

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.

Approved Off-label Compendial use(s)

None

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, 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
- 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
- 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; May 2018.
2. Imaz A, Falcó V, Ribera E. Antiretroviral salvage therapy for multiclass drug-resistant HIV-1-infected patients: from clinical trials to daily clinical practice. *AIDS reviews*. <https://www.ncbi.nlm.nih.gov/pubmed/21799536>. Published 2011. Accessed October 7, 2019.
3. Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. AIDS Education and Training Centers National Coordinating Resource Center (AETC NCRC). <https://aidsetc.org/resource/guidelines-use-antiretroviral-agents-hiv-1-infected-adults-and-adolescents>. Published October 25, 2018. Accessed October 7, 2019.
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.