# Health Insurance Marketplace (HIM) Coverage Exception with Quantity Limit Program Summary

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

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

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

**Objective**

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

**EXCEPTION CRITERIA FOR APPROVAL**

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

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

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

**AND**

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

            **OR**

            - b. BOTH of the following:
                1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
                    - A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
                      **OR**

B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent

**OR**

C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

**AND**

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

      **AND**

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

      **AND**

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

   **OR**

   B. The requested agent is a bowel prep agent **AND** ALL of the following:
      i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary

      **AND**

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

      **AND**

      iii. The patient is 45 years of age or over

   **OR**

   C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
      i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary

      **AND**

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

      **AND**

      iii. The patient is 35 years of age or over

      **AND**

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

   **OR**

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

      **AND**

      ii. The patient is 6 months to 16 years of age

**OR**

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

**OR**

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

      **OR**

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

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

**OR**

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

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

**OR**

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

**OR**

I. The requested agent is a statin **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested statin is medically necessary
   **AND**
   ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
      a. Atorvastatin 10-20 mg per day (20 mg tablet)
      **OR**
      b. Fluvastatin 20-80 mg per day (40 mg capsule)
      **OR**
      c. Fluvastatin ER 80 mg per day (80 mg tablet)
      **OR**
      d. Lovastatin 20-40 mg per day (40 mg tablet)
      **OR**
      e. Lovastatin ER 20-40 mg per day (40 mg tablet)
      **OR**
      f. Pitavastatin 1-4 mg per day (4 mg tablet)
      **OR**
      g. Pravastatin 10-80 mg per day (80 mg tablet)
      **OR**
      h. Rosuvastatin 5-10 mg per day (10 mg tablet)
      **OR**
      i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)
   **AND**
   iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)
   **AND**
   iv. The patient is 40-75 years of age (inclusive)
   **AND**
   v. The patient has at least one of the following risk factors:

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

**AND**

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

**OR**

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

**OR**

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

**OR**

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

**AND**

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

Drugs level A, and Clinical Pharmacology) for the requested agent

**AND**

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

**OR**

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

| **Excluded from Coverage on the Pharmacy Benefit** |
|---|
| **Alcohol Swabs** |
| **Blood Component**<br>(not including Hemophilia Factor) |
| **Bulk Powders***<br>(Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim) |
| **Clinic Packs***<br>(Y in the Clinic Pack field) |
| **Cosmetic Alteration*** |
| **Diagnostic Agents** (not including glucose test strips) |
| **Dietary and Herbal Supplements** |
| **General Anesthetic** |
| **Infertility Agents***<br>For the treatment of infertility |
| **Institutional Packs***<br>Those that contain any one of the following modifier codes in the product file in RXClaims<br>i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK<br>ii. MODIFIER BBAD9A INSTITUTIONAL<br>iii. MODIFIER TTAAJQ INSTITUTIONAL<br>iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY<br>v. MODIFIER AAAB9A HOSPITAL PACK<br>vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE)<br>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)**<br>(Defined by GPI 97**********) |
| **Medical devices approved through a different FDA-approval process than drugs**<br>(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***<br>(Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug') |
| **Over-The-Counter Medications***<br>(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)***<br>(Defined as indicated as Y in Repkg code field in the product file in RxClaim) |
| **Self-Administered Contraceptives*** |

| |
|---|
| (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention) |
| **Sexual Dysfunction Agents*** (Addyi, Viagra, Cialis, Levitra, Staxyn, Caverject, Edex, Muse) for treatment of sexual dysfunction |
| **Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver)** (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim) |
| **Syringes other than insulin syringes** |
| **Weight Loss Agents*** (GPI: 6120**********, 6125**********) for the treatment of weight loss |

*Category specific denial reasons apply

**AND**

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

   **OR**

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

   **OR**

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

      **OR**

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

      **OR**

      3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin,

Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent

**OR**

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

**OR**

5. The patient is pregnant

**OR**

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

**OR**

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

    **AND**

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

        **OR**

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

        **OR**

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

**OR**

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

**OR**

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

| Allowable Diagnoses |
|---|
| Acne vulgaris |
| Amenorrhea |
| Dysfunctional uterine bleeding |
| Dysmenorrhea |
| Endometriosis |

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

**OR**

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

**OR**

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

    **AND**

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

            **OR**

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

            **OR**

            iii. Emtricitabine 200 mg single ingredient agent (Emtriva)

            **OR**

            iv. Raltegravir 400 mg single ingredient agent (Isentress)

            **OR**

            v. Dolutegravir 50 mg single ingredient agent (Tivicay)

            **OR**

            vi. Darunavir 800 mg single ingredient agent (Prezista)

            **OR**

            vii. Ritonavir 100 mg single ingredient agent (Norvir)

        **OR**

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

    **AND**

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

**OR**

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

      **OR**
   2. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria
      **OR**
   3. BOTH of the following:
      A. ONE of the following:
         i. The patient has an FDA labeled indication for the requested agent
            **OR**
         ii. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
            **OR**
         iii. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

      **AND**
      B. ONE of the following:
         i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
            a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
               1. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
                  **OR**
               2. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will

cause an adverse reaction or other harm for the patient

**AND**

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

**OR**

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

**OR**

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

**AND**

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

**AND**

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

**AND**

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

            **OR**

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

**OR**

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

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

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

**Coverage Exception Length of Approval:** 12 months