COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: May 1, 2024 Notification Posted: March 15, 2024

BlueCross BlueShield Minnesota

Contents

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NEW POLICIES DEVELOPED

No new policies for May 1, 2024

POLICIES REVISED

• Program Summary: Afrezza (regular human insulin, inhaled)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27104010002990	Afrezza	Insulin Regular (Human) Inh Powd 4 & 8 & 12 Unit/Cart (60)	60 x 4 & 60 x 8 & 60 x 12 UNIT	1260	Cartridges	30	DAYS				
27104010002988	Afrezza	Insulin Regular (Human) Inh Powd 90 x 8 Unit & 90 x 12 Unit	90 x 8 UNIT & 90 x12 UNIT	1080	Cartridges	30	DAYS				
27104010002978	Afrezza	Insulin Regular (Human) Inhal Powd 90 x 4 Unit & 90 x 8 Unit	90 x 4 UNIT & 90 x 8 UNIT	1800	Cartridges	30	DAYS				
27104010002955	Afrezza	Insulin Regular (Human) Inhalation Powder 12 Unit/Cartridge	12 UNIT	900	Cartridges	30	DAYS				
27104010002940	Afrezza	Insulin Regular (Human) Inhalation Powder 4 Unit/Cartridge	4 UNIT	2520	Cartridges	30	DAYS				
27104010002950	Afrezza	Insulin Regular (Human) Inhalation Powder 8 Unit/Cartridge	8 UNIT	1260	Cartridges	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Preferred Agent(s)	Non-Preferred Agent(s)
Fiasp (insulin aspart) **NovoLog** (insulin aspart)	**Admelog** (insulin lispro) **Apidra** (insulin glulisine) **Fiasp** (insulin aspart) **Humalog** (insulin lispro) **Humalog U200** (insulin lispro) **Insulin aspart** **Insulin lispro** **Lyumjev** (insulin lispro-aabc)

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of diabetes mellitus type 1 AND the patient is currently on long acting insulin therapy **OR** B. The patient has a diagnosis of diabetes mellitus type 2 **AND** 2. The patient has received ALL of the following to identify any potential lung disease: A. Detailed medical history review **AND** B. Physical examination **AND** C. Spirometry with Forced Expiratory Volume in 1 second (FEV1) **AND** 3. The patient has not smoked in the past 6 months **AND** 4. If the patient has an FDA approved diagnosis, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. ONE of the following: A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient's medication history includes a preferred rapid acting insulin agent as indicated by: 1. Evidence of a paid claim(s) within the past 999 days **OR** 2. The prescriber has stated that the patient has tried a preferred rapid acting insulin agent AND the preferred rapid acting insulin agent was discontinued due to lack of effectiveness or an adverse event **OR** C. The patient has an intolerance or hypersensitivity to a preferred rapid acting insulin agent that is not expected to occur with the requested agent **OR** D. The patient has an FDA labeled contraindication to a preferred rapid acting insulin agent **OR** E. The prescriber has provided information that the patient has a physical or a mental disability that would prevent him/her from using a preferred rapid acting insulin product(s) **OR** F. The patient has a documented needle phobia **OR** G. The prescriber has provided documentation that preferred rapid acting insulin products cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The patient 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 **AND** 2. The patient has had clinical benefit with the requested agent **AND**

Module	Clinical Criteria for Approval
	3. The patient has received ALL of the following to identify any potential lung disease: A. Detailed medical history review **AND** B. Physical examination **AND** C. Spirometry with Forced Expiratory Volume in 1 second (FEV1) **AND** 4. The patient has not smoked in the past 6 months **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Coverage Exception with Quantity Limit - Commercial

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

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

Anti-obesity agents on coverage delay must use the Anti-Obesity Formulary Exception criteria for FlexRx Closed, FlexRx Open, GenRx Closed, and GenRx Open.

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

Objective

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

EXCEPTION CRITERIA FOR APPROVAL

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

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

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

AND

2. ONE of the following:
   A. ALL of the following:
      i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category

AND

ii. The member's benefit includes ACA Preventive Care for the category requested
AND

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

   OR

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

      AND

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

         OR

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

         OR

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

         OR

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

OR

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

OR

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

        OR

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

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

OR

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

OR

H. The requested agent is an iron supplement **AND** ALL of the following:
    i. The prescriber has provided information stating that the requested iron supplement is medically necessary

AND

ii. The patient is under 12 months of age

AND

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

OR

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

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

AND

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

a. Atorvastatin 10-20 mg per day (20 mg tablet) **OR**
b. Fluvastatin 20-80 mg per day (40 mg capsule) **OR**
c. Fluvastatin ER 80 mg per day (80 mg tablet) **OR**
d. Lovastatin 20-40 mg per day (40 mg tablet) **OR**
e. Lovastatin ER 20-40 mg per day (40 mg tablet) **OR**
f. Pitavastatin 1-4 mg per day (4 mg tablet) **OR**
g. Pravastatin 10-80 mg per day (80 mg tablet) **OR**
h. Rosuvastatin 5-10 mg per day (10 mg tablet) **OR**
i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)

AND

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

AND

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

AND

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

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

AND

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

OR

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

i. The patient is a non-pregnant adult

AND

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

OR

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

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

AND

ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:

i. ONE of the following:

a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements

OR

b. BOTH of the following:
    1. ONE of the following:
        A. The requested agent is NOT in an ACA Preventive Care category

        OR

        B. The member's benefit does NOT include ACA Preventive Care for the category requested

    AND

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

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
Brand for Generic*   Agents with the following reject message: #NDC NOT COVERED, USE XXX#
Bulk Powders*   (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs*   (Y in the Clinic Pack field)
Cosmetic Alteration*   (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Infertility Agents*   (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility)
Institutional Packs*   Those that contain any one of the following modifier codes in the product file in RXClaims   i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK   ii. MODIFIER BBAD9A INSTITUTIONAL   iii. MODIFIER TTAAJQ INSTITUTIONAL   iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY   v. MODIFIER AAAB9A HOSPITAL PACK   vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE)   vii. MODIFER AAAD6T HOSPITAL USE ONLY
Non-FDA Approved Agents*   (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Repackagers (not including Veterans Administration and Department of Defense Claims)*   (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes)   (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)
Sexual Dysfunction Agents*   (Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction))
Weight Loss Agents*   (Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss)
Other

*Category specific denial reasons apply

AND

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

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

OR

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

   OR

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

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

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

   OR

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

   OR

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

   OR

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

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

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

h. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP for a member with a Fully Insured plan and ALL of the following:
    1. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada) **OR**
            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread) **OR**
            iii. Emtricitabine 200 mg single ingredient agent (Emtriva) **OR**
            iv. Raltegravir 400 mg single ingredient agent (Isentress) **OR**
            v. Dolutegravir 50 mg single ingredient agent (Tivicay) **OR**
            vi. Darunavir 800 mg single ingredient agent (Prezista) **OR**
            vii. Ritonavir 100 mg single ingredient agent (Norvir)

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

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

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

OR

i. BOTH of the following:
    1. The requested agent is for ONE of the following:
        A. Weight loss agent that will not be used for weight loss

            OR

B. Infertility agent that will not be used for infertility

OR

C. Coverage Delay Agent

AND

2. BOTH of the following:
   A. ONE of the following:
      i. The patient has an FDA labeled indication for the requested agent

      OR

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

      OR

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

   AND

   B. ONE of the following:
      i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
         a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
            1. The patient has tried and failed one or more available formulary generic equivalents to the requested agent

            OR

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

         AND

         b. ONE of the following:
            1. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent

            OR

            2. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

      OR

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

      OR

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

AND

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

AND

3. ONE of the following:
    A. The requested agent is not subject to an existing quantity limit program

    OR

    B. The requested agent is subject to an existing quantity limit program and ONE of the following:
        i. The requested quantity (dose) does NOT exceed the program quantity limit

        OR

        ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)

        OR

        iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
            a. BOTH of the following:
                1. The requested agent does not have a maximum FDA labeled dose for the requested indication

                AND

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

            OR

            b. BOTH of the following:
                1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication

                AND

                2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

            OR

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

                AND

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

ACA Length of Approval:

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

HIV PEP Length of Approval:

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

Coverage Exception Length of Approval: 12 months

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

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

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

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

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

Objective

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

EXCEPTION CRITERIA FOR APPROVAL

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

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

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

AND

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

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

                  AND
                2. ONE of the following:
                    - A. The requested agent is an aspirin agent **AND** ALL of the following:
                        - i. The requested agent is the 81 mg strength aspirin
                          AND

ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
AND
iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

OR

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

OR

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

OR

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

OR

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

OR

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

2. Tenofovir alafenamide and emtricitabine combination ingredient agent
OR
3. Cabotegravir

OR

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

AND

iii. The patient is at high risk of HIV infection

AND

iv. The patient has recently tested negative for HIV

OR

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

OR

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

OR

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

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

AND

v. The patient has at least one of the following risk factors:
   a. Dyslipidemia **OR**
   b. Diabetes **OR**
   c. Hypertension **OR**
   d. Smoking

AND

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

OR

J. The requested agent is a tobacco cessation agent **AND** BOTH of the following:
   i. The patient is a non-pregnant adult

   AND

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

OR

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

   AND

   ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
   i. ONE of the following:
      a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements

      OR

      b. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventive Care category

            OR

            B. The member's benefit does NOT include ACA Preventive Care for the category requested

         AND

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

               AND

               ii. The patient has tried and failed ALL formulary alternatives for the diagnosis being treated with the requested agent

            OR

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

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

*Category specific denial reasons apply

AND

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

   OR

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

   OR

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

      OR

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

      OR

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

   OR

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

   OR

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

AND

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

OR

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

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

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

OR

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

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

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

OR

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

AND

3. The patient is at high risk of HIV infection

AND

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

OR

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

OR

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

OR

3. BOTH of the following:
A. ONE of the following:
i. The patient has an FDA labeled indication for the requested agent

OR

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

OR

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

AND

B. ONE of the following:
i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
1. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent

OR

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

AND

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

OR

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

OR

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

AND

iii. If the request is for Restasis or Xiidra and the patient has met the additional clinical review criteria

AND

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

AND

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

         OR

         b. BOTH of the following:
            1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication

AND

2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

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

ACA Length of Approval:

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

HIV PEP Length of Approval:

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

Coverage Exception Length of Approval: 12 months

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

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

Objective

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

EXCEPTION CRITERIA FOR APPROVAL

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

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

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

AND

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

2. The requested agent is being used for contraception

OR

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

    AND

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

        OR

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

        OR

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

        OR

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

        OR

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

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

OR

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

OR

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

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

OR

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

OR

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

OR

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

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

AND

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

a. Atorvastatin 10-20 mg per day (20 mg tablet) **OR**
b. Fluvastatin 20-80 mg per day (40 mg capsule) **OR**
c. Fluvastatin ER 80 mg per day (80 mg tablet) **OR**
d. Lovastatin 20-40 mg per day (40 mg tablet) **OR**
e. Lovastatin ER 20-40 mg per day (40 mg tablet) **OR**
f. Pitavastatin 1-4 mg per day (4 mg tablet) **OR**
g. Pravastatin 10-80 mg per day (80 mg tablet) **OR**
h. Rosuvastatin 5-10 mg per day (10 mg tablet) **OR**
i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)

AND

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

AND

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

AND

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

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

AND

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

OR

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

i. The patient is a non-pregnant adult

AND

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

OR

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

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

AND

ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:

i. ONE of the following:

a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements

OR

b. BOTH of the following:

1. ONE of the following:

A. The requested agent is NOT in an ACA Preventive Care category

OR

B. The member's benefit does NOT include ACA Preventive Care for the category requested

AND

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

Excluded from Coverage on the Pharmacy Benefit
AHFS (devices and pharmaceutical aids, not including needles, syringes, lancets, CGM/sensor/transmitter/receiver) (Defined as those products containing the AHFS code 940000000 (DEVICES) and/ or 960000000 (PHARMACEUTICAL AIDS) in the product file in RxClaim)
Brand for Generic* Agents with the following reject message: #NDC NOT COVERED, USE XXX#
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration* (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Diagnostic Agents (not including glucose test strips) (Defined as those products containing the third-party restriction code of 5 (DIAGNOSTIC AGENT) in the product file in RxClaim)
Drugs That Are Not Covered Exclusion (not including glucose test strips, insulin, AuviQ 0.1 mg, ACA required drugs, lancets, syringes, CGM/sensor/transmitter/receiver) [See MN NDC Lock Out List NetResults]
General Anesthetics (Defined as those products containing the third-party restriction code of 6 (GENERAL ANESTHETIC) in the product file in RxClaim)
Infertility Agents* (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility)
Injectable drugs not on covered drug list, not including the drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx (Defined as those products included on Tier 40 of FID 33102 with any reject message other than "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION".)
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RXClaims i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK ii. MODIFIER BBAD9A INSTITUTIONAL iii. MODIFIER TTAAJQ INSTITUTIONAL iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY v. MODIFIER AAAB9A HOSPITAL PACK vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) vii. MODIFER AAAD6T HOSPITAL USE ONLY
Investigative, experimental, or not medically necessary
Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined by GPI 97**********)
Medical devices approved through a different FDA-approval process than drugs (Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)

Non-FDA Approved Agents* (Refer all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes) (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)
Repackagers (not including Veterans Administration and Department of Defense Claims)* (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
RX drugs with OTC Equivalents (Excluded categories listed below) (Defined by an RX NDC (Rx-OTC indicator R or S) with an OTC NDC (RX-OTC indicator O or P) within the same GPI 14 in the product file in RxClaim. Rx drugs with OTC alternatives where the Rx drug category will be excluded: 1. Omega-3 Fatty Acids (GPI 395000********) 2. Non-Sedating Antihistamines (GPI 415500********) 3. Topical Antivirals (GPI 903500********))
Self-Administered Contraceptives* (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)
Sexual Dysfunction Agents* (Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction)
Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)
Universal Product Code (UPC), Health Related Item Code (HRI) (not including glucose test strips) (UPCs will be defined as those products designated as product type 1 in the product file in RxClaim. HRIs will be defined as those products designated as product type 2 in the product file in RxClaim.)
Weight Loss Agents* (Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss)

*Category specific denial reasons apply

AND

ii. ONE of the following:

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

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

OR

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

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

OR

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

    OR

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

    OR

    3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent

    OR

    4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent

    OR

    5. The patient is pregnant

OR

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

OR

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

OR

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

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

OR

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

h. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP for a member with a Fully Insured plan and ALL of the following:
    1. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents
    AND
    2. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada) **OR**
            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread) **OR**
            iii. Emtricitabine 200 mg single ingredient agent (Emtriva) **OR**
            iv. Raltegravir 400 mg single ingredient agent (Isentress) **OR**
            v. Dolutegravir 50 mg single ingredient agent (Tivicay) **OR**
            vi. Darunavir 800 mg single ingredient agent (Prezista) **OR**
            vii. Ritonavir 100 mg single ingredient agent (Norvir)
        OR
        B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
    AND
    3. The patient is at high risk of HIV infection
    AND
    4. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

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

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

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

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

AND

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

      OR

   B. BOTH of the following:
      i. ONE of the following:
         a. The patient has an FDA labeled indication for the requested agent

            OR

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

            OR

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

      AND

      ii. ONE of the following:
         a. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
            1. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
               A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent

               OR

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

            AND

            2. ONE of the following:
               A. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent

               OR

B. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

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

OR

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

AND

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

AND

3. ONE of the following:
   A. The requested agent is not subject to an existing quantity limit program

   OR

   B. The requested agent is subject to an existing quantity limit program and ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit

      OR

      ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)

      OR

      iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
         a. BOTH of the following:
            1. The requested agent does not have a maximum FDA labeled dose for the requested indication

            AND

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

         OR

         b. BOTH of the following:
            1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication

            AND

            2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

         OR

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

            AND

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

ACA Length of Approval:

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

HIV PEP Length of Approval:

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

Coverage Exception Length of Approval: 12 months

• Program Summary: Formulary Exception

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

APPLICATION

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

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

FORMULARY EXCEPTION CRITERIA FOR APPROVAL

A formulary exception will be granted when the following are met:

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

            OR

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

                AND

                2. ONE of the following:
                    A. The requested agent is an aspirin agent **AND** ALL of the following:
                        i. The requested agent is the 81 mg strength aspirin
                        AND

ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
AND
iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

OR

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

OR

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

OR

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

OR

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

OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PrEP **AND** ALL of the following:
i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
AND
ii. The requested agent is being used for PrEP
AND
iii. ONE of the following:
a. The requested PrEP agent is ONE of the following:

1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
   OR
2. Tenofovir alafenamide and emtricitabine combination ingredient agent
   OR
3. Cabotegravir

OR

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

AND

iv. The patient is at high risk of HIV infection

AND

v. The patient has recently tested negative for HIV

OR

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

   OR

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

   OR

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

   AND

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

AND

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

AND

v. The patient has at least one of the following risk factors:
   a. Dyslipidemia **OR**
   b. Diabetes **OR**
   c. Hypertension **OR**
   d. Smoking

AND

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

OR

J. The requested agent is a tobacco cessation agent **AND** BOTH of the following:
   i. The patient is a non-pregnant adult

   AND

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

   OR

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

   AND

   ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
   i. ONE of the following:
      a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements

      OR

      b. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventive Care category

            OR

            B. The member's benefit does NOT include ACA Preventive Care for the category requested

         AND

         2. The requested agent is not excluded from coverage under the pharmacy benefit

   AND

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

         OR

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

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

OR

c. The requested agent is Omnipod DASH or Omnipod 5

OR

d. If the requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP for a member with a Fully Insured plan, then ALL of the following:
    1. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents

    AND

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

        OR

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

    AND

    3. The patient is at high risk of HIV infection

    AND

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

OR

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

    AND

    2. ONE of the following:
        A. The requested agent has formulary alternatives that can be prescribed in a dose to fit the patient's needs AND ONE of the following:
            i. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives, if available, for the diagnosis being treated with the requested agent

            OR

            ii. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely

to be less effective, or cause an adverse reaction or other harm for the patient

OR

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

OR

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

AND

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

AND

2. ONE of the following:
   A. The requested agent is not subject to an existing quantity limit program

   OR

   B. The requested agent is subject to an existing quantity limit program and ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit

      OR

      ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)

      OR

      iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
         a. BOTH of the following:
            1. The requested agent does not have a maximum FDA labeled dose for the requested indication

            AND

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

         OR

         b. BOTH of the following:
            1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication

            AND

            2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

         OR

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

            AND

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

ACA Length of Approval:

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

HIV PEP Length of Approval:

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

Formulary Exception Length of Approval: 12 months

• Program Summary: Hereditary Angioedema

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
85802022006420	Berinert	C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit	500 UNIT	10	Vials	30	DAYS				
8582004010E520	Firazyr; Sajazir	icatibant acetate inj 30 mg/3ml (base equivalent)	30 MG/3ML	6	Syringes	30	DAYS				
85802022002130	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	27	Vials	28	DAYS				
85802022002140	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit	3000 UNIT	18	Vials	28	DAYS				
85840010200120	Orladeyo	Berotralstat HCl Cap	110 MG	30	Capsules	30	DAYS				
85840010200130	Orladeyo	Berotralstat HCl Cap	150 MG	30	Capsules	30	DAYS				
85802022102130	Ruconest	C1 Esterase Inhibitor (Recombinant) For IV Inj 2100 Unit	2100 UNIT	8	Vials	30	DAYS				
85842040202020	Takhzyro	Lanadelumab-flyo Inj 300 MG/2ML (150 MG/ML)	300 MG/2ML	4	Vials	28	DAYS				
8584204020E510	Takhzyro	lanadelumab-flyo soln pref syringe	150 MG/ML	2	Syringes	28	DAYS				
8584204020E520	Takhzyro	Lanadelumab-flyo Soln Pref Syringe	300 MG/2ML	2	Syringes	28	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85802022006420	Berinert	C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit	500 UNIT	based on CDC 90th percentile for men and women averaged to 247.5 lbs or 112.5 kg (112.5 kg * 20 IU/kg=2,250 IU/500 IU/bottle=4.5 or 5 bottles or 2500 units/attack x 2 attacks/month = 10 vials/28 days			
85802022002130	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	*QL calculation based on CDC 90 percentile for weight in adults, averaged for men and women, and rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical Criteria Table ** Do not wildcard PA- detail to GPI 14			
85802022002140	Haegarda	C1 Esterase Inhibitor (Human)	3000 UNIT	*QL calculation based on CDC 90 percentile for weight in adults, averaged for men and women, and			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		For Subcutaneous Inj 3000 Unit		rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical Criteria Table ** Do not wildcard PA- detail to GPI 14			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Berinert, Firazyr, icatibant, or Ruconest	

Preferred Agent(s)	Non-Preferred Agent(s)
icatibant	Firazyr

Initial Evaluation

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

1. The patient has a diagnosis of hereditary angioedema (HAE) evidenced by ONE of the following:
    A. For patients with HAE with C1 inhibitor deficiency/dysfunction (HAE type 1 or 2), BOTH of the following: (medical records/lab results required)
        1. C4 level below the lower limit of normal as defined by the laboratory performing the test **AND**
        2. ONE of the following:
            A. C1 inhibitor protein level below the lower limit of normal as defined by the laboratory performing the test **OR**
            B. C1 inhibitor function level below the lower limit of normal as defined by the laboratory performing the test **OR**
    B. For patients with HAE with normal C1 inhibitor (HAE-nI-C1INH, previously HAE type 3), ONE of the following: (medical records/lab results required)
        1. Mutation in ONE of the following genes associated with HAE
            A. Coagulation factor XII;
            B. Plasminogen;
            C. Angiopoietin-1;
            D. Kininogen 1;
            E. Heparan sulfate 3-O-sulfotransferase 6;
            F. Myoferlin **OR**
        2. Family history or personal history of angioedema AND failure to respond to chronic, high-dose antihistamine therapy **AND**
2. The requested agent will be used for treatment of acute HAE attacks **AND**
3. ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
4. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) **AND**
5. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate **AND**
6. ONE of the following:
    A. The requested agent is a preferred agent **OR**
    B. The patient has tried and had an inadequate response to ALL of the preferred agent(s) **OR**
    C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL of the preferred agent(s) **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 of the 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 **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **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 **AND** 2. The requested agent is being used for treatment of acute HAE attacks **AND** 3. The patient continues to have acute HAE attacks (medical records required) **AND** 4. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Haegarda, Orladeyo, Takhzyro	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of hereditary angioedema (HAE) evidenced by ONE of the following: A. For patients with HAE with C1 inhibitor deficiency/dysfunction (HAE type 1 or 2), BOTH of the following: (chart notes/lab results required) 1. C4 level below the lower limit of normal as defined by the laboratory performing the test **AND** 2. ONE of the following: A. C1 inhibitor protein level below the lower limit of normal as defined by the laboratory performing the test **OR** B. C1 inhibitor function level below the lower limit of normal as defined by the laboratory performing the test **OR** B. For patients with HAE with normal C1 inhibitor (HAE-nI-C1INH, previously HAE type 3), ONE of

Module	Clinical Criteria for Approval
	the following: (chart notes/lab results required) 1. Mutation in the ONE of the genes associated with HAE A. Coagulation factor XII; B. Plasminogen; C. Angiopoietin-1; D. Kininogen 1; E. Heparan sulfate 3-O-sulfotransferase 6; F. Myoferlin **OR** 2. Family history or personal history of angioedema AND failure to respond to chronic, high-dose antihistamine therapy **AND** 2. The requested agent will be used for prophylaxis against HAE attacks **AND** 3. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo, Takhzyro) **AND** 5. The patient has a history of at least two severe acute HAE attacks per month (e.g., swelling of the throat, incapacitating gastrointestinal or cutaneous swelling) **AND** 6. If Takhzyro is requested, ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient has been treated with the requested agent for less than 6 consecutive months **OR** C. The patient has been treated with the requested agent for at least 6 consecutive months AND ONE of the following: 1. The patient has been free of acute HAE attacks for at least 6 consecutive months and ONE of the following: A. The patient's dose will be reduced to 300 mg every 4 weeks **OR** B. The prescriber has provided information in support of therapy using 300 mg every 2 weeks **OR** 2. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months **AND** 7. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin receptor blockers) have been evaluated and discontinued when appropriate **AND** 8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **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 **AND** 2. The requested agent is being used for prophylaxis against HAE attacks **AND** 3. Information has been provided that indicates the patient has had a decrease in the frequency of acute HAE attacks from baseline (prior to treatment) (chart notes required) **AND** 4. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo, Takhzyro) **AND**

Module	Clinical Criteria for Approval
	5. If Takhzyro is requested, ONE of the following: A. The patient has been free of acute HAE attacks for at least 6 consecutive months and ONE of the following: 1. The patient's dose will be reduced to 300 mg every 4 weeks **OR** 2. The prescriber has provided information in support of therapy using 300 mg every 2 weeks **OR** B. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) 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
Berinert, Firazyr, icatibant, or Ruconest	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) is within the program quantity limit (allows for 2 acute HAE attacks per month) **OR** 2. The requested quantity (dose) exceeds the program quantity limit and prescriber has provided information (e.g., frequency of attacks within the past 3 months has been greater than 2 attacks per month) in support of therapy with a higher dose or quantity **Length of Approval:** 12 months
Haegarda, Orladeyo, or Takhzyro	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) is within the program quantity limit (If Haegarda, prescriber must provide patient weight; refer to Haegarda weight-based quantity limit table and, if needed, extended dosing table) **OR** 2. The requested quantity (dose) exceeds the program quantity limit and prescriber has provided information in support of therapy with a higher dose or quantity **Length of Approval**: 12 months **HAEGARDA WEIGHT-BASED QUANTITY LIMITS: EXTENDED DOSING TABLE**

Weight (lb)	Weight (kg)	Quantity Limit of 3000 IU vials per 28 days	Quantity Limit of 2000 IU vials per 28 days	Number of 3000 IU vials used per dose	Number of 2000 IU vials used per dose
greater than 330-365	greater than 150-166	16	16	2	2
greater than 293-330	greater than 133-150	24	0	3	0
greater than 255-293	greater than 116-133	0	32	0	4

Module	Clinical Criteria for Approval

greater than 220-255	greater than 100-116	8	16	1	2
greater than 182.6-220	greater than 83-100	16	0	2	0
greater than 145-182.6	greater than 66-83	8	8	1	1
greater than 110-145	greater than 50-66	0	16	0	2
greater than or equal to 75-110	greater than or equal to 34-50	8	0	1	0
less than 75	less than 34	0	8	0	1

• Program Summary: Interleukin (IL)-1 Inhibitors

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

POLICY AGENT SUMMARY QUANTITY LIMIT

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

Agents Eligible for Continuation of Therapy
No agents are eligible for continuation of therapy

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

B. BOTH of the following:
1. The patient has ONE of the following indications:

Module	Clinical Criteria for Approval
	A. Cryopyrin Associated Periodic Syndrome (CAPS) **OR** B. Familial Cold Auto-Inflammatory Syndrome (FCAS) **OR** C. Muckle-Wells Syndrome (MWS) **AND** 2. BOTH of the following: A. The patient has elevated pretreatment serum inflammatory markers (C-reactive protein/serum amyloid A) **AND** B. The patient has at least TWO symptoms typical for CAPS (i.e., urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms of arthralgia/arthritis/myalgia, chronic aseptic meningitis, skeletal abnormalities of epiphyseal overgrowth/frontal bossing) **OR** C. BOTH of the following: 1. The patient has a diagnosis of deficiency of interleukin-1 receptor antagonist **AND** 2. The requested agent is being used for maintenance of remission **OR** D. The patient has a diagnosis of recurrent pericarditis AND ONE of the following 1. BOTH of the following: A. The patient has tried and had an inadequate response to at least a 6-month trial of colchicine **AND** B. ONE of the following: 1. Colchicine was used concomitantly with at least a 1 week trial of a non-steroidal anti-inflammatory drug (NSAID) AND a corticosteroid **OR** 2. The patient has an intolerance or hypersensitivity to BOTH an NSAID AND a corticosteroid **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs AND ALL corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to colchicine **OR** 3. The patient has an FDA labeled contraindication to colchicine **OR** 4. The patient has tried and had an inadequate response to an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) used in the treatment of recurrent pericarditis **OR** 5. The patient has an intolerance or hypersensitivity to oral immunosuppressants used in the treatment of recurrent pericarditis **OR** 6. The patient has an FDA labeled contraindication to oral immunosuppressants used in the treatment of recurrent pericarditis **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that colchicine AND oral immunosuppressants cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The patient has another FDA approved indication for the requested agent **OR** F. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
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3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) OR
B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND
2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) AND
5. The patient does NOT have any FDA labeled contraindications to the requested agent

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

Length of Approval: 12 months

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

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:
1. The patient has been previously approved for the requested agent through plan's Prior Authorization process AND
2. The patient has had clinical benefit with the requested agent AND
3. The prescriber is a specialist in area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) OR
B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND
2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) 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.
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Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:
1. ONE of the following:
A. The requested agent is eligible for continuation of therapy AND ONE of the following:
<table>
<tr><th>Agents Eligible for Continuation of Therapy</th></tr>
<tr><td>All target agents are eligible for continuation of therapy</td></tr>
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Module	Clinical Criteria for Approval
	1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has ONE of the following indications: A. Cryopyrin Associated Periodic Syndrome (CAPS) **OR** B. Familial Cold Auto-Inflammatory Syndrome (FCAS) **OR** C. Muckle-Wells Syndrome (MWS) **AND** 2. BOTH of the following: A. The patient has elevated pretreatment serum inflammatory markers (C-reactive protein/serum amyloid A) **AND** B. The patient has at least TWO symptoms typical for CAPS (i.e., urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms of arthralgia/arthritis/myalgia, chronic aseptic meningitis, skeletal abnormalities of epiphyseal overgrowth/frontal bossing) **OR** C. The patient has a diagnosis of Familial Mediterranean Fever (FMF) AND ONE of the following: 1. The patient has tried and had an inadequate response to colchicine for at least 6 months **OR** 2. The patient has an intolerance or hypersensitivity to colchicine **OR** 3. The patient has an FDA labeled contraindication to colchicine **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that colchicine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. BOTH of the following: 1. The patient has a diagnosis of Hyperimmunoglobulin D Syndrome (HIDS) or Mevalonate Kinase Deficiency (MKD) **AND** 2. The patient's diagnosis was confirmed via genetic testing for mutations in the mevalonate kinase (MVK) gene **OR** E. BOTH of the following: 1. The patient has a diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) **AND** 2. The patient's diagnosis was confirmed via genetic testing for mutations in the TNFR1 gene **OR** F. The patient has a diagnosis of active systemic juvenile idiopathic arthritis (SJIA) AND ALL of the following: 1. The patient has ongoing fever for at least 2 weeks **AND** 2. The patient has arthritis in greater than or equal to 1 joint **AND** 3. The patient has ONE or more of the following: A. Evanescent erythematous rash B. Generalized lymphadenopathy C. Hepatomegaly or splenomegaly

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

Module	Clinical Criteria for Approval
	B. The patient has an intolerance or hypersensitivity to ONE non-steroidal anti-inflammatory drug (NSAID) **OR** C. The patient has an FDA labeled contraindication to ALL non-steroidal anti-inflammatory drugs (NSAIDs) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL non-steroidal anti-inflammatory drug (NSAIDs) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following**:** A. The patient has tried and had an inadequate response to colchicine for at least 6 months **OR** B. The patient has an intolerance or hypersensitivity to colchicine **OR** C. The patient has an FDA labeled contraindication to colchicine **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that colchicine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. Repeated courses of corticosteroids are not appropriate for the patient **OR** I. The patient has another FDA approved indication for the requested agent **OR** J. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has an FDA approve indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

CONTRAINDICATION AGENTS

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

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

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

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
4460402000D520	Fasenra pen	Benralizumab Subcutaneous Soln Auto-injector 30 MG/ML	30 MG/ML	1	Pen	56	DAYS				
4460405500D530	Nucala	Mepolizumab Subcutaneous Solution Auto-injector 100 MG/ML	100 MG/ML	3	Syringes	28	DAYS				
4460405500E520	Nucala	Mepolizumab Subcutaneous Solution Pref Syringe	40 MG/0.4 ML	1	Syringe	28	DAYS			10-01-2022	
4460405500E530	Nucala	Mepolizumab	100	3	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
		Subcutaneous Solution Pref Syringe 100 MG/ML	MG/ML								

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** No Target Agents are Eligible for Continuation of Therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of severe eosinophilic asthma and BOTH of the following: 1. The patient's diagnosis has been confirmed by ONE of the following: A. The patient has a baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** B. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** C. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **AND** 2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR** C. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had a diagnosis of EGPA for at least 6 months with a history of relapsing or refractory disease **AND** 3. The patient's diagnosis of EGPA was confirmed by ONE of the following: A. The patient meets 4 of the following: 1. Asthma (history of wheezing or diffuse high-pitched rales on expiration) 2. Eosinophilia (greater than 10% eosinophils on white blood cell differential count)

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	3. Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis 4. Migratory or transient pulmonary infiltrates detected radiographically 5. Paranasal sinus abnormality 6. Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas **OR** B. The patient meets ALL of the following: 1. Medical history of asthma **AND** 2. Peak peripheral blood eosinophilia greater than 1500 cells/microliter **AND** 3. Systemic vasculitis involving two or more extra-pulmonary organs **AND** 4. ONE of the following: A. The patient is currently on maximally tolerated oral corticosteroid therapy **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral corticosteroids **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to ONE non-corticosteroid immunosuppressant (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, rituximab) **OR** B. The patient has an intolerance or hypersensitivity to ONE non-corticosteroid immunosuppressant **OR** C. The patient has an FDA labeled contraindication to ALL of the following immunosuppressants 1. Azathioprine 2. Cyclophosphamide 3. Methotrexate 4. Mycophenolate mofetil **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL non-corticosteroid immunosuppressants cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of hypereosinophilic syndrome (HES) and ALL of the following: 1. The requested agent is Nucala **AND** 2. BOTH of the following: A. The patient has had a diagnosis of HES for at least 6 months **AND** B. The patient has a history of at least 2 HES flares within the past 12 months (i.e., worsening of clinical symptoms and/or blood eosinophil counts requiring an escalation in therapy) **AND** 3. The patient's diagnosis of HES was confirmed by BOTH of the following: A. ONE of the following: 1. The patient has a peripheral blood eosinophil count greater than 1000

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

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	corticosteroids **OR** F. The patient has another FDA approved indication for the requested agent and route of administration **OR** G. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has a diagnosis of severe eosinophilic asthma, ALL of the following: A. ONE of the following: 1. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** 2. The patient is currently being treated with the requested agent AND ONE of the following: A. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** B. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** 3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** B. ONE of the following: 1. The patient is currently being treated with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. Long-acting muscarinic antagonist (LAMA) **OR** C. A leukotriene receptor antagonist (LTRA) **OR** D. Theophylline **OR** 2. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), long-acting muscarinic antagonists (LAMA), leukotriene receptor antagonists (LTRA) or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND** C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 3. If the patient has a diagnosis of hypereosinophilic syndrome (HES), ALL of the following: A. ONE of the following: 1. The patient is currently being treated with maximally tolerated oral corticosteroid (OCS) **OR** 2. The patient has an intolerance or hypersensitivity to oral corticosteroid (OCS) therapy **OR** 3. The patient has an FDA labeled contraindication to ALL oral corticosteroids **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL oral corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient is currently being treated with ONE of the following: A. Hydroxyurea **OR** B. Interferon-α **OR** C. Another immunosuppressive agent (e.g., azathioprine, cyclosporine,

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	methotrexate, tacrolimus) **OR** 2. The patient has an intolerance or hypersensitivity to therapy with hydroxyurea, interferon-α, or immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** 3. The patient has an FDA labeled contraindication to hydroxyurea, interferon-α, and ALL immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that hydroxyurea, interferon-α, and ALL immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** C. The patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-α, immunosuppressants) in combination with the requested agent **AND** 4. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), BOTH of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** 5. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 6 months for severe eosinophilic asthma; 12 months for EGPA, HES, CRSwNP, and all other FDA approved or compendia supported indications

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	For Fasenra, approve loading dose for new starts and the maintenance dose for the remainder of the 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of severe eosinophilic asthma AND BOTH of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. Increase in percent predicted Forced Expiratory Volume (FEV1) **OR** B. Decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. Decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy (i.e., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline) **OR** B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. Remission achieved with the requested agent **OR** B. Decrease in oral corticosteroid maintenance dose required for control of symptoms related to EGPA **OR** C. Decrease in hospitalization due to symptoms of EGPA **OR** D. Dose of maintenance corticosteroid therapy and/or immunosuppressant therapy was not increased **AND** 3. ONE of the following: A. The patient is currently treated and is compliant with maintenance therapy with oral corticosteroids **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL oral corticosteroids cannot be used due to a documented medical condition or comorbid condition that is

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	likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of hypereosinophilic syndrome (HES) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. Decrease in incidence of HES flares **OR** B. Escalation of therapy (due to HES-related worsening of clinical symptoms or increased blood eosinophil counts) has not been required **AND** 3. ONE of the following: A. The patient is currently treated and is compliant with oral corticosteroid and/or other maintenance therapy (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to therapy with oral corticosteroids or other maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** C. The patient has an FDA labeled contraindication to ALL oral corticosteroids AND maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL oral corticosteroids AND maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** E. The patient has another FDA approved indication for the requested agent and route of administration AND has had clinical benefit with the requested agent **OR** F. The patient has another indication that is supported in compendia for the requested agent and route of administration AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**

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	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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

CONTRAINDICATION AGENTS

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

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

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

• Program Summary: Long Acting Insulin

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Metformin ER

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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
27250050007520		Metformin HCl Tab ER 24HR 500 MG	500 MG	120	Tablets	30	DAYS				
27250050007530		Metformin HCl Tab ER 24HR 750 MG	750 MG	60	Tablets	30	DAYS				
27250050007570		Metformin HCl Tab ER 24HR Osmotic 1000 MG	1000 MG	60	Tablets	30	DAYS				
27250050007560		Metformin HCl Tab ER 24HR Osmotic 500 MG	500 MG	90	Tablets	30	DAYS				
27250050007590	Glumetza	Metformin HCl Tab ER 24HR Modified Release 1000 MG	1000 MG	60	Tablets	30	DAYS				
27250050007580	Glumetza	Metformin HCl Tab ER 24HR Modified Release 500 MG	500 MG	90	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Glumetza (metformin modified release)* **metformin osmotic ER** (generic Fortamet ER)	**metformin ER** (generic Glucophage XR)

*-generic available

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

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
2. The patient's medication history includes use of a prerequisite agent **OR**
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried a prerequisite agent **AND**
   B. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event **OR**
4. The patient has a documented intolerance or hypersensitivity to an available prerequisite agent that is not expected to occur with the requested agent **OR**
5. The patient has an FDA labeled contraindication to ALL available prerequisite agents that is not expected to occur with the requested agent **OR**
6. The prescriber has provided documentation that ALL available 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

Length of Approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

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. Information has been provided to support therapy with a higher dose for the requested indication **OR**
   B. BOTH of the following:
      1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
      2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR**
   C. BOTH of the following:
      1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**
      2. Information has been provided to support therapy with a higher dose for the

Module	Clinical Criteria for Approval
	requested indication **Length of Approval**: up to 12 months

• Program Summary: Multiple Sclerosis Agents

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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
62405530006520		Diroximel Fumarate Capsule DR Starter Bottle 231 MG		106	Capsules	180	DAYS				
624040700003	Aubagio	teriflunomide tab	14 MG; 7 MG	30	Tablets	30	DAYS				
6240306045F830	Avonex	Interferon Beta-1a IM Prefilled Syringe Kit 30 MCG/0.5ML	30 MCG/0.5 ML	1	Kit	28	DAYS				
6240306045F530	Avonex pen	Interferon Beta-1a IM Auto-Injector Kit 30 MCG/0.5ML	30 MCG/0.5 ML	1	Kit	28	DAYS				
62405550006520	Bafiertam	Monomethyl Fumarate Capsule Delayed Release	95 MG	120	Capsules	30	DAYS				
62403060506420	Betaseron	Interferon Beta- ; interferon beta-	0.3 MG	14	Vials	28	DAYS	50419052401; 50419052435			
6240003010E520	Copaxone; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 20 MG/ML	20 MG/ML	30	Syringes	30	DAYS				
6240003010E540	Copaxone; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 40 MG/ML	40 MG/ML	12	Syringes	28	DAYS				
62403060506420	Extavia	Interferon Beta- ; interferon beta-	0.3 MG	15	Vials	30	DAYS	00078056912; 00078056961; 00078056999			
624070251001	Gilenya	fingolimod hcl cap	0.25 MG; 0.5 MG	30	Capsules	30	DAYS				
6240506500D520	Kesimpta	Ofatumumab Soln Auto-Injector	20 MG/0.4 ML	1	Pen	28	DAYS				
6240101500B744	Mavenclad	Cladribine Tab Therapy Pack 10 MG (10 Tabs)	10 MG	20	Tablets	301	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
6240101500B718	Mavenclad	Cladribine Tab Therapy Pack 10 MG (4 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B722	Mavenclad	Cladribine Tab Therapy Pack 10 MG (5 Tabs)	10 MG	10	Tablets	301	DAYS				
6240101500B726	Mavenclad	Cladribine Tab Therapy Pack 10 MG (6 Tabs)	10 MG	12	Tablets	301	DAYS				
6240101500B732	Mavenclad	Cladribine Tab Therapy Pack 10 MG (7 Tabs)	10 MG	14	Tablets	301	DAYS				
6240101500B736	Mavenclad	Cladribine Tab Therapy Pack 10 MG (8 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B740	Mavenclad	Cladribine Tab Therapy Pack 10 MG (9 Tabs)	10 MG	9	Tablets	301	DAYS				
62407070200330	Mayzent	Siponimod Fumarate Tab	1 MG	30	Tablets	30	DAYS				
62407070200320	Mayzent	Siponimod Fumarate Tab 0.25 MG (Base Equiv)	0.25 MG	120	Tablets	30	DAYS				
62407070200340	Mayzent	Siponimod Fumarate Tab 2 MG (Base Equiv)	2 MG	30	Tablets	30	DAYS				
6240707020B710	Mayzent starter pack	Siponimod Fumarate Tab	0.25 MG	1	Pack	180	DAYS				
6240707020B720	Mayzent starter pack	Siponimod Fumarate Tab 0.25 MG (12) Starter Pack	0.25 MG	1	Pack	180	DAYS				
6240307530E521	Plegridy	Peginterferon Beta-	125 MCG/0.5 ML	2	Syringes	28	DAYS				
6240307530D220	Plegridy	Peginterferon Beta-1a Soln Pen-injector 125 MCG/0.5ML	125 MCG/0.5 ML	2	Pens	28	DAYS				
6240307530E520	Plegridy	Peginterferon Beta-1a Soln Prefilled Syringe 125 MCG/0.5ML	125 MCG/0.5 ML	2	Syringes	28	DAYS				
6240307530D250	Plegridy starter pack	Peginterferon Beta-1a Soln Pen-inj 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5 ML	1	Kit	180	DAYS				
6240307530E550	Plegridy starter pack	Peginterferon Beta-1a Soln Pref Syr 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5 ML	1	Kit	180	DAYS				
62407060000320	Ponvory	Ponesimod Tab	20 MG	30	Tablets	30	DAYS				
6240706000B720	Ponvory 14-day starter pa	Ponesimod Tab Starter Pack	2-3-4-5-6-7-8-9 & 10 MG	1	Pack	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
6240306045E520	Rebif	Interferon Beta-1a Soln Pref Syr 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045E540	Rebif	Interferon Beta-1a Soln Pref Syr 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045D520	Rebif rebidose	Interferon Beta-1a Soln Auto-Inj 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045D540	Rebif rebidose	Interferon Beta-1a Soln Auto-inj 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045D560	Rebif rebidose titration	Interferon Beta-1a Auto-inj 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				
6240306045E560	Rebif titration pack	Interferon Beta-1a Pref Syr 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				
62407025207220	Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	0.25 MG	30	Tablets	30	DAYS				
62407025207230	Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	0.5 MG	30	Tablets	30	DAYS				
62405525006520	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 120 MG	120 MG	56	Capsules	180	DAYS				
62405525006540	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 240 MG	240 MG	60	Capsules	30	DAYS				
6240552500B320	Tecfidera starter pack	dimethyl fumarate capsule dr starter pack	120 & 240 MG	1	Kit	180	DAYS				
62405530006540	Vumerity	Diroximel Fumarate Capsule Delayed Release 231 MG	231 MG	120	Capsules	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)

Preferred generic agent(s)*	Preferred brand agent(s)	Nonpreferred agent(s)
dimethyl fumarate fingolimod glatiramer **Glatopa** (glatiramer) teriflunomide	**Avonex** (interferon beta-1a) **Betaseron** (interferon beta-1b) **Kesimpta** (ofatumumab) **Mavenclad** (cladribine) **Mayzent** (siponimod) **Plegridy** (peginterferon beta-1a) **Rebif** (interferon beta-1a) **Vumerity** (diroximel fumarate)	Aubagio (teriflunomide)** Bafiertam (monomethyl fumarate) Copaxone (glatiramer)** Extavia (interferon beta-1b) Gilenya (fingolimod)** Ponvory (ponesimod) Tascenso ODT (fingolimod) Tecfidera (dimethyl fumarate)**

* – These agents are subject to duplicate therapy check only
** – generic available

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

1. ONE of following:
    - A. Information has been provided that the patient has been treated with the requested agent within the past 90 days **OR**
    - B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**
    - C. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    - D. The requested agent is a preferred generic agent **OR**
    - E. The patient has highly active MS disease activity AND BOTH of the following:
        1. The patient has greater than or equal to 2 relapses in the previous year **AND**
        2. ONE of the following:
            - A. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI **OR**
            - B. The patient has significant increase in T2 lesion load compared with a previous MRI **OR**
    - F. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table) **OR**
    - G. The requested agent is a preferred brand agent AND ONE of the following:
        1. The patient's medication history includes use of ONE preferred generic agent **OR**
        2. BOTH of the following:
            - A. The prescriber has stated that the patient has tried one preferred generic agent **AND**
            - B. The preferred generic agent was discontinued due to lack of effectiveness or an adverse event **OR**
        3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic agent **OR**
        4. The patient has an FDA labeled contraindication to ALL preferred generic agents **OR**
        5. The prescriber has provided documentation that ALL preferred generic 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**
    - H. The requested agent is a nonpreferred agent AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient is 17 years of age or younger AND ONE of the following: A. The requested agent does NOT have a corresponding preferred generic strength **OR** B. The patient has tried and had an inadequate response to ONE preferred generic agent FDA approved for the patient's age for the requested indication (medical records required) **OR** C. The patient has an intolerance (defined as an intolerance to drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic agent FDA approved for the patient's age for the requested indication **OR** D. The patient has an FDA labeled contraindication to ALL preferred generic agents FDA approved for the patient's age for the requested indication **OR** E. The prescriber has provided documentation that ALL preferred generic agents FDA approved for the patient's age for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient is 18 years of age or older AND BOTH of the following: A. ONE of the following: 1. The patient's medication history incudes use of ONE preferred generic agent **OR** 2. BOTH of the following: A. The prescriber has stated that the patient has tried one preferred generic agent **AND** B. The preferred generic agent was discontinued due to lack of effectiveness or an adverse event **OR** 3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic agent **OR** 4. The patient has an FDA labeled contraindication to ALL preferred generic agents **OR** 5. The prescriber has provided documentation that ALL preferred generic 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. ONE of the following: 1. The patient's medication history includes the use of ONE preferred brand agent or Zeposia (ozanimod) **OR** 2. BOTH of the following: A. The prescriber has stated that the patient has tried one preferred brand agent or Zeposia **AND** B. The preferred brand agent or Zeposia was discontinued due to lack of effectiveness or an adverse event **OR** 3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred brand agent or Zeposia **OR** 4. The patient has an FDA labeled contraindication to ALL preferred brand agents AND Zeposia **OR** 5. The prescriber has provided documentation that ALL preferred brand agents AND Zeposia cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

Module	Clinical Criteria for Approval
	2. If the requested agent is a brand agent with a generic equivalent (listed below) AND ONE of the following: A. The patient's medication history includes use of the corresponding generic equivalent **OR** B. 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** C. The patient has an intolerance or hypersensitivity to the corresponding generic equivalent agent that is not expected to occur with the requested agent **OR** D. The patient has an FDA labeled contraindication to the corresponding generic equivalent agent that is not expected to occur with the requested agent **OR**

Non-Preferred Agents	Corresponding generic equivalent
Aubagio	teriflunomide
Copaxone	Glatopa/glatiramer
Gilenya 0.5 mg	Fingolimod 0.5 mg
Tecfidera	dimethyl fumarate

E. The prescriber has provided documentation that ALL corresponding generic equivalents 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 taking an additional disease modifying agent (DMA) for the requested indication

Length of Approval: 12 months. **NOTE:** For agents requiring a starter dose for initial use, the starter dose will be approved for the FDA labeled starting dose and the maintenance dose will be approved for the remainder of 12 months.

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	requested indication **Length of Approval**: up to 12 months NOTE: For agents requiring a starter dose for initial use, the starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months

CLASS AGENTS

Class	Class Drug Agents
Class Ia antiarrhythmics	
Class Ia antiarrhythmics	NORPACE*Disopyramide Phosphate Cap
Class Ia antiarrhythmics	Pronestyl (procainamide)
Class Ia antiarrhythmics	quinidine
Class III antiarrhythmics	
Class III antiarrhythmics	BETAPACE*Sotalol HCl Tab
Class III antiarrhythmics	Cordarone, Pacerone (amiodarone)
Class III antiarrhythmics	CORVERT*Ibutilide Fumarate Inj
Class III antiarrhythmics	MULTAQ*Dronedarone HCl Tab
Class III antiarrhythmics	TIKOSYN*Dofetilide Cap
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	BRIUMVI*ublituximab-xiiy soln for iv infusion
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	KESIMPTA*Ofatumumab Soln Auto-Injector
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	OCREVUS*Ocrelizumab Soln For IV Infusion
MS Disease Modifying Agents drug class: CD52 monoclonal antibody	
MS Disease Modifying Agents drug class: CD52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
MS Disease Modifying Agents drug class: Fumarates	
MS Disease Modifying Agents drug class: Fumarates	BAFIERTAM*Monomethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Fumarates	TECFIDERA*Dimethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Glatiramer	
MS Disease Modifying Agents drug class: Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug class: Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug class: IgG4k monoclonal antibody	
MS Disease Modifying Agents drug class: IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc

Class	Class Drug Agents
MS Disease Modifying Agents drug class: Interferons	
MS Disease Modifying Agents drug class: Interferons	AVONEX*Interferon beta-1a injection
MS Disease Modifying Agents drug class: Interferons	BETASERON*Interferon beta-1b injection
MS Disease Modifying Agents drug class: Interferons	EXTAVIA*Interferon beta-1b injection
MS Disease Modifying Agents drug class: Interferons	PLEGRIDY*Peginterferon beta-1a injection
MS Disease Modifying Agents drug class: Interferons	REBIF*Interferon Beta-
MS Disease Modifying Agents drug class: Purine antimetabolite	
MS Disease Modifying Agents drug class: Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
MS Disease Modifying Agents drug class: Pyrimidine synthesis inhibitor	
MS Disease Modifying Agents drug class: Pyrimidine synthesis inhibitor	AUBAGIO*Teriflunomide Tab
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	GILENYA*Fingolimod HCl Cap
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	MAYZENT*Siponimod Fumarate Tab
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	PONVORY*Ponesimod Tab
MS Disease Modifying Agents Drug Class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents Drug Class: Sphingosine 1-phosphate (SIP) receptor modulator	TASCENSO*fingolimod lauryl sulfate tablet disintegrating
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Examples of Contraindicated Concomitant Disease Modifying Agents (DMAs) **Aubagio** (teriflunomide)* **Avonex** (interferon β-1a) **Bafiertam** (monomethyl fumarate) **Betaseron** (interferon β-1b) **Briumvi** (ublituximab-xiiy) **Copaxone** (glatiramer)*

Contraindicated as Concomitant Therapy
dimethyl fumarate **Extavia** (interferon β-1b) fingolimod **Gilenya** (fingolimod)* **Glatopa** (glatiramer) glatiramer **Kesimpta** (ofatumumab) **Lemtrada** (alemtuzumab) **Mavenclad** (cladribine) **Mayzent** (siponimod) **Ocrevus** (ocrelizumab) **Plegridy** (peginterferon β-1a) **Ponvory** (ponesimod) **Rebif** (interferon β-1a) **Tascenso ODT** (fingolimod) **Tecfidera** (dimethyl fumarate)* teriflunomide **Tysabri** (natalizumab) **Vumerity** (diroximel fumarate) **Zeposia** (ozanimod) * -generic available

• Program Summary: Opioids ER

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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
65100025008650		Fentanyl TD Patch 72HR 100 MCG/HR	100 MCG/HR	15	Patches	30	DAYS				
65100025008610		Fentanyl TD Patch 72HR 12 MCG/HR	12 MCG/HR	15	Patches	30	DAYS				
65100025008620		Fentanyl TD Patch 72HR 25 MCG/HR	25 MCG/HR	15	Patches	30	DAYS				
65100025008626		Fentanyl TD Patch 72HR 37.5 MCG/HR	37.5 MCG/HR	15	Patches	30	DAYS				
65100025008630		Fentanyl TD Patch 72HR 50 MCG/HR	50 MCG/HR	15	Patches	30	DAYS				
65100025008635		Fentanyl TD Patch 72HR 62.5 MCG/HR	62.5 MCG/HR	15	Patches	30	DAYS				
65100025008640		Fentanyl TD Patch 72HR 75 MCG/HR	75 MCG/HR	15	Patches	30	DAYS				
65100025008645		Fentanyl TD Patch 72HR 87.5 MCG/HR	87.5 MCG/HR	15	Patches	30	DAYS				
65100030106910		Hydrocodone Bitartrate Cap ER	10 MG	60	Capsules	30	DAYS				
65100030106915		Hydrocodone Bitartrate	15 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
		Cap ER									
65100030106920		Hydrocodone Bitartrate Cap ER	20 MG	60	Capsules	30	DAYS				
65100030106930		Hydrocodone Bitartrate Cap ER	30 MG	60	Capsules	30	DAYS				
65100030106940		Hydrocodone Bitartrate Cap ER	40 MG	60	Capsules	30	DAYS				
65100030106950		Hydrocodone Bitartrate Cap ER	50 MG	60	Capsules	30	DAYS				
65100035107521		Hydromorphone HCl Tab ER	8 MG	30	Tablets	30	DAYS				
65100035107531		Hydromorphone HCl Tab ER	12 MG	30	Tablets	30	DAYS				
65100035107541		Hydromorphone HCl Tab ER	16 MG	30	Tablets	30	DAYS				
65100035107556		Hydromorphone HCl Tab ER	32 MG	30	Tablets	30	DAYS				
65100055207050		Morphine Sulfate Beads Cap ER 24HR 120 MG	120 MG	30	Capsules	30	DAYS				
65100055207020		Morphine Sulfate Beads Cap ER 24HR 30 MG	30 MG	30	Capsules	30	DAYS				
65100055207025		Morphine Sulfate Beads Cap ER 24HR 45 MG	45 MG	30	Capsules	30	DAYS				
65100055207030		Morphine Sulfate Beads Cap ER 24HR 60 MG	60 MG	30	Capsules	30	DAYS				
65100055207035		Morphine Sulfate Beads Cap ER 24HR 75 MG	75 MG	30	Capsules	30	DAYS				
65100055207040		Morphine Sulfate Beads Cap ER 24HR 90 MG	90 MG	30	Capsules	30	DAYS				
65100055107010		Morphine Sulfate Cap ER 24HR 10 MG	10 MG	60	Capsules	30	DAYS				
65100055107060		Morphine Sulfate Cap ER 24HR 100 MG	100 MG	60	Capsules	30	DAYS				
65100055107020		Morphine Sulfate Cap ER 24HR 20 MG	20 MG	60	Capsules	30	DAYS				
65100055107030		Morphine Sulfate Cap ER 24HR 30 MG	30 MG	60	Capsules	30	DAYS				
65100055107035		Morphine Sulfate Cap ER 24HR 40 MG		60	Capsules	30	DAYS				
65100055107040		Morphine Sulfate Cap ER 24HR 50 MG	50 MG	60	Capsules	30	DAYS				
65100055107045		Morphine Sulfate Cap ER 24HR 60 MG	60 MG	60	Capsules	30	DAYS				
65100055107050		Morphine Sulfate Cap ER 24HR 80 MG	80 MG	60	Capsules	30	DAYS				
65100080107410		Oxymorphone HCl Tab	10 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
		ER 12HR 10 MG									
65100080107415		Oxymorphone HCl Tab ER 12HR 15 MG	15 MG	60	Tablets	30	DAYS				
65100080107420		Oxymorphone HCl Tab ER 12HR 20 MG	20 MG	60	Tablets	30	DAYS				
65100080107430		Oxymorphone HCl Tab ER 12HR 30 MG	30 MG	60	Tablets	30	DAYS				
65100080107440		Oxymorphone HCl Tab ER 12HR 40 MG	40 MG	60	Tablets	30	DAYS				
65100080107405		Oxymorphone HCl Tab ER 12HR 5 MG	5 MG	60	Tablets	30	DAYS				
65100080107407		Oxymorphone HCl Tab ER 12HR 7.5 MG	7.5 MG	60	Tablets	30	DAYS				
65100095107520		Tramadol HCl Tab ER 24HR 100 MG	100 MG	30	Tablets	30	DAYS				
65100095107530		Tramadol HCl Tab ER 24HR 200 MG	200 MG	30	Tablets	30	DAYS				
65100095107540		Tramadol HCl Tab ER 24HR 300 MG	300 MG	30	Tablets	30	DAYS				
65100095107560		Tramadol HCl Tab ER 24HR Biphasic Release 100 MG	100 MG	30	Tablets	30	DAYS				
65100095107570		Tramadol HCl Tab ER 24HR Biphasic Release 200 MG	200 MG	30	Tablets	30	DAYS				
65100095107580		Tramadol HCl Tab ER 24HR Biphasic Release 300 MG	300 MG	30	Tablets	30	DAYS				
65200010108220	Belbuca	Buprenorphine HCl Buccal Film 150 MCG (Base Equivalent)	150 MCG	60	Films	30	DAY				
65200010108230	Belbuca	Buprenorphine HCl Buccal Film 300 MCG (Base Equivalent)	300 MCG	60	Films	30	DAY				
65200010108240	Belbuca	Buprenorphine HCl Buccal Film 450 MCG (Base Equivalent)	450 MCG	60	Films	30	DAY				
65200010108250	Belbuca	Buprenorphine HCl Buccal Film 600 MCG (Base Equivalent)	600 MCG	60	Films	30	DAYS				
65200010108210	Belbuca	Buprenorphine HCl Buccal Film 75 MCG (Base Equivalent)	75 MCG	60	Films	30	DAYS				
65200010108260	Belbuca	Buprenorphine HCl Buccal Film 750 MCG (Base Equivalent)	750 MCG	60	Films	30	DAYS				
65200010108270	Belbuca	Buprenorphine HCl Buccal Film 900 MCG	900 MCG	60	Films	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
		(Base Equivalent)									
65200010008830	Butrans	Buprenorphine TD Patch Weekly 10 MCG/HR	10 MCG/HR	4	Systems	28	DAYS				
65200010008835	Butrans	Buprenorphine TD Patch Weekly 15 MCG/HR	15 MCG/HR	4	Systems	28	DAYS				
65200010008840	Butrans	Buprenorphine TD Patch Weekly 20 MCG/HR	20 MCG/HR	4	Systems	28	DAYS				
65200010008820	Butrans	Buprenorphine TD Patch Weekly 5 MCG/HR	5 MCG/HR	30	Systems	30	DAYS				
65200010008825	Butrans	Buprenorphine TD Patch Weekly 7.5 MCG/HR	7.5 MCG/HR	4	System	28	DAY				
65100095107070	Conzip	Tramadol HCl Cap ER 24HR Biphasic Release 100 MG	100 MG	30	Capsules	30	DAYS				
65100095107080	Conzip	Tramadol HCl Cap ER 24HR Biphasic Release 200 MG	200 MG	30	Capsules	30	DAYS				
65100095107090	Conzip	Tramadol HCl Cap ER 24HR Biphasic Release 300 MG	300 MG	30	Capsules	30	DAYS				
6510003010A860	Hysingla er	Hydrocodone Bitartrate Tab ER 24HR Deter 100 MG	100 MG	30	Tablets	30	DAYS				
6510003010A870	Hysingla er	Hydrocodone Bitartrate Tab ER 24HR Deter 120 MG	120 MG	30	Tablets	30	DAYS				
6510003010A810	Hysingla er	Hydrocodone Bitartrate Tab ER 24HR Deter 20 MG	20 MG	30	Tablets	30	DAYS				
6510003010A820	Hysingla er	Hydrocodone Bitartrate Tab ER 24HR Deter 30 MG	30 MG	30	Tablets	30	DAYS				
6510003010A830	Hysingla er	Hydrocodone Bitartrate Tab ER 24HR Deter 40 MG	40 MG	30	Tablets	30	DAYS				
6510003010A840	Hysingla er	Hydrocodone Bitartrate Tab ER 24HR Deter 60 MG	60 MG	30	Tablets	30	DAYS				
6510003010A850	Hysingla er	Hydrocodone Bitartrate Tab ER 24HR Deter 80 MG	80 MG	30	Tablets	30	DAYS				
65100055100460	Ms contin	Morphine Sulfate Tab ER 100 MG	100 MG	90	Tablets	30	DAYS				
65100055100415	Ms contin	Morphine Sulfate Tab	15 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
		ER 15 MG									
65100055100480	Ms contin	Morphine Sulfate Tab ER 200 MG	200 MG	90	Tablets	30	DAYS				
65100055100432	Ms contin	Morphine Sulfate Tab ER 30 MG	30 MG	90	Tablets	30	DAYS				
65100055100445	Ms contin	Morphine Sulfate Tab ER 60 MG	60 MG	90	Tablets	30	DAYS				
65100091107430	Nucynta er	Tapentadol HCl Tab ER 12HR 100 MG	100 MG	60	Tablets	30	DAYS				
65100091107440	Nucynta er	Tapentadol HCl Tab ER 12HR 150 MG	150 MG	60	Tablets	30	DAYS				
65100091107450	Nucynta er	Tapentadol HCl Tab ER 12HR 200 MG	200 MG	60	Tablets	30	DAYS				
65100091107460	Nucynta er	Tapentadol HCl Tab ER 12HR 250 MG	250 MG	60	Tablets	30	DAYS				
65100091107420	Nucynta er	Tapentadol HCl Tab ER 12HR 50 MG	50 MG	60	Tablets	30	DAYS				
6510007510A710	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 10 MG	10 MG	60	Tablets	30	DAYS				
6510007510A715	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 15 MG	15 MG	60	Tablets	30	DAYS				
6510007510A720	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 20 MG	20 MG	60	Tablets	30	DAYS				
6510007510A730	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 30 MG	30 MG	60	Tablets	30	DAYS				
6510007510A740	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 40 MG	40 MG	60	Tablets	30	DAYS				
6510007510A760	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 60 MG	60 MG	120	Tablets	30	DAYS				
6510007510A780	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 80 MG	80 MG	120	Tablets	30	DAYS				
6510007500A315	Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 13.5 MG	13.5 MG	60	Capsules	30	DAYS				
6510007500A320	Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 18 MG	18 MG	60	Capsules	30	DAYS				
6510007500A330	Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 27 MG	27 MG	60	Capsules	30	DAYS				
6510007500A340	Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 36 MG	36 MG	240	Capsules	30	DAYS				
6510007500A310	Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 9 MG	9 MG	60	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

EVALUATION

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

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

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

     1. Information has been provided that the patient has been treated with the requested agent within the past 90 days **OR**
     2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**
   - B. ALL of the following:
     1. ONE of the following:
        - A. The patient has a diagnosis of chronic cancer pain due to an active malignancy **OR**
        - B. The patient is eligible for hospice OR palliative care **OR**
        - C. The patient has a diagnosis of sickle cell disease **OR**
        - D. The patient is undergoing treatment of chronic non-cancer pain and ALL of the following:
          1. A formal, consultative evaluation which includes ALL of the following has been conducted:
             - A. Diagnosis **AND**
             - B. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy **AND**
             - C. The need for continued opioid therapy has been assessed **AND**
          2. The requested agent is not prescribed as an as-needed (prn) analgesic **AND**
          3. ONE of the following:
             - A. The patient's medication history includes a trial of at least 7 days of an immediate-acting opioid **OR**
             - B. The patient has an intolerance or hypersensitivity to therapy with immediate-acting opioids that is not expected to occur with the requested agent **OR**
             - C. The patient has an FDA labeled contraindication to ALL immediate-acting opioids that is not expected to occur with the requested agent **OR**
             - D. BOTH of the following:
               1. The prescriber has stated that the patient has tried therapy with immediate-acting opioids **AND**
               2. Therapy with immediate-acting opioids was discontinued due to lack of effectiveness or an adverse event **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

Module	Clinical Criteria for Approval

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 therapy with immediate-acting opioids 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. A patient-specific pain management plan is on file for the patient **AND**
5. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose **AND**

2. ONE of the following:
   A. The patient is not concurrently using a buprenorphine or buprenorphine/naloxone for opioid dependence treatment **OR**
   B. The prescriber has provided information in support of use of concurrent use of opioids with buprenorphine or buprenorphine/naloxone for opioid dependence treatment **AND**
3. If the client has preferred agent(s), then ONE of the following:

Preferred Agents	Non-Preferred Agents
Xtampza ER	OxyContin

   A. The requested agent is a preferred agent **OR**
   B. The patient has tried and had an inadequate response to a preferred agent **OR**
   C. The patient has an intolerance or hypersensitivity to a preferred agent **OR**
   D. The patient has an FDA labeled contraindication to ALL preferred agents **OR**
   E. BOTH of the following:
      1. The prescriber has stated that the patient has tried a preferred agent **AND**
      2. A preferred agent was discontinued due to lack of effectiveness or an adverse event **OR**
   F. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   G. The prescriber has provided documentation that 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**

2. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
   A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**

Module	Clinical Criteria for Approval
	B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR** C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

Brand	Generic Equivalent
Butrans	Buprenorphine patch
Hysingla	Hydrocodone ER tabs
MS Contin	Morphine sulfate ER tabs

D. BOTH of the following:
1. The prescriber has stated that the patient has tried the generic equivalent **AND**
2. A generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**

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

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

3. If the requested agent contains tramadol, dihydrocodeine, or codeine, then ONE of the following:
A. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy **OR**
B. The patient is 18 years of age or over **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND BOTH of the following: A. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **AND** B. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** 6 months

• Program Summary: Opioids Immediate Release (IR) New To Therapy with Daily Quantity Limit

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

Opioids IR New To Therapy (Includes IR, ER, and Oncology) with Daily Quantity Limit

OBJECTIVE

The program will check if a patient is new to opioid therapy as defined as having no prior opioid use in the past 120 days. If the patient is new to therapy, the patient will be restricted to <50 MME per day and ≤7 days of therapy. The program will allow for exceptions for uses beyond these limits based on program requirements. The program will also check for appropriate age for requests for products containing tramadol, dihydrocodeine, and codeine. Requests for these agents will be limited to patients 12 years of age and older, and patients 12 to 18 years will be restricted from use for post-operative pain management following a tonsillectomy and/or adenoidectomy. (program applies to all Multi-Source Codes [M, N, O, Y])

TARGET AGENT(S) FOR NEW TO THERAPY[b]

SINGLE INGREDIENT AGENT(S)				
Brand (generic)	**GPI**	**Daily Quantity Limit**	**Quantity Equaling <50 MME/day**	**Age Limit**
butorphanol[a]				
10 mg/mL nasal spray	65200020102050	0.25 mL	See note*	NA
Codeine				
15 mg tablet	65100020200305	6 tablets	22 tablets	≥18 years
30 mg tablet[a]	65100020200310	6 tablets	11 tablets	≥18 years
60 mg tablet	65100020200315	6 tablets	5 tablets	≥18 years
Dilaudid (hydromorphone)[a]				
2 mg tablet	65100035100310	6 tablets	5 tablets	NA
4 mg tablet	65100035100320	6 tablets	3 tablets	NA
8 mg tablet	65100035100330	6 tablets	1 tablet	NA
1 mg/mL liquid	65100035100920	48 mL	10 mL	NA
Levorphanol[a]				
2 mg tablet	65100040100305	4 tablets	2 tablets	NA
3 mg tablet	65100040100310	4 tablets	1 tablet	NA
Meperidine				
50 mg tablet	65100045100305	12 tablets	10 tablets	NA
50 mg/5 mL solution	65100045102060	60 mL	50 mL	NA
Dolophine (methadone)[a]				
5 mg tablet	65100050100305	3 tablets	3 tablets	NA
10 mg tablet	65100050100310	3 tablets	1 tablet	NA
Methadose, Methadone[a]				
40 mg soluble tablet	65100050107320	3 tablets	see note*	NA
5 mg/5 mL solution	65100050102010	30 mL	11 mL	NA
10 mg/5 mL solution	65100050102015	15 mL	6 mL	NA
10 mg/mL concentrate	65100050101310	3 mL	1 mL	NA
Morphine sulfate				
15 mg tablet[a]	65100055100310	12 tablets	3 tablets	NA
30 mg tablet[a]	65100055100315	6 tablets	1 tablet	NA
10 mg/5 mL solution	65100055102065	90 mL	25 mL	NA
20 mg/5 mL solution[a]	65100055102070	45 mL	12 mL	NA
20 mg/mL concentrate[a]	65100055102090	9 mL	2 mL	NA
Oxaydo, Roxybond, Roxicodone (oxycodone)				
5 mg capsule[a]	65100075100110	12 capsules	6 capsules	NA
5 mg tablet[a]	65100075100310	12 tablets	6 tablets	NA

5 mg tablet	6510007510A530	12 tablets	6 tablets	NA
7.5 mg tablet	65100075100315	6 tablets	4 tablets	NA
10 mg tablet[a]	65100075100320	6 tablets	3 tablets	NA
15 mg tablet[a]	65100075100325	6 tablets	2 tablets	NA
15 mg tablet	6510007510A540	6 tablets	2 tablets	NA
20 mg tablet[a]	65100075100330	6 tablets	1 tablet	NA
30 mg tablet[a]	65100075100340	6 tablets	1 tablet	NA
30 mg tablet	6510007510A560	6 tablets	1 tablet	NA
5 mg/5 mL solution[a]	65100075102005	180 mL	33 mL	NA
20 mg/mL concentrate[a]	65100075101320	9 mL	1 mL	NA
Opana (oxymorphone)[a]				
5 mg tablet	65100080100305	6 tablets	3 tablets	NA
10 mg tablet	65100080100310	6 tablets	1 tablet	NA
Nucynta (tapentadol)				
50 mg tablet	65100091100320	6 tablets	2 tablets	NA
75 mg tablet	65100091100330	6 tablets	1 tablet	NA
100 mg tablet	65100091100340	6 tablets	1 tablet	NA
Qdolo, Ultram, Tramadol				
25 mg tablet	65100095100310	8 tablets	10 tablets	≥18 years
50 mg tablet[a]	65100095100320	8 tablets	5 tablets	≥18 years
100 mg tablet	65100095100340	4 tablets	3 tablets	≥18 years
5 mg/mL solution	65100095102005	80 mL	50 mL	≥18 years
COMBINATION INGREDIENT AGENT(S)				
Apadaz, Benzhydrocodone/acetaminophen				
4.08/325 mg tablet	65990002020310	12 tablets	11 tablets[‡]	NA
6.12/325 mg tablet	65990002020320	12 tablets	7 tablets[‡]	NA
8.16/325 mg tablet	65990002020330	12 tablets	6 tablets[‡]	NA
Tylenol w/Codeine (acetaminophen/codeine)[a]				
120 mg/12 mg/5 mL solution	65991002052020	90 mL	138 mL[‡]	≥18 years
300 mg/15 mg tablet	65991002050310	12 tablets	22 tablets[‡]	≥18 years
300 mg/30 mg tablet	65991002050315	12 tablets	11 tablets[‡]	≥18 years
300 mg/60 mg tablet	65991002050320	6 tablets	5 tablets[‡]	≥18 years
Fioricet w/Codeine (butalbital/acetaminophen/caffeine/codeine)[a]				
50 mg/300 mg/40 mg/30 mg capsule	65991004100113	6 capsules	11 capsules[‡]	≥18 years
50 mg/325 mg/40 mg/30 mg capsule	65991004100115	6 capsules	11 capsules[‡]	≥18 years
Fiorinal w/Codeine (butalbital/aspirin/caffeine/codeine)[a]				
50 mg/325 mg/40 mg/30 mg capsule	65991004300115	6 capsules	11 capsules[‡]	≥18 years
Trezix, Acetaminophen/caffeine/dihydrocodeine				
320.5 mg/30 mg/16 mg capsule	65991303050115	10 capsules	12 capsules[‡]	≥18 years
325 mg/30 mg/16 mg tablet	65991303050320	10 tablets	12 tablets[‡]	≥18 years
Lortab, Norco, Hydrocodone/acetaminophen				
5 mg/300 mg tablet[a]	65991702100309	8 tablets	10 tablets[‡]	NA
5 mg/325 mg tablet[a]	65991702100356	8 tablets	10 tablets[‡]	NA
7.5 mg/300 mg tablet[a]	65991702100322	6 tablets	6 tablets[‡]	NA
7.5 mg/325 mg tablet[a]	65991702100358	6 tablets	6 tablets[‡]	NA
10 mg/300 mg tablet[a]	65991702100375	6 tablets	5 tablets[‡]	NA

10 mg/325 mg tablet[a]	65991702100305	6 tablets	5 tablets‡	NA
7.5 mg/325 mg/15 mL solution[a]	65991702102015	90 mL	100 mL‡	NA
10 mg/300 mg/15 mL solution	65991702102024	67.5 mL	74 mL‡	NA
Hydrocodone/Ibuprofen				
5 mg/200 mg tablet	65991702500315	5 tablets	10 tablets‡	NA
7.5 mg/200 mg tablet[a]	65991702500320	5 tablets	6 tablets‡	NA
10 mg/200 mg tablet[a]	65991702500330	5 tablets	5 tablets‡	NA
Percocet, Prolate, Oxycodone/acetaminophen, Nalocet, Primlev				
2.5 mg/300 mg tablet	65990002200303	12 tablets	13 tablets‡	NA
2.5 mg/325 mg tablet[a]	65990002200305	12 tablets	13 tablets‡	NA
5 mg/300 mg tablet	65990002200308	12 tablets	6 tablets‡	NA
5 mg/325 mg tablet[a]	65990002200310	12 tablets	6 tablets‡	NA
7.5 mg/300 mg tablet	65990002200325	8 tablets	4 tablets‡	NA
7.5 mg/325 mg tablet[a]	65990002200327	8 tablets	4 tablets‡	NA
10 mg/300 mg tablet	65990002200333	6 tablets	3 tablets‡	NA
10 mg/325 mg tablet[a]	65990002200335	6 tablets	3 tablets‡	NA
10 mg/300 mg/5 mL solution	65990002202020	30 mL	15 mL‡	NA
5 mg/325 mg/5 mL solution	65990002202005	60 mL	30 mL‡	NA
Oxycodone/Ibuprofen				
5 mg/400 mg tablet	65990002260320	4 tablets	6 tablets‡	NA
pentazocine/naloxone[a]				
50 mg/0.5 mg tablet	65200040300310	12 tablets	2 tablets‡	NA
Seglentis (celecoxib/tramadol)				
56 mg/44 mg tablet	65995002100320	4 tablets	13 tablets‡	≥18 years
Ultracet (tramadol/acetaminophen)[a]				
37.5 mg/325 mg tablet	65995002200320	8 tablets	7 tablets	≥18 years

a - generic available

b - all target agents are subject to a ≤ 7 days of therapy and <50 morphine milligram equivalents per day if no prior opioid or oncology claims are found in the past 120 days

* - product minimum dosage strength surpasses 50 MME

‡ - quantity for being under 50 MME per day may exceed dosing limit of other ingredients in the combination product

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

1. The request exceeds the 7 day supply limit and/or the 50 morphine milligram equivalent per day limit AND ALL of the following:
    A. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
    AND
    B. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
        i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
        OR
        ii. The patient is 18 years of age or over
    AND
    C. ONE of the following:
        i. The requested quantity (dose) does NOT exceed the program daily quantity limit AND ONE of the following:
            a. There is information that the patient is NOT new to opioid therapy in the past 120 days

OR

b. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed

OR

c. The patient has a claim for an oncology agent in the past 120 days

OR

d. BOTH of the following:

1. ONE of the following:

A. The patient has a diagnosis of chronic cancer pain due to an active malignancy

OR

B. The patient is eligible for hospice OR palliative care

OR

C. The patient has a diagnosis of sickle cell disease

OR

D. The patient is undergoing treatment of non-cancer pain and ALL of the following:

i. The prescriber has provided information in support of use of immediate-release single or combination opioids for an extended duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day

AND

ii. A formal, consultative evaluation which includes BOTH of the following was conducted:

a. Diagnosis

AND

b. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

AND

iii. A patient-specific pain management plan is on file for the patient

AND

iv. The prescriber has reviewed the patient's records in the state's prescribing drug monitoring program (PDMP) **AND** has determined that the opioid dosage and combinations within the patient's records do NOT indicate the patient is at high risk for overdose

AND

2. ONE of the following:

A. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

OR

B. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

OR

ii. The requested quantity (dose) exceeds the program daily quantity limit AND ALL of the following:

a. ONE of the following:

1. There is information that the patient is NOT new to opioid therapy in the past 120 days

OR

2. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed

OR

3. The patient has a claim for an oncology agent in the past 120 days

OR

4. The prescriber has provided information in support of use of immediate-release single or combination opioids for an extended duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day

AND

b. ONE of the following:
    1. The patient has a diagnosis of chronic cancer pain due to an active malignancy
    OR
    2. The patient is eligible for hospice OR palliative care
    OR
    3. The patient has a diagnosis of sickle cell disease
    OR
    4. The patient is undergoing treatment of non-cancer pain and ALL of the following:
        A. A formal, consultative evaluation which includes BOTH of the following was conducted:
            i. Diagnosis
            AND
            ii. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
        AND
        B. A patient-specific pain management plan is on file for the patient
        AND
        C. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations within the patient's records do NOT indicate the patient is at high risk for overdose

AND

c. ONE of the following:
    1. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
    OR
    2. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

AND

d. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
AND
e. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

2. The request does NOT exceed the 7 day supply limit nor the 50 morphine milligram equivalent per day limit; but the requested dose exceeds the program quantity daily limit AND ALL of the following:
    A. ONE of the following:
        i. The patient has a diagnosis of chronic cancer pain due to an active malignancy
        OR
        ii. The patient is eligible for hospice OR palliative care
        OR
        iii. The patient has a diagnosis of sickle cell disease
        OR
        iv. The patient is undergoing treatment of non-cancer pain and ALL of the following:
            a. A formal, consultative evaluation which includes BOTH of the following was conducted:

1. Diagnosis
   AND
2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

AND

b. A patient-specific pain management plan is on file for the patient
   AND
c. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations within the patient's records do NOT indicate the patient is at high risk for overdose

AND

B. ONE of the following:
   i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
      OR
   ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

AND

C. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
   AND
D. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
   i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
      OR
   ii. The patient is 18 years of age or over

AND

E. BOTH of the following:
   i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
      AND
   ii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

3. The request does NOT exceed the 7 day supply limit nor the 50 morphine milligram equivalent per day limit nor the program quantity daily limit AND the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
   A. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
      OR
   B. The patient is 18 years of age or over

Length of Approval: 6 months

• Program Summary: Rezurock (belumosudil)

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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
99398510500320	Rezurock	Belumosudil Mesylate Tab	200 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy**: Rezurock 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has chronic graft-versus-host disease (chronic GVHD) **AND** 2. The patient has failed at least two prior lines of systemic therapy **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, oncologist) or 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 therapy with 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 Review process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, oncologist) or 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

Module	Clinical Criteria for Approval
	Length of Approval: 12 months Note: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Topical Actinic Keratosis, Basal Cell Carcinoma, Genital Warts Agents

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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
90374035304020		Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	300	Grams	90	DAYS				
90773040003720	Aldara	Imiquimod Cream 5%	5 %	48	Packets	112	DAYS				
90372030003705	Carac	Fluorouracil Cream 0.5%	0.5 %	30	Grams	28	DAYS				
90372030003730	Efudex	Fluorouracil Cream 5%	5 %	240	Grams	84	DAYS				
90372030003710	Fluoroplex	Fluorouracil Cream 1%	1 %	60	Grams	42	DAYS				
90374580004220	Klisyri	Tirbanibulin Ointment	1 %	5	Packets	90	DAYS				
90372030003725	Tolak	Fluorouracil Cream 4%	4 %	40	Grams	28	DAYS				
90773040003715	Zyclara; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	56	Grams	56	DAYS				
90773040003710	Zyclara pump	Imiquimod Cream 2.5%	2.5 %	2	Bottles	42	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
Prior Authorization with Quantity Limit							
90374035304020		Diclofenac Sodium (Actinic Keratoses) Gel 3%	3%	Actinic keratoses: one 100 gram tube per month for up to 90 days			
90773040003720	Aldara	Imiquimod Cream 5%	5%	Actinic keratoses: three boxes (36 packets) for up to 16 weeks External genital and perianal warts (EGW) (condyloma acuminata): 12 packets per month for up to 16 weeks Superficial basal cell carcinoma: three boxes (36 packets) for up to 6 weeks			
90372030003705	Carac	Fluorouracil Cream 0.5%	0.5%	Multiple actinic or solar keratoses: one 30 gram tube per month for up to 4 weeks			
90372030003730	Efudex	Fluorouracil Cream 5%	5%	Multiple actinic or solar keratoses: one 40 gram tube per month for up to 4 weeks Superficial basal cell carcinomas: two 40 gram tubes per month for up to 12 weeks			
90372030003710	Fluoroplex	Fluorouracil Cream 1%	1%	Multiple actinic or solar keratoses: one 30 gram tube per month for up to 6 weeks			
90374580004220	Klisyri	Tirbanibulin Ointment	1%	Actinic keratoses (face or scalp): 5 packets for up to 90 days			
90372030003725	Tolak	Fluorouracil Cream 4%	4%	Actinic keratoses: one 40 gram tube per month for up to 4 weeks			
90773040003715	Zyclara; Zyclara pump	Imiquimod Cream 3.75%	3.75%	Actinic keratoses: two boxes (56 packets) for up to 6 weeks two 7.5 gm pump bottles for up to 6 weeks External genital or perianal warts (EGW) (condyloma acuminata): two boxes (56 packets) for up to 8 weeks two 7.5 gm pump bottles for up to 8 weeks			
90773040003710	Zyclara pump	Imiquimod Cream 2.5%	2.5%	Actinic keratoses: two 7.5 gm pump bottles for up to 6 weeks			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Prior Authorization with Quantity Limit	**Evaluation** **Effective 5/1/24 for:** **Those who were approved after 5/1/24** **Those who have started a new plan year since last authorization** **Target Agent(s)** will be approved when ALL of the following are met: 1. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses of the face and/or scalp: **AND** 2. The requested agent is diclofenac 3% gel, Carac (Fluorouracil) 0.5% cream, Efudex

Module	Clinical Criteria for Approval
	(Fluorouracil) 5% cream, Fluoroplex, Tolak, Aldara, Zyclara (Imiquimod) 3.75% cream, Zyclara 2.5% cream, OR Klisyri **OR** B. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses of the trunk and/or extremities: **AND** 2. The requested agent is diclofenac 3% gel, Efudex (Fluorouracil) 5% cream, OR Fluoroplex **OR** C. BOTH of the following: 1. The patient has a diagnosis of superficial basal cell carcinoma **AND** 2. The requested agent is Aldara OR Efudex (Fluorouracil) 5% cream **OR** D. BOTH of the following: 1. The patient has a diagnosis of external genital and/or perianal warts (EGW) / condyloma acuminata **AND** 2. The requested agent is Aldara OR Zyclara (Imiquimod) 3.75% cream **AND** 3. ONE of the following: A. For a diagnosis of actinic keratoses or superficial basal cell carcinoma, ONE of the following: 1. The patient has tried and had an inadequate response to generic imiquimod 5% cream or fluorouracil solution **OR** 2. The patient has an intolerance or hypersensitivity to therapy with generic imiquimod 5% cream or fluorouracil solution **OR** 3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream AND fluorouracil solution **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 generic imiquimod 5% cream AND fluorouracil solution 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. For a diagnosis of external genital warts, ONE of the following: 1. The patient has tried and had an inadequate response to generic imiquimod 5% cream **OR** 2. The patient has an intolerance of hypersensitivity to therapy with generic imiquimod 5% cream **OR** 3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream **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 generic imiquimod 5% cream 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

Module	Clinical Criteria for Approval
	reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria **Effective until 4/30/25 for:** **Those with an original PA date 5/1/24-4/30/25 seeking reauthorization AND that have not started a new plan year.** **Target Agent(s)** will be approved when ALL of the following are met: 1. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses **AND** 2. The requested agent is diclofenac 3% gel, Carac (Fluorouracil) 0.5% cream, Efudex (Fluorouracil) 5% cream, Fluoroplex, Tolak, Aldara, Zyclara (Imiquimod) 3.75% cream, OR Zyclara 2.5% cream **OR** B. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses of the face and/or scalp: **AND** 2. The requested agent is diclofenac 3% gel, Carac (Fluorouracil) 0.5% cream, Efudex (Fluorouracil) 5% cream, Fluoroplex, Tolak, Aldara, Zyclara (Imiquimod) 3.75% cream, Zyclara 2.5% cream, OR Klisyri **OR** C. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses of the trunk and/or extremities: **AND** 2. The requested agent is diclofenac 3% gel, Efudex (Fluorouracil) 5% cream, OR Fluoroplex **OR** D. BOTH of the following: 1. The patient has a diagnosis of superficial basal cell carcinoma **AND** 2. The requested agent is Aldara OR Efudex (Fluorouracil) 5% cream **OR** E. BOTH of the following: 1. The patient has a diagnosis of external genital and/or perianal warts (EGW) / condyloma acuminata **AND** 2. The requested agent is Aldara OR Zyclara (Imiquimod) 3.75% cream **AND** 3. ONE of the following: A. For a diagnosis of actinic keratoses or superficial basal cell carcinoma, ONE of the following: 1. The patient has tried and had an inadequate response to generic imiquimod 5% cream or fluorouracil solution **OR** 2. The patient has an intolerance or hypersensitivity to therapy with generic imiquimod 5% cream or fluorouracil solution **OR** 3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream AND fluorouracil solution **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval
	B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that generic imiquimod 5% cream AND fluorouracil solution 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. For a diagnosis of external genital warts, ONE of the following: 1. The patient has tried and had an inadequate response to generic imiquimod 5% cream **OR** 2. The patient has an intolerance of hypersensitivity to therapy with generic imiquimod 5% cream **OR** 3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream **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 generic imiquimod 5% cream cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 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 Standalone	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) and/or duration does NOT exceed the program quantity limit for the requested indication **OR** 2. Information has been provided to support therapy with the requested quantity (dose) and/or duration of therapy for the requested indication **Length of Approval:** up to 12 months
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) and/or duration does NOT exceed the program quantity limit for the requested indication **OR** 2. Information has been provided to support therapy with the requested quantity (dose) and/or

Module	Clinical Criteria for Approval
	duration of therapy for the requested indication **Length of Approval:** Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 12 months

• Program Summary: Topical Non-Steroidal Anti-Inflammatory Drugs (NSAID)

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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
90210030302025		Diclofenac Sodium Soln 1.5%	1.5%	2	Bottles	30	DAYS				
90210030205920	Flector	Diclofenac Epolamine Patch 1.3%	1.3%	60	Patches	30	DAYS				
90210030208520	Licart	Diclofenac Epolamine Patch 24HR 1.3%	1.3%	30	Patches	30	DAYS				
90210030302030	Pennsaid	Diclofenac Sodium Soln 2%	2%	2	Bottles	30	DAYS				
90210030304020	Voltaren	Diclofenac Sodium Gel 1%	1%	10	Tubes	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENTS -a **Flector®, Diclofenac Epolamine Patch** **Licart™** (diclofenac topical system) **Pennsaid® 2%** (diclofenac solution) -b **Voltaren Gel®** (diclofenac gel 1%) -b a – diclofenac solution 1.5% available as generic; included as a prerequisite in the step therapy program b – generic available; included as a prerequisite in the step therapy program **Target Agents** will be approved when ONE of the following are met: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history includes use of a generic topical NSAID (non-steroidal anti-inflammatory drug) agent as indicated by: A. Evidence of a paid claim(s) **OR** B. The prescriber stated that the patient has tried a generic topical NSAID agent **AND** the generic topical NSAID agent was discontinued due to lack of effectiveness or an adverse event **OR** 3. The prescriber has provided documentation that ALL generic topical NSAID 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

Module	Clinical Criteria for Approval
	or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. Information has been provided that fulfills the criteria listed under the "Allowed exception cases/diagnoses" (if applicable) **OR** 3. 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. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Xolair (omalizumab)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	446030600021	Xolair	omalizumab for inj	150 MG	M; N; O; Y				
	4460306000E5	Xolair	omalizumab subcutaneous soln prefilled syringe	150 MG/ML; 75 MG/0.5ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** No Target Agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: 1. ONE of the following: A. The patient is 6 to less than 12 years of age AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 1300 IU/mL **AND** 2. The patient's weight is 20 kg to 150 kg **OR** B. The patient is 12 years of age or over AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 700 IU/mL **AND** 2. The patient's weight is 30 kg to 150 kg **AND** 2. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen **AND** 3. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **AND** 4. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **OR** C. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND ALL of the following: 1. The patient has had over 6 weeks of hives and itching **AND**

Module	Clinical Criteria for Approval
	2. If the patient is currently being treated with medications known to cause or worsen urticaria, then ONE of the following: A. The prescriber has reduced the dose or discontinued any medications known to cause or worsen urticaria (e.g., NSAIDs) **OR** B. The prescriber has provided information indicating that a reduced dose or discontinuation of any medications known to cause or worsen urticaria is not appropriate **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to the FDA labeled maximum dose of a second-generation H-1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) **AND** ONE of the following: 1. The patient has tried and had an inadequate response to a dose titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** 2. The prescriber has provided information indicating the patient cannot be treated with a dose titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** B. The patient has an intolerance or hypersensitivity to second-generation H-1 antihistamine therapy **OR** C. The patient has an FDA labeled contraindication to ALL second-generation H-1 antihistamines **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 second-generation H-1 antihistamines cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The requested dose is within FDA labeled dosing for the requested indication AND does NOT exceed 300 mg every 4 weeks **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain **AND** 2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND** 3. There is information indicating the patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR** B. Computed tomography (CT) of the sinuses **AND** 4. The requested dose is based on the patient's pretreatment serum IgE level and body

Module	Clinical Criteria for Approval
	weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR** E. The patient has another FDA approved indication for the requested agent AND the requested dose is within FDA labeled dosing for the requested indication **OR** F. The patient has another indication that is supported in compendia for the requested agent AND the requested dose is supported in compendia for the requested indication **AND** 2. If the patient has a diagnosis of moderate to severe persistent asthma, ALL of the following: A. ONE of the following: 1. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** 2. The patient is currently being treated with the requested agent AND ONE of the following: A. Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **OR** B. Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** 3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **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 inhaled corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient is currently being treated for at least 3 months with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. Long-acting muscarinic antagonist (LAMA) **OR** C. A Leukotriene receptor antagonist (LTRA) **OR** D. Theophylline **OR** 2. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), long-acting muscarinic antagonists (LAMA), leukotriene receptor antagonist (LTRA), or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **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 long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction,

Module	Clinical Criteria for Approval
	decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 3. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** 2. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** 3. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **AND** B. BOTH of the following: 1. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 6 months for asthma, chronic idiopathic urticaria, and nasal polyps 12 months for all other indications **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. Increase in percent predicted Forced Expiratory Volume (FEV_1) **OR** B. Decrease in the dose of inhaled corticosteroid required to control the patient's

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	asthma **OR** C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. Decrease in the number of hospitalizations, need for mechanical ventilation, or visits to the emergency room or urgent care due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with standard therapy [i.e., inhaled corticosteroids (ICS), ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **AND** 3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **OR** B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing for the requested indication AND does NOT exceed 300 mg every 4 weeks **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** 3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR** D. The patient has another FDA approved indication for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing for the requested indication **OR** E. The patient has another indication that is supported in compendia for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is supported in compendia for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months

CONTRAINDICATION AGENTS

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

Contraindicated as Concomitant Therapy
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)