SmartHealth Ascension

Ibalizumab-uiyk

(Trogarzo®) J1746 (10 mg)

Covered with prior authorization

Ibalizumab-uiyk (Trogarzo®) may be authorized when the following criteria are met:

- Individual is using to treat human immunodeficiency virus (HIV) infection; **AND**
- Individual has a history of at least 6 months of antiretroviral treatment; **AND**
- If initiating therapy, individual has a viral load of > 1000 copies/mL; **AND**
- If initiating therapy, individual is receiving a failing antiretroviral regimen or has failed and is off therapy; **AND**
- Individual is using in combination with other antiretroviral agents and has documentation of full viral sensitivity/susceptibility to at least one antiretroviral agent (other than Trogarzo) as determined by resistance testing; **AND**
- Documentation of multidrug-resistant HIV-1 infection.

Exclusion criteria:
Requests for Ibalizumab-uiyk (Trogarzo®) may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individual who has received immunomodulating therapy within 12 weeks of initiating treatment with Trogarzo (for example, interferon, systemic steroids or systemic chemotherapy).
- Individual is being treated for an acute infection secondary to HIV infection.

Initial authorization is up to 12 months.

Dosing
Patients should receive a single intravenous loading dose of 2,000 mg followed by a maintenance dose of 800 mg once every 2 weeks.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Trogarzo® is a CD4-directed post-attachment HIV-1 inhibitor, 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.

References:

1. Emu B, Fessel J, Schrader S, et. al. Phase 3 Study of Ibalizumab for Multidrug-Resistant HIV-1. N Engl J Med. 2018; 379(7): 645- 654.
2. Ibalizumab FDA Summary Review. March 4, 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761065Orig1s000SumR.pdf.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. Trogarzo® [Prescribing Information]. Montréal, Québec Canada: Theratechnologies Inc., 2023.

Date	Summary of Changes
January 2023	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
January 2023	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.