MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: December 1, 2024 Notification Posted: November 13, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Resmetirom

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
52601060000320	Rezdiffra	resmetirom	60 MG	30	Tablets	30	DAYS				
52601060000330	Rezdiffra	resmetirom	80 MG	30	Tablets	30	DAYS				
52601060000340	Rezdiffra	resmetirom	100 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL the following are met:

Module	Clinical Criteria for Approval
	1. The patient has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH) (medical records required) **AND** 2. The patient has stage F2 or F3 fibrosis as confirmed by BOTH of the following (prior to therapy with the requested agent): A. A FIB-4 score consistent with stage F2 or F3 fibrosis adjusted for age **AND** B. The patient has ONE of the following: 1. A liver biopsy within the past 2 years **OR** 2. Vibration-controlled transient elastography (VCTE, e.g., Fibroscan) **OR** 3. Enhanced liver fibrosis (ELF) score **OR** 4. Magnetic resonance elastography (MRE) **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. The patient has ONE of the following: A. A BMI less than or equal to 25 kg/m^2 **OR** B. A BMI less than or equal to 23 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR** C. ONE of the following: 1. The patient's medication history includes 72 weeks of Wegovy OR 72 weeks of another subcutaneous GLP-1 for the treatment of the requested indication AND ONE of the following: A. The patient has had an inadequate response to Wegovy OR another subcutaneous GLP-1 for the treatment of the requested indication **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over Wegovy **OR** 2. The patient has an intolerance or hypersensitivity to therapy with Wegovy **OR** 3. The patient has an FDA labeled contraindication to Wegovy **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 Wegovy 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. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR** B. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND** 6. The patient is being monitored and/or treated for any comorbid conditions (e.g., cardiovascular disease, diabetes, dyslipidemia, hypertension) **AND** 7. BOTH of the following: A. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** B. The patient will continue the weight loss regimen in combination with the requested agent **AND** 8. The patient does NOT have ANY of the following: A. Decompensated cirrhosis **AND** B. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND**

Module	Clinical Criteria for Approval
	C. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND** 9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist) 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:** 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. ONE of the following: A. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR** B. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND** 3. BOTH of the following: A. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** B. The patient will continue the weight loss regimen in combination with the requested agent **AND** 4. The patient does NOT have ANY of the following: A. Decompensated cirrhosis **AND** B. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND** C. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND** 5. The patient has had clinical benefit with the requested agent **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 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**

Module	Clinical Criteria for Approval
	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 **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

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
23100030004044		Testosterone TD Gel 20.25 MG/1.25GM (1.62%)	20.25 MG/1.25GM	30	Packets	30	DAYS				
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				
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	Canisters	30	DAYS				
23100030004080	Natesto	Testosterone Nasal Gel 5.5 MG/ACT	5.5 MG/ACT	3	Pump Bottles	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)** **Androderm** (testosterone patch) **Androgel*** (testosterone gel) **Fortesta*** (testosterone gel) **Natesto** (testosterone nasal gel) **Testim*** (testosterone gel) **testosterone topical solution*** **Vogelxo*** (testosterone gel) * - generic available **The preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Testosterone Gel Pump (Generic of Androgel) and Testim.** **Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. If the request is for Androderm, Androgel, Aveed, Fortesta, Jatenzo, Kyzatrex, Natesto, Testim, testosterone topical solution, Tlando, Vogelxo, or Xyosted, the patient has a diagnosis of ONE of the following: 1. Primary or secondary (hypogonadotropic) hypogonadism **OR** 2. Gender dysphoria/gender incongruence **OR** B. If the request is for Depo-Testosterone or 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 dysphoria/gender incongruence **OR** C. If the request is for testosterone enanthate intramuscular injection solution, 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. Breast cancer **OR** 4. Gender dysphoria/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. Hereditary angioedema and will be taking for the prevention of attacks **OR** 3. Myelofibrosis associated anemia **OR** E. 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. 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**

Module	Clinical Criteria for Approval
	2. Free serum testosterone level that is below the testing laboratory's normal range **OR** 2. The patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels: 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 gender dysphoria/gender incongruence, then 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 comprehensive biopsychosocial assessment has been conducted by a qualified physician AND the prescriber has consulted with other medical professionals (e.g., mental health professional, endocrinologist) when required **AND** 2. The parents or other caretakers or guardians were involved in the assessment process, unless their involvement has been determined to be harmful to the adolescent or not feasible **AND** 3. A persistent diagnosis of gender dysphoria/gender incongruence has been marked and sustained over time **AND** 4. 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** 5. The patient has been informed and counseled regarding effects and side effects of sex hormone treatment, including those which are irreversible, and the potential loss of fertility and options available to preserve fertility **AND** 6. The patient has sufficient emotional and cognitive maturity required to provide informed consent/assent for treatment **AND** 7. The patient has provided informed consent/assent for treatment AND, as applicable, the parents or other caretakers or guardians have provided consent to therapy **AND** 8. The patient's coexisting mental health concerns, physical conditions, or social problems that may interfere with diagnosing and/or sex hormone treatment have been addressed to provide optimal treatment **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 of gender dysphoria/gender incongruence has been marked and sustained over time **AND** 2. Other possible causes of apparent gender incongruence have been identified and excluded prior to initiation of treatment **AND** 3. The patient has been informed and counseled regarding effects and side effects of sex hormone treatment, including those which are irreversible, and the potential loss of fertility and options available to preserve fertility **AND** 4. The patient has sufficient emotional and cognitive maturity required to provide informed consent for treatment **AND** 5. The patient has provided informed consent for treatment **AND** 6. The patient's coexisting mental health and/or physical conditions that could have a negative impact on sex hormone treatment have been addressed, with risks and benefits discussed, to provide optimal treatment **OR** B. The patient is currently on sex hormone treatment and BOTH of the following:

Module	Clinical Criteria for Approval
	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 for the patient's gender identity OR is less than 300 ng/dL **OR** 2. Free serum testosterone level that is within OR below the testing laboratory's normal range for the patient's gender identity **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** C. If the request is for delayed puberty in an adolescent, then ONE of the following: 1. The patient's sex is male **OR** 2. There is support that the requested agent is medically appropriate for the patient's sex **OR** D. If the request is for breast cancer, then ONE of the following: 1. BOTH of the following: A. The patient is 1 to 5 years postmenopausal **AND** B. The patient has inoperable metastatic breast cancer **OR** 2. ALL of the following: A. The patient is premenopausal **AND** B. The patient has benefitted from oophorectomy **AND** C. The patient has a hormone-responsive tumor **OR** E. The request is for endometriosis amenable to hormone management **OR** F. The request is for the prevention of attacks of hereditary angioedema **OR** G. If the request is for myelofibrosis associated anemia, then ONE of the following: 1. The patient has a serum erythropoietin (EPO) greater than or equal to 500 mU/mL **OR** 2. The patient has a serum erythropoietin (EPO) less than 500 mU/mL and had no response or loss of response to an erythropoiesis-stimulating agent (ESA) **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 (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**

Module	Clinical Criteria for Approval
	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) NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. ONE of the following: A. The patient has a diagnosis of primary or secondary hypogonadism and the patient's current testosterone level is ONE of the following: 1. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR** 2. Free serum testosterone level that is within OR below the testing laboratory's normal range **OR** B. The patient has a diagnosis of gender dysphoria/gender incongruence AND ONE of the following: 1. If the patient is an adult, then 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 for the patient's gender identity OR is less than 300 ng/dL **OR** B. Free serum testosterone level that is within OR below the testing laboratory's normal range for the patient's gender identity **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** C. The patient has a diagnosis other than primary or secondary hypogonadism or gender dysphoria/gender incongruence **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient will NOT be using the requested agent in combination with another androgen or anabolic steroid agent for the requested indication **OR** B. There is support for therapy with more than one androgen or anabolic steroid agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
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

• Program Summary: Antifungals

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
11507040100320	Brexafemme	Ibrexafungerp Citrate Tab	150 MG	4	Tablets	90	DAYS				
1140805000B220	Vivjoa	Oteseconazole Cap Therapy Pack	150 MG	18	Capsules	180	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brexafemme	**Brexafemme (ibrexafungerp)** will be approved when BOTH of the following are met 1. ONE of the following: A. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The patient is an adult or a post-menarchal pediatric patient AND ONE of the following: A. The patient has a diagnosis of vulvovaginal candidiasis (VVC) **OR** B. BOTH of the following: 1. The patient is using the requested agent to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) **AND** 2. The patient has experienced greater than or equal to 4 episodes of VVC within a 12-month period **AND** 2. ONE of the following: A. The patient's medication history includes fluconazole AND ONE of the following: 1. The patient has had an inadequate response to fluconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over to fluconazole **OR** B. The patient has an intolerance or hypersensitivity to fluconazole **OR** C. The patient has an FDA labeled contraindication to fluconazole **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 fluconazole 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 **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:** CMS Approved Compendia **Length of Approval:** VVC - 3 months, RVVC - 6 months, all other indications - 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Cresemba	**Initial Evaluation** **Cresemba (isavuconazole)** will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient has a diagnosis of invasive aspergillosis **OR** B. The patient has a diagnosis of invasive mucormycosis **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. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 months

Module	Clinical Criteria for Approval
	Renewal Evaluation **Cresemba (isavuconazole)** 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 review 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. The patient has a diagnosis of invasive aspergillosis or invasive mucormycosis **AND** 2. The patient has continued indicators of active disease (e.g., biomarkers in serum assay, biopsy, microbiologic culture, radiographic evidence) **OR** B. BOTH of the following: 1. The patient has a diagnosis other than invasive aspergillosis or invasive mucormycosis **AND** 2. There is support for continued use of the requested agent 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:** 6 months
Noxafil	**Initial Evaluation** **Noxafil (posaconazole)** will be approved when ONE of the following are met: 1. ALL of the following: A. ONE of the following: 1. The patient has a diagnosis of oropharyngeal candidiasis AND ONE of the following: A. The patient's medication history includes itraconazole or fluconazole AND ONE of the following: 1. The patient has had an inadequate response to itraconazole or fluconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over itraconazole or fluconazole **OR** B. The patient has an intolerance or hypersensitivity to itraconazole or fluconazole **OR** C. The patient has an FDA labeled contraindication to BOTH fluconazole AND itraconazole **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH fluconazole AND itraconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. BOTH of the following: A. The requested agent is prescribed for prophylaxis of invasive Aspergillus or Candida **AND**

Module	Clinical Criteria for Approval
	B. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant [HSCT] recipient, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (e.g., lung, heart, kidney, liver, pancreas, small bowel) transplant recipient **OR** 3. The patient has a diagnosis of invasive aspergillosis AND ONE of the following: A. The patient's medication history includes voriconazole, amphotericin B, or isavuconazole AND ONE of the following: 1. The patient has had an inadequate response to voriconazole, amphotericin B, or isavuconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over voriconazole, amphotericin B, or isavuconazole **OR** B. The patient has an intolerance or hypersensitivity to voriconazole, amphotericin B, or isavuconazole **OR** C. The patient has an FDA labeled contraindication to voriconazole, amphotericin B, AND isavuconazole **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 voriconazole, amphotericin B, AND isavuconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 4. The patient has another FDA labeled indication for the requested agent and route of administration **OR** 5. 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: 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. 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 feedings or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** oropharyngeal candidiasis - 1 month, all other indications - 6 months **Renewal Evaluation** **Noxafil (posaconazole)** will be approved when BOTH of the following are met:

Module	Clinical Criteria for Approval
	1. The patient has been previously approved for the requested agent through the plan's Prior Authorization review process [Note: patients not previously approved for the requested agent will require initial evaluation review]. (A diagnosis of oropharyngeal candidiasis must go through initial criteria) **AND** 2. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. BOTH of the following: 1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient continues to be severely immunocompromised (e.g., HSCT recipient, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (e.g., lung, heart, kidney, liver, pancreas, small bowel) transplant recipient **OR** B. BOTH of the following: 1. The patient has a diagnosis of invasive aspergillosis **AND** 2. The patient has continued indicators of active disease (e.g., biomarkers in serum assay, biopsy, microbiologic cultures, radiographic evidence) **OR** C. BOTH of the following: 1. The patient has a diagnosis other than invasive aspergillosis or prophylaxis of invasive Aspergillus or Candida **AND** 2. There is support for continued use of the requested agent for the requested indication **AND** 2. 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 approved indication **AND** 2. The patient uses an enteral tube for feedings or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 months
Vfend	**Initial Evaluation** **Vfend (voriconazole)** will be approved when ONE of the following are met: 1. ALL of the following: A. ONE of the following: 1. The patient has a diagnosis of invasive Aspergillus **OR** 2. BOTH of the following: A. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** B. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipient, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (e.g., lung, heart, kidney, liver, pancreas, small bowel) transplant recipient **OR** 3. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection AND ONE of the following: A. The patient's medication history includes fluconazole AND ONE of the following: 1. The patient has had an inadequate response to fluconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over fluconazole **OR**

Module	Clinical Criteria for Approval
	B. The patient has an intolerance or hypersensitivity to fluconazole **OR** C. The patient has an FDA labeled contraindication to fluconazole **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 fluconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 4. The patient has a serious infection caused by Scedosporium or Fusarium species **OR** 5. The patient has another FDA labeled indication for the requested agent and route of administration **OR** 6. 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: 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. 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 feedings or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** esophageal candidiasis - 1 month, all other indications - 6 months **Renewal Evaluation** **Vfend (voriconazole)** 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 review process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. ALL of the following: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of invasive aspergillosis; serious infection caused by Scedosporium or Fusarium species; esophageal candidiasis, candidemia, or other deep tissue Candida infection **AND** 2. The patient has continued indicators of active disease (e.g., biomarkers in serum assay, biopsy, microbiologic cultures, radiographic evidence) **OR** B. BOTH of the following: 1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND**

Module	Clinical Criteria for Approval
	2. The patient is severely immunocompromised (e.g., HSCT recipient, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (e.g., lung, heart, kidney, liver, pancreas, small bowel) transplant recipient **OR** C. BOTH of the following: 1. The patient has a diagnosis other than invasive aspergillosis; prophylaxis of invasive Aspergillus or Candida; serious infection caused by Scedosporium or Fusarium species; esophageal candidiasis, candidemia, or other deep tissue Candida infection **AND** 2. There is support for continued use of the requested agent for the intended diagnosis **AND** 2. 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 approved indication **AND** 2. The patient uses an enteral tube for feedings or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** esophageal candidiasis - 1 month, all other indications - 6 months
Vivjoa	**Vivjoa (oteseconazole)** will be approved when BOTH of the following are met: 1. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of recurrent vulvovaginal candidiasis (RVVC) **AND** 2. The patient has experienced greater than or equal to 4 episodes of VVC within a 12 month period **AND** 3. ONE of the following: A. The patient will be using fluconazole in combination with the requested agent **OR** B. The patient's medication history includes fluconazole AND ONE of the following: 1. The patient has had an inadequate response to fluconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over to fluconazole **OR** C. The patient has an intolerance or hypersensitivity to fluconazole **OR** D. The patient has an FDA labeled contraindication to fluconazole **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 fluconazole 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 **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

Module	Clinical Criteria for Approval
	Compendia Allowed: CMS Approved Compendia **Length of Approval:** RVVC - 4 months, all other indications - 6 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

• Program Summary: Biologic Immunomodulator

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
6627001502F540		adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219061299			
6627001540F820		adalimumab-ryvk prefilled syringe kit	40 MG/0.4ML	2	Syringes	28	DAYS				
66290030002120		Etanercept For Subcutaneous Inj 25 MG		8	Vials	28	DAYS				
6627001507F810	Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001507F820	Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001507F520	Abrilada 1-pen kit; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				

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
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	4	Syringes	28	DAYS				
6650007000D520	Actemra actpen	Tocilizumab Subcutaneous Soln Auto-injector 162 MG/0.9ML	162 MG/0.9ML	4	Pens	28	DAYS				
6627001510D517	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001510D537	Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS				
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001510E508	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E517	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	2	Syringes	28	DAYS				
9025051800D520	Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 ; 160 MG/ML	2	Pens	56	DAYS				
9025051800E520	Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160; 160 MG/ML	2	Syringes	56	DAYS				
52505020106420	Cimzia	Certolizumab Pegol For Inj Kit 2 X 200 MG	200 MG	2	Kits	28	DAYS				
5250502010F840	Cimzia	certolizumab pegol prefilled syringe kit	200 MG/ML	2	Kits	28	DAYS	50474071079;			
5250502010F840	Cimzia starter kit	certolizumab pegol prefilled syringe kit	200 MG/ML	1	Kit	180	DAYS	50474071081;			
9025057500E530	Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	2	Syringes	28	DAYS				
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	1	Syringe	28	DAYS				
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS				
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-	150 MG/ML	2	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
		inj 150 MG/ML (300 MG Dose)									
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS				
6627001505F515	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	00597049550; 00597057550; 82009014422			
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00597037597; 00597054522; 82009014822			
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001505F815	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	6	Pens	180	DAYS	00597037516; 00597054566;			
6627001505F515	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.4ML	1	Kit	180	DAYS	00597049560; 00597057560;			
6627001505F515	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.4ML	1	Kit	180	DAYS	00597049540; 00597057540;			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	4	Pens	180	DAYS	00597037523; 00597054544;			
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	8	Vials	28	DAYS				
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	4	Syringes	28	DAYS				
6629003000E530	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS				
6629003000E230	Enbrel mini	Etanercept Subcutaneous Solution Cartridge 50 MG/ML	50 MG/ML	4	Cartridges	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6629003000D530	Enbrel sureclick	Etanercept Subcutaneous Solution Auto-injector 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS				
5250308000D520	Entyvio	vedolizumab soln pen-injector 108 mg/0.68ml	108 MG/0.68ML	2	Pens	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1ML	2	Syringes	28	DAYS				
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F840	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8ML	1	Kit	180	DAYS				
6627001500F880	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001500F540	Humira pen	adalimumab auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	00074012402; 83457012402			
6627001500F520	Humira pen	adalimumab auto-injector kit; adalimumab pen-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00074433902;			
6627001500F530	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	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
6627001500F540	Humira pen-cd/uc/hs start	adalimumab auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012403;			
6627001500F520	Humira pen-cd/uc/hs start	adalimumab auto-injector kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433906;			
6627001500F540	Humira pen-pediatric uc s	adalimumab auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012404;			
6627001500F520	Humira pen-ps/uv starter	adalimumab auto-injector kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433907;			
6627001500F550	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001504D540	Hyrimoz; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS	61314045420; 83457010701			
6627001504D540	Hyrimoz crohn's disease a; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	1	Starter Kit	180	DAYS	61314045436; 83457011301			
6627001504E560	Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4ML	2	Syringes	180	DAYS				
6627001504E540	Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8ML	3	Syringes	180	DAYS				

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
6627001504D560	Hyrimoz plaque psoriasis; Hyrimoz plaque psoriasis/	adalimumab-adaz soln auto-injector	80 MG/0.8ML & 40MG/0.4ML	1	Starter Kit	180	DAYS				
6627001502F540	Idacio (2 pen)	adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219055408; 65219061299			
6627001502F840	Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	1	Kit	28	DAYS				
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Starter Kit	180	DAYS	65219055438; 65219061289			
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Starter Kit	180	DAYS	65219055428; 65219061269			
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML ; 200 MG/1.14ML	2	Syringes	28	DAYS				
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML ; 200 MG/1.14ML	2	Pens	28	DAYS				
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	28	Syringes	28	DAYS				
90731060100120	Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS				
666030100003	Olumiant	baricitinib tab	1 MG; 2 MG; 4 MG	30	Tablets	30	DAYS				
5250405040E520	Omvoh	mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML	2	Syringes	28	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS				
6640001000D520	Orencia clickject	Abatacept Subcutaneous Soln	125 MG/ML	4	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Auto-Injector 125 MG/ML									
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS				
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS				
66603072002020	Rinvoq lq	upadacitinib oral soln	1 MG/ML	360	mLs	30	DAYS				
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	2	Syringes	28	DAYS				
6627001540F520	Simlandi 1-pen kit; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS				
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
9025057070F820	Skyrizi	Risankizumab-rzaa Sol Prefilled Syringe 2 x 75 MG/0.83ML Kit	75 MG/0.83ML	1	Kit	84	DAYS				
9025057070E540	Skyrizi	Risankizumab-rzaa Soln Prefilled Syringe	150 MG/ML	1	Syringe	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridge	56	DAYS				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridge	56	DAYS				
9025057070D520	Skyrizi pen	Risankizumab-rzaa Soln Auto-injector	150 MG/ML	1	Pen	84	DAYS				
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS				
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS				

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
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	1	Syringe	84	DAYS				
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS				
9025055400D520	Taltz	Ixekizumab Subcutaneous Soln Auto-injector 80 MG/ML	80 MG/ML	1	Injection	28	DAYS				
9025055400E510	Taltz	ixekizumab subcutaneous soln prefilled syringe	20 MG/0.25ML	1	Syringe	28	DAYS				
9025055400E515	Taltz	ixekizumab subcutaneous soln prefilled syringe	40 MG/0.5ML	1	Syringe	28	DAYS				
9025055400E520	Taltz	Ixekizumab Subcutaneous Soln Prefilled Syringe 80 MG/ML	80 MG/ML	1	Syringe	28	DAYS				
9025054200D540	Tremfya	guselkumab soln auto-injector	200 MG/2ML	1	Pen	28	DAYS				
9025054200D520	Tremfya	Guselkumab Soln Pen-Injector 100 MG/ML	100 MG/ML	1	Pen	56	DAYS				
9025054200E540	Tremfya	guselkumab soln prefilled syringe	200 MG/2ML	1	Syringe	28	DAYS				
9025054200E520	Tremfya	Guselkumab Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	56	DAYS				
6650007017D520	Tyenne	tocilizumab-aazg subcutaneous soln auto-inj	162 MG/0.9ML	4	Pens	28	DAYS				
6650007017E520	Tyenne	tocilizumab-aazg subcutaneous soln pref syr	162 MG/0.9ML	4	Syringes	28	DAYS				
52504525100350	Velsipity	etrasimod arginine tab	2 MG	30	Tablets	30	DAYS				
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS				
66603065100330	Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS				
66603065100320	Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS				
66603065107530	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS				

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
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS				
6627001503F560	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	72606002304; 72606004004			
6627001503F530	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002209; 72606003009			
6627001503F530	Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002210; 72606003010			
6627001503F820	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001503F830	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4ML	1	Kit	28	DAYS				
6627001503F560	Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	72606002307			
6627001509D520	Yusimry	adalimumab-aqvh soln pen-injector 40 mg/0.8ml	40 MG/0.8ML	2	Pens	28	DAYS				
5250504020F530	Zymfentra 1-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002501			
5250504020F530	Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002502			
5250504020F830	Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	2	Syringes	28	DAYS				
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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	For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Enbrel kits, Enbrel pens, Enbrel syringes, Enbrel vial, Enbrel mini cartridges, Humira kits, Humira pen kits, infliximab intravenous injection, Otezla tablets, and Xeljanz Immediate Release tablets.

Disease State	PDL Preferred Agents	PDL Non-Preferred Agents
Ankylosing Spondylitis (AS)	SQ: Enbrel, Humira Oral: Xeljanz IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Bimzelx, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simponi, Taltz, Yuflyma Oral: Rinvoq, Xeljanz XR
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	N/A	SQ: Bimzelx, Cimzia, Cosentyx, Taltz Oral: Rinvoq

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	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Humira Oral: Xeljanz	SQ: Abrilada, Actemra, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Kevzara, Orencia, Yuflyma Oral: Rinvoq, Xeljanz solution
	Psoriatic Arthritis (PsA)	SQ: Enbrel, Humira Oral: Otezla, Xeljanz IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Bimzelx, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Orencia, Simponi, Skyrizi, Stelara, Taltz, Tremfya, Yuflyma Oral: Rinvoq, Xeljanz XR
	Rheumatoid Arthritis	SQ: Enbrel, Humira Oral: Xeljanz IV: infliximab*	SQ: Abrilada, Actemra, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Kevzara, Kineret, Orencia, Simponi, Yuflyma Oral: Olumiant, Rinvoq, Xeljanz XR
	Hidradenitis Suppurativa (HS)	SQ: Humira	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma
	Psoriasis (PS)	SQ: Enbrel, Humira Oral: Otezla IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Bimzelx, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Siliq, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, Yuflyma
	Crohn's Disease	SQ: Humira IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Skyrizi, Stelara, Yuflyma

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	Ulcerative Colitis	SQ: Humira Oral: Xeljanz IV: infliximab*	SQ: Abrilada syringe/pen, adalimumab-adaz syringe/pen, adalimumab-adbm syringe/pen, adalimumab-fkjp syringe/pen, Amjevita syringe/autoinjector, Cyltezo syringe/pen, Entyvio, Hadlima, Hulio, Hyrimoz, Idacio, Simponi, Skyrizi, Stelara, Tremfya, Yuflyma Oral: Rinvoq, Xeljanz XR
	Uveitis	SQ: Humira	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma
	Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA)	N/A	N/A

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	<table><tr><td>Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)</td><td></td><td></td></tr></table> * Infliximab is a preferred product on the MN Medicaid Preferred Drug List (PDL) and is locked to the medical benefit ** Note: For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as ONE product
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. ONE of the following: A. 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 **OR** B. ALL of the following: 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. ALL of the following: 1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following: A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following: 1. ONE of the following: A. The patient's medication history includes ONE conventional agent (i.e., maximally tolerated methotrexate [e.g., titrated to 25 mg weekly], hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA AND ONE of the following: 1. The patient has had an inadequate response to a conventional agent used in the treatment of RA **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over

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	conventional agents used in the treatment of RA **OR** B. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** C. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** D. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **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 ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the request is for Simponi, ONE of the following: A. The patient will be taking the requested agent in combination with methotrexate **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR** B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient'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 used in the treatment of PsA **OR**

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	B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of PsA **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive 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 ALL of the conventional agents used in the treatment of PsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following: 1. The patient's medication history includes 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 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 over conventional agents used in the treatment of PS **OR**

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

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

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	7. The prescriber has provided documentation that ALL of the conventional agents used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient's medication history includes oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: A. The patient has had an inadequate response to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 2. The patient has an intolerance or hypersensitivity to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently

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	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 oral corticosteroids and periocular/intravitreal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient's medication history includes ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following: 1. The patient's medication history includes systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA AND ONE of the following: A. The patient has had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA **OR** 2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR** 3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of GCA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

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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** 6. The prescriber has provided documentation that ALL systemic 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** H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following: 1. The patient's medication history includes TWO different NSAIDs used in the treatment of AS AND ONE of the following: A. The patient has had an inadequate response to TWO different NSAIDs used in the treatment of AS **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over TWO different NSAIDs used in the treatment of AS **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of AS **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following: 1. The patient's medication history includes two different NSAIDs used in the treatment of nr-axSpA AND ONE of the following:

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

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

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	reasonable functional ability in performing daily activities or cause physical or mental harm **OR** L. BOTH of the following: 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR** M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient's medication history includes TWO different NSAIDs used in the treatment of ERA AND ONE of the following: A. The patient has had an inadequate response to TWO different NSAIDs used in the treatment of ERA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over NSAIDs used in the treatment of ERA **OR** 2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement 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**

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	D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND** 2. ONE of the following: A. The patient's medication history includes at least a medium-potency topical corticosteroid used in the treatment of AD **AND** 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 at least a medium-potency topical corticosteroid used in the treatment of AD **AND** a topical calcineurin inhibitor (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 at least medium-potency topical corticosteroids used in the treatment of AD **AND** 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 at least a medium-potency topical corticosteroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive 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 ALL medium-, high-, and super-potency topical corticosteroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve

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	or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has documented the patient's baseline (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) **OR** O. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient's medication history includes ONE systemic corticosteroid at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR AND ONE of the following: A. The patient has had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive 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 systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** Q. The patient has a diagnosis of juvenile psoriatic arthritis (JPsA) AND ONE of the following: 1. The patient's medication history includes a conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA AND ONE of the following:

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	A. The patient has had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of JPsA **OR** 3. The patient has an FDA labeled contraindication to methotrexate **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation ALL conventional agents (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 6. The patient has severe active JPsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to JPsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 7. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 8. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of JPsA **OR** R. The patient has a diagnosis not mentioned previously **AND** 2. 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 Velsipity, Omvoh, or 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**

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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** 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 **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 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** 3. If Cosentyx 300 mg is requested as maintenance dosing, then ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND BOTH of the following: 1. The requested dose is 300 mg every 4 weeks **AND**

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	2. The patient has tried and had an inadequate response to Cosentyx 150 mg every 4 after at least 3-month duration of therapy **AND** 4. If Entyvio is requested for the treatment of ulcerative colitis or Crohn's disease, then ONE of the following: A. The patient has received at least 2 doses of Entyvio intravenous therapy **OR** B. The patient is new to therapy and will receive 2 doses of Entyvio IV therapy **AND** 5. If Omvoh is requested for the treatment of ulcerative colitis, then ONE of the following: A. The patient received Omvoh IV for induction therapy **OR** B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following: A. The patient received Skyrizi IV for induction therapy **OR** B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND** 7. If an ustekinumab product is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following: A. The patient received an ustekinumab IV product for induction therapy **OR** B. The patient is new to therapy and will receive an ustekinumab IV product for induction therapy **AND** 8. If Zymfentra is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following: A. The patient received an infliximab IV product for induction therapy **OR** B. The patient is new to therapy and will receive an infliximab IV product for induction therapy **AND** 9. If Tremfya is requested for the treatment of ulcerative colitis, then ONE of the following: A. The patient received Tremfya IV for induction therapy **OR** B. The patient is new to therapy and will receive Tremfya IV for induction therapy **AND** 10. 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. If an ustekinumab 90 mg product is requested, then ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 3. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 4. If Kevzara is requested for a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), the patient weighs 63 kg or greater **AND** 5. If the patient has moderate-to-severe atopic dermatitis (AD), then BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND**

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	B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the length of approval. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **Compendia Allowed:** CMS Approved Compendia **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note ustekinumab product renewal must be for the same strength as the initial approval) [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 4. ONE of the following: A. 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 **OR** B. ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following:

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	1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 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 (submitted copy of clinical trials, phase III studies, guidelines required) **AND** 4. If Cosentyx 300 mg is requested as maintenance dosing, then ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND BOTH of the following: 1. The requested dose is 300 mg every 4 weeks **AND** 2. The patient has tried and had an inadequate response to Cosentyx 150 mg after at least a 3-month duration of therapy **AND** 5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent

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	Compendia Allowed: CMS Approved Compendia **Length of Approval:** 12 months **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
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)
Leqselvi (deuruxolitinib)
Litfulo (ritlecitinib)
Nemluvio (nemolizumab-ilto)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Saphnelo (anifrolumab-fnia)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)

Contraindicated as Concomitant Therapy
Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) subcutaneous injection 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: 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
67701010000320	Qulipta	Atogepant Tab	30 MG	30	Tablets	30	DAYS				
67701010000310	Qulipta	Atogepant Tab	10 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				

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
6770203530E515	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 100 MG/ML	100 MG/ML	9	Syringes	180	DAYS				
6770203530E520	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 120 MG/ML	120 MG/ML	1	Syringe	28	DAYS				
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	PDL Non-Preferred Agents
Acute treatment of migraine with or without aura	Ubrelvy	Nurtec ODT, Zavzpret
Preventative treatment of migraine	Aimovig, Ajovy, Emgality	Nurtec ODT, Qulipta
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 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:

Module	Clinical Criteria for Approval
	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. Medication overuse headache has been ruled out **AND** 3. 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 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 periods 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**

Module	Clinical Criteria for Approval
	D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that verapamil, melatonin, corticosteroids, topiramate, 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** 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**

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

Module	Clinical Criteria for Approval
	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 days per month of migraine-like or tension-like headache (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** 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**

Module	Clinical Criteria for Approval
	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

Module	Clinical Criteria for Approval
QL	**Quantity limit for Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. ALL of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. If the requested agent is being used for treatment of acute migraine, then ONE of the following: A. The patient is currently being treated with a migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], onabotulinum toxin A [Botox]) **OR** B. The patient has an intolerance or hypersensitivity to therapy with migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], OR onabotulinum toxin A [Botox]) **OR** C. The patient has an FDA labeled contraindication to ALL migraine prophylactic medications (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], AND onabotulinum toxin A [Botox]) **OR** D. There is support that the patient's migraine is manageable with acute therapy alone **AND** 3. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of approval up to 12 months.

• Program Summary: Dry Eye Disease

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
86720020002040	Cequa	Cyclosporine (Ophth) Soln 0.09% (PF)	0.09 %	60	Vials	30	DAYS				
86807018002020	Miebo	perfluorohexyloctane ophth soln	1.338 GM/ML	1	Bottle	30	DAYS				
86720020001620	Restasis	cyclosporine (ophth) emulsion	0.05 %	60	Vials	30	DAYS	00023916330; 00023916360; 00378876058; 00378876091; 10702080803; 10702080806; 50090124200; 50090447600; 60505620201; 60505620202; 68180021430; 68180021460; 73043000501; 73043000502			
86720020001620	Restasis multidose	cyclosporine (ophth) emulsion	0.05 %	1	Bottle	30	DAYS	00023530105;			
86280080202020	Tyrvaya	Varenicline Tartrate Nasal Soln	0.03 MG/ACT	2	Bottles	30	DAYS				
86720020002043	Vevye	cyclosporine (ophth) soln	0.1 %	1	Bottle	30	DAYS				
86734050002020	Xiidra	Lifitegrast Ophth Soln 5%	5 %	60	Vials	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs.** **Preferred Agents** Restasis Xiidra **Nonpreferred Agents** Cequa Cyclosporine Eysuvis Miebo Tyrvaya Vevye

Module	Clinical Criteria for Approval
	Initial Evaluation **Cequa (cyclosporine), Miebo (perfluorohexyloctane), Tyrvaya (varenicline), Vevye (cyclosporine), and Xiidra (lifitegrast)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. ONE of the following: A. The patient's medication history includes aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) AND ONE of the following: 1. The patient has had an inadequate response to aqueous enhancements **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL aqueous enhancements **OR** B. The patient has an intolerance or hypersensitivity to aqueous enhancements **OR** C. The patient has an FDA labeled contraindication to ALL aqueous enhancements **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 aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) 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 an indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The requested agent is a nonpreferred agent in the Minnesota Medicaid Preferred Drug List (PDL) 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**

Module	Clinical Criteria for Approval
	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 **AND** 3. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** Miebo (perfluorohexyloctane) and Tyrvaya (varenicline) - 2 months; Cequa (cyclosporine), Vevye (cyclosporine), Xiidra (lifitegrast) - 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Initial Evaluation** **Eysuvis (loteprednol etabonate)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) AND ONE of the following: 1. The patient has NOT been previously treated with the requested agent AND ONE of the following: A. The patient's medication history includes at least ONE generic ophthalmic corticosteroid AND ONE of the following: 1. The patient has had an inadequate response the generic ophthalmic corticosteroid **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL generic ophthalmic corticosteroids **OR** B. The patient has an intolerance or hypersensitivity to therapy with generic ophthalmic corticosteroids that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to ALL generic ophthalmic corticosteroids that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL generic ophthalmic corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient has been previously treated with the requested agent AND ALL of the following: A. ONE of the following: 1. The patient's medication history includes at least ONE generic ophthalmic corticosteroid AND ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has had an inadequate response the generic ophthalmic corticosteroid **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL generic ophthalmic corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to therapy with generic ophthalmic corticosteroids that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to ALL generic ophthalmic corticosteroids 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 generic ophthalmic corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. The patient has had clinical benefit with the requested agent **AND** C. The patient's eyes have been examined under magnification (e.g., slit lamp), and the intraocular pressure has been evaluated **OR** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has an indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Initial Evaluation** **Restasis (cyclosporine ophthalmic emulsion)** 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 dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. The patient will NOT be using the requested agent in combination with punctal plug(s) **AND** 3. ONE of the following: A. The patient's medication history includes aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) AND ONE of the following: 1. The patient has had an inadequate response to aqueous enhancements **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL aqueous enhancements **OR** B. The patient has an intolerance or hypersensitivity to aqueous enhancements **OR** C. The patient has an FDA labeled contraindication to ALL aqueous enhancements **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 aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) 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 an indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The requested agent is a nonpreferred agent in the Minnesota Medicaid Preferred Drug List (PDL) 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 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 Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 months

Module	Clinical Criteria for Approval
	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 Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **AND** 4. If the requested agent is Eysuvis (loteprednol etabonate), the patient's eyes have been examined under magnification (e.g., slit lamp), and the intraocular pressure has been evaluated **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** Eysuvis (loteprednol etabonate) - 3 months, all other agents - 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. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Erythropoietins

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	824010151020	Aranesp albumin free	darbepoetin alfa soln inj	100 MCG/ML; 200 MCG/ML; 25 MCG/ML; 40 MCG/ML; 60 MCG/ML	M; N; O; Y				
	8240101510E5	Aranesp albumin free	darbepoetin alfa soln prefilled syringe	10 MCG/0.4ML; 100 MCG/0.5ML; 150 MCG/0.3ML; 200 MCG/0.4ML; 25 MCG/0.42ML; 300 MCG/0.6ML; 40 MCG/0.4ML; 500 MCG/ML; 60 MCG/0.3ML	M; N; O; Y				
	824010200020	Epogen; Procrit	epoetin alfa inj	10000 UNIT/ML; 2000 UNIT/ML; 20000 UNIT/ML; 3000 UNIT/ML; 4000 UNIT/ML; 40000 UNIT/ML	M; N; O; Y				
	8240104010E5	Mircera	methoxy peg-epoetin beta soln prefilled syr	100 MCG/0.3ML; 120 MCG/0.3ML; 150 MCG/0.3ML; 200 MCG/0.3ML; 30 MCG/0.3ML; 50 MCG/0.3ML; 75 MCG/0.3ML	M; N; O; Y				
	824010200420	Retacrit	epoetin alfa-epbx inj	10000 UNIT/ML; 2000 UNIT/ML; 20000 UNIT/2ML;	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
				20000 UNIT/ML; 3000 UNIT/ML; 4000 UNIT/ML; 40000 UNIT/ML					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs **Preferred Agents** Aranesp (darbepoetin alfa) Epogen (epoetin alfa) Retacrit (epoetin alfa-epbx; all manufacturers EXCEPT Vifor) **Nonpreferred Agents** Mircera (methoxy polyethylene glycol – epoetin beta) Procrit (epoetin alfa) Retacrit (epoetin alfa-epbx; manufactured by Vifor) **Target Agent(s)** will be approved when BOTH of the following are met: 1. The patient's hemoglobin was measured within the previous 4 weeks **AND** 2. ONE of the following: A. The patient will use the requested agent as part of dialysis AND ONE of the following: 1. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR** 2. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **OR** B. ALL of the following: 1. ONE of the following: A. The requested agent is being prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL **OR** B. The requested agent is being prescribed for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following: 1. The requested agent is NOT Mircera **AND** 2. ONE of the following: A. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR** B. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **AND** 3. The patient is concurrently treated with chemotherapy (with or without radiation) **AND** 4. Chemotherapy is being used for palliative intent **AND** 5. The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks AND BOTH of the following: A. The patient's serum ferritin is NOT greater than 800 ng/mL **AND** B. The patient's transferrin saturation is NOT greater than 50% **OR**

Module	Clinical Criteria for Approval
	C. The requested agent is being prescribed for anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following: 1. ONE of the following: A. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR** B. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **AND** 2. The rate of hemoglobin decline is likely to result in a red blood cell (RBC) transfusion **AND** 3. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks **OR** D. The requested agent is being prescribed for anemia due to myelodysplastic syndrome, or for anemia resulting from zidovudine treatment of HIV infection AND ONE of the following: 1. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 12 g/dL **OR** 2. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **OR** E. The requested agent is being prescribed for another FDA labeled indication or another indication that is supported in compendia AND the patient's hemoglobin level is within the FDA labeling or compendia recommended range for the requested indication for patients initiating ESA therapy OR for patients stabilized on therapy for the requested indication **AND** 2. The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks **AND** 3. ONE of the following: A. The patient's serum ferritin is greater than or equal to 100 ng/mL AND the patient's transferrin saturation is greater than or equal to 20% **OR** B. The patient has started supplemental iron therapy **AND** 4. 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** 5. 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 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**

Module	Clinical Criteria for Approval
	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 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** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval**: 1 month for allogenic blood transfusion in a surgery patient; 6 months for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy 12 months for anemia associated with chronic kidney disease in patients on/not on dialysis, anemia due to myelodysplastic syndrome, anemia resulting from zidovudine treatment of HIV infection 6 months for all other diagnoses

• Program Summary: Opzelura

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
90272060503720	Opzelura	Ruxolitinib Phosphate Cream	1.5 %	1	Tube	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<table><tr><th>Indication</th><th>PDL Preferred Agents</th></tr><tr><td>Atopic Dermatitis</td><td>Dupixent</td></tr></table> **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 mild to moderate atopic dermatitis (AD) AND ALL of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 2. The patient is NOT immunocompromised **AND** 3. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient's medication history includes at least a low-potency topical corticosteroid used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to least a low-potency topical corticosteroid 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 ALL topical corticosteroids used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to at least a low-potency topical corticosteroid used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids 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 topical corticosteroids 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. ONE of the following: A. The patient's medication history includes a topical calcineurin inhibitor used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to a topical calcineurin inhibitor 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 ALL topical calcineurin inhibitors used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on 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** 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**

Module	Clinical Criteria for Approval
	B. The patient has a diagnosis of nonsegmental vitiligo AND ALL of the following: 1. Vitiligo is NOT restricted from coverage under the patient's benefit **AND** 2. The patient's affected body surface area (BSA) is less than or equal to 10% **AND** 3. ONE of the following: A. The patient has vitiligo impacting areas OTHER THAN the face, neck, axilla, or groin AND ONE of the following: 1. The patient's medication history includes at least a medium-potency topical corticosteroid used in the treatment of nonsegmental vitiligo AND ONE of the following: A. The patient has had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of nonsegmental vitiligo **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of nonsegmental vitiligo **OR** 2. The patient has an intolerance or hypersensitivity to at least a medium-potency topical corticosteroid used in the treatment of nonsegmental vitiligo **OR** 3. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of nonsegmental vitiligo **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 medium-, high-, and super-potency topical corticosteroids used in the treatment of nonsegmental vitiligo 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 vitiligo on the face, neck, axilla, or groin AND ONE of the following: 1. The patient's medication history includes at least a medium-potency topical corticosteroid used in the treatment of nonsegmental vitiligo AND ONE of the following: A. The patient has had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of nonsegmental vitiligo **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of nonsegmental vitiligo **OR** 2. The patient's medication history includes a topical calcineurin inhibitor used in the treatment of nonsegmental vitiligo AND ONE of the following: A. The patient has had an inadequate response to a topical calcineurin inhibitor used in the treatment of nonsegmental vitiligo **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent

Module	Clinical Criteria for Approval
	over ALL a topical calcineurin inhibitors used in the treatment of nonsegmental vitiligo **OR** 3. The patient has an intolerance or hypersensitivity to therapy with at least a medium-potency topical corticosteroid OR a topical calcineurin inhibitor used in the treatment of nonsegmental vitiligo **OR** 4. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids AND topical calcineurin inhibitors used in the treatment of nonsegmental vitiligo **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL medium-, high-, and super-potency topical corticosteroids AND topical calcineurin inhibitors used in the treatment of nonsegmental vitiligo 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** 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. 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 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) within the past 999 days **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days **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

Module	Clinical Criteria for Approval
	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) 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 (submitted copy of clinical trials, phase III studies, guidelines required) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo 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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto)

Contraindicated as Concomitant Therapy
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)
Leqselvi (deuruxolitinib)
Litfulo (ritlecitinib)
Nemluvio (nemolizumab-ilto)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Saphnelo (anifrolumab-fnia)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo) subcutaneous injection
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)

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

• Program Summary: Peanut Allergy

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 Suppl	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2010004020H510	Palforzia initial dose es	Peanut Powder-dnfp Starter Pack 0.5 & 1 & 1.5 & 3 & 6 MG	0.5 & 1 & 1.5 & 3 & 6 MG	1	Kit	180	DAYS				
2010004020H525	Palforzia level 1	Peanut Powder-dnfp Cap Sprinkle Pack 3 x 1 MG (3 MG Dose)	1 MG	90	Capsules	30	DAYS				
2010004020H570	Palforzia level 10	Peanut Powder-dnfp Pack 2 x 20 MG & 2 x 100 MG (240 MG Dose)	2 x 20 MG & 2 x 100 MG	120	Capsules	30	DAYS				
20100040203050	Palforzia level 11 (maint	Peanut Allergen Powder-dnfp Maintenance Packet 300 MG	300 MG	30	Packets	30	DAYS				
20100040203030	Palforzia level 11 (titra	Peanut Allergen Powder-dnfp Titration Packet 300 MG	300 MG	30	Packets	30	DAYS				
2010004020H530	Palforzia level 2	Peanut Powder-dnfp Cap Sprinkle Pack 6 x 1 MG (6 MG Dose)	1 MG	180	Capsules	30	DAYS				
2010004020H535	Palforzia level 3	Peanut Powder-dnfp Pack 2 x 1 MG & 10 MG (12 MG Dose)	2 x 1 MG & 10 MG	90	Capsules	30	DAYS				
2010004020H540	Palforzia level 4	Peanut Powder-dnfp Cap Sprinkle	20 MG	30	Capsules	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Suppl	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Pack 20 MG (20 MG Dose)									
2010004020H545	Palforzia level 5	Peanut Powder-dnfp Cap Sprinkle Pack 2 x 20 MG (40 MG Dose)	20 MG	60	Capsules	30	DAYS				
2010004020H550	Palforzia level 6	Peanut Powder-dnfp Cap Sprinkle Pack 4 x 20 MG (80 MG Dose)	20 MG	120	Capsules	30	DAYS				
2010004020H555	Palforzia level 7	Peanut Powder-dnfp Pack 20 MG & 100 MG (120 MG Dose)	20 MG & 100 MG	60	Capsules	30	DAYS				
2010004020H560	Palforzia level 8	Peanut Powder-dnfp Pack 3 x 20 MG & 100 MG (160 MG Dose)	3 x 20 MG & 100 MG	120	Capsules	30	DAYS				
2010004020H565	Palforzia level 9	Peanut Powder-dnfp Pack 2 x 100 MG (200 MG Dose)	100 MG	60	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. ONE of the following: A. The patient has been treated with the requested agent within the past 30 days **OR** B. The prescriber states the patient has been treated with the requested agent within the past 30 days AND is at risk if therapy is changed **OR** C. BOTH of the following: 1. The patient has a diagnosed peanut allergy confirmed by ONE of the following: A. A serum peanut-specific IgE level greater than or equal to 0.35 kUA/L **OR** B. A positive skin-prick test determined by a mean wheal diameter that is at least 3mm larger than the negative control upon skin-prick testing for peanut **OR** C. The patient has a positive result to an oral peanut food challenge **AND** 2. The patient was 1-17 years of age at the time of initiating therapy **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient has injectable epinephrine on hand **AND** 4. The requested agent is to be used in conjunction with a peanut-avoidance diet **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
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 **Length of Approval:** up to 12 months

• Program Summary: Primary Biliary Cholangitis (fka Ocaliva)

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
52780020000320	Iqirvo	elafibranor tab	80 MG	30	Tablets	30	DAYS				
52780070500120	Livdelzi	seladelpar lysine cap	10 MG	30	Capsules	30	DAYS				
52750060000330	Ocaliva	Obeticholic Acid Tab 10 MG	10 MG	30	Tablets	30	DAYS				
52750060000320	Ocaliva	Obeticholic Acid Tab 5 MG	5 MG	30	Tablets	30	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 primary biliary cholangitis (PBC) AND ALL of the following: 1. Diagnosis has been confirmed by at least TWO of the following: A. There is biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation B. ONE of the following: 1. Positive presence of antimitochondrial antibody (AMA) **OR** 2. Positive presence of other PBC-specific autoantibodies (e.g., sp100, gp210) if AMA is negative C. Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts **AND**

Module	Clinical Criteria for Approval
	2. The prescriber has measured the patient's baseline alkaline phosphatase (ALP) level and total bilirubin level (prior to therapy with the requested agent) **AND** 3. ONE of the following: A. BOTH of the following: 1. The patient has tried and had an inadequate response after at least 1 year of therapy with ursodeoxycholic acid (UDCA) (inadequate response defined as ALP greater than the upper limit of normal [ULN], and/or total bilirubin greater than ULN but less than 2x ULN, after 1 year of treatment with UDCA) **AND** 2. The patient will continue treatment with ursodeoxycholic acid (UDCA) in combination with the requested agent **OR** B. The patient has an intolerance or hypersensitivity to therapy with ursodeoxycholic acid (UDCA) **OR** C. The patient has an FDA labeled contraindication to ursodeoxycholic acid (UDCA) **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 prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) 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. **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 primary biliary cholangitis (PBC) AND ALL of the following: 1. ONE of the following: A. The requested agent will be used in combination with ursodeoxycholic acid (UDCA) **OR** B. The patient has an intolerance, hypersensitivity, or an FDA labeled contraindication to therapy with ursodeoxycholic acid (UDCA) **AND** 2. The patient has had an alkaline phosphatase (ALP) decrease of greater than or equal to 15% from baseline (prior to therapy with the requested agent) AND ALP is less than the upper limit of normal (ULN) **AND** 3. The patient's total bilirubin is less than or equal to the upper limit of normal (ULN) **OR** B. The patient has another FDA labeled indication for the requested agent **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) 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

Module	Clinical Criteria for Approval
	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

• Program Summary: Self-Administered Oncology Agents

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
21406010200310		Abiraterone Acetate Tab 125 MG		120	Tablets	30	DAYS				
215325300003	Afinitor; Torpenz	everolimus tab	10 MG; 2.5 MG; 5 MG; 7.5 MG	30	Tablets	30	DAYS				
21532530007310	Afinitor disperz	Everolimus Tab for Oral Susp 2 MG	2 MG	60	Tablets	30	DAYS				
21532530007320	Afinitor disperz	Everolimus Tab for Oral Susp 3 MG	3 MG	90	Tablets	30	DAYS				
21532530007340	Afinitor disperz	Everolimus Tab for Oral Susp 5 MG	5 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
21409902120320	Akeega	niraparib tosylate-abiraterone acetate tab	50-500 MG	60	Tablets	30	DAYS				
21409902120330	Akeega	niraparib tosylate-abiraterone acetate tab	100-500 MG	60	Tablets	30	DAYS				
215305071001	Alecensa	alectinib hcl cap	150 MG	240	Capsules	30	DAYS				
21530510000330	Alunbrig	Brigatinib Tab	30 MG	120	Tablets	30	DAYS				
21530510000350	Alunbrig	Brigatinib Tab	90 MG	30	Tablets	30	DAYS				
21530510000365	Alunbrig	Brigatinib Tab	180 MG	30	Tablets	30	DAYS				
2153051000B720	Alunbrig	Brigatinib Tab Initiation Therapy Pack	90 & 180 MG	30	Tablets	180	DAYS				
21533865000120	Augtyro	repotrectinib cap	40 MG	240	Capsules	30	DAYS				
214900090003	Ayvakit	avapritinib tab	100 MG; 200 MG; 25 MG; 300 MG; 50 MG	30	Tablets	30	DAYS				
21532225000320	Balversa	Erdafitinib Tab 3 MG	3 MG	90	Tablets	30	DAYS				
21532225000325	Balversa	Erdafitinib Tab 4 MG	4 MG	60	Tablets	30	DAYS				
21532225000330	Balversa	Erdafitinib Tab 5 MG	5 MG	30	Tablets	30	DAYS				
2170007750E520	Besremi	Ropeginterferon alfa-	500 MCG/ML	2	Syringes	28	DAYS				
21531812000120	Bosulif	bosutinib cap	50 MG	30	Capsules	30	DAYS				
21531812000130	Bosulif	bosutinib cap	100 MG	150	Capsules	30	DAYS				
21531812000320	Bosulif	Bosutinib Tab	100 MG	90	Tablets	30	DAYS				
21531812000327	Bosulif	Bosutinib Tab	400 MG	30	Tablets	30	DAYS				
21531812000340	Bosulif	Bosutinib Tab	500 MG	30	Tablets	30	DAYS				
215320400001	Braftovi	encorafenib cap	75 MG	180	Capsules	30	DAYS				
21532195000120	Brukinsa	Zanubrutinib Cap	80 MG	120	Capsules	30	DAYS				
21533010100320	Cabometyx	Cabozantinib S-Malate Tab	20 MG	30	Tablets	30	DAYS				
21533010100330	Cabometyx	Cabozantinib S-Malate Tab	40 MG	30	Tablets	30	DAYS				
21533010100340	Cabometyx	Cabozantinib S-Malate Tab	60 MG	30	Tablets	30	DAYS				
215321030001	Calquence	acalabrutinib cap	100 MG	60	Capsules	30	DAYS				
215321035003	Calquence	acalabrutinib maleate tab	100 MG	60	Tablets	30	DAYS				
21533085000320	Caprelsa	Vandetanib Tab	100 MG	60	Tablets	30	DAYS				
21533085000340	Caprelsa	Vandetanib Tab	300 MG	30	Tablets	30	DAYS				
21533010106470	Cometriq	Cabozantinib S-Mal Cap	80 & 20 MG	1	Carton	28	DAYS				
21533010106480	Cometriq	Cabozantinib S-Mal Cap	3 x 20 MG & 80 MG	1	Carton	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
21533010106460	Cometriq	Cabozantinib S-Malate Cap	20 MG	1	Carton	28	DAYS				
215380300001	Copiktra	duvelisib cap	15 MG; 25 MG	56	Capsules	28	DAYS				
215335302003	Cotellic	cobimetinib fumarate tab	20 MG	63	Tablets	28	DAYS				
21370030300335	Daurismo	Glasdegib Maleate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21370030300320	Daurismo	Glasdegib Maleate Tab 25 MG (Base Equivalent)	25 MG	60	Tablets	30	DAYS				
21370070000120	Erivedge	Vismodegib Cap 150 MG	150 MG	30	Capsules	30	DAYS				
21402410000360	Erleada	apalutamide tab	240 MG	30	Tablets	30	DAYS				
21402410000320	Erleada	Apalutamide Tab 60 MG	60 MG	120	Tablets	30	DAYS				
21533076250120	Fotivda	Tivozanib HCl Cap	0.89 MG	21	Capsules	28	DAYS				
21533076250130	Fotivda	Tivozanib HCl Cap	1.34 MG	21	Capsules	28	DAYS				
21335035000120	Fruzaqla	fruquintinib cap	1 MG	84	Capsules	28	DAYS				
21335035000140	Fruzaqla	fruquintinib cap	5 MG	21	Capsules	28	DAYS				
215357500001	Gavreto	pralsetinib cap	100 MG	120	Capsules	30	DAYS				
213600061003	Gilotrif	afatinib dimaleate tab	20 MG; 30 MG; 40 MG	30	Tablets	30	DAYS				
21531835100320	Gleevec	Imatinib Mesylate Tab	100 MG	90	Tablets	30	DAYS				
21531835100340	Gleevec	Imatinib Mesylate Tab	400 MG	60	Tablets	30	DAYS				
215310600001	Ibrance	palbociclib cap	100 MG; 125 MG; 75 MG	21	Capsules	28	DAYS				
215310600003	Ibrance	palbociclib tab	100 MG; 125 MG; 75 MG	21	Tablets	28	DAYS				
21531875100315	Iclusig	Ponatinib HCl Tab	10 MG	30	Tablets	30	DAYS				
21531875100320	Iclusig	Ponatinib HCl Tab	15 MG	30	Tablets	30	DAYS				
21531875100330	Iclusig	Ponatinib HCl Tab	30 MG	30	Tablets	30	DAYS				
21531875100340	Iclusig	Ponatinib HCl Tab	45 MG	30	Tablets	30	DAYS				
21535030200340	Idhifa	Enasidenib Mesylate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21535030200320	Idhifa	Enasidenib Mesylate Tab 50 MG (Base Equivalent)	50 MG	30	Tablets	30	DAYS				
21532133000110	Imbruvica	Ibrutinib Cap	70 MG	30	Capsules	30	DAYS				
21532133000120	Imbruvica	Ibrutinib Cap	140 MG	90	Capsules	30	DAYS				
21532133001820	Imbruvica	Ibrutinib Oral Susp	70 MG/ML	2	Bottles	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
215321330003	Imbruvica	ibrutinib tab	140 MG; 280 MG; 420 MG; 560 MG	30	Tablets	30	DAYS				
21335013000320	Inlyta	Axitinib Tab	1 MG	180	Tablets	30	DAYS				
21335013000340	Inlyta	Axitinib Tab	5 MG	120	Tablets	30	DAYS				
219900022503	Inqovi	decitabine-cedazuridine tab	35-100 MG	5	Tablets	28	DAYS				
21537520200120	Inrebic	Fedratinib HCl Cap 100 MG	100 MG	120	Capsules	30	DAYS				
213600300003	Iressa	gefitinib tab	250 MG	30	Tablets	30	DAYS				
21757220300320	Iwilfin	eflornithine hcl tab	192 MG	240	Tablets	30	DAYS				
215375602003	Jakafi	ruxolitinib phosphate tab	10 MG; 15 MG; 20 MG; 25 MG; 5 MG	60	Tablets	30	DAYS				
21532165000320	Jaypirca	pirtobrutinib tab	50 MG	30	Tablets	30	DAYS				
21532165000330	Jaypirca	pirtobrutinib tab	100 MG	60	Tablets	30	DAYS				
2153107050B720	Kisqali	Ribociclib Succinate Tab Pack 200 MG Daily Dose	200 MG	21	Tablets	28	DAYS				
2153107050B740	Kisqali	Ribociclib Succinate Tab Pack 400 MG Daily Dose (200 MG Tab)	200 MG	42	Tablets	28	DAYS				
2153107050B760	Kisqali	Ribociclib Succinate Tab Pack 600 MG Daily Dose (200 MG Tab)	200 MG	63	Tablets	28	DAYS				
2199000260B730	Kisqali femara 200 dose	Ribociclib 200 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	49	Tablets	28	DAYS				
2199000260B740	Kisqali femara 400 dose	Ribociclib 400 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	70	Tablets	28	DAYS				
2199000260B760	Kisqali femara 600 dose	Ribociclib 600 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	91	Tablets	28	DAYS				
21533565500110	Koselugo	Selumetinib Sulfate Cap 10 MG	10 MG	240	Capsules	30	DAYS				
21533565500125	Koselugo	Selumetinib Sulfate Cap 25 MG	25 MG	120	Capsules	30	DAYS				
21532410000320	Krazati	Adagrasib Tab	200 MG	180	Tablets	30	DAYS				
21360048300320	Lazcluze	lazertinib mesylate tab	80 MG	60	Tablets	30	DAYS				
21360048300340	Lazcluze	lazertinib mesylate tab	240 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
2133505420B220	Lenvima 10 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	30	Capsules	30	DAYS				
2133505420B223	Lenvima 12mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	90	Capsules	30	DAYS				
2133505420B240	Lenvima 14 mg daily dose	Lenvatinib Cap Therapy Pack	10 & 4 MG	60	Capsules	30	DAYS				
2133505420B244	Lenvima 18 mg daily dose	Lenvatinib Cap Ther Pack	10 MG & 2 x 4 MG	90	Capsules	30	DAYS				
2133505420B230	Lenvima 20 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	60	Capsules	30	DAYS				
2133505420B250	Lenvima 24 mg daily dose	Lenvatinib Cap Ther Pack	2 x 10 MG & 4 MG	90	Capsules	30	DAYS				
2133505420B210	Lenvima 4 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	30	Capsules	30	DAYS				
2133505420B215	Lenvima 8 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	60	Capsules	30	DAYS				
21990002750320	Lonsurf	Trifluridine-Tipiracil Tab 15-6.14 MG	15-6.14 MG	60	Tablets	28	DAYS				
21990002750330	Lonsurf	Trifluridine-Tipiracil Tab 20-8.19 MG	20-8.19 MG	80	Tablets	28	DAYS				
21530556000320	Lorbrena	Lorlatinib Tab	25 MG	90	Tablets	30	DAYS				
21530556000330	Lorbrena	Lorlatinib Tab	100 MG	30	Tablets	30	DAYS				
21532480000340	Lumakras	sotorasib tab	320 MG	90	Tablets	30	DAYS				
21532480000320	Lumakras	Sotorasib Tab	120 MG	240	Tablets	30	DAYS				
215355600003	Lynparza	olaparib tab	100 MG; 150 MG	120	Tablets	30	DAYS				
2153222800B720	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	84	Tablets	28	DAYS				
2153222800B725	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	112	Tablets	28	DAYS				
2153222800B730	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	140	Tablets	28	DAYS				
21533570102120	Mekinist	trametinib dimethyl sulfoxide for soln	0.05 MG/ML	1170	mLs	28	DAYS				
21533570100310	Mekinist	Trametinib Dimethyl Sulfoxide Tab 0.5 MG (Base Equivalent)	0.5 MG	90	Tablets	30	DAYS				
21533570100330	Mekinist	Trametinib Dimethyl Sulfoxide Tab 2 MG (Base Equivalent)	2 MG	30	Tablets	30	DAYS				
215335200003	Mektovi	binimetinib tab	15 MG	180	Tablets	30	DAYS				
21533035100320	Nerlynx	Neratinib Maleate Tab	40 MG	180	Tablets	30	DAYS				
21533060400320	Nexavar	Sorafenib Tosylate Tab 200 MG (Base Equivalent)	200 MG	120	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
215360451001	Ninlaro	ixazomib citrate cap	2.3 MG; 3 MG; 4 MG	3	Capsules	28	DAYS				
21402425000320	Nubeqa	Darolutamide Tab 300 MG	300 MG	120	Tablets	30	DAYS				
213700602001	Odomzo	sonidegib phosphate cap	200 MG	30	Capsules	30	DAYS				
21532350200320	Ogsiveo	nirogacestat hydrobromide tab	50 MG	180	Tablets	30	DAYS				
21532350200330	Ogsiveo	nirogacestat hydrobromide tab	100 MG	56	Tablets	28	DAYS				
21532350200340	Ogsiveo	nirogacestat hydrobromide tab	150 MG	56	Tablets	28	DAYS				
21532075001920	Ojemda	tovorafenib for oral susp	25 MG/ML	8	Bottles	28	DAYS				
21532075000320	Ojemda	tovorafenib tab	100 MG	21	Tablets	28	DAYS				
21537540300320	Ojjaara	momelotinib dihydrochloride tab	100 MG	30	Tablets	30	DAYS				
21537540300330	Ojjaara	momelotinib dihydrochloride tab	150 MG	30	Tablets	30	DAYS				
21537540300340	Ojjaara	momelotinib dihydrochloride tab	200 MG	30	Tablets	30	DAYS				
213000030003	Onureg	azacitidine tab	200 MG; 300 MG	14	Tablets	28	DAYS				
214055700003	Orgovyx	relugolix tab	120 MG	30	Tablets	30	DAYS				
21403720100320	Orserdu	elacestrant hydrochloride tab	86 MG	90	Tablets	30	DAYS				
21403720100340	Orserdu	elacestrant hydrochloride tab	345 MG	30	Tablets	30	DAYS				
21532260000340	Pemazyre	Pemigatinib Tab 13.5 MG	13.5 MG	14	Tablets	21	DAYS				
21532260000320	Pemazyre	Pemigatinib Tab 4.5 MG	4.5 MG	14	Tablets	21	DAYS				
21532260000330	Pemazyre	Pemigatinib Tab 9 MG	9 MG	14	Tablets	21	DAYS				
2153801000B720	Piqray 200mg daily dose	Alpelisib Tab Therapy Pack 200 MG Daily Dose	200 MG	28	Tablets	28	DAYS				
2153801000B725	Piqray 250mg daily dose	Alpelisib Tab Pack 250 MG Daily Dose (200 MG & 50 MG Tabs)	200 & 50 MG	56	Tablets	28	DAYS				
2153801000B730	Piqray 300mg daily dose	Alpelisib Tab Pack 300 MG Daily Dose (2x150 MG Tab)	150 MG	56	Tablets	28	DAYS				
214500800001	Pomalyst	pomalidomide cap	1 MG; 2 MG; 3 MG; 4 MG	21	Capsules	28	DAYS				
21533053000320	Qinlock	Ripretinib Tab	50 MG	90	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
21535779000120	Retevmo	Selpercatinib Cap	40 MG	90	Capsules	30	DAYS				
21535779000140	Retevmo	Selpercatinib Cap	80 MG	60	Capsules	30	DAYS				
21535779000320	Retevmo	selpercatinib tab	40 MG	90	Tablets	30	DAYS				
21535779000330	Retevmo	selpercatinib tab	80 MG	60	Tablets	30	DAYS				
21535779000340	Retevmo	selpercatinib tab	120 MG	60	Tablets	30	DAYS				
21535779000350	Retevmo	selpercatinib tab	160 MG	60	Tablets	30	DAYS				
99394050000130	Revlimid	Lenalidomide Cap 10 MG	10 MG	30	Capsules	30	DAYS				
99394050000140	Revlimid	Lenalidomide Cap 15 MG	15 MG	21	Capsules	28	DAYS				
99394050000145	Revlimid	Lenalidomide Cap 20 MG	20 MG	21	Capsules	28	DAYS				
99394050000150	Revlimid	Lenalidomide Cap 25 MG	25 MG	21	Capsules	28	DAYS				
99394050000120	Revlimid	Lenalidomide Cap 5 MG	5 MG	30	Capsules	30	DAYS				
99394050000110	Revlimid	Lenalidomide Caps 2.5 MG	2.5 MG	30	Capsules	30	DAYS				
21534960000120	Rezlidhia	Olutasidenib Cap	150 MG	60	Capsules	30	DAYS				
21533820000120	Rozlytrek	Entrectinib Cap 100 MG	100 MG	30	Capsules	30	DAYS				
21533820000130	Rozlytrek	Entrectinib Cap 200 MG	200 MG	90	Capsules	30	DAYS				
21533820003020	Rozlytrek	entrectinib pellet pack	50 MG	336	Packets	28	DAYS				
21535570200320	Rubraca	Rucaparib Camsylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS				
21535570200325	Rubraca	Rucaparib Camsylate Tab 250 MG (Base Equivalent)	250 MG	120	Tablets	30	DAYS				
21535570200330	Rubraca	Rucaparib Camsylate Tab 300 MG (Base Equivalent)	300 MG	120	Tablets	30	DAYS				
21533030000130	Rydapt	Midostaurin Cap 25 MG	25 MG	240	Capsules	30	DAYS				
21531806100320	Scemblix	Asciminib HCl Tab	20 MG	60	Tablets	30	DAYS				
21531806100340	Scemblix	Asciminib HCl Tab	40 MG	240	Tablets	30	DAYS				
21531806100380	Scemblix	asciminib hcl tab	100 MG	120	Tablets	30	DAYS				
21531820000320	Sprycel	Dasatinib Tab	20; 20 MG	90	Tablets	30	DAYS				
21531820000340	Sprycel	Dasatinib Tab	50; 50 MG	30	Tablets	30	DAYS				
21531820000350	Sprycel	Dasatinib Tab	70; 70 MG	30	Tablets	30	DAYS				
21531820000354	Sprycel	Dasatinib Tab	80; 80 MG	30	Tablets	30	DAYS				
21531820000360	Sprycel	Dasatinib Tab	100; 100 MG	30	Tablets	30	DAYS				
21531820000380	Sprycel	Dasatinib Tab	140; 140 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
215330500003	Stivarga	regorafenib tab	40 MG	84	Tablets	28	DAYS				
21533070300120	Sutent	Sunitinib Malate Cap 12.5 MG (Base Equivalent)	12.5 MG	90	Capsules	30	DAYS				
21533070300130	Sutent	Sunitinib Malate Cap 25 MG (Base Equivalent)	25 MG	30	Capsules	30	DAYS				
21533070300135	Sutent	Sunitinib Malate Cap 37.5 MG (Base Equivalent)	37.5 MG	30	Capsules	30	DAYS				
21533070300140	Sutent	Sunitinib Malate Cap 50 MG (Base Equivalent)	50 MG	30	Capsules	30	DAYS				
215337162003	Tabrecta	capmatinib hcl tab	150 MG; 200 MG	120	Tablets	30	DAYS				
215320251001	Tafinlar	dabrafenib mesylate cap	50 MG; 75 MG	120	Capsules	30	DAYS				
21532025107320	Tafinlar	dabrafenib mesylate tab for oral susp	10 MG	840	Tablets	28	DAYS				
213600682003	Tagrisso	osimertinib mesylate tab	40 MG; 80 MG	30	Tablets	30	DAYS				
21535580400105	Talzenna	talazoparib tosylate cap	0.1 MG	30	Capsules	30	DAYS				
21535580400112	Talzenna	talazoparib tosylate cap	0.35 MG	30	Capsule	30	DAYS				
21535580400114	Talzenna	Talazoparib Tosylate Cap	0.5 MG	30	Capsules	30	DAYS				
21535580400118	Talzenna	Talazoparib Tosylate Cap	0.75 MG	30	Capsules	30	DAYS				
21535580400110	Talzenna	Talazoparib Tosylate Cap 0.25 MG (Base Equivalent)	0.25 MG	90	Capsules	30	DAYS				
21535580400120	Talzenna	Talazoparib Tosylate Cap 1 MG (Base Equivalent)	1 MG	30	Capsules	30	DAYS				
21360025100320	Tarceva	Erlotinib HCl Tab	25 MG	60	Tablets	30	DAYS				
21360025100330	Tarceva	Erlotinib HCl Tab	100 MG	30	Tablets	30	DAYS				
21360025100360	Tarceva	Erlotinib HCl Tab	150 MG	30	Tablets	30	DAYS				
215318602001	Tasigna	nilotinib hcl cap	150 MG; 200 MG; 50 MG	120	Capsules	30	DAYS				
215336752003	Tazverik	tazemetostat hbr tab	200 MG	240	Tablets	30	DAYS				
21533773100320	Tepmetko	Tepotinib HCl Tab	225 MG	60	Tablets	30	DAYS				
99392070000130	Thalomid	Thalidomide Cap 100 MG	100 MG	120	Capsules	30	DAYS				
99392070000135	Thalomid	Thalidomide Cap 150 MG	150 MG	60	Capsules	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
99392070000140	Thalomid	Thalidomide Cap 200 MG	200 MG	60	Capsules	30	DAYS				
99392070000120	Thalomid	Thalidomide Cap 50 MG	50 MG	90	Capsules	30	DAYS				
21534940000320	Tibsovo	Ivosidenib Tab 250 MG	250 MG	60	Tablets	30	DAYS				
21530320000320	Truqap	capivasertib tab	160 MG	64	Tablets	28	DAYS				
21530320000325	Truqap	capivasertib tab	200 MG	64	Tablets	28	DAYS				
2153223540B235	Truseltiq	Infigratinib Phos Cap Pack	100 & 25 MG	42	Capsules	28	DAYS				
2153223540B220	Truseltiq	Infigratinib Phos Cap Ther Pack	25 MG	42	Capsules	28	DAYS				
2153223540B225	Truseltiq	Infigratinib Phos Cap Ther Pack	25 MG	63	Capsules	28	DAYS				
2153223540B230	Truseltiq	Infigratinib Phos Cap Ther Pack	100 MG	21	Capsules	28	DAYS				
21170080000320	Tukysa	Tucatinib Tab	50 MG	300	Tablets	30	DAYS				
21170080000340	Tukysa	Tucatinib Tab	150 MG	120	Tablets	30	DAYS				
21533045010110	Turalio	Pexidartinib HCl Cap	125 MG	120	Capsules	30	DAYS				
21533045010120	Turalio	Pexidartinib HCl Cap	200 MG	120	Capsules	30	DAYS				
21533026100320	Tykerb	Lapatinib Ditosylate Tab	250 MG	180	Tablets	30	DAYS				
21533047100320	Vanflyta	quizartinib dihydrochloride tab	17.7 MG	28	Tablets	28	DAYS				
21533047100325	Vanflyta	quizartinib dihydrochloride tab	26.5 MG	56	Tablets	28	DAYS				
21470080000320	Venclexta	Venetoclax Tab 10 MG	10 MG	60	Tablets	30	DAYS				
21470080000360	Venclexta	Venetoclax Tab 100 MG	100 MG	180	Tablets	30	DAYS				
21470080000340	Venclexta	Venetoclax Tab 50 MG	50 MG	30	Tablets	30	DAYS				
2147008000B720	Venclexta starting pack	Venetoclax Tab Therapy Starter Pack 10 & 50 & 100 MG	10 & 50 & 100 MG	1	Pack	180	DAYS				
215310100003	Verzenio	abemaciclib tab	100 MG; 150 MG; 200 MG ; 50 MG	60	Tablets	30	DAYS				
21533835200150	Vitrakvi	Larotrectinib Sulfate Cap 100 MG (Base Equivalent)	100 MG	60	Capsules	30	DAYS				
21533835200120	Vitrakvi	Larotrectinib Sulfate Cap 25 MG (Base Equivalent)	25 MG	180	Capsules	30	DAYS				
21533835202020	Vitrakvi	Larotrectinib Sulfate Oral Soln 20 MG/ML (Base Equivalent)	20 MG/ML	300	mLs	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
213600190003	Vizimpro	dacomitinib tab	15 MG; 30 MG; 45 MG	30	Tablets	30	DAYS				
215375501001	Vonjo	pacritinib citrate cap	100 MG	120	Capsules	30	DAYS				
21535180000320	Voranigo	vorasidenib tab	10 MG	60	Tablets	30	DAYS				
21535180000340	Voranigo	vorasidenib tab	40 MG	30	Tablets	30	DAYS				
21533042100320	Votrient	Pazopanib HCl Tab	200 MG	120	Tablets	30	DAYS				
21421020000320	Welireg	Belzutifan Tab	40 MG	90	Tablets	30	DAYS				
215305170001	Xalkori	crizotinib cap	200 MG; 250 MG	120	Capsules	30	DAYS				
21530517006820	Xalkori	crizotinib cap sprinkle	20 MG	120	Capsules	30	DAYS				
21530517006830	Xalkori	crizotinib cap sprinkle	50 MG	120	Capsules	30	DAYS				
21530517006850	Xalkori	crizotinib cap sprinkle	150 MG	180	Capsules	30	DAYS				
21533020200320	Xospata	Gilteritinib Fumarate Tablet	40 MG	90	Tablets	30	DAYS				
2156006000B760	Xpovio	Selinexor Tab Therapy Pack	40 MG	4	Tablets	28	DAYS				
2156006000B765	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B770	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B775	Xpovio	Selinexor Tab Therapy Pack	50 MG	8	Tablets	28	DAYS				
2156006000B780	Xpovio	Selinexor Tab Therapy Pack	60 MG	4	Tablets	28	DAYS				
2156006000B755	Xpovio 60 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (60 MG Twice Weekly)	20 MG	24	Tablets	28	DAYS				
2156006000B720	Xpovio 80 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (80 MG Twice Weekly)	20 MG	32	Tablets	28	DAYS				
214024300001	Xtandi	enzalutamide cap	40 MG	120	Capsules	30	DAYS				
21402430000320	Xtandi	Enzalutamide Tab	40 MG	120	Tablets	30	DAYS				
21402430000340	Xtandi	Enzalutamide Tab	80 MG	60	Tablets	30	DAYS				
21406010250310	Yonsa	abiraterone acetate tab 125 mg	125 MG	120	Tablets	30	DAYS				
215355502001	Zejula	niraparib tosylate cap	100 MG	90	Capsules	30	DAYS				
21535550200320	Zejula	niraparib tosylate tab	100 MG	30	Tablets	30	DAYS				
21535550200330	Zejula	niraparib tosylate tab	200 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
21535550200340	Zejula	niraparib tosylate tab	300 MG	30	Tablets	30	DAYS				
21532080000320	Zelboraf	Vemurafenib Tab 240 MG	240 MG	240	Tablets	30	DAYS				
21531575000120	Zolinza	Vorinostat Cap 100 MG	100 MG	120	Capsules	30	DAYS				
215380400003	Zydelig	idelalisib tab	100 MG; 150 MG	60	Tablets	30	DAYS				
215305140003	Zykadia	ceritinib tab	150 MG	90	Tablets	30	DAYS				
21406010200320	Zytiga	Abiraterone Acetate Tab 250 MG	250 MG	120	Tablets	30	DAYS				
21406010200330	Zytiga	Abiraterone Acetate Tab 500 MG	500 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA QL	**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 patient has been treated with the requested agent within the past 180 days **OR** 2. The prescriber states the patient is being treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR** 3. ALL of the following: A. ONE of the following: 1. The patient has an FDA labeled indication for the requested agent and route of administration **OR** 2. The patient has an indication that is supported in compendia for the requested agent and route of administration (i.e., the indication must be supported in compendia by ALL requirements [e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy]) **AND** 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 indication does NOT require specific genetic/diagnostic testing per FDA labeling or compendia for the requested agent **OR** 2. The requested indication requires specific genetic/diagnostic testing per FDA labeling or compendia for the requested agent AND BOTH of the following: A. Specific genetic/diagnostic testing has been completed **AND** B. The results of the specific genetic/diagnostic testing indicate therapy with the requested agent is appropriate **AND**

Module	Clinical Criteria for Approval
	D. ONE of the following: 1. The requested agent will be used as monotherapy and is approved for use as monotherapy within FDA labeling or compendia for the requested indication **OR** 2. The requested agent will be used as combination therapy with all agents and/or treatments (e.g., radiation) AND is approved for use as combination therapy with all agents and/or treatments within FDA labeling or compendia for the requested indication **AND** E. ONE of the following: 1. The requested agent will be used as a first-line therapy AND is a first-line agent within FDA labeling or compendia for the requested indication **OR** 2. The patient has tried and had an inadequate response to the appropriate number and types of prerequisite agents within FDA labeling or compendia for the requested indication **OR** 3. The patient has an intolerance or hypersensitivity to the appropriate number and types of prerequisite agents within FDA labeling or compendia for the requested indication **OR** 4. The patient has an FDA labeled contraindication to ALL of the required prerequisite agents within FDA labeling or compendia for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the appropriate prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. The patient does not have any FDA labeled contraindications to the requested agent **AND** C. The patient does not have any FDA labeled limitations of use that are otherwise not supported in NCCN for 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:** NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, or Clinical Pharmacology **Length of Approval:** titration requests over the program quantity limit or Vitrakvi - up to 3 months; all other requests - up to 12 months. *Approve starter packs and loading doses where appropriate and maintenance dose for the remainder of the authorization. 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 BOTH of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. ALL of the following: 1. ONE of the following: A. The requested agent is Vitrakvi AND the patient has had clinical benefit (partial response, complete response, or stable disease) with the requested agent **OR** B. The requested agent is NOT Vitrakvi **AND** 2. The patient does not have any FDA labeled contraindications to the requested agent **AND** 3. The patient does not have any FDA labeled limitations of use that are otherwise not supported in NCCN for 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 **Length of Approval:** up to 12 months NOTE: if Quantity Limit applies, please refer to Quantity Limit Criteria. FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

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

● Program Summary: Weight Loss Agents

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
61200010100305		Benzphetamine HCl Tab 25 MG		90	Tablets	30	DAYS				
61200010100310		Benzphetamine HCl Tab 50 MG	50 MG	90	Tablets	30	DAYS				
61200020100305		Diethylpropion HCl Tab 25 MG	25 MG	90	Tablet	30	DAYS				
61200020107510		Diethylpropion HCl Tab ER 24HR 75 MG	75 MG	30	Tablets	30	DAYS				
61200050107010		Phendimetrazine Tartrate Cap ER 24HR 105 MG	105 MG	30	Capsules	30	DAYS				
61200050100305		Phendimetrazine Tartrate Tab 35 MG	35 MG	180	Tablets	30	DAYS				
61200070100110		Phentermine HCl Cap 15 MG	15 MG	30	Capsules	30	DAYS				
61200070100115		Phentermine HCl Cap 30 MG	30 MG	30	Capsules	30	DAYS				
61200070100120	Adipex-p	Phentermine HCl Cap 37.5 MG	37.5 MG	30	Capsules	30	DAYS				
61200070100310	Adipex-p	Phentermine HCl Tab 37.5 MG	37.5; 37.5 MG	30	Tablets	30	DAYS				
61259902507420	Contrave	Naltrexone HCl-Bupropion HCl Tab ER 12HR 8-90 MG	8-90 MG	120	Tablets	30	DAYS				
61200070100305	Lomaira	Phentermine HCl Tab 8 MG	8 MG	90	Tablets	30	DAYS				
61209902307040	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 11.25-69 MG	11.25-69 MG	30	Capsules	30	DAYS				
61209902307050	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 15-92 MG	15-92 MG	30	Capsules	30	DAYS				
61209902307020	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 3.75-23 MG	3.75-23 MG	30	Capsules	30	DAYS				
61209902307030	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG	7.5-46 MG	30	Capsules	30	DAYS				
61253560000120	Xenical	Orlistat Cap 120 MG	120 MG	90	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	

Targeted Agents that are part of the MN Medicaid Preferred Drug List (PDL)	
PDL Preferred Agents	**PDL Non-Preferred Agents**
Saxenda Wegovy	orlistat Xenical

Initial Evaluation

(Patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy)

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

1. The patient's baseline weight and BMI (prior to initiation of pharmacotherapy) have been provided (medical records required) **AND**
2. ONE of the following:
    A. The patient is an adult (18 years of age or over) AND ALL of the following:
        1. ONE of the following:
            A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 OR a BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent (medical records required) **OR**
            B. The patient has a BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease) (medical records required) **AND**
        2. BOTH of the following:
            A. The patient has been on a comprehensive weight management regimen that includes BOTH of the following:
                1. ONE of the following:
                    A. Ongoing reduced calorie diet for at least 6 months **OR**
                    B. Ongoing care of a registered dietician or nutritionist for at least 6 months **AND**
                2. Increased physical activity for at least 6 months, unless medically contraindicated **AND**
            B. The patient has experienced weight loss of less than 1 pound per week while on a comprehensive weight management regimen (e.g., low-calorie diet, increased physical activity, and behavioral modifications) prior to initiating therapy with the requested agent **AND**
        3. The patient will continue a comprehensive weight management regimen in combination with the requested agent **OR**
    B. The patient is pediatric (12 to 17 years of age) AND ALL of the following:
        1. ONE of the following:
            A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 95th percentile for age and gender (medical records required) **OR**
            B. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 (medical records required) **OR**
            C. The patient has a BMI greater than or equal to 85th percentile for age and gender AND at least one weight-related comorbidity/risk factor/complication (e.g., hypertension, dyslipidemia, type 2 diabetes, or obstructive sleep apnea) (medical records required) **AND**
        2. BOTH of the following:
            A. The patient has been on a comprehensive weight management regimen that includes BOTH of the following:

Module	Clinical Criteria for Approval
	1. ONE of the following: A. Ongoing reduced calorie diet for at least 6 months **OR** B. Ongoing care of a registered dietician or nutritionist for at least 6 months **AND** 2. Increased physical activity for at least 6 months, unless medically contraindicated **AND** B. The patient has experienced weight loss of less than 1 pound per week while on a comprehensive weight management regimen (e.g., low-calorie diet, increased physical activity, and behavioral modifications) prior to initiating therapy with the requested agent **AND** 3. The patient will continue a comprehensive weight management regimen in combination with the requested agent **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. ONE of the following: A. The patient has NOT tried a targeted weight loss agent (e.g., benzphetamine, Contrave, diethylpropion, phendimetrazine, phentermine, Qsymia, Xenical/Orlistat) in the past 12 months **OR** B. BOTH of the following: 1. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months **AND** 2. The prescriber anticipates success with repeating therapy with any targeted weight loss agent **AND** 5. 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 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** 6. ONE of the following:

Module	Clinical Criteria for Approval
	A. The requested agent is benzphetamine, diethylpropion, phendimetrazine, or phentermine **OR** B. The requested agent is Qsymia AND ONE of the following: 1. The requested dose is 3.75mg/23mg **OR** 2. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following: A. ONE of the following: 1. For a pediatric patient, the patient has experienced a reduction of at least 5% of baseline BMI (prior to initiation of the requested agent) (medical records required) **OR** 2. For an adult, the patient has demonstrated and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent) (medical records required) **OR** B. The patient received less than 14 weeks of therapy **OR** C. The patient's dose is being titrated upward **OR** D. The patient has received less than 12 weeks (3 months) of therapy on the 15mg/92mg strength **OR** 3. There is support for therapy for the requested dose for this patient **OR** C. The requested agent is Contrave AND ONE of the following: 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR** 3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent) (medical records required) **OR** D. The requested agent is Xenical (or Orlistat) AND ONE of the following: 1. The patient is 12 to 16 years of age AND ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR** C. The patient has achieved and maintained a weight loss of greater than 4% from baseline (prior to initiation of requested agent) (medical records required) **OR** 2. The patient is 17 years of age or over and ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR** C. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent) (medical records required) **AND** 7. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical, Saxenda, Wegovy, Zepbound) for the requested indication **AND** 8. 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** (Patient continuing a current weight loss course of therapy) **Target Agent(s)** will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
	1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient's current weight and BMI have been provided (medical records required) **AND** 3. The patient meets ONE of the following: A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) (medical records required) **OR** B. The requested agent is Qsymia AND ONE of the following: 1. For a pediatric patient (12 to 17 years of age), the patient has achieved and maintained a reduction of greater than or equal to 5% of baseline BMI (prior to initiation of the requested agent) (medical records required) **OR** 2. For an adult (18 years of age or over), the patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of the requested agent) (medical records required) **OR** 3. BOTH of the following: A. ONE of the following: 1. For a pediatric patient, the patient has achieved and maintained less than a 5% reduction of baseline BMI (prior to initiation of the requested agent) (medical records required) **OR** 2. For an adult, the patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) (medical records required) **AND** B. BOTH of the following: 1. The patient's dose is being titrated upward (for the 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg strengths only) **AND** 2. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength **OR** C. The requested agent is Xenical (or Orlistat) AND ONE of the following: 1. The patient 12 to 16 years of age AND has achieved and maintained a weight loss greater than 4% from baseline (prior to initiation of requested agent) (medical records required) **OR** 2. The patient is 17 years of age or over AND has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) (medical records required) **AND** 4. BOTH of the following: A. The patient is on a comprehensive weight management regimen that includes BOTH of the following: 1. ONE of the following: A. Ongoing reduced calorie diet **OR** B. Ongoing care of a registered dietician or nutritionist **AND** 2. Increased physical activity, unless medically contraindicated **AND** B. The patient will continue a comprehensive weight management regimen in combination with the requested agent **AND** 5. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical, Saxenda, Wegovy, Zepbound) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** • Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months • Qsymia: less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months • All other agents: 12 months

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

• Program Summary: Weight Management

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
6125205000D220	Saxenda	Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML)	18 MG/3ML	15	mLs	30	DAYS				
6125207000D535	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1.7 MG/0.75ML	4	Pens	28	DAYS				
6125207000D525	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5ML	8	Pens	180	DAYS				
6125207000D520	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.25 MG/0.5ML	8	Pens	180	DAYS				
6125207000D540	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	2.4 MG/0.75ML	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
6125207000D530	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5ML	8	Pens	180	DAYS				
61252580002023	Zepbound	tirzepatide (weight mngmt) soln	5 MG/0.5ML	4	Vials	28	DAYS				
61252580002018	Zepbound	tirzepatide (weight mngmt) soln	2.5 MG/0.5ML	4	Vials	180	DAYS				
6125258000D540	Zepbound	tirzepatide (weight mngmt) soln auto-injector	12.5 MG/0.5ML	4	Pens	28	DAYS				
6125258000D545	Zepbound	tirzepatide (weight mngmt) soln auto-injector	15 MG/0.5ML	4	Pens	28	DAYS				
6125258000D525	Zepbound	tirzepatide (weight mngmt) soln auto-injector	5 MG/0.5ML	4	Pens	28	DAYS				
6125258000D520	Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5ML	4	Pens	180	DAYS				
6125258000D535	Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5ML	4	Pens	28	DAYS				
6125258000D530	Zepbound	tirzepatide (weight mngmt) soln auto-injector	7.5 MG/0.5ML	4	Pens	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Targeted Agents that are part of the MN Medicaid Preferred Drug List (PDL)	
PDL Preferred Agents	**PDL Non-Preferred Agents**
Saxenda Wegovy	Zepbound

Initial Evaluation

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

1. ONE of the following:
   A. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:
      1. The requested agent is FDA labeled for the requested indication and route of administration **AND**
      2. The patient has a history of established cardiovascular disease as evidenced by ONE of the following: (medical records required)

Module	Clinical Criteria for Approval
	A. Myocardial infarction **OR** B. Stroke **OR** C. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND** 3. The patient has a BMI greater than or equal to 27 kg/m^2 (medical records required) **AND** 4. The patient does NOT have type 1 or type 2 diabetes **AND** 5. The patient does NOT have a hemoglobin A1C greater than or equal to 6.5% (medical records required) **AND** 6. The patient does NOT have a history of a myocardial infarction, stroke, transient ischemic attack, or hospitalization for unstable angina in the last 60 days **AND** 7. The patient's age is 45 years or over **OR** B. The patient is overweight or obese and is using the requested agent for weight management and ALL of the following: 1. The patient is new to therapy, new to Prime, or attempting a repeat weight loss course of therapy **AND** 2. The patient's baseline weight and BMI (prior to initiation of pharmacotherapy) have been provided (medical records required) **AND** 3. ONE of the following: A. The patient is an adult (18 years of age or over) and has ONE of the following: 1. A BMI greater than or equal to 30 kg/m^2 (medical records required) **OR** 2. A BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent (medical records required) **OR** 3. A BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., hypertension, obstructive sleep apnea, cardiovascular disease, dyslipidemia) (medical records required) **OR** B. The patient is pediatric (12 to 17 years of age) and has ONE of the following: 1. A BMI greater than or equal to 95th percentile for age and sex (medical records required) **OR** 2. A BMI greater than or equal to 30 kg/m^2 (medical records required) **OR** 3. A BMI greater than or equal to 85th percentile for age and sex AND at least one weight-related comorbidity/risk factor/complication (medical records required) **AND** 4. BOTH of the following: A. The patient has been on a comprehensive weight management regimen that includes BOTH of the following: 1. ONE of the following: A. Ongoing reduced calorie diet for at least 6 months **OR** B. Ongoing care of a registered dietician or nutritionist for at least 6 months **AND** 2. Increased physical activity for at least 6 months, unless medically contraindicated **AND** B. The patient has experienced weight loss of less than 1 pound per week while on a comprehensive weight management regimen (e.g., low-calorie diet, increased physical activity, and behavioral modifications) prior to any pharmacotherapy **AND** 5. ONE of the following: A. If the requested agent is Saxenda, then ONE of the following: 1. The patient is an adult (18 years of age or over) AND ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR** C. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR**

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	2. The patient is pediatric (12 to 17 years of age) AND BOTH of the following: A. The patient does NOT have type 2 diabetes **AND** B. ONE of the following: 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR** 3. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR** B. If the requested agent is Wegovy, then ONE of the following: 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 6 months of therapy **OR** 3. ONE of the following: A. The patient is an adult (18 years of age or over) AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR** B. The patient is pediatric (12 to 17 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR** C. If the requested agent is Zepbound, then ONE of the following: 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 6 months of therapy **OR** 3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR** C. The patient has another indication AND BOTH of the following: 1. The indication is FDA labeled or compendia supported for the requested agent and route of administration **AND** 2. If the diagnosis is noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH) (medical records required), then ALL of the following: A. The patient has stage F2 or F3 fibrosis as confirmed by BOTH of the following (prior to therapy with the requested agent): 1. A FIB-4 score consistent with stage F2 or F3 fibrosis adjusted for age **AND** 2. The patient has ONE of the following: A. A liver biopsy **OR** B. Vibration-controlled transient elastography (VCTE, e.g., Fibroscan) **OR** C. Enhanced liver fibrosis (ELF) score **OR** D. Magnetic resonance elastography (MRE) **AND** B. The patient is an adult (18 years of age or over) **AND** C. The patient has ONE of the following: 1. A BMI greater than 25 kg/m^2 (medical records required) **OR** 2. A BMI greater than 23 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian (medical records required) **AND** D. ONE of the following: 1. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR**

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	2. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND** E. The patient is being monitored and/or treated for any comorbid conditions (e.g., cardiovascular disease, diabetes, dyslipidemia, hypertension) **AND** F. The patient does NOT have ANY of the following: 1. Decompensated cirrhosis **AND** 2. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND** 3. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND** G. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 2. 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 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** 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 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** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. BOTH of the following: A. The patient is on a comprehensive weight management regimen that includes BOTH of the following: 1. ONE of the following: A. Ongoing reduced calorie diet **OR** B. Ongoing care of a registered dietician or nutritionist **AND** 2. Increased physical activity, unless medically contraindicated **AND**

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	B. The patient will continue a comprehensive weight management regimen in combination with the requested agent **AND** 5. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND** 6. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent (e.g., Saxenda, Wegovy, Zepbound, Mounjaro, Ozempic, Trulicity) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** For Wegovy, Zepbound: 6 months For Saxenda: Pediatric patients (age 12 to 17 years of age): 5 months; Adults: 4 months **Compendia Allowed:** CMS Approved Compendia NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) (medical records required) in adults with established cardiovascular disease and the patient was or is either obese or overweight AND ALL of the following: 1. The requested agent is FDA labeled for the requested indication and route of administration **AND** 2. The patient does NOT have a history of type 1 or type 2 diabetes **AND** 3. The patient has had clinical benefit with the requested agent **OR** B. The patient is overweight or obese and is using the requested agent for weight management and ALL of the following: 1. The patient is continuing a current weight loss course of therapy **AND** 2. The patient's current weight and BMI have been provided (medical records required) **AND** 3. ONE of the following: A. If the requested agent is Saxenda, then ONE of the following: 1. The patient is pediatric (12 to 17 years of age) AND BOTH of the following: A. The patient does NOT have type 2 diabetes **AND** B. ONE of the following: 1. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR** 2. The patient has received less than 4 months of therapy **OR** 2. The patient is an adult (18 years of age or over) AND ONE of the following: A. The patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR** B. The patient has received less than 5 months of therapy **OR**

Module	Clinical Criteria for Approval
	B. If the requested agent is Wegovy, then BOTH of the following: 1. The requested dose is 1.7 mg or 2.4 mg **AND** 2. ONE of the following: A. ONE of the following: 1. The patient is pediatric (12 to 17 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR** 2. The patient is an adult (18 years of age or over) AND has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR** B. The patient has received less than 6 months of therapy **OR** C. If the requested agent is Zepbound, then BOTH of the following: 1. The requested dose is NOT 2.5 mg **AND** 2. ONE of the following: A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) (medical records required) **OR** B. The patient has received less than 6 months of therapy **OR** C. The patient has another FDA labeled indication or another compendia supported indication for the requested agent and route of administration AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested indication is noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH) (medical records required), then ALL of the following: A. ONE of the following: 1. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR** 2. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND** B. The patient does NOT have ANY of the following: 1. Decompensated cirrhosis **AND** 2. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND** 3. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND** C. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. BOTH of the following: A. The patient is on a comprehensive weight management regimen that includes BOTH of the following: 1. ONE of the following: A. Ongoing reduced calorie diet **OR** B. Ongoing care of a registered dietician or nutritionist **AND** 2. Increased physical activity, unless medically contraindicated **AND** B. The patient will continue a comprehensive weight management regimen in combination with the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND**

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	5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent (e.g., Saxenda, Wegovy, Zepbound, Mounjaro, Ozempic, Trulicity) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** Patients who received less than 6 months of therapy AND did not achieve the targeted weight or BMI loss: 6 months All others: 12 months **Compendia Allowed:** CMS Approved Compendia 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. 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