BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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SELZENTRY (maraviroc)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

SELZENTRY (maraviroc)

Criteria:

- **Criteria for initial therapy:** Selzentry (maraviroc) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an HIV/AIDS Specialist or Infectious Disease Specialist

  2. Individual is an adult or a pediatric individual weighing at least 2 kg

  3. A confirmed diagnosis of CCR5-tropic human immunodeficiency virus type-1 (HIV-1)

  4. **ONE** of the following:
     a. Pediatric individual has an HIV-1 viral load of greater than or equal to 1,000 copies/mL despite at least 6-months of prior therapy

     b. Adult individual has an HIV-1 viral load of greater than or equal to 5,000 copies/mL despite at least 6-months of prior therapy

  5. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Individual has been tested for CCR5-tropism using a highly sensitive tropism assay such as Trofile® which reveals the presence of CCR5-tropism

     b. Individual does not have dual/mixed-tropic HIV-1 or CXCR4-tropic HIV-1

     c. Individual does not have HIV-2

  6. Individual will continue to use an optimized background therapy (OBT) consisting of 3-6 antiretroviral agents (excluding low-dose ritonavir) selected based on prior treatment history and baseline genotypic and phenotypic viral resistance measurements

  7. Documented failure, contraindication per FDA label, intolerance, or documented resistance is **ONE** of the following:
     a. Pediatric individual to an agent from at least 2 antiretroviral drug classes
     b. Adult individual in 3 of the 4 following antiretroviral drug classes:
        i. One or more nucleoside reverse transcriptase inhibitors (NRTI)
        ii. One or more non-nucleoside reverse transcriptase inhibitor (NNRTI)
        iii. Two or more protease inhibitor (PI)
        iv. Fuzeon (Enfuvirtide)

  8. There are **NO** FDA-label contraindications, such as:
     a. Severe renal impairment or end-stage renal disease (CrCl less than 30 mL per minute) who are taking potent cytochrome P450 3A inhibitors or potent or moderate P450 3A inducers

  9. There are no significant interacting drugs

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10. **For pediatric individuals only,** both of the following:
    a. Will not be used in a pediatric individual with mild or moderate renal impairment
    b. Will not be used in a pediatric individual with any degree of hepatic impairment

11. **For adult individuals only**:
    a. Will not be used in an adult individual with severe hepatic impairment

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Selzentry (maraviroc) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an HIV/AIDS Specialist or Infectious Disease Specialist

2. Individual's condition has responded while on therapy
    a. Response or Worsening is defined as:
        i. Viral load has remained stable or improved
        ii. CD4+ cell count has remained stable or improved

3. Individual has been adherent with the medication and adherent and continues use of optimized background therapy (OBT)

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy
    b. Significant adverse effect such as:
        i. Hepatotoxicity accompanied by severe rash or systemic allergic reaction
        ii. Severe potentially life-threatening skin and hypersensitivity reactions such as Stevens-Johnson syndrome or toxic epidermal necrolysis
        iii. Myocardial ischemia and/or infarction

5. There are no significant interacting drugs

6. **For pediatric individuals only,** both of the following:
    b. Will not be used in a pediatric individual with mild or moderate renal impairment
    c. Will not be used in a pediatric individual with any degree of hepatic impairment

7. **For adult individuals only**:
    a. Will not be used in an adult individual with severe hepatic impairment

Renewal duration: 12 months

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- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of a Non-Cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Selzentry (maraviroc), a C-C chemokine receptor type 5 (CCR5) co-receptor antagonist, is indicated for combination therapy with other antiretroviral agents for the treatment of only CCR5-tropic human immunodeficiency virus type-1 (HIV-1) infection in adult and pediatric patients weighing at least 2 kg.

HIV enters CD4 cells via the CD4 receptor in combination with one of its co-receptors: the chemokine coreceptor 5 (CCR5) or the CXC chemokine coreceptor 4 (CXCR4). Viruses that use the CCR5 coreceptor are called "R5 viruses," whereas others that use the CXCR4 coreceptor are called "X4 viruses.

Selzentry (maraviroc) is not recommended in patients with dual/mixed-tropic HIV-1 or CXCR4-tropic HIV-1. In both treatment-experienced and treatment-naive subjects, detection of CXCR4-using virus prior to initiation of therapy has been associated with a reduced virologic response to maraviroc. The activity of maraviroc against HIV-2 has not been evaluated.

Trofile® is a phenotypic viral RNA assay that is a commercially available tropism assay that has been used to identify CCR5 antagonist candidates. The purpose of the assay is to identify the tropism of an individual patient's HIV strain: R5, X4, or a combination of these known as dual/mixed (D/M). Pretreatment testing with Trofile® will show whether the patient is infected with virus that enters cells using the R5 co-receptor, the X4 co-receptor, or both (dual/mixed). X4 is also known as CXCR4 tropic virus; R5 as CCR5-tropic virus; and X4R5 dual/mixed. Selzentry (maraviroc) is ineffective against CXCR4 or dual/mixed (targets both CCR5 and CXCR4 pathways) topic HIV strains.

Maraviroc is a member of a therapeutic class called CCR5 co-receptor antagonists. Maraviroc selectively binds to the human chemokine receptor CCR5 present on the cell membrane, preventing the interaction of HIV-1 gp120 and CCR5 necessary for CCR5-tropic HIV-1 to enter cells. CXCR4-tropic and dual-tropic HIV-1 entry is not inhibited by maraviroc.

Definitions:

HIV antiretroviral medications: (not an all-inclusive list)

Non-nucleoside reverse transcriptase inhibitors (NNRTI):

Edurant (rilpivirine, RPV)
Intelence (etravirine, ETR)
Rescriptor (delavidine, DLV)

Sustiva (efavirenz, EFV)
Viramune, Viramune XR (nevirapine, NVP)

Nucleoside reverse transcriptase inhibitors (NRTI):
Combivir (lamivudine+zidovudine)
Emtriva (emtricitabine, FTC)
Epivir (lamivudine, 3TC)
Epzicom (abacavir + lamivudine)
Hivid (zalcitabine, ddC)
Retrovir (zidovudine, AZT or ZDV)
Trizivir (abacavir + lamivudine + zidovudine)
Videx (didanosine [ddI])
Zerit (stavudine, d4T)
Ziagen (abacavir, ABC)

Protease inhibitors (PI):
Aptivus (tipranavir, TPV)
Crixivan (indinavir)
Invirase (saquinavir, SQV)
Lexiva (fosamprenavir, f-APV)
Norvir (ritonavir, RTV)
Prezista (darunavir, DRV)
Reyataz (atazanavir, ATV)
Viracept (nelfinavir, NFV)

Integrase strand transfer inhibitors (INSTI):
Isentress, Isentress HD (raltegravir, RAL)
Tivacay (dolutegravir, DTG)
Vitekta (elvitegravir, EVG)

HIV combination products:
Atripla (efavirenz-emtricitabine-tenofovir disoproxil fumarate)
Biktary (bictegravir-emtricitabine-tenofovir alafenamide fumarate)
Complera (emtricitabine-rilpivrine-tenofovir disoproxil fumarate)
Descovy (emtricitabine-tenofovir alafenamide fumarate)
Evotaz (atazanavir-cobicistat)
Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide fumarate)
Juluca (dolutegravir-rilpivirine)
Kaletra (lopinavir + ritonavir, LPV/r)
Odefsey (emtricitabine-rilpivrine-tenofovir alafenamide fumarate)
Prezcobix (darunavir-cobicistat)
Stribild (elvitegravir-cobicistat-emtricitabine-tenofovir disoproxil fumarate)
Symfi Lo (efavirenz-lamivudine-tenofovir disoproxil fumarate)
Triumeq (abacavir-dolutegravir-lamivudine)
Truvada (emtricitabine-tenofovir disoproxil fumate)

SELZENTRY (maraviroc)

Cellular chemokine receptor (CCR5) antagonist:
Selzentry (maraviroc, MVC)

Boosting agent:
Tybost (cobicistat, COBI)

Resources:

Selzentry (maraviroc) product information, revised by ViiV Healthcare Company 10-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on June 09, 2021.

Fletcher CV. Overview of antiretroviral agents used to treat HIV. In: UpToDate, Sax PE, Mitty J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on June 17, 2021.

Sax PE. Selecting antiretroviral regimens for treatment-naïve persons with HIV-1: General approach. In: UpToDate, Hirsch MS, Mitty J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on June 17, 2021.

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Kozal MJ. Interpretation of HIV drug resistance testing. In: UpToDate, Hirsch MS, Sax PE (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on June 17, 2021.