

Trogarzo® (ibalizumab-uiyk injection)

When requesting Trogarzo® (ibalizumab-uiyk injection), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Trogarzo, in combination with other antiretroviral(s), is indicated 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.

Coverage Guidelines

Human Immunodeficiency Virus type 1 (HIV-1) infection

The individual must meet **all** of the following criteria for initial authorization:

- Is 18 years of age or older;
- Is failing a current antiretroviral regimen;
- Has multiple antiretroviral drug resistance to at least one antiretroviral from at least THREE of the following antiviral classes:
 - Nucleoside reverse transcriptase inhibitor (NRTI) [e.g., abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine]; OR
 - Non-nucleoside reverse transcriptase inhibitor (NNRTI) [e.g., delaviridine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine]; OR
 - Protease inhibitor (PI) [e.g., atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir]; OR
 - Fusion inhibitor [e.g., Fuzeon® (enfuvirtide for injection)]; OR
 - Integrase strand transfer inhibitor (INSTI) [e.g., raltegravir, dolutegravir, and elvitegravir]; OR
 - CCR5-antagonist [e.g., Selzentry® (maraviroc tablets)];
- Trogarzo will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agent(s);
- Trogarzo is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

The individual must meet **all** of the following criteria for reauthorization:

- Trogarzo will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agent(s);
- Has responded to a Trogarzo-containing regimen (e.g., HIV-1 RNA $\geq$ 0.5 log₁₀ reduction from baseline in viral load)

Approval durations:

- Initial authorization: 6 months
- Reauthorization: 12 months

Dosing Recommendation

Trogarzo is administered intravenously as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks.

References

1. Trogarzo™ injection [prescribing information]. Montreal, Quebec, Canada: Theratechnologies, Inc; 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 January 18, 2024. Updated December 6, 2023.