COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: July 15, 2024 Notification Posted: June 1, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for July 15, 2024

POLICIES REVISED

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

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

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

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

Objective

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

EXCEPTION CRITERIA FOR APPROVAL

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

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

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

AND

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

     AND

ii. The member's benefit includes ACA Preventive Care for the category requested
AND
iii. ONE of the following:
a. The requested agent is a contraception agent **AND** BOTH of the following:
1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
AND
2. The requested agent is being used for contraception
OR
b. BOTH of the following:
1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
OR
B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
OR
C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent
AND
2. ONE of the following:
A. The requested agent is an aspirin agent **AND** ALL of the following:
i. The requested agent is the 81 mg strength aspirin
AND
ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
AND
iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation
OR
B. The requested agent is a bowel prep agent **AND** ALL of the following:
i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
AND
ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
AND
iii. The patient is 45 years of age or over
OR
C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
AND
ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
AND
iii. The patient is 35 years of age or over
AND
iv. The agent is requested for the primary prevention of breast cancer
OR
D. The requested agent is a fluoride supplement **AND** BOTH of the following:

i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
AND
ii. The patient is 6 months to 16 years of age

OR

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

OR

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

OR

b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir alafenamide and emtricitabine combination ingredient agent, or cabotegravir is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
AND
iii. The patient is at high risk of HIV infection
AND
iv. The patient has recently tested negative for HIV

OR

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

OR

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

ii. The patient is under 12 months of age

AND

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

OR

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

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

AND

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

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

OR

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

OR

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

OR

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

OR

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

OR

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

OR

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

OR

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

OR

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

AND

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

AND

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

AND

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

a. Dyslipidemia

OR

b. Diabetes

OR

c. Hypertension

OR

d. Smoking

AND

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

OR

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

i. The patient is a non-pregnant adult

AND

ii. 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*

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
(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

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

OR

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

OR

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

    AND

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

    AND

    3. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
            OR
            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
            OR
            iii. Emtricitabine 200 mg single ingredient agent (Emtriva)

OR

iv. Raltegravir 400 mg single ingredient agent (Isentress)

OR

v. Dolutegravir 50 mg single ingredient agent (Tivicay)

OR

vi. Darunavir 800 mg single ingredient agent (Prezista)

OR

vii. Ritonavir 100 mg single ingredient agent (Norvir)

OR

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

AND

4. The patient is at high risk of HIV infection

AND

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

OR

i. BOTH of the following:

1. The requested agent is for ONE of the following:

A. Weight loss agent that will not be used for weight loss

OR

B. Infertility agent that will not be used for infertility

OR

C. Coverage Delay Agent

AND

2. BOTH of the following:

A. ONE of the following:

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

OR

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

OR

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

AND

B. ONE of the following:

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

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

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

AND

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

OR

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

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

AND

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

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

         OR

         b. BOTH of the following:

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

OR

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

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

HIV PEP Length of Approval:
- 12 months
- Apply $0 copay if HIV PEP criteria met

Coverage Exception Length of Approval: 12 months

• Program Summary: Coverage Exception with Quantity Limit - Health Insurance Marketplace (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.

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

Objective

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

EXCEPTION CRITERIA FOR APPROVAL

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

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

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

   AND
2. ONE of the following:

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

      OR

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

         AND

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

            OR

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

            OR

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

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

OR

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

OR

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

OR

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

      OR

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

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

OR

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

OR

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

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

OR

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

AND
iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)
AND
iv. The patient is 40-75 years of age (inclusive)
AND
v. The patient has at least one of the following risk factors:
a. Dyslipidemia
OR
b. Diabetes
OR
c. Hypertension
OR
d. Smoking

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

OR

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

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

OR

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

OR

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

AND

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

OR

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

Excluded from Coverage on the Pharmacy Benefit
Alcohol Swabs
Blood Component (not including Hemophilia Factor)
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration*
Diagnostic Agents (not including glucose test strips)
Dietary and Herbal Supplements
General Anesthetic
Infertility Agents*

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

*Category specific denial reasons apply

AND

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

   OR

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

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

OR

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

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

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

OR

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

OR

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

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

OR

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

OR

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

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

OR

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

OR

i. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP and ALL of the following:
    1. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents

       AND
    2. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)

               OR
            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)

               OR
            iii. Emtricitabine 200 mg single ingredient agent (Emtriva)

               OR
            iv. Raltegravir 400 mg single ingredient agent (Isentress)

               OR
            v. Dolutegravir 50 mg single ingredient agent (Tivicay)

               OR
            vi. Darunavir 800 mg single ingredient agent (Prezista)

               OR

vii. Ritonavir 100 mg single ingredient agent (Norvir)

OR

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

AND

3. The patient is at high risk of HIV infection

AND

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

OR

j. ONE of the following:

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

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

OR

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

OR

3. BOTH of the following:

A. ONE of the following:

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

OR

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

OR

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

AND

B. ONE of the following:

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

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

1. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent

OR

2. The prescriber has provided information stating that ALL available formulary (any formulary tier)

generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

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

OR

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

OR

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

AND

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

AND

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

AND

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

            OR

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

strength that does not exceed the program quantity limit

OR

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

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

HIV PEP Length of Approval:
- 12 months
- Apply $0 copay if HIV PEP criteria is met

Coverage Exception Length of Approval: 12 months

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

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

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

Objective

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

EXCEPTION CRITERIA FOR APPROVAL

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

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

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

AND

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

AND

2. The requested agent is being used for contraception

OR

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

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

        OR

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

        OR

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

        OR

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

        OR

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

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

OR

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

OR

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

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

OR

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

OR

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

OR

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

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

AND

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

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

OR

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

OR

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

OR

a. 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

Excluded from Coverage on the Pharmacy Benefit
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

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

OR

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

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

    AND

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

    AND

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

        OR

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

AND

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

OR

i. BOTH of the following:
   1. 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 ointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

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

Coverage Exception Length of Approval: 12 months

• Program Summary: Saxenda Wegovy Zepbound – Coverage & Formulary Exception with Quantity Limit *(f.k.a. Anti-Obesity GLP-1 Agents)*

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

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, and GenRx Open for weight loss agents on coverage delay.

TARGET AGENT(S)

Saxenda® (liraglutide)
Wegovy™ (semaglutide)
Zepbound™ (tirzepatide)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Saxenda (liraglutide)			
6 mg/mL, 3 mL/pen	6125205000D220	M, N, O, or Y	0.5 mL
Wegovy (semaglutide)			
0.25 mg/0.5 mL pen*	6125207000D520	M, N, O, or Y	8 pens (4 mL)/180 days
0.5 mg/0.5 mL pen*	6125207000D525	M, N, O, or Y	8 pens (4 mL)/180 days
1 mg/0.5 mL pen*	6125207000D530	M, N, O, or Y	8 pens (4 mL)/180 days
1.7 mg/0.75 mL pen	6125207000D535	M, N, O, or Y	4 pens (3 mL)/28 days
2.4 mg/0.75 mL pen	6125207000D540	M, N, O, or Y	4 pens (3 mL)/28 days
Zepbound (tirzepatide)			
2.5 mg/0.5 mL pen*	6125258000D520	M, N, O, or Y	4 pens (2 mL)/180 days
5 mg/0.5 mL pen	6125258000D525	M, N, O, or Y	4 pens (2 mL)/28 days
7.5 mg/0.5 mL pen	6125258000D530	M, N, O, or Y	4 pens (2 mL)/28 days
10 mg/0.5 mL pen	6125258000D535	M, N, O, or Y	4 pens (2 mL)/28 days
12.5 mg/0.5 mL pen	6125258000D540	M, N, O, or Y	4 pens (2 mL)/28 days
15 mg/0.5 mL pen	6125258000D545	M, N, O, or Y	4 pens (2 mL)/28 days

* - These strengths are not approvable for maintenance dosing

COVERAGE EXCEPTION AND FORMULARY EXCEPTION CRITERIA FOR APPROVAL

Initial Evaluation

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

1. ALL of the following:
    A. ONE of the following:
        i. The patient's requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:
            a. The requested agent and strength have an FDA labeled indication for the requested diagnosis and route of administration **AND**
            b. The patient has a history of ONE of the following: (medical records required)
                1. Myocardial infarction **OR**
                2. Stroke **OR**
                3. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND**
            c. The patient has a BMI greater than or equal to 27 kg/m^2 **AND**
            d. The patient does NOT have type 2 diabetes **AND**
            e. The patient's age is 45 years or over **AND**
            f. ONE of the following:
                1. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR**
                2. The patient is being managed for tobacco cessation **AND**
            g. ALL of the following:
                1. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND**
                2. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
                3. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any statin, ezetimibe) **AND**

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

ii. The patient is overweight or obese and is using the requested agent for weight management AND ALL of the following:
   a. Weight loss is NOT excluded from coverage under the patient's pharmacy benefit **AND**
   b. The patient is new to therapy, new to Prime, or attempting a repeat weight loss course of therapy **AND**
   c. ONE of the following:
      1. The patient is 17 years of age or over and has ONE of the following:
         A. A BMI greater than or equal to 30 kg/m^2 **OR**
         B. A BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR**
         C. A BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., hypertension, type 2 diabetes mellitus, obstructive sleep apnea, cardiovascular disease, dyslipidemia) **OR**
      2. The patient is 12 to 16 years of age and has ONE of the following:
         A. A BMI greater than or equal to 95th percentile for age and sex **OR**
         B. A BMI greater than or equal to 30 kg/m^2 **OR**
         C. A BMI greater than or equal to 85th percentile for age and sex AND at least one severe weight-related comorbidity/risk factor/complication **AND**
   d. BOTH of the following:
      1. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months from baseline (prior to initiation of pharmacotherapy) **AND**
      2. The patient has experienced weight loss of less than 1 pound per week while on a weight loss regimen from baseline (prior to initiation of pharmacotherapy) **AND**
   e. If the requested agent is Saxenda, then ONE of the following:
      1. The patient is 18 years of age or over AND ONE of the following:
         A. The patient is newly starting therapy **OR**
         B. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**
         C. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR**
      2. The patient is pediatric (12 to less than 18 years of age) AND BOTH of the following:
         A. The requested agent is NOT being used to treat type 2 diabetes **AND**
         B. ONE of the following:
            i. The patient is newly starting therapy **OR**
            ii. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR**
            iii. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **AND**
   f. If the requested agent is Wegovy, then ONE of the following:
      1. The patient is newly starting therapy **OR**
      2. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**
      3. ONE of the following:
         A. The patient is an adult AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
         B. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **AND**
   g. If the requested agent is Zepbound, then ONE of the following:

1. The patient is newly starting therapy **OR**
2. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**
3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**

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

B. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND**

C. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**

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

E. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**

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

2. ONE of the following:
   A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives **OR**
   B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm **AND**
3. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
   B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
      i. BOTH of the following:
         a. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**
         b. There is support for therapy with a higher dose for the requested indication **OR**
      ii. BOTH of the following:
         a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
         b. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR**
      iii. BOTH of the following:
         a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**
         b. There is support for therapy with a higher dose for the requested indication

Length of Approval:

- For Wegovy, Zepbound: 12 months
- For Saxenda: Pediatric patients (age 12 to less than 18): 5 months; Adults: 4 months

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ALL of the following:
   A. ONE of the following:
      i. The patient's requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular

disease (medical records required) and the patient is either obese or overweight AND ALL of the following:

a. The requested agent and strength have an FDA labeled indication for the requested diagnosis and route of administration **AND**
b. The patient has a history of ONE of the following: (medical records required)
    1. Myocardial infarction **OR**
    2. Stroke **OR**
    3. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND**
c. The patient does NOT have type 2 diabetes **AND**
d. ONE of the following:
    1. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR**
    2. The patient is being managed for tobacco cessation **AND**
e. ALL of the following:
    1. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND**
    2. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
    3. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
f. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR**

ii. The patient is overweight or obese and is using the requested agent for weight management AND ALL of the following:

a. Weight loss is NOT excluded from coverage under the patient's pharmacy benefit **AND**
b. The patient is continuing a current weight loss course of therapy **AND**
c. If the patient is 12 to less than 18 years of age, then the current BMI is greater than 85th percentile for age and sex **AND**
d. If the requested agent is Saxenda, then BOTH of the following:
    1. The requested agent is NOT being used to treat type 2 diabetes **AND**
    2. ONE of the following:
        A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
        B. If the patient is 18 years of age or over, the patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR**
        C. If the patient is pediatric (12 to less than 18 years of age), the patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **AND**
e. If the requested agent is Wegovy, then BOTH of the following:
    1. The requested dose is 1.7 mg or 2.4 mg **AND**
    2. ONE of the following:
        A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
        B. The patient is 12 years of age and over AND has received less than 52 weeks of therapy on the maximum-tolerated dose **OR**
        C. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **AND**
f. If the requested agent is Zepbound, then ONE of the following:

1. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
2. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose **OR**

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

B. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND**
C. The patient is currently on and will continue to be on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**
D. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**
E. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

3. ONE of the following:
   A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives **OR**
   B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm **AND**
4. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
   B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
      i. BOTH of the following:
         a. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**
         b. There is support for therapy with a higher dose for the requested indication **OR**
      ii. BOTH of the following:
         a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
         b. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR**
      iii. BOTH of the following:
         a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**
         b. There is support for therapy with a higher dose for the requested indication

Length of Approval: 12 months