Trogarzo (ibalizumab-uiyk)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Trogarzo (ibalizumab-uiyk) Injection	8 vials per 28 days*

*Initiation or re-initiation of therapy with Trogarzo (ibalizumab-uiyk): May approve up to 6 additional vials in the first 28 days of treatment or re-initiation of treatment.

APPROVAL CRITERIA

Requests for Trogarzo (ibalizumab-uiyk) may be approved if the following criteria are met:

I. Individual is using to treat human immunodeficiency virus (HIV) infection; **AND**
II. Individual has a history of at least 6 months on antiretroviral treatment; **AND**
III. If initiating therapy, individual has a viral load of > 1000 copies/mL; **AND**
IV. If initiating therapy, individual is receiving a failing antiretroviral regimen or has failed and is off therapy; **AND**
V. Individual has documented resistance to at least one antiretroviral agent from three different classes as measured by resistance testing; **AND**
VI. 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.

Trogarzo (ibalizumab-uiyk) may **not** be approved for the following:

I. Individuals who has received immunomodulating therapy within the 12 weeks of initiating treatment with Trogarzo (for example, interferon, systemic steroids or systemic chemotherapy) (NCT00784147); **OR**
II. Individuals being treated for an acute infection secondary to HIV infection (NCT00784147); **OR**
III. May not be approved when the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 13, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. 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.
4. Ibalizumab FDA Summary Review. March 4, 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761065Orig1s000SumR.pdf. Accessed: October 13, 2022.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. TaiMed Biologics Inc. Dose-Response Study of Ibalizumab (Monoclonal Antibody) Plus Optimized Background Regimen in Patients With HIV-1 (TMB-202). NLM Identifier: NCT00784147. Last Update: May 5, 2104. Available at: https://clinicaltrials.gov/ct2/show/study/NCT00784147?term=ibalizumab&rslt=With&rank=1&sect=X70156. Accessed: October 13, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.