pens	28	DAYS				
9027302000D220	Dupixent	Dupilumab Subcutaneous Soln Pen-injector 300 MG/2ML	300 MG/2ML	4	Pens	28	DAYS				
9027302000E510	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe	100 MG/0.67ML	2	Syringes	28	DAYS				
9027302000E515	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14ML	2	Syringes	28	DAYS				
9027302000E520	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 300 MG/2ML	300 MG/2ML	4	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Module	Clinical Criteria for Approval
	Agents Eligible for Continuation of Therapy All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **OR** D. The patient has an Investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to BOTH at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to BOTH at least a mid- potency topical steroid AND a topical calcineurin inhibitor **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has assessed the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND**

Module	Clinical Criteria for Approval
	4. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of moderate to severe asthma AND BOTH of the following: 1. ONE of the following: A. The patient has eosinophilic type asthma AND ONE of the following: 1. The patient has a baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** 2. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** 3. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** B. The patient has oral corticosteroid dependent type asthma **AND** 2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain **AND** 2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND** 3. The patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR** B. Computed tomography (CT) of the sinuses **AND** 4. ONE of the following: A. ONE of the following: 1. The patient had an inadequate response to sinonasal surgery **OR** 2. The patient is NOT a candidate for sinonasal surgery **OR** B. ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to oral systemic corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to therapy with oral systemic corticosteroids **OR** 3. The patient has an FDA labeled contraindication to ALL oral systemic corticosteroids **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **OR** D. The patient has a diagnosis of eosinophilic esophagitis (EoE) AND BOTH of the following: 1. The patient's diagnosis was confirmed by ALL of the following: A. Chronic symptoms of esophageal dysfunction **AND** B. Greater than or equal to 15 eosinophils per high-power field on esophageal biopsy **AND** C. Other causes that may be responsible for or contributing to symptoms and esophageal eosinophilia have been ruled out **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to ONE standard corticosteroid therapy for EoE (i.e., budesonide suspension, nebulized budesonide, fluticasone MDI swallowed) **OR** B. The patient has an intolerance or hypersensitivity to standard corticosteroid therapy for EoE **OR** C. The patient has an FDA labeled contraindication to standard corticosteroid therapy for EoE **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL standard corticosteroid therapy for EoE cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The patient has a diagnosis of prurigo nodularis (PN) and BOTH of the following: 1. The patient has ALL of the following features associated with PN: A. Presence of firm, nodular lesions **AND** B. Pruritus that has lasted for at least 6 weeks **AND** C. History and/or signs of repeated scratching, picking, or rubbing **AND** 2. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has tried and had an inadequate response to at least a mid-potency topical steroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with at least a mid-potency topical steroid **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) BOTH of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** 3. If the patient has a diagnosis of moderate to severe asthma, ALL of the following: A. ONE of the following: 1. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid **OR** 2. The patient is currently being treated with the requested agent AND ONE of the following: A. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** B. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** 3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** B. ONE of the following: 1. The patient is currently being treated with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. Long-acting muscarinic antagonist (LAMA) **OR** C. A leukotriene receptor antagonist (LTRA) **OR** D. Theophylline **OR**

Module	Clinical Criteria for Approval
	2. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), long-acting muscarinic antagonists (LAMA), leukotriene receptor antagonist (LTRA), or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists LABA) AND long-acting muscarinic antagonists (LAMA) **AND** C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of moderate to severe asthma AND BOTH of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:

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	A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV1) **OR** B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, ICS/long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** D. The patient has a diagnosis other than moderate-to-severe atopic dermatitis (AD), moderate to severe asthma, or chronic rhinosinusitis with nasal polyposis (CRSwNP) AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have an FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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	Quantity Limits for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose, or the compendia supported dose, for the requested indication **AND**

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	C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: up to 6 months for Initial; up to 12 months for Renewal

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Litfulo (ritlecitinib) Nucala (mepolizumab) Olumiant (baricitinib) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab)

Contraindicated as Concomitant Therapy
Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Siliq (brodalumab) Simlandi (adalimumab-ryvk) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tysabri (natalizumab) Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Interleukin-5 (IL-5) Inhibitors

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
4460402000D520	Fasenra pen	Benralizumab Subcutaneous Soln Auto-injector 30 MG/ML	30 MG/ML	1	Pen	56	DAYS				
4460405500D530	Nucala	Mepolizumab Subcutaneous Solution Auto-injector 100 MG/ML	100 MG/ML	3	Syringes	28	DAYS				
4460405500E520	Nucala	Mepolizumab Subcutaneous Solution Pref Syringe	40 MG/0.4 ML	1	Syringe	28	DAYS				
4460405500E530	Nucala	Mepolizumab Subcutaneous Solution Pref Syringe 100 MG/ML	100 MG/ML	3	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
No Target Agents are Eligible for Continuation of Therapy

      1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

   B. BOTH of the following:
      1. ONE of the following
         A. The patient has a diagnosis of severe eosinophilic asthma and BOTH of the following:
            1. The patient's diagnosis has been confirmed by ONE of the following:
               A. The patient has a baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR**
               B. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR**
               C. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **AND**
            2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following:
               A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR**
               B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR**
               C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR**
               D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR**
         B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and ALL of the following:
            1. The requested agent is Nucala **AND**
            2. The patient has had a diagnosis of EGPA for at least 6 months with a history of relapsing or refractory disease **AND**
            3. The patient's diagnosis of EGPA was confirmed by ONE of the following:
               A. The patient meets 4 of the following:
                  1. Asthma (history of wheezing or diffuse high-pitched rales on expiration)
                  2. Eosinophilia (greater than 10% eosinophils on white blood cell differential count)

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	3. Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis 4. Migratory or transient pulmonary infiltrates detected radiographically 5. Paranasal sinus abnormality 6. Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas **OR** B. The patient meets ALL of the following: 1. Medical history of asthma **AND** 2. Peak peripheral blood eosinophilia greater than 1000 cells/microliter **AND** 3. Systemic vasculitis involving two or more extra-pulmonary organs **AND** 4. ONE of the following: A. The patient is currently on maximally tolerated oral corticosteroid therapy **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral corticosteroids **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to ONE non-corticosteroid immunosuppressant (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, rituximab) **OR** B. The patient has an intolerance or hypersensitivity to ONE non-corticosteroid immunosuppressant **OR** C. The patient has an FDA labeled contraindication to ALL of the following immunosuppressants 1. Azathioprine 2. Cyclophosphamide 3. Methotrexate 4. Mycophenolate mofetil **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL non-corticosteroid immunosuppressants cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of hypereosinophilic syndrome (HES) and ALL of the following: 1. The requested agent is Nucala **AND**

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	2. BOTH of the following: A. The patient has had a diagnosis of HES for at least 6 months **AND** B. The patient has a history of at least 2 HES flares within the past 12 months (i.e., worsening of clinical symptoms and/or blood eosinophil counts requiring an escalation in therapy) **AND** 3. The patient's diagnosis of HES was confirmed by BOTH of the following: A. ONE of the following: 1. The patient has a peripheral blood eosinophil count greater than 1000 cells/microliter **OR** 2. The patient has a percentage of eosinophils in bone marrow section exceeding 20% of all nucleated cells **OR** 3. The patient has marked deposition of eosinophil granule proteins found **OR** 4. The patient has tissue infiltration by eosinophils that is extensive in the opinion of a pathologist **AND** B. ALL of the following: 1. Secondary (reactive, non-hematologic) causes of eosinophilia have been excluded (e.g., infection, allergy/atopy, medications, collagen vascular disease, metabolic [e.g., adrenal insufficiency], solid tumor/lymphoma) **AND** 2. There has been evaluation of hypereosinophilia-related organ involvement (e.g., fibrosis of lung, heart, digestive tract, skin; thrombosis with or without thromboembolism; cutaneous erythema, edema/angioedema, ulceration, pruritis, or eczema; peripheral or central neuropathy with chronic or recurrent neurologic deficit; other organ system involvement such as liver, pancreas, kidney) **AND** 3. The patient does NOT have FIP1L1-PDGFRA-positive disease **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain **AND** 3. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND** 4. The patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR** B. Computed tomography (CT) of the sinuses **AND** 5. ONE of the following: A. ONE of the following: 1. The patient had an inadequate response to sinonasal surgery **OR** 2. The patient is NOT a candidate for sinonasal surgery **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to oral systemic corticosteroids **OR**

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	2. The patient has an intolerance or hypersensitivity to therapy with oral systemic corticosteroids **OR** 3. The patient has an FDA labeled contraindication to ALL oral systemic corticosteroids **AND** 6. ONE of the following: A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **OR** E. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has a diagnosis of severe eosinophilic asthma, then ALL of the following: A. ONE of the following: 1. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** 2. The patient is currently being treated with the requested agent AND ONE of the following: A. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** B. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** 3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** B. ONE of the following: 1. The patient is currently being treated with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. Long-acting muscarinic antagonist (LAMA) **OR** C. A leukotriene receptor antagonist (LTRA) **OR** D. Theophylline **OR** 2. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), long-acting muscarinic antagonists (LAMA), leukotriene receptor antagonists (LTRA) or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND** C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 3. If the patient has a diagnosis of hypereosinophilic syndrome (HES), ALL of the following: A. ONE of the following: 1. The patient is currently being treated with maximally tolerated oral corticosteroid (OCS) **OR** 2. The patient has an intolerance or hypersensitivity to oral corticosteroid (OCS) therapy **OR** 3. The patient has an FDA labeled contraindication to ALL oral corticosteroids **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

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	B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL oral corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient is currently being treated with ONE of the following: A. Hydroxyurea **OR** B. Interferon-α **OR** C. Another immunosuppressive agent (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** 2. The patient has an intolerance or hypersensitivity to therapy with hydroxyurea, interferon-α, or immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** 3. The patient has an FDA labeled contraindication to hydroxyurea, interferon-α, and ALL immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that hydroxyurea, interferon-α, and ALL immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** C. The patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-α, immunosuppressants) in combination with the requested agent **AND** 4. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), BOTH of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent

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	Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 6 months for severe eosinophilic asthma; 12 months for EGPA, HES, CRSwNP, and all other FDA approved or compendia supported indications For Fasenra, approve loading dose for new starts and the maintenance dose for the remainder of the 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. The patient has a diagnosis of severe eosinophilic asthma AND BOTH of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. Increase in percent predicted Forced Expiratory Volume (FEV1) **OR** B. Decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. Decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy (i.e., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline) **OR** B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. Remission achieved with the requested agent **OR** B. Decrease in oral corticosteroid maintenance dose required for control of symptoms related to EGPA **OR** C. Decrease in hospitalization due to symptoms of EGPA **OR** D. Dose of maintenance corticosteroid therapy and/or immunosuppressant therapy was not increased **AND** 3. ONE of the following: 1. The patient is currently treated and is compliant with maintenance therapy with oral corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to oral corticosteroid therapy **OR** 3. The patient has an FDA labeled contraindication to ALL oral corticosteroids **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL oral corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of hypereosinophilic syndrome (HES) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. Decrease in incidence of HES flares **OR** B. Escalation of therapy (due to HES-related worsening of clinical symptoms or increased blood eosinophil counts) has not been required **AND** 3. ONE of the following: A. The patient is currently treated and is compliant with oral corticosteroid and/or other maintenance therapy (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to therapy with oral corticosteroids or other maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** C. The patient has an FDA labeled contraindication to ALL oral corticosteroids AND maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL oral corticosteroids AND maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** E. The patient has another FDA labeled indication for the requested agent and route of administration AND has had clinical benefit with the requested agent **OR** F. The patient has another indication that is supported in compendia for the requested agent and route of administration AND has had clinical benefit with the requested agent **AND**

Module	Clinical Criteria for Approval
	3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval:** Initial: up to 6 months for severe eosinophilic asthma; up to 12 months for EGPA, HES, CRSwNP, and all other FDA approved or compendia supported indications; For Fasenra, approve loading dose for new starts and the maintenance dose for the remainder of the 6 months; Renewal: up to 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)

Contraindicated as Concomitant Therapy
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)

Contraindicated as Concomitant Therapy
Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Interleukin-13 (IL-13) Antagonist

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9027308045E520	Adbry	Tralokinumab-ldrm Subcutaneous Soln Prefilled Syr	150 MG/ML	4	Syringes	28	DAYS			09-01-2022	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR** D. The patient has an Investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. BOTH of the following: A. ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to at least a mid-potency topical steroid **OR** 2. The patient has an intolerance or hypersensitivity to at least a mid-potency topical steroid **OR** 3. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids used in the treatment of AD **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** 2. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor **OR** 3. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has assessed the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND**

Module	Clinical Criteria for Approval
	4. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient has been treated with the requested agent for less than 16 consecutive weeks **OR** C. The patient has been treated with the requested agent for at least 16 consecutive weeks AND ONE of the following: 1. The patient weighs less than 100 kg and ONE of the following: A. The patient has achieved clear or almost clear skin AND the patient's dose will be reduced to 300 mg every 4 weeks **OR** B. The patient has NOT achieved clear or almost clear skin **OR** C. There is support for using 300 mg every 2 weeks **OR** 2. The patient weighs greater than or equal to 100 kg **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 6 months **Note**: Approve Adbry subcutaneous loading dose for 1 month, then maintenance dose can be approved for the remainder of 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
	1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis other than moderate-to-severe atopic dermatitis AND has had clinical benefit with the requested agent **AND** 3. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient has been treated with the requested agent for less than 16 consecutive weeks **OR** C. The patient has been treated with the requested agent for at least 16 consecutive weeks AND ONE of the following: 1. The patient weighs less than 100 kg and ONE of the following: A. The patient has achieved clear or almost clear skin AND the patient's dose will be reduced to 300 mg every 4 weeks **OR** B. The patient has NOT achieved clear or almost clear skin **OR** C. There is support for using 300 mg every 2 weeks **OR** 2. The patient weighs greater than or equal to 100 kg **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed**: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:

Module	Clinical Criteria for Approval
	1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of approval**: Initial approval - up to 6 months; Renewal approval - up to 12 months **Note**: Approve Adbry subcutaneous loading dose for 1 month, then maintenance dose can be approved for the remainder of 6 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Litfulo (ritlecitinib) Nucala (mepolizumab) Olumiant (baricitinib) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept)

Contraindicated as Concomitant Therapy
Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Siliq (brodalumab) Simlandi (adalimumab-ryvk) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tysabri (natalizumab) Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Iron Chelation

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
93100025007320	Exjade	Deferasirox Tab For Oral Susp 125 MG	125 MG	30	Tablets	30	DAYS				
93100025007330	Exjade	Deferasirox Tab For Oral Susp 250 MG	250 MG	30	Tablets	30	DAYS				
93100025007340	Exjade	Deferasirox Tab For Oral Susp 500 MG	500 MG	90	Tablets	30	DAYS				
93100028002020	Ferriprox	Deferiprone Oral Soln 100 MG/ML	100 MG/ML	2700	mLs	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
93100028000340	Ferriprox	Deferiprone Tab 1000 MG	1000 MG	270	Tablets	30	DAYS				
93100028000320	Ferriprox	Deferiprone Tab 500 MG	500 MG	540	Tablets	30	DAYS				
93100028000345	Ferriprox twice-a-day	Deferiprone (Twice Daily) Tab 1000 MG	1000 MG	270	Tablets	30	DAYS				
93100025000330	Jadenu	Deferasirox Tab 180 MG	180 MG	30	Tablets	30	DAYS				
93100025000340	Jadenu	Deferasirox Tab 360 MG	360 MG	180	Tablets	30	DAYS				
93100025000320	Jadenu	Deferasirox Tab 90 MG	90 MG	30	Tablets	30	DAYS				
93100025003030	Jadenu sprinkle	Deferasirox Granules Packet 180 MG	180 MG	30	Packets	30	DAYS				
93100025003040	Jadenu sprinkle	Deferasirox Granules Packet 360 MG	360 MG	180	Packets	30	DAYS				
93100025003020	Jadenu sprinkle	Deferasirox Granules Packet 90 MG	90 MG	30	Packets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Exjade, Jadenu	**Initial Evaluation** **Exjade (deferasirox) or Jadenu (deferasirox)** will be approved when ALL of the following are met: 1. The patient has an FDA labeled indication or compendia supported indication for the requested agent and route of administration AND ONE the following: A. The patient has a diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis) AND BOTH of the following: 1. The patient's baseline (pretreatment) serum ferritin is greater than 1,000 mcg/L **AND** 2. If the patient has been treated with a deferasirox agent within the past 90 days, the patient's current (within the last 30 days) serum ferritin is greater than 500 mcg/L **OR** B. The patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome AND BOTH of the following: 1. ONE of the following: A. The patient's baseline (pretreatment) liver iron (FE) concentration (LIC) is at least 5 mg FE/g of dry weight **OR** B. The patient's serum ferritin is greater than 300 mcg/L **OR** C. MRI confirmation of iron deposition **AND** 2. If the patient has been treated with a deferasirox agent within the past 90 days, the LIC is greater than 3 mg FE/g of dry weight **OR** C. The patient has a diagnosis other than chronic iron overload **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following: A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval

B. The patient's medication history includes the required generic equivalent as indicated by:
   1. Evidence of a paid claim(s) **OR**
   2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**

C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**

D. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**

E. There is support for the use of the requested brand agent over the generic equivalent **OR**

F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

Brand	Generic Equivalent
Exjade (deferasirox) Jadenu (deferasirox)	Generic deferasirox

4. The patient does NOT have severe hepatic impairment (Child-Pugh-Turcotte C) **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
6. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program **AND**
7. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please see Quantity Limit Criteria

Renewal Evaluation

Exjade (deferasirox) or Jadenu (deferasirox) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. The patient has an FDA labeled indication or compendia supported indication for the requested agent and route of administration AND ONE of the following:
   A. The patient has a diagnosis of chronic iron overload due to blood transfusions, AND BOTH of the following:
      1. The patient has had a decrease in serum ferritin from baseline (pretreatment) **AND**
      2. The patient's current serum ferritin is greater than 500 mcg/L **OR**
   B. The patient has a diagnosis of non-transfusional chronic iron overload due to thalassemia syndromes AND the patient's current serum ferritin is greater than 300 mcg/L **OR**
   C. The patient has a diagnosis other than chronic iron overload and has had clinical benefit with the requested agent **AND**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>3. The patient does NOT have severe hepatic impairment (Child-Pugh-Turcotte C) AND
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
5. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program AND
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please see Quantity Limit Criteria</td></tr>
<tr><td>Ferriprox</td><td>Initial Evaluation

Ferriprox (deferiprone) will be approved when ALL of the following are met:

1. The patient has an FDA labeled indication or compendia supported indication for the requested agent and route of administration AND ONE of the following:
A. The patient has a diagnosis of transfusional iron overload with thalassemia syndromes OR
B. The patient has a diagnosis of transfusional iron overload with sickle cell disease or other anemias AND BOTH of the following:
1. The patient does NOT have myelodysplastic syndrome AND
2. The patient does NOT have Diamond Blackfan anemia OR
C. The patient has a diagnosis other than transfusional iron overload AND
2. The patient has an absolute neutrophil count (ANC) greater than or equal to 1.5 X 10^9/L AND
3. If the patient has an FDA labeled indication, then ONE of the following:
A. The patient's age is within FDA labeling for the requested indication for the requested agent OR
B. There is support for using the requested agent for the patient's age for the requested indication AND
4. If the request is for a brand agent, then ONE of the following:
A. The patient has tried and had an inadequate response to a generic deferiprone OR
B. The patient has an intolerance or hypersensitivity to a generic deferiprone that is not expected to occur with the brand agent OR
C. The patient has an FDA labeled contraindication to a generic deferiprone that is not expected to occur with the brand agent OR
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent AND
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR
E. The prescriber has provided documentation that generic deferiprone cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm OR
F. There is support for the use of the requested brand agent over a generic deferiprone (NOTE: patient compliance will only be accepted after a trial of a generic) AND

<table><tr><th>Brand</th><th>Generic Equivalent</th></tr><tr><td>Ferriprox (deferiprone)</td><td>Generic deferiprone</td></tr></table>
5. ONE of the following:</td></tr>
</table>

Module	Clinical Criteria for Approval
	A. The patient has tried and had an inadequate response to Exjade (deferasirox) or Jadenu (deferasirox) **OR** B. The patient has an intolerance or hypersensitivity to Exjade (deferasirox) or Jadenu (deferasirox) **OR** C. The patient has an FDA labeled contraindication to BOTH Exjade (deferasirox) AND Jadenu (deferasirox) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH Exjade (deferasirox) AND Jadenu (deferasirox) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please see Quantity Limit Criteria **Renewal Evaluation** **Ferriprox** (deferiprone) will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient has an absolute neutrophil count (ANC) greater than or equal to 1.5 X 10^9/L **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please see Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following are met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

Module	Clinical Criteria for Approval
	2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support of therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Joenja (leniolisib)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
99391540600320	Joenja	leniolisib phosphate tab	70 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** Joenja 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The patient has a diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS) **AND** 2. The patient has a variant in either PIK3CD or PIK3R1 **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

Module	Clinical Criteria for Approval
	B. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. The patient's weight is 45 kg or greater **AND** 3. The prescriber has assessed the patient's baseline (prior to therapy with the requested agent) status of clinical manifestations of APDS (e.g., recurrent sinopulmonary infections, recurrent herpesvirus infections, lymphadenopathy, hepatomegaly, splenomegaly, nodular lymphoid hyperplasia, autoimmunity, cytopenias, enteropathy, bronchiectasis, organ dysfunction) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation] **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., sinopulmonary infections, herpesvirus infections, lymphadenopathy, hepatomegaly, splenomegaly, nodular lymphoid hyperplasia, autoimmunity, cytopenias, enteropathy, bronchiectasis, organ dysfunction) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	C. There is support of therapy with a higher dose for the requested indication **Length of Approval:** Initial up to 3 months; Renewal up to 12 months

• Program Summary: Long Acting Insulin

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2710400300D220	Basaglar kwikpen ; Lantus solostar ; Semglee	Insulin Glargine Soln Pen-Injector 100 Unit/ML	100 UNIT/ML	100	mLs	30	DAYS				
2710400300D222	Basaglar tempo pen	Insulin Glargine Pen-Inj with Transmitter Port	100 UNIT/ML	100	mLs	30	DAYS				
27104003002020	Lantus ; Semglee	Insulin Glargine Inj 100 Unit/ML	100 UNIT/ML	100	mLs	30	DAYS				
27104006002020	Levemir	Insulin Detemir Inj 100 Unit/ML	100 UNIT/ML	100	mLs	30	DAYS				
2710400600D220	Levemir flexpen ; Levemir flextouch	Insulin Detemir Soln Pen-injector 100 Unit/ML	100 UNIT/ML	100	mLs	30	DAYS				
2710400305D220	Rezvoglar kwikpen	insulin glargine-aglr soln pen-injector	100 UNIT/ML	100	mLs	30	DAYS				
27104003902020	Semglee	Insulin Glargine-yfgn Inj	100 UNIT/ML	100	mLs	30	DAYS				
2710400390D220	Semglee	Insulin Glargine-yfgn Soln Pen-Injector	100 UNIT/ML	100	mLs	30	DAYS				
2710400300D236	Toujeo max solostar	Insulin Glargine Soln Pen-Injector 300 Unit/ML (2 Unit Dial)	300 UNIT/ML	100	mLs	30	DAYS				
2710400300D233	Toujeo solostar	Insulin Glargine Soln Pen-Injector 300 Unit/ML (1 Unit Dial)	300 UNIT/ML	100	mLs	30	DAYS				
27104007002020	Tresiba	Insulin Degludec Inj 100 Unit/ML	100 UNIT/ML	100	mLs	30	DAYS				
2710400700D210	Tresiba flextouch	Insulin Degludec Soln Pen-Injector 100 Unit/ML	100 UNIT/ML	100	mLs	30	DAYS				
2710400700D220	Tresiba flextouch	Insulin Degludec Soln Pen-Injector 200 Unit/ML	200 UNIT/ML	100	mLs	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Lupus

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9942201500D5	Benlysta	belimumab subcutaneous solution auto-injector	200 MG/ML	4	Syringes	28	DAYS				
9942201500E5	Benlysta	belimumab subcutaneous solution prefilled syringe	200 MG/ML	4	Syringes	28	DAYS				
994020800001	Lupkynis	voclosporin cap	7.9 MG	180	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**

Module	Clinical Criteria for Approval
	2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of active systemic lupus erythematosus (SLE) disease WITHOUT active Lupus Nephritis AND BOTH of the following: 1. The requested agent is FDA labeled for SLE **AND** 2. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to hydroxychloroquine **OR** 2. The patient has an intolerance or hypersensitivity to hydroxychloroquine **OR** 3. The patient has an FDA labeled contraindication to hydroxychloroquine **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that hydroxychloroquine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to corticosteroids OR immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** 2. The patient has an intolerance or hypersensitivity to corticosteroids OR immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids AND immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval
	5. The prescriber has provided documentation that ALL corticosteroids AND immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has a diagnosis of active lupus nephritis (LN) AND BOTH of the following: 1. The requested agent is FDA labeled for lupus nephritis **AND** 2. The patient has Class III, IV, or V lupus nephritis confirmed via kidney biopsy **OR** C. The patient has another FDA labeled indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent and route of administration **OR** B. There is support for using the requested agent for the patient's age for the requested indication and route of administration **AND** 2. If the patient has a diagnosis of active systemic lupus erythematosus (SLE) disease WITHOUT active Lupus Nephritis BOTH of the following: A. The patient is currently treated with standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **AND** B. The patient will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) in combination with the requested agent **AND** 3. If the patient has a diagnosis of active lupus nephritis, the patient will be using the requested agent with background immunosuppressive lupus nephritis therapy (e.g., corticosteroids with mycophenolate or for Benlysta corticosteroids with mycophenolate or IV cyclophosphamide) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have severe active central nervous system lupus **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agents **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 7. If the requested agent is Lupkynis, the patient will NOT be using the requested agent in combination with cyclophosphamide **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months ***NOTE:** Approve Benlysta subcutaneous loading dose for 1 month, then maintenance dose can be approved for the remainder of 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. ONE of the following: A. The patient has a diagnosis of active systemic lupus erythematosus (SLE) disease WITHOUT active Lupus Nephritis AND ALL of the following: 1. The requested agent is FDA labeled for SLE **AND** 2. The patient is currently using standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **AND** 3. The patient will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** B. The patient has a diagnosis of active lupus nephritis (LN) AND ALL of the following: 1. The requested agent is FDA labeled for lupus nephritis **AND** 2. The patient is currently using background lupus nephritis therapy (e.g., corticosteroids with mycophenolate or for Benlysta corticosteroids with mycophenolate or IV cyclophosphamide) **AND** 3. The patient will continue background lupus nephritis therapy (e.g., corticosteroids with mycophenolate or for Benlysta corticosteroids with mycophenolate or IV cyclophosphamide) **OR** C. The patient has another FDA labeled indication for the requested agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have severe active central nervous system lupus **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agents **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 7. If the requested agent is Lupkynis, the patient will NOT be using the requested agent in combination with cyclophosphamide **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following:

Module	Clinical Criteria for Approval
	A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval**: up to 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Litfulo (ritlecitinib) Nucala (mepolizumab) Olumiant (baricitinib) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib)

Contraindicated as Concomitant Therapy
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Northera (droxidopa)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
38700030000130	Northera	Droxidopa Cap 100 MG	100 MG	450	Capsules	30	DAYS				
38700030000140	Northera	Droxidopa Cap 200 MG	200 MG	180	Capsules	30	DAYS				
38700030000150	Northera	Droxidopa Cap 300 MG	300 MG	180	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND ALL of the following:

Module	Clinical Criteria for Approval

1. The prescriber has performed baseline (prior to therapy with the requested agent) blood pressure readings while the patient is sitting or supine (laying face up) AND also within 3 minutes of standing from a supine position **AND**
2. The patient has a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing **AND**
3. The patient has persistent and consistent symptoms of neurogenic orthostatic hypotension (nOH) caused by ONE of the following:
    A. Primary autonomic failure (Parkinson's disease [PD], multiple system atrophy, or pure autonomic failure) **OR**
    B. Dopamine beta-hydroxylase deficiency **OR**
    C. Non-diabetic autonomic neuropathy **AND**
4. The prescriber has assessed the severity of the patient's baseline (prior to therapy with the requested agent) symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out **AND**
5. The prescriber has assessed and adjusted, if applicable, any medications known to exacerbate orthostatic hypotension (e.g., diuretics, vasodilators, beta-blockers) **AND**
6. ONE of the following:
    A. The patient has tried and had an inadequate response to midodrine **OR**
    B. The patient has an intolerance or hypersensitivity to therapy with midodrine **OR**
    C. The patient has an FDA labeled contraindication to midodrine **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    E. The prescriber has provided documentation that midodrine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

B. The patient has another FDA labeled indication for the requested agent **AND**

2. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. There is support for using the requested agent for the patient's age for the requested indication **AND**
3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Northera	droxidopa

    A. The patient's medication history includes the required generic equivalent as indicated by:
        1. Evidence of a paid claim(s) **OR**
        2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
    B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
    C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
    D. There is support for the use of the requested brand agent over the generic equivalent **OR**

Module	Clinical Criteria for Approval

E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
   3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 1 month

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
   A. The patient has a diagnosis of neurogenic orthostatic hypotension (nOH) **AND** BOTH of the following:
      1. The patient has had improvement in severity from baseline symptoms (prior to therapy with the requested agent) of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out **AND**
      2. The patient had an increase in systolic blood pressure from baseline (prior to therapy with the requested agent) of at least 10 mmHg upon standing from a supine (laying face up) position **OR**

   B. BOTH of the following:
      1. The patient has another FDA labeled indication for the requested agent **AND**
      2. The patient has had clinical benefit with the requested agent **AND**
3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Northera	droxidopa

   A. The patient's medication history includes the required generic equivalent as indicated by:
      1. Evidence of a paid claim(s) **OR**
      2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**

   B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   D. There is support for the use of the requested brand agent over the generic equivalent **OR**
   E. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of Approval**: Initial - Up to 1 month; Renewal - Up to 3 months

● Program Summary: Otezla (apremilast)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6670001500	Otezla	apremilast tab ; apremilast tab starter therapy pack	10 & 20 & 30 MG ; 30 MG	60	Tablets	30	DAYS				
66700015000330	Otezla	Apremilast Tab 30 MG	30 MG	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6670001500B720	Otezla	Apremilast Tab Starter Therapy Pack 10 MG & 20 MG & 30 MG	10 & 20 & 30 MG	1	Kit	180	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

Target Agent(s) will be approved when the ALL of the following are met:

1. ONE of the following:
   - A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

      1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**
   - B. BOTH of the following:
      1. ONE of the following:
         - A. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following:
            1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **OR**
            2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA **OR**
            3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR**
            4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PsA **OR**
            5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
               - A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
               - B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
               - C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
            6. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**
         - B. The patient has a diagnosis of plaque psoriasis (PS) AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of Behcet's disease (BD) AND ALL of the following: 1. The patient has active oral ulcers associated with BD **AND** 2. The patient has had at least 3 occurrences of oral ulcers in the last 12-months **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to ONE conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR** B. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of BD **OR** C. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of BD **OR** D. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of BD **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL conventional agents (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has another FDA labeled indication for the requested agent not mentioned previously **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **OR** C. The patient has another indication that is supported in compendia for the requested agent not mentioned previously **AND** 2. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**

Module	Clinical Criteria for Approval
	B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support of therapy with a higher dose for the requested indication (e.g., clinical trials, phase III studies, guidelines required) **Length of Approval**: up to 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)

Contraindicated as Concomitant Therapy
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)

Contraindicated as Concomitant Therapy
Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Parathyroid Hormone Analog for Osteoporosis

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
3004407000D221		Teriparatide (Recombinant) Soln Pen-inj 620 MCG/2.48ML	620 MCG/2.48ML	1	Pen	28	DAYS				
3004407000D220	Forteo	Teriparatide (Recombinant) Soln Pen-inj 600 MCG/2.4ML	600 MCG/2.4ML	1	Pen	28	DAYS				
3004400500D230	Tymlos	Abaloparatide Subcutaneous Soln Pen-injector 3120 MCG/1.56ML	3120 MCG/1.56ML	1	Pen	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Forteo preferred	**Preferred Agent (Forteo)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states that the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of osteoporosis and ALL of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND**

Module	Clinical Criteria for Approval
	3. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of glucocorticoid-induced osteoporosis and ALL of the following: 1. The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 5 mg or higher of prednisone **AND** 2. The patient's expected current course of therapy of glucocorticoids is for a period of at least 3 months **AND** 3. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX or the 10-year probability of hip fracture of greater than or equal to 3% **AND** 4. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR**

Module	Clinical Criteria for Approval
	4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg or another parathyroid hormone analog (e.g., abaloparatide) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. ONE of the following: A. The patient has never received treatment with a parathyroid hormone analog (Teriparatide, Forteo, and Tymlos) **OR** B. The patient has been previously treated with parathyroid hormone analog(s) and ONE of the following: 1. The total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 2 years in lifetime **OR** 2. BOTH of the following: A. The patient has received 2 years or more of parathyroid hormone analog treatment in their lifetime, and is at high risk for fracture (e.g., shown by T-score, FRAX score, continued use of glucocorticoids at a daily equivalent of 5 mg of prednisone or higher) **AND** B. The patient was previously treated with Forteo **Length of approval:** up to a total of 2 years of treatment in lifetime between Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide). Approve for 1 year if patient has already had 2 years of Forteo (teriparatide) or Teriparatide in lifetime and is at high risk of fracture. Only one parathyroid hormone analog will be approved for use at a time. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Teriparatide through preferred	**Non-Preferred Agent(s) Teriparatide** will be approved when ALL of the following are met: 1. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states that the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to BOTH of the preferred agents (Forteo AND Tymlos) **OR** B. The patient has an intolerance or hypersensitivity to BOTH of the preferred agents (Forteo AND Tymlos) that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to BOTH of the preferred agent (Forteo AND Tymlos) that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation BOTH Forteo AND Tymlos cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** 4. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR**

Module	Clinical Criteria for Approval
	7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of glucocorticoid-induced osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to a preferred agent (Forteo) **OR** B. The patient has an intolerance or hypersensitivity to the preferred agent (Forteo) that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to the preferred agent (Forteo) that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that the preferred agent (Forteo) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 5 mg or higher of prednisone **AND** 3. The patient's expected current course of therapy of glucocorticoids is for a period of at least 3 months **AND** 4. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following:

Module	Clinical Criteria for Approval
	1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** 5. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg or another parathyroid hormone analog (e.g., abaloparatide) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. ONE of the following: A. The patient has never received treatment with a parathyroid hormone analog (Teriparatide, Forteo, and Tymlos) **OR** B. The patient has been previously treated with parathyroid hormone analog(s) AND the total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 2 years in lifetime **Length of approval:** up to a total of 2 years of treatment in lifetime between Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide). Approve for 1 year if patient has already had 2 years of Forteo (teriparatide) or Teriparatide in lifetime and is at high risk of fracture. Only one parathyroid hormone analog will be approved for use at a time. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
Tymlos - through preferred	**Preferred Agent (Tymlos)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** 3. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg, or another parathyroid hormone analog (e.g., teriparatide) therapy **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 2 years in lifetime **Length of approval:** up to a total of 2 years of treatment in lifetime between Forteo (teriparatide) Teriparatide, and Tymlos (abaloparatide), approve for the remainder of the 2 years of therapy remaining. Only one parathyroid hormone analog will be approved for use at a time. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA Forteo preferred	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of approval:** up to 2 years for new Forteo (teriparatide) starts or patients new to the plan's Prior Authorization process. Approve for 1 year if patient has already had 2 years of Forteo (teriparatide) or Teriparatide in lifetime and is at high risk of fracture.
QL with PA Teriparatide through preferred	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of approval:** up to 2 years for new Teriparatide starts or patients new to the plan's Prior Authorization process. Approve for 1 year if patient has already had 2 years of Forteo (teriparatide) or Teriparatide in lifetime and is at high risk of fracture.
QL with PA Tymlos	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

Module	Clinical Criteria for Approval
	2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of approval:** up to 2 years of treatment in lifetime between Forteo (teriparatide) Teriparatide, and Tymlos (abaloparatide), approve for the remainder of the 2 years of therapy remaining.

● Program Summary: Protein Convertase Subtilisin / Kexin Type 9 (PCSK9) Inhibitors

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
3935002000E5	Repatha	evolocumab subcutaneous soln prefilled syringe	140 MG/ML	2	Syringes	28	DAYS				
3935002000E2	Repatha pushtronex system	evolocumab subcutaneous soln cartridge/infusor	420 MG/3.5ML	2	Cartridges	28	DAYS				
3935002000D5	Repatha sureclick	evolocumab subcutaneous soln auto-injector	140 MG/ML	2	Pens	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	<table><tr><th>Preferred Target Agent(s)</th><th>Non-Preferred Target Agent(s)</th></tr><tr><td>Repatha (evolocumab)</td><td>Praluent (alirocumab)</td></tr></table> **Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) and ALL of the following: 1. The patient has a diagnosis of HoFH confirmed by ONE of the following: A. Genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the *LDLR, Apo-B, PCSK9,* or *LDLRAP1* genes, or greater than or equal to 2 such variants at different loci **OR** B. History of untreated LDL-C greater than 400 mg/dL (greater than 10 mmol/L) and ONE of the following: 1. The patient had cutaneous or tendon xanthomas before age of 10 years **OR**

Module	Clinical Criteria for Approval
	2. Untreated elevated LDL-C levels consistent with heterozygous FH in both parents, (or in digenic form, one parent may have normal LDL-C levels and the other may have LDL-C levels consistent with HoFH) **AND** 2. ONE of the following: A. The patient has tried a high-intensity statin (e.g., atorvastatin 40-80 mg, rosuvastatin 20-40 mg daily) for 2 months and had an inadequate response **OR** B. The patient has an intolerance or hypersensitivity to ALL high-intensity statins **OR** C. The patient has an FDA labeled contraindication to ALL high-intensity statins **OR** D. The patient's medication history includes use of high intensity atorvastatin or rosuvastatin therapy **OR** E. BOTH of the following: 1. The prescriber has stated that the patient has tried high intensity atorvastatin or rosuvastatin therapy **AND** 2. High intensity atorvastatin or rosuvastatin was discontinued due to lack of effectiveness or an adverse event **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that atorvastatin AND rosuvastatin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient will use other lipid-lowering therapy (e.g., statin, ezetimibe, lipoprotein apheresis, lomitapide, evinacumab) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, endocrinologist, lipid specialist, geneticist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) AND BOTH of the following: 1. ONE of the following: A. Genetic confirmation of one mutant allele at the *LDLR, Apo-B, PCSK9*, or *1/LDLRAP1* gene **OR** B. Pre-treatment LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) **OR** C. The patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, corneal arcus) **OR** D. The patient has "definite" or "possible" familial hypercholesterolemia as defined by the Simon Broome criteria **OR** E. The Patient has a Dutch Lipid Clinic Network Criteria score of greater than 5 **OR** F. The patient has a treated LDL-C level greater than or equal to 100 mg/dL after statin treatment with or without ezetimibe **AND**

Module	Clinical Criteria for Approval
	2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, endocrinologist, lipid specialist, geneticist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR** B. The patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) AND has ONE of the following: 1. Acute coronary syndrome 2. History of myocardial infarction 3. Stable or unstable angina 4. Coronary or other arterial revascularization 5. Stroke 6. Transient ischemic attack 7. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin **OR** C. The patient has a diagnosis of primary hyperlipidemia AND ONE of the following: 1. The patient has a coronary artery calcium or calcification (CAC) score greater than or equal to 300 Agatston units **OR** 2. The patient has a pre-treatment LDL-C level greater than or equal to 190 mg/dL (greater than or equal to 4.9 mmol/L) **OR** D. The patient has at least a 20% 10-year ASCVD risk AND ONE of the following: 1. The patient has greater than or equal to 40% 10-year ASCVD risk AND BOTH of the following: A. LDL-C greater than or equal to 70 mg/dL while on maximally tolerated statin therapy **AND** B. ONE of the following: 1. The patient has extensive or active burden of ASCVD (i.e., polyvascular ASCVD, which affects all 3 vascular beds—coronary, cerebrovascular, and peripheral arterial; clinical peripheral arterial disease in addition to coronary and/or cerebrovascular disease; a clinical ASCVD event with multivessel coronary artery disease defined as greater than or equal to 40% stenosis in greater than or equal to 2 large vessels; or recurrent myocardial infarction within 2 years of the initial event) in the presence of adverse or poorly controlled cardiometabolic risk factors **OR** 2. Extremely high-risk elevations in cardiometabolic factors with less-extensive ASCVD (i.e., diabetes, LDL-C greater than or equal to 100 mg/dL, less than high–intensity statin therapy, chronic kidney disease, poorly controlled hypertension, high-sensitivity C-reactive protein greater than 3 mg/L, or metabolic syndrome, usually occurring with other extremely high–risk or very-high-risk characteristics), usually with other adverse or poorly controlled cardiometabolic risk factors present. **OR** 3. Patients with ASCVD and LDL-C greater than or equal to 220 mg/dL with greater than or equal to 45% 10- year ASCVD risk despite statin therapy **OR** 2. The patient has 30-39% 10-year ASCVD risk AND ALL of the following: A. LDL-C greater than or equal to 100 mg/dL while on maximally tolerated statin therapy **AND** B. Less-extensive clinical ASCVD (i.e., no polyvascular ASCVD, no clinical peripheral arterial disease, a prior ASCVD event greater than or equal to 2 years prior, and no coronary artery bypass grafting) **AND**

Module	Clinical Criteria for Approval
	C. Adverse or poorly controlled cardiometabolic risk factor(s) including age 65 years or older, current smoking, chronic kidney disease, lipoprotein(a) greater than or equal to 37 nmol/L, high-sensitivity C-reactive protein 1–3 mg/L, metabolic syndrome with a history of myocardial infarction, ischemic stroke, or symptomatic peripheral arterial disease, usually in the presence of other adverse or poorly controlled cardiometabolic risk factors **OR** 3. The patient has 20-29% 10-year ASCVD risk AND BOTH of the following: A. LDL-C greater than or equal to 130 mg/dL while on maximally tolerated statins **AND** B. ONE of the following: 1. The patient has less extensive ASCVD and well-controlled cardiometabolic risk factors (i.e., no diabetes, nonsmoker, on high-intensity statin with LDL-C less than 100 mg/dL, blood pressure less than 140/90 mm Hg, and C-reactive protein less than 1 mg/dL) **OR** 2. The use is for primary prevention with LDL-C greater than or equal to 220 mg/dL AND BOTH of the following: A. No clinical ASCVD or CAC less than 100 Agatston units **AND** B. Poorly controlled cardiometabolic risk factor **AND** 2. ONE of the following: A. The patient has been adherent to high-intensity statin therapy (i.e., atorvastatin 40-80mg, rosuvastatin 20-40 mg daily) for at least 8 consecutive weeks AND ONE of the following: 1. The patient's LDL-C level after this statin therapy remains greater than or equal to 70 mg/dL **OR** 2. The patient has not achieved a 50% reduction in LDL-C from this statin therapy **OR** 3. If the patient has ASCVD at very high risk, ONE of the following: A. The patient's LDL-C level after this statin therapy remains greater than or equal to 55 mg/dL **OR** B. The patient's non HDL-C level after this statin therapy remains greater than or equal to 85 mg/dL **OR** B. The patient has been determined to be statin intolerant by meeting ONE of the following: 1. The patient experienced statin-related rhabdomyolysis **OR** 2. The patient experienced skeletal-related muscle symptoms (e.g., myopathy, myalgia) and BOTH of the following: A. The skeletal-related muscle symptoms occurred while receiving separate trials of both atorvastatin AND rosuvastatin **AND** B. When receiving separate trials of both atorvastatin and rosuvastatin, the skeletal-related muscle symptoms resolved upon discontinuation of each statin **OR** 3. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin **OR** C. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR** D. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **OR** E. The patient's medication history includes use of high intensity atorvastatin or rosuvastatin therapy **OR** F. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The prescriber has stated that the patient has tried high intensity atorvastatin or rosuvastatin therapy **AND** 2. High intensity atorvastatin or rosuvastatin was discontinued due to lack of effectiveness or an adverse event **OR** G. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** H. The prescriber has provided documentation that atorvastatin AND rosuvastatin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has another FDA labeled indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with another PCSK9 agent for the requested indication **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. If the client has preferred agent(s), then ONE of the following: A. The request is for a preferred agent **OR** B. The patient has tried and had an inadequate response to the preferred agent **OR** C. The patient has an intolerance or hypersensitivity to the preferred agent **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
	1. The patient has been previously approved for therapy for PCSK9 inhibitors through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. If the client has preferred agent(s), then ONE of the following: A. The request is for a preferred agent **OR** B. The patient has tried and had an inadequate response to the preferred agent **OR** C. The patient has an intolerance or hypersensitivity to the preferred agent **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient has shown clinical benefit with a PCSK9 inhibitor **AND** 4. The patient is currently adherent to therapy with a PCSK9 inhibitor **AND** 5. If the patient has a diagnosis of HoFH, they will continue to use other lipid-lowering therapy (e.g., statin, ezetimibe, lipoprotein apheresis, lomitapide, evinacumab) **AND** 6. If the patient has a diagnosis of HeFH or HoFH, the prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, endocrinologist, lipid specialist, geneticist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. If the patient has ASCVD, HeFH, or hyperlipidemia, then ONE of the following: A. The patient is currently adherent to high-intensity statin therapy (i.e., atorvastatin 40-80mg, rosuvastatin 20-40 mg daily) **OR** B. The patient has been determined to be statin intolerant by meeting ONE of the following criteria: 1. The patient experienced statin-related rhabdomyolysis **OR** 2. The patient experienced skeletal-related muscle symptoms (e.g., myopathy, myalgia) and BOTH of the following: A. The skeletal-related muscle symptoms occurred while receiving separate trials of both atorvastatin AND rosuvastatin **AND** B. When receiving separate trials of both atorvastatin and rosuvastatin the skeletal-related muscle symptoms resolved upon discontinuation of each statin **OR** 3. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin **OR** C. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR** D. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **OR** E. The patient's medication history includes use of high intensity atorvastatin or rosuvastatin **OR** F. BOTH of the following: 1. The prescriber has stated that the patient has tried high intensity atorvastatin or rosuvastatin **AND** 2. High intensity atorvastatin or rosuvastatin was discontinued due to lack of effectiveness or an adverse event **OR** G. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval
	H. The prescriber has provided documentation that atorvastatin and rosuvastatin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 8. The patient will NOT be using the requested agent in combination with another PCSK9 agent for the requested indication **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of approval:** up to 12 months

• Program Summary: Pyrukynd (mitapivat)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
85870050700310	Pyrukynd	Mitapivat Sulfate Tab	5 MG	56	Tablets	28	DAYS				
85870050700325	Pyrukynd	Mitapivat Sulfate Tab	20 MG	56	Tablets	28	DAYS				
85870050700340	Pyrukynd	Mitapivat Sulfate Tab	50 MG	56	Tablets	28	DAYS				
8587005070B710	Pyrukynd taper pack	Mitapivat Sulfate Tab Therapy Pack	5 MG	7	Tablets	365	DAYS				
8587005070B720	Pyrukynd taper pack	Mitapivat Sulfate Tab Therapy Pack	7 x 20 MG & 7 x 5 MG	14	Tablets	365	DAYS				
8587005070B735	Pyrukynd taper pack	Mitapivat Sulfate Tab Therapy Pack	7 x 50 MG & 7 x 20 MG	14	Tablets	365	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of hemolytic anemia with pyruvate kinase deficiency (PKD) as confirmed by genetic testing showing a pathogenic PKLR gene mutation **AND** 2. The patient is NOT homozygous for the c.1436G > A (p.R479H) variant **AND** 3. The patient has at least 2 variant alleles in the PKLR gene, of which at least 1 is a missense variant **AND** 4. ONE of the following: A. The patient has a hemoglobin of less than or equal to 10g/dL **OR** B. The patient has had more than 4 red blood cell (RBC) transfusions in the past year **AND** 5. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please see Quantity Limit Criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent (e.g., hemoglobin has increased or is within normal range, decrease in red blood cell transfusion burden) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please see Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND**

Module	Clinical Criteria for Approval
	B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** Initial request up to 6 months; Renewal request up to 12 months

• Program Summary: Samsca (tolvaptan)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
30454060000320	Samsca	tolvaptan tab	15 MG	30	Tablets	365	DAYS	31722086803 ; 31722086831 ; 49884076852 ; 49884076854 ; 59148002050 ; 60505431700 ; 67877063502 ; 67877063533 ; 72205013011			
30454060000330	Samsca	tolvaptan tab	30 MG	60	Tablets	365	DAYS	31722086903 ; 49884077052 ; 49884077054 ; 59148002150 ; 60505431800 ; 60505470500 ; 60505470501 ; 67877063602 ; 67877063633 ; 72205013111			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Target Agent(s)** will be approved when ALL of the following are met: 1. The requested agent was initiated (or re-initiated) in the hospital **AND** 2. Prior to initiating the requested agent, the patient has/had a diagnosis of clinically significant hypervolemic or euvolemic hyponatremia defined by one of the following: A. serum sodium less than 125 mEq/L **OR** B. serum sodium greater than or equal to 125 mEq/L and has symptomatic hyponatremia that has resisted correction with fluid restriction **AND** 3. The patient does NOT have underlying liver disease, including cirrhosis **AND** 4. Medications known to cause hyponatremia (e.g., antidepressants [SSRIs, tricyclics, MAOIs, venlafaxine], anticonvulsants [carbamazepine, oxcarbazepine, sodium valproate, lamotrigine], antipsychotics [phenothiazines, butyrophenones], anticancer [vinca alkaloids, platinum compounds, ifosfamide, melphalan, cyclophosphamide, methotrexate, pentostatin], antidiabetic [chlorpropamide, tolbutamide], vasopressin analogues [desmopressin, oxytocin, terlipressin, vasopressin], miscellaneous [amiodarone, clofibrate, interferon, NSAIDs, levamisole,

Module	Clinical Criteria for Approval
	linezolid, monoclonal antibodies, nicotine, opiates, PPIs]) have been evaluated and discontinued when appropriate **AND** 5. The patient will NOT be using the requested agent in combination with another tolvaptan agent for the requested indication **AND** 6. The patient does not have any FDA labeled contraindications to the requested agent **AND** 7. The patient has not already received 30 days of therapy with the requested agent for the current hospitalization **Length of Approval:** 30 tablets/365 days of the 15 mg tablets 60 tablets/365 days of the 30 mg tablets NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose and/or duration of therapy) does NOT exceed the program quantity limit **OR** 2. BOTH of the following: A. The requested quantity (dose and/or duration of therapy) exceeds the program quantity limit **AND** B. The patient has had an additional hospitalization for hyponatremia for initiation of the requested agent **Length of Approval:** 30 tablets/365 days of the 15 mg tablets 60 tablets/365 days of the 30 mg tablets

• Program Summary: Skyclarys (omaveloxolone)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
74135060000120	Skyclarys	omaveloxolone cap	50 MG	90	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** Skyclarys

Module	Clinical Criteria for Approval
	1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The patient has a diagnosis of Friedreich ataxia (FA, FRDA) with genetic analysis confirming mutation in the frataxin (FXN) gene **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber has assessed baseline status (prior to therapy with the requested agent) of the patient's symptoms (e.g., mobility, balance, strength, lower limb spasticity) **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., mobility, balance, strength, lower limb spasticity) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND**

Module	Clinical Criteria for Approval
	B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support of therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Tarpeyo

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
22100012006520	Tarpeyo	Budesonide Delayed Release Cap	4 MG	120	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy **AND** 2. The requested agent will be used to reduce the loss of kidney function in a patient at risk for disease progression **AND** 3. ONE of the following: A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 g/g **OR** B. The patient has proteinuria greater than or equal to 1 g/day **AND** 4. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m^2 **AND** 5. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 6. ONE of the following A. BOTH of the following: 1. The patient has tried and had an inadequate response to therapy with maximally tolerated ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACEI or ARB **AND** 2. The patient will be using an ACEI or ARB or a combination medication containing an ACEI or ARB in combination with the requested agent **OR** B. The patient has an intolerance or hypersensitivity to an ACEI or ARB, or a combination medication containing an ACE or ARB **OR** C. The patient has an FDA labeled contraindication to ALL ACEI and ARB **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval
	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL ACEI and ARB cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 7. ONE of the following: A. The patient has an intolerance or hypersensitivity to oral generic budesonide that is not expected to occur with the requested agent **OR** B. The patient has an FDA labeled contraindication to the oral generic budesonide that is not expected to occur with the requested agent **OR** C. BOTH of the following: 1. The prescriber has stated that the patient has tried oral generic budesonide **AND** 2. Oral generic budesonide was discontinued due to lack of effectiveness or an adverse event **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that oral generic budesonide cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 8. ONE of the following: A. The patient has not previously been treated with a course of therapy (9 months) with the requested agent **OR** B. The patient has previously been treated with a course of therapy with the requested agent, AND there is support for an additional course of therapy with the requested agent **AND** 9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 10 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** up to 10 months

• Program Summary: Tavneos (avacopan)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
85805510000120	Tavneos	Avacopan Cap	10 MG	180	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy is changed **OR** C. ALL of the following: 1. The patient has a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and/or microscopic polyangiitis [MPA]) **AND** 2. The patient has a positive ANCA-test **AND** 3. The patient has been screened for prior or current hepatitis B infection AND if positive a prescriber specializing in hepatitis B treatment has been consulted **OR** D. BOTH of the following: 1. The patient has another FDA approved indication for the requested agent **AND** 2. The patient has been screened for prior or current hepatitis B infection AND if positive a prescriber specializing in hepatitis B treatment has been consulted **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have severe hepatic impairment (Child-Pugh C) **AND** 4. If the patient has a diagnosis of ANCA-associated vasculitis, then BOTH of the following: A. The patient is currently treated with standard therapy (e.g., cyclophosphamide, rituximab, azathioprine, mycophenolate mofetil) for the requested indication **AND** B. The patient will continue standard therapy (e.g., cyclophosphamide, rituximab, azathioprine, mycophenolate mofetil) in combination with the requested agent for the requested indication **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approva**l: 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does NOT have severe hepatic impairment (Child-Pugh C) **AND** 4. ONE of the following: A. The patient has a diagnosis of ANCA associated vasculitis AND BOTH of the following: 1. The patient is currently treated with standard therapy (e.g., azathioprine, mycophenolate mofetil) for the requested indication **AND** 2. The patient will continue standard therapy (e.g., azathioprine, mycophenolate mofetil) in combination with the requested agent for the requested indication **OR** B. The patient has another FDA approved indication for the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of approval**: Initial approval - up to 6 months; Renewal approval - up to 12 months

• Program Summary: Thrombopoietin Receptor Agonists and Tavalisse

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
82405030050310	Alvaiz	eltrombopag choline tab	9 MG	30	Tablets	30	DAYS				
82405030050320	Alvaiz	eltrombopag choline tab	18 MG	30	Tablets	30	DAYS				
82405030050330	Alvaiz	eltrombopag choline tab	36 MG	60	Tablets	30	DAYS				
82405030050340	Alvaiz	eltrombopag choline tab	54 MG	60	Tablets	30	DAYS				
82405010200320	Doptelet	Avatrombopag Maleate Tab 20 MG (Base Equiv)	20 MG	60	Tablets	30	DAYS				
82405045000320	Mulpleta	Lusutrombopag Tab 3 MG	3 MG	7	Tablets	7	DAYS				
82405030103030	Promacta	Eltrombopag Olamine Powder Pack for Susp 12.5 MG (Base Eq)	12.5 MG	30	Packets	30	DAYS				
82405030103020	Promacta	Eltrombopag Olamine Powder Pack for Susp 25 MG (Base Equiv)	25 MG	30	Packets	30	DAYS				
82405030100310	Promacta	Eltrombopag Olamine Tab 12.5 MG (Base Equiv)	12.5 MG	30	Tablets	30	DAYS				
82405030100320	Promacta	Eltrombopag Olamine Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
82405030100330	Promacta	Eltrombopag Olamine Tab 50 MG (Base Equiv)	50 MG	60	Tablets	30	DAYS				
82405030100340	Promacta	Eltrombopag Olamine Tab 75 MG (Base Equiv)	75 MG	60	Tablets	30	DAYS				
857560401003	Tavalisse	fostamatinib disodium tab	100 MG ; 150 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when the ALL of the following are met: 1. ONE of the following: A. The requested agent is Doptelet AND ONE of the following: 1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: A. ONE of the following: 1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** 2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 X 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** B. ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Nplate, Promacta) or Tavalisse **OR** 5. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** 6. The patient has had an inadequate response to a splenectomy **OR** 7. The patient has tried and had an inadequate response to rituximab **OR** 8. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 9. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following: A. The patient has a platelet count less than 50 X 10^9/L **AND** B. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** C. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** 3. The patient has another FDA labeled indication for the requested agent **OR** 4. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** B. The requested agent is Mulpleta (lusutrombopag) AND ONE of the following: 1. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following: A. The patient has a platelet count less than 50 X 10^9/L **AND** B. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** C. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** 2. The patient has another FDA labeled indication for the requested agent **OR** 3. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** C. The requested agent is Nplate (romiplostim) AND ONE of the following: 1. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **OR** 2. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ALL of the following:

Module	Clinical Criteria for Approval
	A. If the patient is a pediatric patient, then the patient has had ITP for at least 6 months **AND** B. ONE of the following: 1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** 2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** C. ONE of the following: 1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** 5. The patient has had an inadequate response to a splenectomy **OR** 6. The patient has tried and had an inadequate response to rituximab **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 3. The patient has another FDA labeled indication for the requested agent **OR** 4. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** D. The requested agent is Promacta (eltrombopag) or Alvaiz AND ONE of the following: 1. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following: A. The intent of therapy with the requested agent is to increase platelet counts sufficiently to initiate interferon therapy AND the patient's platelet count is less than 75 x 10^9/L **OR** B. The patient is on concomitant therapy with interferon AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR** 2. The patient has a diagnosis of severe aplastic anemia AND ALL of the following: A. The patient has at least 2 of the following blood criteria: 1. Neutrophils less than 0.5 X 10^9/L 2. Platelets less than 30 X 10^9/L 3. Reticulocyte count less than 60 X 10^9/L **AND** B. The patient has 1 of the following marrow criteria: 1. Severe hypocellularity: less than 25% **OR** 2. Moderate hypocellularity, 25-50% with hematopoietic cells representing less than 30% of residual cells **AND** C. ONE of the following:

Module	Clinical Criteria for Approval
	1. BOTH of the following: A. The patient will use the requested agent as first-line treatment **AND** B. The patient will use the requested agent in combination with standard immunosuppressive therapy (i.e., antithymocyte globulin [ATG] AND cyclosporine) **OR** 2. ONE of the following: A. The patient has tried and had an inadequate response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR** B. The patient has an intolerance or hypersensitivity to BOTH ATG AND cyclosporine **OR** C. The patient has an FDA labeled contraindication to BOTH ATG AND cyclosporine **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH antithymocyte globulin (ATG) AND cyclosporine therapy cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 3. The patient has a diagnosis of persistent or chronic (defined as lasting for at least 3 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: A. ONE of the following: 1. The patient has a platelet count less than or equal to 30 x 10^9/L **OR** 2. The patient has a platelet count greater than 30 x 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** 5. The patient has had an inadequate response to a splenectomy **OR** 6. The patient has tried and had an inadequate response to rituximab **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 4. The patient has another FDA labeled indication for the requested agent **OR** 5. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** E. The requested agent is Tavalisse (fostamatinib disodium hexahydrate) AND ONE of the following: 1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: A. ONE of the following: 1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** 2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to a thrombopoietin receptor agonist (e.g., Doptelet, Nplate, Promacta) **OR** 5. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** 6. The patient has had an inadequate response to a splenectomy **OR** 7. The patient has tried and had an inadequate response to rituximab **OR** 8. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 9. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient has another FDA labeled indication for the requested agent **OR** 3. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient will NOT be using the requested agent in combination with another agent included in this program **OR** B. The patient will use the requested agent in combination with another agent included in this program AND BOTH of the following: 1. The requested agent is Nplate **AND** 2. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Lengths of Approval:** **Doptelet**: thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - 6 months **Mulpleta**: thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - 6 months **Nplate**: HS-ARS - 1 time; ITP - 4 months; all other indications - 6 months **Promacta**: ITP - 2 months; thrombocytopenia in hep C - 3 months; first-line therapy in severe aplastic anemia - 6 months; all other severe aplastic anemia - 4 months; all other indications - 6 months **Alvaiz:** ITP - 2 months; thrombocytopenia in hep C - 3 months; all other severe aplastic anemia - 4 months; all other indications - 6 months **Tavalisse**: all indications - 6 months NOTE if Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process. [Note: patients not previously approved for the requested agent will require initial evaluation review] (Note: Doptelet and Mulpleta for thrombocytopenia with chronic liver disease AND Nplate for hematopoietic syndrome of acute radiation syndrome (HS-ARS) should always be reviewed under initial criteria.) **AND** 2. ONE of the following: A. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following: 1. The patient's platelet count is greater than or equal to 50 x 10^9/L **OR** 2. The patient's platelet count has increased sufficiently to avoid clinically significant bleeding **OR** B. The patient has the diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the following: 1. The patient will be initiating or maintaining hepatitis C therapy with interferon **AND** 2. ONE of the following: A. The patient's platelet count is greater than or equal to 90 x 10^9/L **OR** B. The patient's platelet count has increased sufficiently to initiate or maintain interferon therapy for the treatment of hepatitis C **OR** C. The patient has a diagnosis other than ITP or hepatitis C associated thrombocytopenia AND has shown clinical improvement with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another agent included in this program **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Lengths of Approval: thrombocytopenia in hepatitis C - 6 months; all other indications - 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Initial Lengths of Approval:** **Doptelet:** thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - up to 6 months **Mulpleta:** thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - up to 6 months **Nplate:** HS-ARS - 1 time; ITP - up to 4 months; all other indications - up to 6 months **Promacta:** ITP - up to 2 months; thrombocytopenia in hep C - up to 3 months; first-line therapy in severe aplastic anemia - up to 6 months; all other severe aplastic anemia - up to 4 months; all other indications - up to 6 months **Alvaiz:** ITP - 2 months; thrombocytopenia in hep C - 3 months; all other severe aplastic anemia - 4 months; all other indications - 6 months **Tavalisse:** all indications - up to 6 months **Renewal Lengths of Approval:** thrombocytopenia in hepatitis C - up to 6 months; all other indications - up to 12 months

• Program Summary: Zeposia (ozanimod)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
624070502001	Zeposia	ozanimod hcl cap	0.92 MG	30	Capsules	30	DAYS				
6240705020B210	Zeposia 7-day starter pac	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG	4 x 0.23MG & 3 x 0.46MG	7	Capsules	180	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6240705020B215	Zeposia starter kit	ozanimod cap pack	0.23MG &0.46MG 0.92MG(21)	28	Capsules	180	DAYS				
6240705020B220	Zeposia starter kit	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG & 30 x 0.92 MG	0.23MG & 0.46MG & 0.92MG	37	Capsules	180	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA with MS Step	**Initial Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested agent is eligible for continuation of therapy AND ONE of following: **Agents Eligible for Continuation of Therapy** Zeposia (ozanimod) A. The patient has been treated with the requested agent within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** 2. The patient has a diagnosis of multiple sclerosis (MS) AND BOTH of the following: A. ONE of the following: 1. The patient has highly active MS disease activity AND BOTH of the following: A. The patient has greater than or equal to 2 relapses in the previous year **AND** B. ONE of the following: 1. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI **OR** 2. The patient has significant increase in T2 lesion load compared with a previous MRI **OR** 2. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table) **OR** 3. ONE of the following A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient's medication history incudes use of ONE Preferred generic MS agent* **OR** C. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred generic MS agent* **AND** 2. The preferred generic MS agent* was discontinued due to lack of effectiveness or an adverse event **OR**

Module	Clinical Criteria for Approval
	D. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic MS agent* **OR** E. The patient has an FDA labeled contraindication to ALL preferred generic MS agents* **OR** F. The prescriber has provided documentation that ALL preferred generic MS agents* cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. The patient will NOT be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR** 3. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ALL of the following: A. ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC **OR** 3. The patient has severely active ulcerative colitis **OR** 4. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 5. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR** 7. The prescriber has provided documentation that ALL of the conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, steroid suppositories, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to TWO Step 1a and/or Step 1b immunomodulatory agents (see Immunomodulatory Agent Step table) **OR**

Module	Clinical Criteria for Approval

3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least TWO Step 1a and/or Step 1b immunomodulatory agents **OR**
4. The patient has an FDA labeled contraindication to ALL Step 1a AND Step1b immunomodulatory agents **OR**
5. The prescriber has provided documentation that ALL Step 1a AND Step1b immunomodulatory agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

C. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table) **AND**

D. If the patient has an FDA labeled indication, then ONE of the following:
1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
2. There is support for using the requested agent for the patient's age for the requested indication **AND**

E. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

F. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Renewal Evaluation

Target Agent(s) will be approved when BOTH of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND**
2. ONE of the following:
   A. The patient has a diagnosis of multiple sclerosis (MS) AND BOTH of the following:
      1. ONE of the following:
         A. The requested agent is eligible for continuation of therapy AND ONE of following:

Agents Eligible for Continuation of Therapy
Zeposia (ozanimod)

1. The patient has been treated with the requested agent within the past 90 days **OR**
2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**

B. The patient has highly active MS disease activity AND BOTH of the following:
1. The patient has greater than or equal to 2 relapses in the previous year **AND**

Module	Clinical Criteria for Approval
	2. ONE of the following: A. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI **OR** B. The patient has significant increase in T2 lesion load compared with a previous MRI OR C. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table) **OR** D. ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history incudes use of ONE Preferred generic MS agent* **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred generic MS agent* **AND** B. The preferred generic MS agent* was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic MS agent* **OR** 5. The patient has an FDA labeled contraindication to ALL preferred generic MS agents* **OR** 6. The prescriber has provided documentation that ALL preferred generic MS agents* cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will not be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR** B. The patient has a diagnosis of ulcerative colitis AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (see "Immunomodulatory Agents NOT to be used Concomitantly" table) **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. *** Preferred and Non-preferred MS agents**

Module	Clinical Criteria for Approval

Preferred generic agents
dimethyl fumarate
fingolimod
Glatopa (glatiramer)
glatiramer
teriflunomide

Preferred brand agents
Avonex (interferon b-1a)
Betaseron (interferon b-1b)
Kesimpta (ofatumumab)
Mavenclad (cladribine)
Mayzent (siponimod)***
Plegridy (peginterferon b-1a)
Rebif (interferon b-1a)
Vumerity (diroximel fumarate)
Zeposia (ozanimod)

Non-Preferred Agents
Aubagio (teriflunomide)**
Bafiertam (monomethyl fumarate)
Copaxone (glatiramer)**
Extavia (interferon b-1b)
Gilenya (fingolimod)**
Ponvory (ponesimod)
Tascenso ODT (fingolimod)
Tecfidera (dimethyl fumarate)**

** generic available

*** Mayzent preferred or non-preferred status is determined by the client

Immunomodulatory Agent Step table****

Formulary ID	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE please see Step 1a for preferred TNF inhibitors	Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO Step 1 agents)	Step 3b (Directed to TWO agents from step 1a and/or Step 1b)	Step 3c (Directed to THREE step 1 agents)
FocusRx	SQ: Cyltezo, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Cyltezo, Hadlima, or Humira is required Step 1 agent)	N/A	SQ: Entyvio Oral: Zeposia (Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are	SQ: Abrilada*, Amjevita*, Hadlima*, Hulio*, Hyrimoz*, Idacio*, Omvoh, Yuflyma*, Yusimry*, Zymfentra

Module	Clinical Criteria for Approval						
						required Step 1 agents)	Oral: Velsipity *Cyltezo or Humira is required Step 1 agent
	FlexRx, GenRx, KeyRx, BasicRx	SQ: Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima or Humira is required Step 1 agent)	N/A	SC: Entyvio Oral: Zeposia (Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step 1 agents)	SQ: Abrilada*, Amjevita*, Cyltezo*, Hulio*, Hyrimoz*, Idacio*, Omvoh, Yuflyma*, Yusimry*, Zymfentra Oral: Velsipity *Hadlima or Humira are required Step 1 agents
	**** Noted preferred status is effective upon launch						

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA through preferred and Zeposia PA with MS step	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months.

CLASS AGENTS

Class	Class Drug Agents
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	BRIUMVI*ublituximab-xiiy soln for iv infusion
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	

Class	Class Drug Agents
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	KESIMPTA*Ofatumumab Soln Auto-Injector
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	OCREVUS*Ocrelizumab Soln For IV Infusion
MS Disease Modifying Agents drug classes: CD52 monoclonal antibody	
MS Disease Modifying Agents drug classes: CD52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
MS Disease Modifying Agents drug classes: Fumarates	
MS Disease Modifying Agents drug classes: Fumarates	BAFIERTAM*Monomethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Fumarates	TECFIDERA*Dimethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Glatiramer	
MS Disease Modifying Agents drug classes: Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc
MS Disease Modifying Agents drug classes: Interferons	
MS Disease Modifying Agents drug classes: Interferons	AVONEX*Interferon beta-1a injection
MS Disease Modifying Agents drug classes: Interferons	BETASERON*Interferon beta-1b injection
MS Disease Modifying Agents drug classes: Interferons	EXTAVIA*Interferon beta-1b injection
MS Disease Modifying Agents drug classes: Interferons	PLEGRIDY*Peginterferon beta-1a injection
MS Disease Modifying Agents drug classes: Interferons	REBIF*Interferon beta-1a injection
MS Disease Modifying Agents drug classes: Purine antimetabolite	
MS Disease Modifying Agents drug classes: Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
MS Disease Modifying Agents drug classes: Pyrimidine synthesis inhibitor	
MS Disease Modifying Agents drug classes: Pyrimidine synthesis inhibitor	AUBAGIO*Teriflunomide Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	GILENYA*Fingolimod HCl Cap
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	MAYZENT*Siponimod Fumarate Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	PONVORY*Ponesimod Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	TASCENSO*fingolimod lauryl sulfate tablet disintegrating
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
MS Disease Modifying Agents Aubagio (teriflunomide) Avonex (interferon b-1a) Bafiertam (monomethyl fumarate) Betaseron (interferon b-1b) Briumvi (ublituximab-xiiy) Copaxone (glatiramer) dimethyl fumarate Extavia (interferon b-1b) fingolimod Gilenya (fingolimod) Glatopa (glatiramer) glatiramer Kesimpta (ofatumumab) Mavenclad (cladribine) Mayzent (siponimod) Plegridy (peginterferon b-1a) Ponvory (ponesimod) Rebif (interferon b-1a) Tascenso ODT (fingolimod) Tecfidera (dimethyl fumarate) Vumerity (diroximel fumarate) Zeposia (ozanimod) **Immunomodulatory Agents NOT to be used concomitantly** Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb)

Contraindicated as Concomitant Therapy
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)