

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

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

- The patient is greater than or equal to 18 years of age;
- The patient has human immunodeficiency virus type 1 (HIV-1) infection;
- The patient is failing a current antiretroviral regimen for HIV;
- The patient has multiple antiretroviral drug resistance as demonstrated by 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)];
- The requested agent will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND
- The requested agent is prescribed by or in consultation with a physician who specializes in the treatment of human immunodeficiency virus (HIV) infection.

Approval duration (initial): 6 months

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

- The patient has human immunodeficiency virus type 1 (HIV-1) infection;
- The requested agent will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND
- The patient has responded (e.g., HIV RNA $\geq 0.5 \log_{10}$ reduction from baseline in viral load) to a Trogarzo-containing regimen.

Approval duration (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; April 2020.
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.
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 30, 2020. Updated December 18, 2019.
3. Emu B, Fessel J, Schrader S, et al. Phase III study of ibalizumab for multidrug-resistant HIV-1. *N Engl J Med*. 2018;379:645-654.
4. Emu B, Lalezari J, Kumar P, et al. Ibalizumab: 96-week data and efficacy in patients resistant to common antiretrovirals [poster]. Presented at: the Conference on Retroviruses and Opportunistic Infections; Seattle, WA; March 4-7. 2019.