PRIOR AUTHORIZATION POLICY

POLICY: Human Immunodeficiency Virus – Trogarzo Prior Authorization Policy
- Trogarzo® (ibalizumab-uiyk intravenous – Theratechnologies)

REVIEW DATE: 04/06/2022

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 via intravenous (IV) infusion followed by a maintenance dose of 800 mg once every 2 weeks by IV infusion or 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 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. 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.

Guidelines

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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 prescription benefit coverage of Trogarzo. 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 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 Indications

1. **Human Immunodeficiency Virus (HIV)-1 Infection.** Approve for the duration outlined below if the patient meets the following criteria (A and 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 (e.g., abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine);
       - **b)** Non-nucleoside reverse transcriptase inhibitor (e.g., delavirdine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine);
       - **c)** Protease inhibitor (e.g., atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir);
       - **d)** Fusion inhibitor (e.g., Fuzeon® [enfuviritide for injection]);
       - **e)** Integrase strand transfer inhibitor (e.g., raltegravir, raltegravir, dolutegravir, and elvitegravir);
       - **f)** CCR5-antagonist (e.g., Selzentry® [maraviroc tablets]); AND
     - **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 ALL of the following conditions (i, ii, and iii):
     - **i.** The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND

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

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; 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 http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed March 31, 2022. Updated January 20, 2022.

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