



# NetResults (KeyRx and FocusRx) Coverage Exception with Quantity Limit Program Summary

## **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)

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

**AND**

2. ONE of the following:
  - A. ALL of the following:
    - i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category  
**AND**
    - ii. The member's benefit includes ACA Preventive Care for the category requested  
**AND**
    - iii. ONE of the following:
      - a. The requested agent is a contraception agent **AND** BOTH of the following:
        1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary  
**AND**
        2. The requested agent is being used for contraception  
**OR**
      - b. BOTH of the following:
        1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
          - A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent  
**OR**

- B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent  
**OR**
- C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

**AND**

2. ONE of the following:

- A. The requested agent is an aspirin agent **AND** ALL of the following:

- i. The requested agent is the 81 mg strength aspirin

**AND**

- ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary

**AND**

- iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

**OR**

- B. The requested agent is a bowel prep agent **AND** ALL of the following:

- i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary

**AND**

- ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy

**AND**

- iii. The patient is 45 years of age or over

**OR**

- C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:

- i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary

**AND**

- ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)

**AND**

- iii. The patient is 35 years of age or over

**AND**

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

**OR**

- D. The requested agent is a fluoride supplement **AND** BOTH of the following:
- i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
- AND**
- ii. The patient is 6 months to 16 years of age
- OR**
- E. The requested agent is a folic acid agent **AND** ALL of the following:
- i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
- AND**
- ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
- AND**
- iii. The requested folic acid supplement is to be used in support of pregnancy
- OR**
- F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PrEP **AND** ALL of the following:
- i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
- AND**
- ii. ONE of the following:
    - a. The requested PrEP agent is ONE of the following:
      - 1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent

**OR**

      - 2. Tenofovir alafenamide and emtricitabine combination ingredient agent

**OR**

      - 3. Cabotegravir

**OR**

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

**AND**

iii. The patient is at high risk of HIV infection

**AND**

iv. The patient has recently tested negative for HIV

**OR**

G. The requested agent is an infant eye ointment

**AND** ALL of the following:

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

**AND**

ii. The patient is 3 months of age or younger

**AND**

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

**OR**

H. The requested agent is an iron supplement **AND**

ALL of the following:

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

**AND**

ii. The patient is under 12 months of age

**AND**

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

**OR**

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

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

**AND**

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

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

**OR**

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

**OR**

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

**OR**

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

**OR**

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

**AND**

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

**AND**

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

**AND**

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

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

**AND**

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

**OR**

J. The requested agent is a tobacco cessation agent

**AND BOTH** of the following:

i. The patient is a non-pregnant adult

**AND**

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

**OR**

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

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

**AND**

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

**OR**

B. ALL of the following:

i. ONE of the following:

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

**OR**

b. BOTH of the following:

1. ONE of the following:

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

**OR**

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

**AND**

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

<b>Excluded from Coverage on the Pharmacy Benefit</b>
<b>AHFS (devices and pharmaceutical aids, not including needles, syringes, lancets, CGM/sensor/transmitter/receiver)</b> (Defined as those products containing the AHFS code 940000000 (DEVICES) and/ or 960000000 (PHARMACEUTICAL AIDS) in the product file in RxClaim)
<b>Brand for Generic*</b> Agents with the following reject message: #NDC NOT COVERED, USE XXX#
<b>Bulk Powders*</b> (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
<b>Clinic Packs*</b> (Y in the Clinic Pack field)
<b>Cosmetic Alteration*</b> (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
<b>Diagnostic Agents (not including glucose test strips)</b> (Defined as those products containing the third-party restriction code of 5 (DIAGNOSTIC AGENT) in the product file in RxClaim)
<b>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)</b> [See MN NDC Lock Out List NetResults]
<b>General Anesthetics</b> (Defined as those products containing the third-party restriction code of 6 (GENERAL ANESTHETIC) in the product file in RxClaim)
<b>Infertility Agents*</b> (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)
<b>Injectable drugs not on covered drug list, not including the drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx</b>

(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".)
<p><b>Institutional Packs*</b></p> <p>Those that contain any one of the following modifier codes in the product file in RXClaims</p> <ul style="list-style-type: none"> <li>i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK</li> <li>ii. MODIFIER BBAD9A INSTITUTIONAL</li> <li>iii. MODIFIER TTAAJQ INSTITUTIONAL</li> <li>iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY</li> <li>v. MODIFIER AAAB9A HOSPITAL PACK</li> <li>vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE)</li> <li>vii. MODIFER AAAD6T HOSPITAL USE ONLY</li> </ul>
<b>Investigative, experimental, or not medically necessary</b>
<p><b>Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver)</b></p> <p>(Defined by GPI 97*****)</p>
<p><b>Medical devices approved through a different FDA-approval process than drugs</b></p> <p>(Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)</p>
<p><b>Non-FDA Approved Agents*</b></p> <p>(Refer all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')</p>
<p><b>Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes)</b></p> <p>(Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)</p>
<p><b>Repackagers (not including Veterans Administration and Department of Defense Claims)*</b></p> <p>(Defined as indicated as Y in Repkg code field in the product file in RxClaim)</p>
<p><b>RX drugs with OTC Equivalent (Excluded categories listed below)</b></p> <p>(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.</p> <p>Rx drugs with OTC alternatives where the Rx drug category will be excluded:</p> <ul style="list-style-type: none"> <li>1. Omega-3 Fatty Acids (GPI 39500*****)</li> <li>2. Non-Sedating Antihistamines (GPI 41550*****)</li> <li>3. Topical Antivirals (GPI 90350*****)</li> </ul>
<p><b>Self-Administered Contraceptives*</b> (2510*****, 2540*****, 2596*****, 2597*****, 2599*****, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)</p>
<p><b>Sexual Dysfunction Agents*</b></p> <p>(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><b>Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver)</b></p> <p>(Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)</p>

**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

<b>Allowable Diagnoses</b>
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. 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**