

Trogarzo® (ibalizumab-uiyk injection)

When requesting Trogarzo® (ibalizumab-uiyk injection), the individual requiring treatment must be diagnosed with the following 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:
 - o Nucleoside reverse transcriptase inhibitor (NRTI) [e.g., abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine]; OR
 - o Non-nucleoside reverse transcriptase inhibitor (NNRTI) [e.g., delaviridine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine]; OR
 - o Protease inhibitor (PI) [e.g., atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir]; OR
 - o Fusion inhibitor [e.g., Fuzeon® (enfuvirtide for injection)]; OR
 - o Integrase strand transfer inhibitor (INSTI) [e.g., raltegravir, dolutegravir, and elvitegravir]; OR
 - o 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 RNA < 50 cells/mm³, HIV-1 RNA ≥ 0.5 log₁₀ reduction from baseline in viral load, improvement or stabilization of CD4 T-cell count).

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.
4. Gandhi RT, Bedimo R, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults 2022 recommendations of the International Antiviral Society–USA Panel. *JAMA*. 2023;329(1):63-84.
5. Cluck DB, Chastain DB, Murray M, et al. Consensus recommendations for the use of novel antiretrovirals in persons with HIV who are heavily treatment-experienced and/or have multidrug-resistant HIV-1: Endorsed by the American Academy of HIV Medicine, American College of Clinical Pharmacology. *Pharmacotherapy*. 2024;44:360-382.