MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

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

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

Program Summary: Irritable Bowel Syndrome with Severe Diarrhea (IBS-D) – Lotronex, Viberzi, Xifaxan

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
52554015100310		Alosetron HCl Tab 0.5 MG (Base Equiv)	0.5 MG	60	Tablets	30	DAYS				
52554015100320		Alosetron HCl Tab 1 MG (Base Equiv)	1 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Alosetron	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of irritable bowel syndrome with severe diarrhea (IBS-D) **AND** 2. The patient has an onset of IBS-D symptoms starting at least 6 months prior **AND** 3. The patient exhibits at least ONE of the following: A. Frequent and severe abdominal pain/discomfort **OR** B. Frequent bowel urgency or fecal incontinence **OR** C. Disability or restriction of daily activities due to IBS **AND** 4. The patient will NOT be using the requested agent in combination with another agent from this program for IBS-D **AND** 5. ONE of the following: A. The patient's sex is female **OR** B. The requested agent is medically appropriate for the patient's sex **AND** 6. The patient has had anatomic or biochemical abnormalities of the gastrointestinal tract excluded **AND** 7. ONE of the following: A. The patient's medication history includes conventional therapy AND ONE of the following: 1. The patient has had an inadequate response to at least one conventional therapy **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional therapy **OR** B. The patient has an intolerance or hypersensitivity to conventional therapy **OR** C. The patient has an FDA labeled contraindication to ALL conventional therapy **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 conventional therapy cannot be

Module	Clinical Criteria for Approval
	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. 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. **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 will NOT be using the requested agent in combination with another agent from this program for a diagnosis of IBS-D **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
Universal 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. 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

POLICIES REVISED

• Program Summary: Androgens and Anabolic Steroids

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Testosterone Gel Pump (Generic of Androgel) and Testim.

Diagnoses related to gender reassignment (e.g., gender dysphoria, gender identity disorder, transgender, gender reassignment surgery, other gender reassignment medical procedures including drug therapy) are covered for MN Medicaid.

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
23100030002020		Testosterone TD Soln 30 MG/ACT	30 MG/ACT	2	Pump Bottles	30	DAYS				
23100030008503	Androderm	Testosterone TD Patch 24HR 2 MG/24HR	2 MG/24HR	30	Patches	30	DAYS				
23100030008510	Androderm	Testosterone TD Patch 24HR 4 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	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)

Module	Clinical Criteria for Approval
	Testim® (testosterone gel)* Testosterone solution Vogelxo® (testosterone gel)* * - Generic available and included in prior authorization and quantity limit programs **The preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Testosterone Gel Pump (Generic of Androgel) and Testim.** **Initial Review** **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 syndrome **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, Kyzatrex, or Tlando, 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 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**

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	2. The patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels: 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**

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	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, 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, 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. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required preferred agents **AND** B. ONE of the following: 1. The required preferred agents were discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List

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	(PDL) that is not expected to occur with the requested agent **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 therapeutic 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 the required preferred agent(s) 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** 5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **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) **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** 2. If the patient is an adolescent, the patient is being monitored at least once per year **OR**

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	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. 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

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** 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:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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: Calcitonin Gene-Related Peptide (CGRP)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
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				
67701090202020	Zavzpret	zavegepant hcl nasal spray	10 MG/ACT	8	Devices	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	120 MG/ML	1	Syringe	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
		Prefilled Syr 120 MG/ML									
67701060707220	Nurtec	Rimegepant Sulfate Tab Disint 75 MG	75 MG	16	Tablets	30	DAYS			05-19-2022	
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	PDL Preferred Agents
Acute treatment of migraine with or without aura	Ubrelvy
Preventative treatment of migraine	Ajovy, Emgality
Treatment of episodic cluster headache	Emgality

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's medication history includes at least one migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol,

Module	Clinical Criteria for Approval
	metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] AND ONE of the following: 1. The patient has had an inadequate response to at least one 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] **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over 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] **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** 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 classed [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. Medication overuse headache has been ruled out **AND** 4. ONE of the following: A. The requested agent is a preferred agent **OR** B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following: 1. The patient's medication history includes TWO preferred agents AND ONE of the following: A. The patient has had an inadequate response TWO preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **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 cannot be

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	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 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's medication history includes verapamil, melatonin, corticosteroids, topiramate, OR lithium AND ONE of the following: 1. The patient has had an inadequate response to verapamil, melatonin, corticosteroids, topiramate, OR lithium **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over verapamil, melatonin, corticosteroids, topiramate, AND 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** 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, AND 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 **AND** 7. ONE of the following: A. The requested agent is a preferred agent **OR** B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following: 1. The patient's medication history includes TWO preferred agents AND ONE of the following: A. The patient has had an inadequate response TWO preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **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 preferred 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 **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's medication history includes at least one triptan agent AND ONE of the following: 1. The patient has had an inadequate response to at least one triptan agent **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL triptan agents **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, ergotamine, triptan) **AND** 3. Medication overuse headache has been ruled out **AND** 4. The requested agent and strength are FDA labeled for acute migraine treatment **AND** 5. ONE of the following: A. The requested agent is a preferred agent **OR** B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following: 1. The patient's medication history includes TWO preferred agents AND ONE of the following: A. The patient has had an inadequate response TWO preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **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

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	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 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 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:** CMS Approved Compendia **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**

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	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, ergotamine, triptan) 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:** CMS Approved Compendia **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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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 [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

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	(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: Cibinqo (abrocitinib)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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** 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

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	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's medication history includes at least a mid- potency topical steroid used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to mid- potency topical steroids used in the treatment of AD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over mid- potency topical steroids 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 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's medication history includes a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to a topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over topical calcineurin inhibitors (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

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	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 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:** CMS Approved Compendia **Length of Approval**: 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. 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**: CMS Approved Compendia **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: Combination NSAID

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
349987021003	Consensi	amlodipine besylate-celecoxib tab	10-200 MG ; 2.5-200 MG ; 5-200 MG	30	Tablets	30	DAYS				
661099023203	Duexis	ibuprofen-famotidine tab	800-26.6 MG	90	Tablets	30	DAYS				
661099024406	Vimovo	naproxen-esomeprazole magnesium tab dr	375-20 MG ; 500-20 MG	60	Tablets	30	DAYS				
851599020406	Yosprala	aspirin-omeprazole tab delayed release	325-40 MG ; 81-40 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. ONE of the following: A. For Consensi, BOTH of the following: 1. The patient has a diagnosis of hypertension **AND** 2. The patient has a diagnosis of osteoarthritis **OR** B. BOTH of the following: 1. ONE of the following: A. For Duexis or ibuprofen/famotidine requests, the patient has a diagnosis of at least ONE of the following: 1. Rheumatoid arthritis **OR** 2. Osteoarthritis **OR**

Module	Clinical Criteria for Approval
	B. For Vimovo or naproxen/esomeprazole requests, the patient has a diagnosis of at least ONE of the following: 1. Osteoarthritis in adults **OR** 2. Rheumatoid arthritis in adults **OR** 3. Ankylosing spondylitis in adults **OR** 4. Juvenile idiopathic arthritis (JIA) in adolescents weighing greater than or equal to 38 kg **AND** 2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers: A. Age greater than or equal to 65 years B. Prior history of peptic, gastric, or duodenal ulcer C. History of NSAID-related ulcer D. History of clinically significant GI bleeding E. Untreated or active *H. pylori* gastritis F. Concurrent use of oral corticosteroids G. Concurrent use of anticoagulants H. Concurrent use of antiplatelets **OR** C. For Yosprala or aspirin/omeprazole requests, BOTH of the following: 1. The patient has an indication of use of at least ONE of the following: A. Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli **OR** B. Reducing the combined risk of death and nonfatal myocardial infarction (MI) in patients with previous MI or unstable angina pectoris **OR** C. Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris **OR** D. Use in patients who have undergone revascularization procedures (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated **AND** 2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers: A. Age greater than or equal to 55 years B. Prior history of peptic, gastric, or duodenal ulcer C. History of NSAID–related ulcer D. History of clinically significant GI bleeding E. Untreated or active *H. pylori* gastritis F. Concurrent use of oral corticosteroids G. Concurrent use of anticoagulants H. Concurrent use of antiplatelets **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: A. Information has been provided that use of the individual ingredients within the target combination agent, as separate dosage forms, is not clinically appropriate for the patient **OR** B. BOTH of the following: 1. The patient's medication history includes use of the individual ingredients within the target combination agent, as separate dosage forms, as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the individual ingredients within the target combination agent, as separate dosage forms **AND** 2. ONE of the following: A. The individual ingredients within the target combination agent, as separate dosage forms was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice

Module	Clinical Criteria for Approval
	guideline supporting the use of the requested agent over use of the individual ingredients within the target combination agent, as separate dosage forms **OR** C. 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** D. The prescriber has provided documentation that the individual ingredients within the target combination agent, as separate dosage forms, 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 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 for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: DPP-4 Inhibitors and Combinations

Applies to:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Formulary Exception

Step Therapy only applies to Sitaglitpin and the MN Medicaid Preferred Drug List (PDL) preferred drugs: Januvia, Janumet, Janumet XR, Jentadueto, Jentadueto XR, Kombiglyze XR, Nesina, Onglyza, and Tradjenta.

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
27992502700340	Janumet	Sitagliptin-Metformin HCl Tab 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502700320	Janumet	Sitagliptin-Metformin HCl Tab 50-500 MG	50-500 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
27992502707540	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 100-1000 MG	100-1000 MG	30	Tablets	30	DAYS				
27992502707530	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502707520	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	30	Tablets	30	DAYS				
27550070100340	Januvia	Sitagliptin Phosphate Tab 100 MG (Base Equiv)	100 MG	30	Tablets	30	DAYS				
27550070100320	Januvia	Sitagliptin Phosphate Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
27550070100330	Januvia	Sitagliptin Phosphate Tab 50 MG (Base Equiv)	50 MG	30	Tablets	30	DAYS				
27992502400340	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502400320	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	60	Tablets	30	DAYS				
27992502400330	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-850 MG	2.5-850 MG	60	Tablets	30	DAYS				
27992502407520	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502407530	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502100330	Kazano	Alogliptin-Metformin HCl Tab 12.5-1000 MG	12.5-1000 MG	60	Tablets	30	DAYS				
27992502100320	Kazano	Alogliptin-Metformin HCl Tab 12.5-500 MG	12.5-500 MG	60	Tablets	30	DAYS				
27992502607520	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502607540	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502607530	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS				
27550010100320	Nesina	Alogliptin Benzoate Tab 12.5 MG (Base Equiv)	12.5 MG	30	Tablets	30	DAYS				
27550010100330	Nesina	Alogliptin Benzoate Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
27550010100310	Nesina	Alogliptin Benzoate Tab 6.25 MG (Base Equiv)	6.25 MG	30	Tablets	30	DAYS				
27550065100320	Onglyza	Saxagliptin HCl Tab 2.5 MG (Base Equiv)	2.5 MG	30	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
27550065100330	Onglyza	Saxagliptin HCl Tab 5 MG (Base Equiv)	5 MG	30	Tablets	30	DAYS				
27994002100320	Oseni	Alogliptin-Pioglitazone Tab 12.5-15 MG	12.5-15 MG	30	Tablets	30	DAYS				
27994002100325	Oseni	Alogliptin-Pioglitazone Tab 12.5-30 MG	12.5-30 MG	30	Tablets	30	DAYS				
27994002100330	Oseni	Alogliptin-Pioglitazone Tab 12.5-45 MG	12.5-45 MG	30	Tablets	30	DAYS				
27994002100340	Oseni	Alogliptin-Pioglitazone Tab 25-15 MG	25-15 MG	30	Tablets	30	DAYS				
27994002100345	Oseni	Alogliptin-Pioglitazone Tab 25-30 MG	25-30 MG	30	Tablets	30	DAYS				
27994002100350	Oseni	Alogliptin-Pioglitazone Tab 25-45 MG	25-45 MG	30	Tablets	30	DAYS				
27550050000320	Tradjenta	Linagliptin Tab 5 MG	5 MG	30	Tablets	30	DAYS				
27550070000320	Zituvio	sitagliptin tab	25 MG	30	Tablets	30	DAYS				
27550070000330	Zituvio	sitagliptin tab	50 MG	30	Tablets	30	DAYS				
27550070000340	Zituvio	sitagliptin tab	100 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Januvia** (sitagliptin) **Janumet** (sitagliptin/metformin) **Janumet XR** (sitagliptin/metformin ER) **Jentadueto** (linagliptin/metformin) **Jentadueto XR** (linagliptin/metformin ER) **Kombiglyze XR** (saxagliptin/metformin ER) **Nesina** (alogliptin) **Onglyza** (saxagliptin) **Sitagliptin** **Tradjenta** (linagliptin) **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been being 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** C. 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** D. The patient's medication history includes use of an agent containing metformin or insulin **OR** E. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following:

Module	Clinical Criteria for Approval
	1. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin or an agent containing metformin **OR** F. The patient has an intolerance or hypersensitivity to ONE of the following: metformin or insulin **OR** G. The patient has an FDA labeled contraindication to ALL of the following: metformin and insulin **OR** H. The prescriber has provided documentation that metformin AND insulins 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 DPP-4 inhibitor/combination agent for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with a GLP-1 agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	**TARGET AGENT(S)** **Januvia** (sitagliptin) **Janumet** (sitagliptin/metformin) **Janumet XR** (sitagliptin/metformin ER) **Jentadueto** (linagliptin/metformin) **Jentadueto XR** (linagliptin/metformin ER) **Kombiglyze XR** (saxagliptin/metformin ER) **Nesina** (alogliptin) **Onglyza** (saxagliptin) **Sitagliptin** **Tradjenta** (linagliptin) **Target Agent(s)** will be approved when ALL of the following are met: 4. ONE of the following: A. The patient has been being 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** C. 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** D. The patient's medication history includes use of an agent containing metformin or insulin **OR** E. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: 1. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin or an agent containing metformin **OR** F. The patient has an intolerance or hypersensitivity to ONE of the following: metformin or insulin **OR**

Module	Clinical Criteria for Approval
	G. The patient has an FDA labeled contraindication to ALL of the following: metformin and insulin **OR** H. The prescriber has provided documentation that metformin AND insulins 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. The patient will NOT be using the requested agent in combination with another DPP-4 inhibitor/combination agent for the requested indication **AND** 6. The patient will NOT be using the requested agent in combination with a GLP-1 agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

• Program Summary: Glucagon-like Peptide-1 (GLP-1) Agonists

Applies to:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Formulary Exception

Step Therapy only applies to the MN Medicaid Preferred Drug List (PDL) preferred drugs: Byetta, Bydureon pens, Bydureon BCise, Ozempic, and Victoza.

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
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	2	Pens	28	DAYS				
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	2	Pens	180	DAYS				
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	4	Injection Devices	28	DAYS				
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	1	Pen	30	DAYS				
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	1	Pen	30	DAYS				
2717308000D210	Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	4	Pens	180	DAYS				
2717308000D215	Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D220	Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D225	Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	4	Pens	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
2717308000D230	Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D235	Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	4	Pens	28	DAYS				
2717007000D221	Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	1	Pen	28	DAYS				
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	1	Pen	28	DAYS				
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	1	Pen	28	DAYS				
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	1	Pen	28	DAYS				
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	30	Tablets	30	DAYS				
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS				
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	30	Tablets	30	DAYS				
2717001500D2	Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	4	Pens	28	DAYS				
27170050	Victoza	liraglutide soln pen-injector	18 MG/3ML	3	Pens	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
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	The patient must have a diagnosis of type 2 diabetes mellitus.			
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	The patient must have a diagnosis of type 2 diabetes mellitus.			
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	The patient must have a diagnosis of type 2 diabetes mellitus			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	The patient must have a diagnosis of type 2 diabetes mellitus			
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	The patient must have a diagnosis of type 2 diabetes mellitus.			
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	The patient must have a diagnosis of type 2 diabetes mellitus			
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	The patient must have a diagnosis of type 2 diabetes mellitus.			
2717001500D2	Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	The patient must have a diagnosis of type 2 diabetes mellitus			
27170050	Victoza	liraglutide soln pen-injector	18 MG/3ML	The patient must have a diagnosis of type 2 diabetes mellitus.			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Bydureon BCise™** (exenatide extended-release) **Byetta®** (exenatide) **Ozempic®** (semaglutide) **Victoza®** (liraglutide) **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of type 2 diabetes mellitus **AND** 2. ONE of the following: A. The patient is currently being treated with the requested GLP-1 within the past 90 days **OR** B. The prescriber states the patient is currently being treated with the requested GLP-1 within the past 90 days AND is at risk if therapy is changed **OR** C. 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** D. The patient's medication history includes use of one or more of the following: an agent containing metformin or insulin **OR** E. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: 1. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin or an agent containing metformin **OR** F. The patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** G. The patient has an FDA labeled contraindication to ALL of the following agents: metformin AND insulin **OR** H. The patient has a diagnosis of type 2 diabetes with/or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** I. The prescriber has provided documentation that ALL of the following agents: metformin and insulin cannot

Module	Clinical Criteria for Approval
	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 NOT be using the requested agent in combination with a DPP-4 containing agent for the requested indication **AND** 4. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also 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 for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Growth Hormone

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

All products in this program are targeted, formulary and non-formulary. Additional FE review required for non-formulary drugs.

For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Genotropin, Genotropin MiniQuick, Norditropin, and Nutropin AQ.

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
	3010	Genotropin ; Genotropin miniquick ; Humatrope ; Ngenla ; Norditropin flexpro ; Nutropin aq nuspin 10 ; Nutropin aq	lonapegsomatropin-tcgd for subcutaneous inj cart ; lonapegsomatropin-tcgd for subcutaneous inj cartridge ; somapacitan-beco solution pen-injector ; somatrogon-ghla solution pen-injector ; somatropin (non-refrigerated) for inj ; somatropin (non-	0.2 MG ; 0.4 MG ; 0.6 MG ; 0.8 MG ; 1 MG ; 1.2 MG ; 1.4 MG ; 1.6 MG ; 1.8 MG ; 10 MG ; 10 MG/1.5ML ; 10 MG/2ML ; 11 MG ; 12 MG ; 13.3 MG ; 15 MG/1.5ML ; 2 MG ; 20 MG/2ML ; 24 MG ; 24 MG/1.2ML ; 3 MG ; 3.6 MG ; 30 MG/3ML ; 4 MG ; 4.3 MG ; 5 MG ; 5	M ; N ; O ; Y				

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
		nuspin 20 ; Nutropin aq nuspin 5 ; Omnitrope ; Saizen ; Saizenprep reconstitution ; Serostim ; Skytrofa ; Sogroya ; Zomacton ; Zorbtive	refrigerated) for subcutaneous inj ; somatropin for inj ; somatropin for inj cartridge ; somatropin for subcutaneous inj ; somatropin for subcutaneous inj cartridge ; somatropin for subcutaneous inj prefilled syr ; somatropin solution cartridge ; somatropin solution pen-injector	MG/1.5ML ; 5 MG/2ML ; 5.2 MG ; 5.8 MG ; 6 MG ; 6.3 MG ; 60 MG/1.2ML ; 7.6 MG ; 8.8 MG ; 9.1 MG					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Adult	**TARGET AGENTS:** **For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Genotropin, Genotropin MiniQuick, Norditropin, and Nutropin AQ** Omnitrope® (somatropin) Genotropin® , Genotropin® MiniQuick (somatropin) Humatrope® (somatropin) Ngenla™ (somatrogon-ghla) Norditropin FlexPro® (somatropin) Nutropin AQ NuSpin® (somatropin) Saizen®, Saizenprep® (somatropin) Serostim® (somatropin) Skytrofa™ (lonapegsomatropin-tcgd) Sogroya® (somapacitan-beco) Zomacton® (somatropin) Zorbtive® (somatropin) **Adults – Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient is an adult (as defined by the prescriber) **AND** 2. The patient has ONE of the following diagnoses: A. If the request is for Serostim, the patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following: 1. The patient is currently treated with antiretroviral therapy **AND** 2. The patient will continue antiretroviral therapy in combination with the requested agent **AND** 3. BOTH of the following: A. ONE of the following: 1. The patient has had weight loss that meets ONE of the following: A. 10% unintentional weight loss over 12 months **OR** B. 7.5% unintentional weight loss over 6 months **OR** 2. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months **OR**

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	3. 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/m^2 **OR** 4. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m^2 **OR** 5. The prescriber has provided information that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/m^2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex **OR** 6. The patient's BMI is less than 20 kg/m^2 **AND** B. All other causes of weight loss have been ruled out **OR** B. If the request is for Zorbtive, then BOTH of the following: 1. The patient has a diagnosis of short bowel syndrome (SBS) **AND** 2. The patient is receiving specialized nutritional support **OR** C. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following: 1. The patient had a diagnosis of childhood-onset growth hormone deficiency AND has failed at least one growth hormone (GH) stimulation test as an adult **OR** 2. The patient has a low insulin-like growth factor-1 (IGF-1) level AND ONE of the following: A. Organic hypothalamic-pituitary disease **OR** B. Pituitary structural lesion or trauma **OR** C. The patient has panhypopituitarism or multiple (greater than or equal to 3) pituitary hormone deficiency **OR** 3. The patient has an established causal genetic mutation OR hypothalamic-pituitary structural defect other than ectopic posterior pituitary **OR** 4. The patient has failed at least two growth hormone (GH) stimulation tests as an adult **OR** 5. The patient has failed at least one GH stimulation test as an adult AND the patient has an organic pituitary disease **OR** D. The patient has another FDA approved 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** 3. The request is for a long-acting GH agent AND 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **AND** 7. ONE of the following: A. The request is for a preferred agent, Serostim or Zorbtive **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the

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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 information that ALL preferred 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

Compendia Allowed: CMS Approved Compendia

Length of Approval:

SBS	4 weeks
AIDS wasting/cachexia	12 weeks
Any other indication	12 months

Adults – Renewal Evaluation

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

1. The patient has been approved for therapy with GH previously through the plan's prior authorization process **AND**
2. The patient is an adult (as defined by the prescriber) **AND**
3. ONE of the following:
   A. The request is for a preferred agent or Serostim or Zorbtive **OR**
   B. ONE of the following:
      1. The patient's medication history includes two preferred agents AND ONE of the following:
         A. The patient has had an inadequate response to two preferred agents **OR**
         B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR**
      2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**
      3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**
      4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **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 information that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
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. ONE of the following:
A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent OR
B. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following:
1. The patient is currently treated with antiretroviral therapy AND
2. The patient will continue antiretroviral therapy in combination with the requested agent AND
3. The patient has had clinical benefit with the requested agent (i.e., an increase in weight or weight stabilization) OR
C. The patient has growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND BOTH of the following:
1. The patient's IGF-I level has been evaluated to confirm the appropriateness of the current dose AND
2. The patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life) OR
D. The patient has a diagnosis other than SBS, AIDS wasting/cachexia, GHD, or growth failure due to inadequate secretion of endogenous growth hormone AND has had clinical benefit with the requested agent AND
5. The patient does NOT have any FDA labeled contraindications to the requested agent AND
6. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient’s diagnosis AND
7. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication AND
8. The patient is being monitored for adverse effects of GH

Compendia Allowed: CMS Approved Compendia

Length of Approval:
<table>
<tr><td>SBS</td><td>4 weeks</td></tr>
<tr><td>AIDS wasting/cachexia</td><td>12 weeks</td></tr>
<tr><td>Any other indication</td><td>12 months</td></tr>
</table>
</td></tr>
<tr><td>Child</td><td>
<table>
<tr><td>TARGET AGENTS:

For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Genotropin, Genotropin MiniQuick, Norditropin, and Nutropin AQ</td></tr>
<tr><td>Omnitrope® (somatropin)
Genotropin® , Genotropin® MiniQuick (somatropin)
Humatrope® (somatropin)
Ngenla™ (somatrogon-ghla)
Norditropin FlexPro® (somatropin)
Nutropin AQ NuSpin® (somatropin)
Saizen®, Saizenprep® (somatropin)
Serostim® (somatropin)
Skytrofa™ (lonapegsomatropin-tcgd)
Sogroya® (somapacitan-beco)
Zomacton® (somatropin)</td></tr>
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Module	Clinical Criteria for Approval
	Zorbtive® (somatropin) **Growth Hormone (GH) products** will be approved as below. **Children – Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient is a child (as defined by the prescriber) **AND** 2. The patient has ONE of the following diagnoses: A. ALL of the following: 1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND** 2. The patient has a serum growth hormone (GH) concentration less than or equal to 5 mcg/L **AND** 3. ONE of the following: A. Congenital pituitary abnormality (e.g., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk) **OR** B. Deficiency of at least one additional pituitary hormone **OR** B. ALL of the following: 1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND** 2. The patient has a growth hormone (GH) concentration less than 20 mcg/L **AND** 3. The patient does not have a known metabolic disorder **AND** 4. The patient has a reduced IGFBP-3 level (e.g., less than -2 SD) **OR** C. The patient has a diagnosis of Turner syndrome **OR** D. The patient has a diagnosis of Noonan syndrome **OR** E. The patient has a diagnosis of Prader-Willi syndrome **OR** F. The patient has a diagnosis of SHOX gene deficiency **OR** G. If the request is for Zorbtive, the patient has a diagnosis of short bowel syndrome (SBS) AND is receiving specialized nutritional support AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** H. The patient has a diagnosis of panhypopituitarism or has deficiencies in at least 3 or more pituitary axes AND serum IGF-I levels below the age- and sex-appropriate reference range when off GH therapy **OR** I. The patient has a diagnosis of chronic renal insufficiency and BOTH of the following: 1. The patient's height velocity (HV) for age is less than -1.88 standard deviations (SD) OR HV for age is less than the third percentile **AND** 2. Other etiologies for growth impairment have been addressed **OR** J. The patient has a diagnosis of small for gestational age (SGA) and ALL of the following: 1. The patient is 2 years of age or older **AND** 2. The patient has a documented birth weight and/or birth length that is 2 or more standard deviations (SD) below the mean for gestational age **AND** 3. At 24 months of age, the patient failed to manifest catch-up growth evidenced by a height that remains 2 or more standard deviations (SD) below the mean for age and sex **OR** K. The patient has a diagnosis of idiopathic short stature (ISS) AND ALL of the following: 1. The patient has a height less than or equal to -2.25 SD below the corresponding mean height for age and sex **AND** 2. The patient has open epiphyses **AND** 3. ONE of the following: A. The patient has a predicted adult height that is below the normal range AND ONE of the following: 1. The patient's sex is male and predicted adult height is less than 63 inches **OR** 2. The patient's sex is female and predicted adult height is less than 59

Module	Clinical Criteria for Approval
	inches **OR** B. The patient is more than 2 SD below their mid-parental target height **AND** 4. BOTH of the following: A. The patient has been evaluated for constitutional delay of growth and puberty (CDGP) **AND** B. The patient does NOT have a diagnosis of CDGP **OR** L. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following: 1. The patient has extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD), and delayed bone age **OR** 2. BOTH of the following: A. The patient has ONE of the following: 1. Height more than 2 SD below the mean for age and sex **OR** 2. Height more than 1.5 SD below the midparental height **OR** 3. A decrease in height SD of more than 0.5 over one year in children greater than 2 years of age **OR** 4. Height velocity (HV) more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years **OR** 5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) **OR** 6. BOTH of the following: A. The patient's age is 2-4 years **AND** B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) **OR** 7. BOTH of the following: A. The patient's age is 4-6 years **AND** B. The patient has a HV less than 5 cm/year (less than 2 inches/year) **OR** 8. The patient's age is 6 years to puberty AND ONE of the following: A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) **OR** B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) **AND** B. ONE of the following: 1. The patient has failed at least 2 growth hormone (GH) stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) **OR** 2. The patient has failed at least 1 GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following: A. Pathology of the central nervous system **OR** B. History of irradiation **OR** C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) **OR** D. A genetic defect **OR** 3. The patient has a pituitary abnormality and a known deficit of at least one other pituitary hormone **OR** M. The patient has another FDA approved indication for the requested agent and route of administration **OR** N. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 3. ONE of the following:

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	A. The request is for a preferred agent or Zorbtive or Serostim **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **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 information that ALL preferred 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** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 4 weeks for SBS 12 months for other indications **Children – Renewal Evaluation** **Target Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for therapy with GH through the plan's prior authorization process **AND** 2. The patient is a child (as defined by the prescriber) **AND** 3. ONE of the following: A. The request is for a preferred agent or Zorbtive or Serostim **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**

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	3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **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 information that ALL preferred 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** 4. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** B. The patient has a diagnosis of ISS and BOTH of the following: 1. The patient's height has increased greater than or equal to 2 cm over the previous year with GH therapy **AND** 2. Bone age is less than 16 years in patients with a sex of male and 15 years in patients with a sex of female AND the patient has open epiphyses **OR** C. The patient has a diagnosis of growth hormone deficiency (GHD), growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner Syndrome, small for gestational age), or renal function impairment with growth failure AND BOTH of the following: 1. The patient does NOT have closed epiphyses **AND** 2. The patient's height has increased greater than or equal to 2 cm over the previous year with GH therapy **OR** D. The patient has a diagnosis of Prader-Willi syndrome AND has had clinical benefit with the requested agent **OR** E. The patient has a diagnosis other than SBS, ISS, GHD, growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner syndrome, small for gestational age), or renal function impairment with growth failure, and Prader-Willi AND has had clinical benefit with the requested agent **AND** 5. The patient is being monitored for adverse effects of GH **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 4 weeks for SBS 12 months for other indications

• Program Summary: Homozygous Familial Hypercholesterolemia Agents (HoFH)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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** **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 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

Module	Clinical Criteria for Approval
	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's medication history includes a PCSK9 inhibitor AND ONE of the following: 1. The prescriber has determined that the patient failed to be sufficiently controlled on a PCSK9 inhibitor (e.g., Repatha, Praluent) **OR** 2. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over a PCSK9 inhibitor (e.g., Repatha, Praluent) **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** 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**

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	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** 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: Interleukin-1 (IL-1) Inhibitors

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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 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**

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	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's medication history includes colchicine AND ONE of the following: 1. The patient had an inadequate response to colchicine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over 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's medication history includes at least a 1 week trial of a non-steroidal anti-inflammatory (NSAID) AND a corticosteroid AND ONE of the following: A. The patient had an inadequate response to a non-steroidal anti-inflammatory (NSAID) AND a corticosteroid **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a non-steroidal anti-inflammatory (NSAID) AND a corticosteroid **OR** 3. The patient has an intolerance or hypersensitivity to BOTH an NSAID AND a corticosteroid **OR** 4. 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's medication history includes an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) AND ONE of the following: A. The patient had an inadequate response to an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an oral immunosuppressant **OR**

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	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** 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 in combination with NSAIDs, systemic corticosteroids, 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:** CMS Approved Compendia **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):

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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, 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** 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 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 of the following 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's medication history includes colchicine AND ONE of the following: A. The patient had an inadequate response to colchicine **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over colchicine **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

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	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 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 (AOSD) and BOTH of the following: 1. ONE of the following: A. The patient's medication history includes ONE corticosteroid or ONE non-steroidal anti-inflammatory drug (NSAID) and ONE of the following: 1. The patient had an inadequate response to at least ONE corticosteroid or ONE non-steroidal anti-inflammatory drug (NSAID) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroids and non-steroidal anti-inflammatory drugs (NSAIDs) **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 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**

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	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 ALL non-steroidal anti-inflammatory drugs (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: A. The patient's medication history includes ONE immunosuppressant used in treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) AND ONE of the following: 1. The patient had an inadequate response to ONE immunosuppressant used in treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over immunosuppressants used in treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** B. The patient has an intolerance or hypersensitivity to ONE immunosuppressant used in treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** C. The patient has an FDA labeled contraindication to ALL immunosuppressants used in 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 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 immunosuppressants used in treatment of AOSD (i.e., methotrexate, cyclosporine, 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's medication history includes ONE non-steroidal anti-inflammatory drug (NSAID) AND ONE of the following: 1. The patient had an inadequate response to ONE non-steroidal anti-inflammatory drug (NSAID) **OR**

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	2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over non-steroidal anti-inflammatory drugs (NSAIDs) **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 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 non-steroidal anti-inflammatory drugs (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: A. The patient's medication history includes colchicine AND ONE of the following: 1. The patient had an inadequate response to colchicine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over colchicine **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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR**

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	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:** CMS Approved Compendia **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: 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 **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 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**

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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 **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)
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-4 (IL-4) Inhibitors

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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				

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
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's medication history includes use of BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) AND ONE of the following:
1. The patient has 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**
2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over 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 (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **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

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	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** 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. There is information indicating the patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR**

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	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: 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's medication history includes use of ONE standard corticosteroid therapy for EoE (i.e., budesonide suspension, nebulized budesonide, fluticasone MDI swallowed) AND ONE of the following: 1. The patient has had an inadequate response to ONE standard corticosteroid therapy for EoE (i.e., budesonide suspension, nebulized budesonide, fluticasone MDI swallowed) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over 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

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	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: A. The patient's medication history includes use of at least a mid-potency topical steroid AND ONE of the following: 1. The patient has had an inadequate response to at least a mid-potency topical steroid **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least a mid- potency topical steroid **OR** B. The patient has an intolerance or hypersensitivity to 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

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	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. A 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 a LABA, LAMA, 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/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 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:** CMS Approved Compendia **Length of Approval:** 6 months **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**

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	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: A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV_1) **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, 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:** CMS Approved Compendia **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**

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	B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose, or the compendia supported 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 **Compendia Allowed:** CMS Approved Compendia **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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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				
4460405500E520	Nucala	Mepolizumab Subcutaneous Solution Pref Syringe	40 MG/0.4ML	1	Syringe	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:

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	A. If the patient has a diagnosis of severe eosinophilic asthma, then ALL 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 **AND** 3. ONE of the following: A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid **OR** B. The patient is currently being treated with the requested agent AND ONE of the following: 1. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** 2. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** 4. ONE of the following: A. The patient is currently being treated with ONE of the following: 1. A long-acting beta-2 agonist (LABA) **OR** 2. A leukotriene receptor antagonist (LTRA) **OR** 3. Long-acting muscarinic antagonist (LAMA) **OR** 4. Theophylline **OR** B. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), or theophylline **OR** C. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND** 5. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 6. If the requested agent is Nucala, then ONE of the following: A. The patient's medication history includes use of Fasenra AND ONE of the following: 1. The patient has had an inadequate response to Fasenra **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over Fasenra **OR** B. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to Fasenra **OR** C. 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

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	therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that Fasenra 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. If the patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), then 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) 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 **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 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's medication history includes use of a non-corticosteroid immunosuppressant (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, rituximab) AND ONE of the following: 1. The patient has had an inadequate response to ONE non-corticosteroid immunosuppressant (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, rituximab) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over non-

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	corticosteroid immunosuppressant therapy **OR** B. The patient has an intolerance or hypersensitivity to ONE non-corticosteroid immunosuppressant therapy **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 azathioprine, cyclophosphamide, methotrexate, AND mycophenolate mofetil 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. If the patient has a diagnosis of hypereosinophilic syndrome (HES), then ALL of the following: 1. The requested agent is Nucala **AND** 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 **AND** 4. ONE of the following: A. The patient is currently being treated with maximally tolerated oral corticosteroid (OCS) **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid (OCS) therapy **OR**

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	C. The patient has an FDA labeled contraindication to ALL oral corticosteroids **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 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 is currently being treated with ONE of the following: 1. Hydroxyurea **OR** 2. Interferon-α **OR** 3. Another immunosuppressive agent (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to therapy with hydroxyurea, interferon-α, or immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** C. The patient has an FDA labeled contraindication to hydroxyurea, interferon-α, and ALL immunosuppressive agents (e.g., 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 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** 6. The patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-α, immunosuppressants) in combination with the requested agent **OR** D. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), then 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**

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	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** 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 **AND** 7. 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 **OR** E. The patient has another FDA labeled indication for the requested agent and route of administration **OR** F. 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 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:** CMS Approved Compendia **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.

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. 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 (FEV_1) **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 (e.g., 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: A. The patient is currently treated and is compliant with maintenance therapy with oral corticosteroids **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 **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 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:

Module	Clinical Criteria for Approval
	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 other 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** 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:** CMS Approved Compendia

Module	Clinical Criteria for Approval
	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)
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)

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

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

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

For Medicaid, the Non-Preferred Drug Supplement applies.

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

Indication	PDL Preferred Agents
Atopic Dermatitis	Dupixent

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:
                  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 submitted an evidence-based and peer-

Module	Clinical Criteria for Approval
	reviewed clinical practice guideline supporting the use of the requested agent over ALL mid-, high-, and super-potency topical steroids used in the treatment of AD **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 submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL topical calcineurin inhibitors **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** 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. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE

Module	Clinical Criteria for Approval
	of the following: 1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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 prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **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:** CMS Approved Compendia **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: 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

Module	Clinical Criteria for Approval
	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**: CMS Approved Compendia **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

Module	Clinical Criteria for Approval
	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) 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: Joenja (leniolisib)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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

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 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** 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**

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 **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:** Initial up to 3 months; Renewal up to 12 months

• Program Summary: Otezla (apremilast)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

For Medicaid, the Non-Preferred Drug Supplement applies.

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				
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**

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	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 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 includes ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA AND ONE of the following: A. The patient has had an inadequate response to a conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA **OR** 3. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA **OR** 4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **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 PsA **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: 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 includes use of 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 AND ONE of the following: A. The patient has had an inadequate response to a 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 **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent

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	over 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 **OR** 3. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 4. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **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 PS **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 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 includes ONE conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD AND ONE OF the following: 1. The patient has had an inadequate response to a conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR** C. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of BD **OR** D. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of BD **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 BD **OR** F. The prescriber has provided documentation that ALL conventional agents (i.e., topical oral corticosteroids [i.e., triamcinolone dental

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	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. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and 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 two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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

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	functional ability in performing daily activities or cause physical or mental harm **OR** 5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **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 **Compendia Allowed:** CMS approved compendia **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** 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**

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	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) 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)

Contraindicated as Concomitant Therapy
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: Proprotein Convertase Subtilisin / Kexin Type 9 (PCSK9) Inhibitors

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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				
3935001000	Praluent	alirocumab subcutaneous solution auto-injector	150 MG/ML ; 75 MG/ML	2	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**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:

Module	Clinical Criteria for Approval
	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 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 a drug in the same pharmacological class with the same mechanism of action, AND ONE of the following: 1. High intensity atorvastatin or rosuvastatin or a drug in the same pharmacological class with the same mechanism of action was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over high-intensity rosuvastatin or atorvastatin therapy **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 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

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	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** 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**

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	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 a drug in the same pharmacological class with the same mechanism of action, AND ONE of the following: 1. High intensity atorvastatin or rosuvastatin or a drug in the same pharmacological class with the same mechanism of action was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical

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	practice guideline supporting the use of the requested agent over high-intensity rosuvastatin or atorvastatin therapy **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 **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 **Compendia Allowed:** CMS Approved Compendia **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 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. The patient has shown clinical benefit with a PCSK9 inhibitor **AND** 3. The patient is currently adherent to therapy with a PCSK9 inhibitor **AND** 4. 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** 5. 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** 6. 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

Module	Clinical Criteria for Approval
	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 rosuvastatin or atorvastatin therapy or a drug in the same pharmacological class with the same mechanism of action AND ONE of the following: 1. High-intensity rosuvastatin or atorvastatin, or a drug in the same pharmacological class with the same mechanism of action, was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over high-intensity rosuvastatin or atorvastatin therapy **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** 7. The patient will NOT be using the requested agent in combination with another PCSK9 agent for the requested indication **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
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: Pulmonary Arterial Hypertension

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

For injectable agents refer to BCBSMN medical policy.

For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: oral forms of generic ambrisentan, generic sildenafil, generic sildenafil suspension, sildenafil suspension (ag), and brand Tracleer tablet.

Requests for an oral liquid form of a drug must be approved if BOTH of the following apply:
1) the indication is FDA labeled AND
2) the patient is using an enteral tube for feeding or medication administration

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
401430800003	Adcirca ; Alyq	tadalafil tab	20 MG	60	Tablets	30	DAYS				
4013405000	Adempas	riociguat tab	0.5 MG ; 1 MG ; 1.5 MG ; 2 MG ; 2.5 MG	90	Tablets	30	DAYS				
4016000700	Letairis	ambrisentan tab	10 MG ; 5 MG	30	Tablets	30	DAYS				
40143060101825	Liqrev	sildenafil citrate oral susp	10 MG/ML	244	mLs	30	DAYS				
4016005000	Opsumit	macitentan tab	10 MG	30	Tablets	30	DAYS				
40995502500310	Opsynvi	macitentan-tadalafil tab	10-20 MG	30	Tablets	30	DAYS				
40995502500320	Opsynvi	macitentan-tadalafil tab	10-40 MG	30	Tablets	30	DAYS				
4017008005C110	Orenitram titr kit Month 1	Treprostinil tab er Mo 1 titr kit	0.125 & 0.25 MG	1	Pack	180	DAYS				
4017008005C120	Orenitram titr kit Month 2	Treprostinil tab er Mo 2 titr kit	0.125 & 0.25 MG	1	Pack	180	DAYS				
4017008005C130	Orenitram titr kit Month 3	Treprostinil tab er Mo 3 titr kit	0.125 & 0.25 &1 MG	1	Pack	180	DAY				
401430601019	Revatio	sildenafil citrate for suspension	10 MG/ML	2	Bottles	30	DAYS				
401430601003	Revatio	sildenafil citrate tab	20 MG	90	Tablets	30	DAYS				
40143080001820	Tadliq	Tadalafil Oral Susp	20 MG/5ML	300	mLs	30	DAYS				
401600150003	Tracleer	bosentan tab	125 MG ; 62.5 MG	60	Tablets	30	DAYS				
401600150073	Tracleer	bosentan tab for oral susp	32 MG	120	Tablets	30	DAYS				
40170080002020	Tyvaso	treprostinil inhalation solution	0.6 MG/ML	7	Packages	28	DAYS	66302020603			
40170080002920	Tyvaso dpi institutional ; Tyvaso dpi maintenance ki	Treprostinil Inh Powder	16 MCG	112	Cartridges	28	DAYS				
40170080002930	Tyvaso dpi institutional ; Tyvaso dpi maintenance ki	Treprostinil Inh Powder	32 MCG	112	Cartridges	28	DAYS				
40170080002940	Tyvaso dpi institutional ; Tyvaso dpi	Treprostinil Inh Powder	48 MCG	112	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
	maintenance ki										
40170080002950	Tyvaso dpi institutional ; Tyvaso dpi maintenance ki	Treprostinil Inh Powder	64 MCG	112	Cartridges	28	DAYS				
40170080002960	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	112 x 32MCG & 112 x48MCG	224	Cartridges	28	DAYS				
40170080002980	Tyvaso dpi titration kit	Treprostinil Inh Powd	16 & 32 & 48 MCG	252	Cartridges	180	DAYS				
40170080002970	Tyvaso dpi titration kit	Treprostinil Inh Powder	112 x 16MCG & 84 x 32MCG	196	Cartridges	180	DAYS				
40170080002020	Tyvaso refill	treprostinil inhalation solution	0.6 MG/ML	1	Kit	28	DAYS	66302020602			
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS	66302020604			
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS	66302020601			
401200700003	Uptravi	selexipag tab	1000 MCG ; 1200 MCG ; 1400 MCG ; 1600 MCG ; 200 MCG ; 400 MCG ; 600 MCG ; 800 MCG	60	Tablets	30	DAYS				
40120070000310	Uptravi	selexipag tab	200 MCG	140	Tablets	180	DAYS	66215060214			
40120070000310	Uptravi	selexipag tab	200 MCG	60	Tablets	30	DAYS	66215060206			
4012007000B7	Uptravi titration pack	selexipag tab therapy pack	200 & 800 MCG	1	Package	180	DAYS				
401700600020	Ventavis	iloprost inhalation solution	10 MCG/ML ; 20 MCG/ML	270	Ampules	30	DAYS				
40110070206420	Winrevair	sotatercept-csrk for subcutaneous soln kit	45 MG	1	Kit	21	DAYS				
40110070206425	Winrevair	sotatercept-csrk for subcutaneous soln kit	60 MG	1	Kit	21	DAYS				
40110070206430	Winrevair	sotatercept-csrk for subcutaneous soln kit	2 x 45 MG	1	Kit	21	DAYS				
40110070206435	Winrevair	sotatercept-csrk for subcutaneous soln kit	2 x 60 MG	1	Kit	21	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

The preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: oral forms of generic ambrisentan, generic sildenafil, generic sildenafil suspension, sildenafil suspension (ag), and brand Tracleer tablet.

Initial Evaluation

Target Agent(s) will be approved when ONE of the following is met:

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

Target 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 **AND**
        - B. The patient has an FDA labeled indication for the requested agent and route of administration **OR**
     2. The patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 and ALL of the following:
        - A. The requested agent is Adempas **AND**
        - B. The patient's diagnosis has been confirmed by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography **AND**
        - C. The patient has a mean pulmonary artery pressure of greater than 20 mmHg **AND**
        - D. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND**
        - E. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND**
        - F. ONE of the following:
          1. The patient is NOT a candidate for surgery **OR**
          2. The patient has had a pulmonary endarterectomy AND has persistent or recurrent disease **AND**
        - G. The patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **OR**
     3. The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 and ALL of the following:
        - A. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND**
        - B. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND**
        - C. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND**
        - D. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND**
        - E. The patient's World Health Organization (WHO) functional class is II or greater **AND**
        - F. If the requested agent is sotatercept, then BOTH of the following:
          1. The patient has been stable on background PAH therapy for at least 90 days (Please note: Background therapy refers to combination therapy consisting of

Module	Clinical Criteria for Approval
	drugs from two or more of the following drug classes: ERA, PDE5i, soluble guanylate cyclase stimulator, and/or prostacyclin analogue or receptor agonist) **AND** 2. The patient is not pregnant or planning to become pregnant while on therapy with the requested agent **AND** G. If the requested agent is Adcirca, Adempas, Revatio, sildenafil, or tadalafil, the patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **AND** H. If the requested agent is NOT sotatercept, then ONE of the following: 1. The requested agent will be utilized as monotherapy **OR** 2. The requested agent will be utilized as dual therapy that consists of an endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) as initial therapy **OR** 3. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy) [except combo requests for endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) for dual therapy], and BOTH of following: A. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** B. The requested agent is in a different therapeutic class **OR** 4. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and ALL of the following: A. The patient is WHO functional class III or IV **AND** B. ONE of the following: 1. A prostanoid has been started as one of the agents in the triple therapy **OR** 2. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL prostanoids **AND** C. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** D. All three agents in the triple therapy are from a different therapeutic class **OR** 5. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND both of the following: A. The patient is WHO functional class IV **AND** B. The 3 agents being utilized consist of: endothelin receptor antagonist (ERA) plus PDE5i plus prostanoid **OR** 4. The patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3) AND ALL of the following: A. The requested agent is Tyvaso **AND** B. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** C. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** D. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** E. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** F. The patient has an FVC less than 70% of predicted **AND** G. The patient has extensive parenchymal changes on computed tomography (CT) **AND** H. BOTH of the following: 1. The patient is currently treated with standard of care therapy for ILD (e.g., Ofev) **AND** 2. The patient will continue standard of care therapy for ILD (e.g., Ofev) **OR** 5. The patient has another FDA labeled indication for the requested agent **AND**

Module	Clinical Criteria for Approval
	B. 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** C. ONE of the following: 1. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** 2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: A. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** B. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** 2. ONE of the following: A. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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 prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** E. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA labeled indication **AND** B. The patient uses an enteral tube for feeding or medication administration **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 ONE of the following is met: 1. ALL of the following: A. 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

Module	Clinical Criteria for Approval
	review] **AND** B. The patient has had clinical benefit with the requested agent (e.g., stabilization, decreased disease progression) (medical records required) **AND** C. If the requested agent is Tyvaso for a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3), then the patient will continue standard of care therapy for ILD (e.g., Ofev) **AND** D. If the requested agent is sotatercept for a diagnosis of pulmonary arterial hypertension (PAH), the patient will continue to use background PAH therapy (Please note: Background therapy refers to combination therapy consisting of drugs from two or more of the following drug classes: ERA, PDE5i, soluble guanylate cyclase stimulator, and/or prostacyclin analogue or receptor agonist) **AND** E. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) 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 **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA labeled indication **AND** B. The patient uses an enteral tube for feeding or medication administration **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**: 12 months

• Program Summary: Skyclarys (omaveloxolone)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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 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** 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: Sodium-glucose Co-Transporter (SGLT) Inhibitors and Combinations

Applies to:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Formulary Exception

Step Therapy only applies to the MN Medicaid Preferred Drug List (PDL) preferred drugs: Farxiga, Invokana, and Jardiance.

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
27700010000320	Brenzavvy	bexagliflozin tab	20 MG	30	Tablets	30	DAYS				
277000402003	Farxiga	dapagliflozin propanediol tab	10 MG ; 5 MG	30	Tablets	30	DAYS				
279965023003	Glyxambi	empagliflozin-linagliptin tab	10-5 MG ; 25-5 MG	30	Tablets	30	DAYS				
40750010000320	Inpefa	sotagliflozin tab	200 MG	30	Tablets	30	DAYS				
40750010000340	Inpefa	sotagliflozin tab	400 MG	30	Tablets	30	DAYS				
279960022003	Invokamet	canagliflozin-metformin hcl tab	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	60	Tablets	30	DAYS				
279960022075	Invokamet xr	canagliflozin-metformin hcl tab er	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	60	Tablets	30	DAYS				
277000200003	Invokana	canagliflozin tab	100 MG ; 300 MG	30	Tablets	30	DAYS				
277000500003	Jardiance	empagliflozin tab	10 MG ; 25 MG	30	Tablets	30	DAYS				
27996502200330	Qtern	Dapagliflozin-Saxagliptin Tab 10-5 MG	10-5 MG	30	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
27996502200320	Qtern	Dapagliflozin-Saxagliptin Tab 5-5 MG	5-5 MG	30	Tablets	30	DAYS				
27996002450320	Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27996002450310	Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	120	Tablets	30	DAYS				
27996002450340	Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-1000 MG	7.5-1000 MG	60	Tablets	30	DAYS				
27996002450330	Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-500 MG	7.5-500 MG	60	Tablets	30	DAYS				
27700055200340	Steglatro	Ertugliflozin L-Pyroglutamic Acid Tab 15 MG (Base Equiv)	15 MG	30	Tablets	30	DAYS				
27700055200320	Steglatro	Ertugliflozin L-Pyroglutamic Acid Tab 5 MG (Base Equiv)	5 MG	60	Tablets	30	DAYS				
279965023503	Steglujan	ertugliflozin-sitagliptin tab	15-100 MG ; 5-100 MG	30	Tablets	30	DAYS				
279960024003	Synjardy	empagliflozin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG ; 5-1000 MG ; 5-500 MG	60	Tablets	30	DAYS				
27996002407540	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	60	Tablets	30	DAYS				
27996002407550	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 12.5-1000 MG	12.5-1000 MG	60	Tablets	30	DAYS				
27996002407560	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 25-1000 MG	25-1000 MG	30	Tablets	30	DAYS				
27996002407530	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	60	Tablets	30	DAYS				
27996703407530	Trijardy xr	Empagliflozin-Linaglip-Metformin Tab ER 24HR 12.5-2.5-1000MG	12.5-2.5-1000 MG	60	Tablets	30	DAYS				
27996703407520	Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 10-5-1000 MG	10-5-1000 MG	30	Tablets	30	DAYS				
27996703407540	Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 25-5-1000 MG	25-5-1000 MG	30	Tablets	30	DAYS				
27996703407510	Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 5-2.5-1000MG	5-2.5-1000 MG	60	Tablets	30	DAYS				
27996002307525	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	30	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
27996002307520	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-500 MG	10-500 MG	30	Tablets	30	DAYS				
27996002307507	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27996002307515	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	60	Tablets	30	DAYS				
27996002307510	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Invokana	**Invokana** (canagliflozin) will be approved when ONE of the following is met: 1. The patient's medication history includes use of an agent containing metformin or insulin **OR** 2. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: 1. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin or an agent containing metformin **OR** 3. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days **OR** 4. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed **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 therapeutic 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 patient has an intolerance or hypersensitivity to one of the following agents: metformin or insulin **OR** 7. The patient has an FDA labeled contraindication to ALL of the following agents: metformin AND insulins **OR** 8. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** 9. The prescriber has provided documentation that metformin AND insulin 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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Farxiga	**Farxiga** (dapagliflozin) will be approved when ONE of the following is met: 1. The patient has a diagnosis of heart failure **OR** 2. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** 3. The patient has a diagnosis of chronic kidney disease (CKD) **OR**

Module	Clinical Criteria for Approval
	4. The patient's medication history includes use of an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine in the past **OR** 5. The prescriber has stated that the patient has tried an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine AND ONE of the following: A. An agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 6. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days **OR** 7. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed **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 patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** 10. The patient has an FDA labeled contraindication to ALL of the following agents: metformin and insulins **OR** 11. The prescriber has provided documentation that metformin AND insulin 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** 12. The patient has an intolerance or hypersensitivity to ONE of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 13. The patient has an FDA labeled contraindication to ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine **OR** 14. The prescriber has provided documentation that ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine 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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Jardiance	**Jardiance** (empagliflozin) will be approved when ONE of the following is met: 1. If the requested agent is Jardiance, then BOTH of the following: A. The patient has a diagnosis of chronic kidney disease (CKD) **AND** B. The patient is at high risk for progression of CKD, including, risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization **OR** 2. The patient has a diagnosis of heart failure **OR** 3. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR**

Module	Clinical Criteria for Approval
	4. The patient's medication history includes use of an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine in the past **OR** 5. The prescriber has stated that the patient has tried an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine AND ONE of the following: A. An agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 6. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days **OR** 7. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed **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 patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** 10. The patient has an FDA labeled contraindication to ALL of the following agents: metformin and insulin **OR** 11. The prescriber has provided documentation that metformin AND insulin 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** 12. The patient has an intolerance or hypersensitivity to ONE of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 13. The patient has an FDA labeled contraindication to ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine **OR** 14. The prescriber has provided documentation that ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine 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 **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. 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

Module	Clinical Criteria for Approval
	indication **AND** 2. Information has been provided to support 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. Information has been provided to support 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. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Tarpeyo

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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. The patient's medication history includes therapy with a maximally tolerated ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACEI or ARB AND ONE of the following: 1. BOTH of the following: A. The patient has had an inadequate response to a maximally tolerated ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACEI or ARB **AND** B. The patient will be using an ACEI or ARB or a combination medication containing an ACEI

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	or ARB in combination with the requested agent **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a maximally tolerated ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACEI or ARB **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** 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 ARBs 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. 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** D. BOTH of the following: 1. The patient's medication history includes oral generic budesonide as indicated by ONE of the following: A. Evidence of a paid claim(s) within the past 999 days **OR** B. The prescriber has stated that the patient has tried oral generic budesonide in the past 999 days **AND** 2. ONE of the following: A. Oral generic budesonide was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over oral generic budesonide **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: Thrombopoietin Receptor Agonists and Tavalisse

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

Nplate is not a target in this program.

Requests for an oral liquid form of a drug must be approved if BOTH of the following apply:
1) the indication is FDA labeled AND
2) the patient is using an enteral tube for feeding or medication administration

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				

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
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 ONE of the following are met: 1. ALL of the following: A. ONE of the following: 1. The requested agent is Doptelet AND ONE of the following: A. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: 1. ONE of the following: A. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** B. 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** 2. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Nplate, Promacta) or Tavalisse **OR** E. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** F. The patient has had an inadequate response to a splenectomy **OR** G. The patient has tried and had an inadequate response to rituximab **OR** H. 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** I. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid

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	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 thrombocytopenia and has chronic liver disease AND ALL of the following: 1. The patient has a platelet count less than 50 X 10^9/L **AND** 2. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** 3. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** C. The patient has another FDA labeled indication for the requested agent **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** 2. The requested agent is Mulpleta (lusutrombopag) AND ONE of the following: A. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following: 1. The patient has a platelet count less than 50 X 10^9/L **AND** 2. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** 3. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** 3. The requested agent is Nplate (romiplostim) AND ONE of the following: A. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **OR** B. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ALL of the following: 1. If the patient is a pediatric patient, then the patient has had ITP for at least 6 months **AND** 2. ONE of the following: A. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** B. 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** 3. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to

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	immunoglobulins (IVIg or anti-D) **OR** E. The patient has had an inadequate response to a splenectomy **OR** F. The patient has tried and had an inadequate response to rituximab **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 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 another FDA labeled indication for the requested agent **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** 4. The requested agent is Promacta (eltrombopag) or Alvaiz AND ONE of the following: A. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following: 1. 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** 2. The patient is on concomitant therapy with interferon AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR** B. The patient has a diagnosis of severe aplastic anemia AND ALL of the following: 1. The patient has at least 2 of the following blood criteria: A. Neutrophils less than 0.5 X 10^9/L B. Platelets less than 30 X 10^9/L C. Reticulocyte count less than 60 X 10^9/L **AND** 2. The patient has 1 of the following marrow criteria: A. Severe hypocellularity: less than 25% **OR** B. Moderate hypocellularity, 25-50% with hematopoietic cells representing less than 30% of residual cells **AND** 3. ONE of the following: A. BOTH of the following: 1. The patient will use the requested agent as first-line treatment **AND** 2. The patient will use the requested agent in combination with standard immunosuppressive therapy (i.e., antithymocyte globulin [ATG] AND cyclosporine) **OR** B. ONE of the following: 1. The patient's medication history includes BOTH antithymocyte globulin (ATG) AND cyclosporine therapy AND ONE of the following: A. The patient has had an inadequate response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH

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	antithymocyte globulin (ATG) AND cyclosporine therapy **OR** 2. The patient has an intolerance or hypersensitivity to BOTH ATG AND cyclosporine **OR** 3. The patient has an FDA labeled contraindication to BOTH ATG AND cyclosporine **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 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** C. 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: 1. ONE of the following: A. The patient has a platelet count less than or equal to 30 x 10^9/L **OR** B. 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** 2. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** E. The patient has had an inadequate response to a splenectomy **OR** F. The patient has tried and had an inadequate response to rituximab **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

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	be ineffective or cause harm **OR** H. 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** D. The patient has another FDA labeled indication for the requested agent **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** 5. The requested agent is Tavalisse (fostamatinib disodium hexahydrate) AND ONE of the following: A. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: 1. ONE of the following: A. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** B. 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** 2. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Doptelet, Nplate, Promacta) **OR** E. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** F. The patient has had an inadequate response to a splenectomy **OR** G. The patient has tried and had an inadequate response to rituximab **OR** H. 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** I. 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** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** B. If the patient has an FDA labeled indication, then ONE of the following:

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	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** C. ONE of the following: 1. The patient will NOT be using the requested agent in combination with another agent included in this program **OR** 2. The patient will use the requested agent in combination with another agent included in this program AND BOTH of the following: A. The requested agent is Nplate **AND** B. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **AND** D. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA labeled indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Compendia Allowed:** CMS Approved Compendia **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 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] (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. ALL of the following: 1. 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**

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	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 had clinical benefit with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another agent included in this program **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** B. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA labeled indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **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: Topical Lidocaine

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
90850060102015		Lidocaine HCl Soln 4%	4 %	150	mLs	30	DAYS				
90850060104006		Lidocaine HCl Urethral/Mucosal Gel 2%	2 %	150	mLs	30	DAYS				
90859902903710		Lidocaine-Prilocaine Cream 2.5-2.5%	2.5-2.5 %	60	Grams	30	DAYS				
90850060104005	7t lido gel ; Burn gel ; Proxivol ; Regenecare ha ; Xeroburn	Lidocaine HCl Gel 2%	2 %	150	mLs	30	DAYS				
9085006010E420	Glydo	Lidocaine HCl Urethral/Mucosal Gel Prefilled Syringe 2%	2 %	150	mLs	30	DAYS				
90850060005930	Lidocan ; Lidoderm	Lidocaine Patch 5%	5 %	90	Patches	30	DAYS				
90859902843730	Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7 %	120	Grams	30	DAYS				
90850060004210	Premium lidocaine	Lidocaine Oint 5%	5 ; 5 %	100	Grams	30	DAYS				
90859902845920	Synera	Lidocaine-Tetracaine Topical Patch 70-70 MG	70-70 MG	4	Patches	30	DAYS				
90850060005910	Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8 %	90	Systems	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
lidocaine topical jelly 2%	**lidocaine topical jelly 2%** will be approved when BOTH of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Prevention and control of pain in procedures involving the urethra **OR** B. Topical treatment of painful urethritis **OR** C. Anesthetic lubricant for endotracheal intubation (oral and nasal) **OR** D. Mucositis associated with cancer treatment **OR** E. BOTH of the following: 1. The patient has ONE of the following: A. Neuropathic pain associated with cancer pain or cancer treatment **OR** B. Another FDA approved indication for the requested agent and route of administration **OR** C. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient's medication history includes covered topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to covered topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL covered topical lidocaine **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has provided information that indicates covered topical lidocaine is not clinically appropriate **OR** C. 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** D. The prescriber has provided documentation that covered topical lidocaine 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 does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
lidocaine topical solution 4%	**lidocaine topical solution 4%** will be approved when BOTH of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract **OR** B. Mucositis associated with cancer treatment **OR** C. BOTH of the following: 1. The patient has ONE of the following: A. Another FDA approved indication for the requested agent and route of administration **OR** B. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient's medication history includes covered topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to covered topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL covered topical lidocaine **OR** B. The prescriber has provided information that indicates covered topical lidocaine is not clinically appropriate **OR** C. 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** D. The prescriber has provided documentation that covered topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to

Module	Clinical Criteria for Approval
	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 does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%)	**Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%)** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Pain associated with post-herpetic neuralgia (PHN) **OR** B. Neuropathic pain associated with cancer or cancer treatment **OR** C. Another FDA approved indication for the requested agent and route of administration **OR** D. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient has ONE of the following: A. The patient's medication history includes covered topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to covered topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL covered topical lidocaine **OR** B. The prescriber has provided information that indicates covered topical lidocaine is not clinically appropriate **OR** C. 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** D. The prescriber has provided documentation that covered topical lidocaine 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 does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **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**

Module	Clinical Criteria for Approval
	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. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months