Effective Date **9/1/2023**
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Coverage Policy Number **IP0171**

Ibalizumab-uiyk

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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.

Overview

This policy supports medical necessity review for Ibalizumab-uiyk (**Trogarzo®**).

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

Medical Necessity Criteria

Ibalizumab-uiyk (Trogarzo®) is considered medically necessary when the following are met:

1. **Human immunodeficiency virus type 1 (HIV-1) infection.** Individual meets **BOTH** of the following criteria:
    A. Documentation of multidrug-resistant HIV-1 infection
    B. Use is in combination with other antiretroviral(s)

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.

Reauthorization Criteria

Ibalizumab-uiyk (Trogarzo) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

1. **Human Immunodeficiency Virus (HIV)-2.** Trogarzo has only been evaluated in HIV-1 infection. The Department of Health and Human Services guidelines for the treatment of adults and adolescents with HIV-1 state that there are no data on the activity of Trogarzo against HIV-2.[3]

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1746	Injection, ibalizumab-uiyk, 10 mg

Background

OVERVIEW
Trogarzo is a long-acting humanized immunoglobulin G4 monoclonal antibody indicated in combination with other antiretroviral(s) for the treatment of **human immunodeficiency virus type-1 (HIV-1) infection** in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.[1] Patients should receive a single intravenous loading dose of 2,000 mg followed by a maintenance dose of 800 mg once every 2 weeks. Maintenance doses of Trogarzo can be administered as a diluted intravenous (IV) infusion or undiluted IV push.

Disease Overview
Multiclass or three-class drug resistant HIV-1 infection is usually defined as the presence of phenotypic or genotypic resistance to at least one drug in each of the following three classes: the nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, and protease inhibitors classes.[2] Trogarzo blocks HIV-1 from infecting CD4+ T cells by binding to domain 2 of CD4.[1] This interferes with post-attachment steps required for the entry of HIV-1 virus particles into host cells and prevents the viral transmission that occurs via cell-cell fusion. The binding specificity to domain 2 of CD4 allows Trogarzo to block viral entry into host cells without causing immunosuppression. There is no antagonism with other antiretrovirals. In the pivotal trial for Trogarzo, all patients had documented resistance to at least one antiretroviral from the nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, and protease inhibitor classes.

Guidelines
The Department of Health and Human Services guidelines for the treatment of adults and adolescents with HIV-1 recognize the difficulty in treating patients with extensive resistance.[3] Managing patients with extensive resistance is complex and usually requires consultation with an HIV expert. Patients with ongoing detectable viremia who lack sufficient treatment options to construct a fully suppressive regimen may be candidates for Trogarzo. Table 1 provides examples of drugs from each class. This is not an all-inclusive list.

Table 1. Examples of HIV Antiretrovirals by Class.

Drug Class	Examples
NRTIs	Ziagen® (abacavir), Videx EC® (didanosine delayed-release), Videx® Pediatric (didanosine), Emtriva® (emtricitabine), Epivir®, (lamivudine), Zerit®, (stavudine), Viread®, (tenofovir disoproxil fumarate), Retrovir® (zidovudine), Combivir® (lamivudine/zidovudine), Epzicom® (abacavir/lamivudine), Trizivir® (abacavir/lamivudine/zidovudine), Truvada® (emtricitabine/tenofovir disoproxil fumarate), Descovy® (emtricitabine/tenofovir alafenamide)
NNRTIs	Rescriptor® (delavirdine), Sustiva® (efavirenz), Intelence® (etravirine), Viramune® (nevirapine), Viramune® XR™ (nevirapine XR), Edurant® (rilpivirine)
PIs	Reyataz® (atazanavir), Prezista® (darunavir), Lexiva® (fosamprenavir), Crixivan® (indinavir), Viracept® (nelfinavir), Norvir® (ritonavir), Invirase® (saquinavir), Aptivus® (tipranavir), Kaletra® (lopinavir/ritonavir), Prezcobix® (darunavir/cobicistat), and Evotaz® (atazanavir/cobicistat)
INSTIs	Isentress® (raltegravir), Isentress® HD (raltegravir), Tivicay® (dolutegravir), and Vitekta® (elvitegravir)
Fusion Inhibitor	Fuzeon® (enfuviritide)
CCR5-Antagonist	Selzentry® (maraviroc tablets)
Combination Products	Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide tablets), Dutrebis™ (lamivudine/raltegravir potassium), Complera® (emtricitabine/rilpivirine/tenofovir disoproxil fumarate), Odefsey® (emtricitabine/rilpivirine/tenofovir alafenamide), Atripla® (efavirenz/ emtricitabine/tenofovir disoproxil fumarate), Stribild® (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate), Triumeq® (abacavir/dolutegravir/lamivudine), and Genvoya® (cobicistat/elvitegravir/emtricitabine/tenofovir alafenamide), Symtuza® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)

HIV – Human immunodeficiency virus; NRTIs – Nucleoside reverse transcriptase inhibitors; NNRTIs – Non-nucleoside reverse transcriptase inhibitors; PIs – Protease inhibitors; INSTIs – Integrase strand-transfer inhibitor.

References

1. Trogarzo® injection [prescribing information]. Montreal, Quebec, Canada: Theratechnologies; October 2022.
2. Imaz, A, Falco V, Ribera E, et al. Antiretroviral salvage therapy for multiclass drug-resistant HIV-1-infected patients: from clinical trials to daily clinical practice. *AIDS*. 2011;13:180-193.
3. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed March 24, 2023. Updated March 23, 2023.