Pharmacy Benefit Coverage Criteria

Effective Date..... 8/15/2024
Coverage Policy Number P0050

HIV Products

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

This coverage policy addresses the use of HIV Products covered under the pharmacy benefit. The use of intravenous ibalizumab-uiyk is not addressed in this coverage policy.

This policy addresses the following for Employer Group plans: [follow link to section]

I. Medical Necessity Criteria for HIV Products Requiring Prior Authorization
II. Medical Necessity Criteria for Non-Covered HIV Products

I. The list of HIV Products Requiring Prior Authorization is contained within Appendix 1: [follow link to section] **Prior authorization criteria for these products are listed below unless otherwise specified.**

HIV Products are considered medically necessary for the treatment of HIV infection when ANY of the following criteria are met:

- Individual is less than 13 years of age
- Individual is pregnant
- Individual is established on an HIV product
- Individual is not a candidate (for example, drug-drug interactions, drug-disease interactions, resistance) for **FIVE** preferred single tablet complete regimens (multi-ingredient formulations):
  - For example*, Biktarvy, Dovato, efavirenz/lamivudine/tenofovir disoproxil fumarate (generic Symfi/Symfi Lo), Genvoya, Symtuza, Triumeq

***Coverage for products varies across plans. Refer to the customer's benefit plan document for coverage details**

Specific Prior Authorization Criteria apply for the following products:

A. Tenofovir Disoproxil Fumarate (TDF)

I. Tenofovir Disoproxil Fumarate tablet is considered medically necessary when ONE of the following criteria are met:

- Treatment of HIV
- HIV Preexposure Prophylaxis (PrEP)
- HIV Postexposure Prophylaxis (PEP)
- Treatment of Hepatitis B

II. Non-Covered HIV Products (table below):

Employer group plans may adopt a Prescription Drug List that does not cover certain drugs or biologics unless those products are approved based on a medical necessity review. Cigna approves coverage for these drugs or biologics as medically necessary when sufficient information demonstrates that the clinical criteria set forth below are met. Unless otherwise stated, all Covered Alternative Drugs are required prior to the approval of the non-covered drug or biologic.

Non-Covered HIV Products	Standard Drug List Plan Performance Drug List Plan (Not Covered [NC])	Value Drug List Plan Advantage Drug List Plan/Cigna Total Savings Plan (Not Covered [NC])	Legacy Drug List Plan (Prior Auth. [PA] Required)
Atripla	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Atripla		
Combivir®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Combivir		
Crixivan®	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on indinavir sulfate (Crixivan) o Not a candidate for other antiretroviral agents		
darunavir propylene glycolate 600 mg, 800 mg tablet	Criteria is met by the following: • Documented trial of **darunavir ethanolate** (generic for Prezista) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.		
didanosine/didanosine delayed-release	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on didanosine/DR (Videx/Videx EC) o Not a candidate for other antiretroviral agents		
Emtriva capsule	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Emtriva		
Epivir®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Epivir		
Epzicom™	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Epzicom		
Intelence	Criteria is met by the following: Documented intolerance to (1) generic formulation of Intelence		
Kaletra™ oral solution	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Kaletra		

Kaletra™ tablet	
Lexiva™ tablet	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Lexiva
Prezista® 600mg, 800mg tablet	Documented trial of **darunavir tablet** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Norvir®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Norvir
Rescriptor®	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on delavirdine mesylate (Rescriptor) o Not a candidate for other antiretroviral agents
Retrovir® capsule, solution, syrup, tablet	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Retrovir
Reyataz® capsule	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Reyataz
Selzentry 150mg, 300mg tablet	Documented trial of **maraviroc tablet** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
stavudine	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on stavudine o Not a candidate for other antiretroviral agents
Sustiva®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Sustiva
Symfi	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Symfi
Symfi Lo	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Symfi Lo
Trizivir®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Trizivir
Truvada®	Criteria is met by the following: • Documentation that individual has tried the bioequivalent generic product AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, is likely to result in a significant allergy or serious adverse reaction or is otherwise medically inappropriate
Videx®**/Videx**® **EC**	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on didanosine/DR (Videx/Videx EC) o Not a candidate for other antiretroviral agents
Viracept®	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on nelfinavir mesylate (Viracept) o Not a candidate for other antiretroviral agents
Viramune®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Viramune

Viramune® XR™	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Viramune XR

Viread® 300 mg tablet	Criteria is met by **BOTH** of the following:
	• **ONE** of the following:
	  • Treatment of HIV
	  • HIV Preexposure Prophylaxis (PrEP)
	  • HIV Postexposure Prophylaxis (PEP)
	  • Treatment of Hepatitis B
	• Documented intolerance to (1) generic formulation of Viread

Ziagen™	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Ziagen

Initial and reauthorization is up to 12 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Other uses of HIV Products not addressed in the above criteria are considered experimental, investigational, or unproven for ANY other use.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

FDA Approved Indications

Drugs@FDA:
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/

Background

OVERVIEW

Approximately 1.2 million individuals ≥ 13 years of age in the US have HIV infection.[1] Among these individuals, approximately 65% receive some HIV care, 50% are retained in care, and 57% are virally suppressed or undetectable. Viral suppression or undetectable viral load not only protects the health of the individuals with HIV, but there is also a preventative benefit. Patients with HIV who take antiretroviral therapy (ART), as prescribed, and achieve and maintain undetectable viral load can live healthy lives and will not transmit HIV to an HIV-negative partner.

Antiretrovirals (ARVs) are used for the treatment of HIV infection in adults and children.[1] The ARVs have also been used for the prevention of HIV acquisition following occupational or non-occupational exposure in the post-exposure prophylaxis setting (PEP and nPEP, respectively) and for the prevention of HIV acquisition among high-risk uninfected individuals (pre-exposure prophylaxis [PrEP]). Three products are indicated in heavily treatment-experienced adults with multidrug resistant HIV (Rukobia [fostemsavir extended-release tablets], Sunlenca [lenacapavir subcutaneous injection and tablets], and Trogarzo [ibalizumab-uiyk intravenous injection]).

GUIDELINES

The DHHS provides guidelines for the management of HIV in adults and adolescents, in pediatric patients, and during the perinatal period.[2-4] In addition, ARVs have been used for PrEP and occupational PEP as well as nPEP; published guidelines on these topics are also available.[6-9,11] Guidelines are updated frequently and should be consulted for the most up-to-date information. The International Antiviral Society (IAS)-USA Panel generally makes similar first-line recommendations for ARV-naïve adults with HIV-1 to the DHHS guidelines.[16]

Appendix 1*

[follow link to Cigna for Health Care Professionals drug look up list for individual customer information]

HIV Products Requiring Prior Authorization
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)
abacavir
Emtriva™**
lamivudine
Retrovir®**
tenofovir disoproxil fumarate**
Viread®**
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)
Edurant®
efavirenz
nevirapine
Pifeltro™
Protease Inhibitors (PIs)
Aptivus®
Fosamprenavir
Invirase®
Lexiva™**
Reyataz®**
Fusion Inhibitors
Fuzeon®
CCR5 Antagonists
Maraviroc
Selzentry®
Integrase Inhibitors
Isentress® HD
Combination HIV Medicines
abacavir/lamivudine
abacavir/lamivudine/zidovudine
Cimduo™
Complera®
Delstrigo™
Evotaz®
Odefsey®
Prezcobix®
Stribild®
Temixys™

**Certain products, strengths, formulations may not be covered; see Non-Covered HIV Products table. [follow link to section]

*If you're a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.

References

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