Formulary Exception with Quantity Limit Program Summary for FlexRx Formulary and GenRx Formulary

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

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

FORMULARY EXCEPTION CRITERIA FOR APPROVAL
A formulary exception will be granted when the following are met:

1. ONE of the following:
    A. ALL of the following:
        i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
        AND
        ii. The member's benefit includes ACA Preventive Care for the category requested
        AND
        iii. ONE of the following:
            a. The requested agent is a contraception agent **AND** 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 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

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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

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OR

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

OR

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

      OR

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

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

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v. The patient has recently tested negative for HIV

OR

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

OR

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

OR

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

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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

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Committee on Immunization Practices/CDC

OR

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

    AND

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

        OR

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

        OR

        c. The requested agent is Omnipod DASH or Omnipod 5
        OR
        d. 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):

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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

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

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A. The requested agent has formulary alternatives that can be prescribed in a dose to fit the patient's needs AND ONE of the following:
   i. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives, if available, for the diagnosis being treated with the requested agent
   OR
   ii. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

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

OR

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

AND

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

AND

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

OR

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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 ACA criteria met

Formulary Exception Length of Approval: 12 months

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