POLICY: Human Immunodeficiency Virus – Trogarzo™ (ibalizumab-uiyk injection for intravenous use – Theratechnologies)

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 12/20/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

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. The loading dose and 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.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Trogarzo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Trogarzo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Trogarzo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Trogarzo is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. Human Immunodeficiency Virus (HIV)-1. Approve for the duration outlined below if the patient meets ONE of the following conditions (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following conditions (i, ii, iii, iv, and v):

i. Patient is ≥ 18 years of age; AND

ii. According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; AND

iii. Patient has multiple antiretroviral drug resistance as demonstrated by resistance to at least one antiretroviral from at least THREE of the following antiviral classes (a, b, c, d, e, f):

a) Nucleoside reverse transcriptase inhibitor;
Note: Examples of nucleoside reverse transcriptase inhibitors include but are not limited to abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine.

b) Non-nucleoside reverse transcriptase inhibitor;
Note: Examples of non-nucleoside reverse transcriptase inhibitors include but are not limited to delavirdine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine.

c) Protease inhibitor;
Note: Examples of protease inhibitors include but are not limited to atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir.

d) Fusion inhibitor;
Note: An example of a fusion inhibitor includes but is not limited to Fuzeon (enfuviritide subcutaneous injection).

e) Integrase strand transfer inhibitor;
Note: Examples of integrase strand transfer inhibitors include but are not limited to raltegravir, dolutegravir, elvitegravir.

f) CCR5-antagonist; AND
Note: An example of a CCR5-antagonist includes but it not limited to Selzentry (maraviroc tablets).

iv. The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND

v. The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

B) Patient is Currently Receiving Trogarzo. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):

i. The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND

ii. Patient has responded (e.g., HIV-1 RNA ≥ 0.5 $\log_{10}$ reduction from baseline in viral load) to a Trogarzo-containing regimen, as determined by the prescriber.

Dosing. Approve the following dosing regimens (A and B):

A) Loading dose of 2,000 mg as an intravenous infusion or intravenous push, given one time; AND

Note: Approve an additional 2,000 mg loading dose if an 800-mg maintenance dose is missed by ≥ 3 days of the scheduled dosing day, with maintenance dosing (800 mg intravenously every 2 weeks) resumed thereafter.

B) Maintenance dose of 800 mg, as an intravenous infusion or intravenous push, given every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Trogarzo is not recommended in the following situations:

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]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Trogarzo® injection [prescribing information]. Montreal, Quebec, Canada: Theratechnologies; December 2023.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Human Immunodeficiency Virus (HIV)-1.** For initial therapy, the requirement that the patient is failing a current antiretroviral regimen according to the prescribing physician was changed to according to the prescriber. For the requirement of a response to therapy, according to the prescribing physician was changed to according to the prescriber.	04/06/2022
Selected Revision	**Human Immunodeficiency Virus (HIV)-1.** Dosing was updated to include maintenance dosing by intravenous push.	10/12/2022
Annual Revision	**Human Immunodeficiency Virus (HIV)-1 Infection.** Examples of antiretroviral therapies tried were moved to notes.	03/29/2023
Selected Revision	**Human Immunodeficiency Virus (HIV)-1 Infection.** Dosing was updated to include loading dose by intravenous push.	12/20/2023