



Commercial Coverage Exception with Quantity Limit Program Summary

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 BOTH** of the following:
 1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
AND
 2. The requested agent is being used for contraception
OR
 - b. BOTH of the following:
 1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
 - A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
OR
 - B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
OR
 - C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

AND

2. ONE of the following:
- A. The requested agent is an aspirin agent **AND** ALL of the following:
 - i. The requested agent is the 81 mg strength aspirin
AND
 - ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
AND
 - iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation
 - OR**
 - B. The requested agent is a bowel prep agent **AND** ALL of the following:
 - i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
AND
 - ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
AND
 - iii. The patient is 45 years of age or over
 - OR**
 - C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
 - i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
AND
 - ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
AND
 - iii. The patient is 35 years of age or over
AND
 - iv. The agent is requested for the primary prevention of breast cancer
 - OR**
 - D. The requested agent is a fluoride supplement **AND** BOTH of the following:
 - i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
AND
 - ii. The patient is 6 months to 16 years of age
 - OR**
 - E. The requested agent is a folic acid agent **AND** ALL of the following:
 - i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
AND

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

AND

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

OR

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

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

AND

ii.ONE of the following:

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

1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent

OR

2. Tenofovir alafenamide and emtricitabine combination ingredient agent

OR

3. Cabotegravir

OR

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

AND

iii.The patient is at high risk of HIV infection

AND

iv.The patient has recently tested negative for HIV

OR

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

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

AND

ii.The patient is 3 months of age or younger

AND

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

OR

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

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

AND

ii.The patient is under 12 months of age

AND

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

OR

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

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

AND

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

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

OR

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

OR

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

OR

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

OR

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

OR

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

OR

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

OR

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

OR

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

AND

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

AND

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

AND

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

a. Dyslipidemia

OR

b. Diabetes

OR

c. Hypertension

OR

d. Smoking

AND

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

OR

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

i. The patient is a non-pregnant adult

AND

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

OR

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

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

AND

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

OR

B. ALL of the following:

i. ONE of the following:

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

OR

b. BOTH of the following:

1. ONE of the following:

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

OR

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

AND

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

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
Brand for Generic* Agents with the following reject message: #NDC NOT COVERED, USE XXX#
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration* (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Infertility Agents* (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility)
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RXClaims

<ul style="list-style-type: none"> 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
<p>Non-FDA Approved Agents* (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')</p>
<p>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)</p>
<p>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)</p>
<p>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))</p>
<p>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)</p>
<p>Other</p>

*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
 - 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