Medical Drug Clinical Criteria

Subject:	Trogarzo (ibalizumab-uiyk)		
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Overview

This document addresses the use of Trogarzo (ibalizumab-uiyk), a post-attachment inhibitor approved by the Food and Drug Administration (FDA) for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV) infection in heavily treatment-experienced adults with multidrug resistant HIV infection failing their current antiretroviral regimen.

The safety and effectiveness of Trogarzo was evaluated in a 24-week, open-label, single-arm clinical trial including 40 heavily treatment-experienced participants with multidrug resistant HIV infection. Participants were required to have been on antiretroviral therapy for at least 6 months and failed the regimen within 8 weeks of study screening. Inclusion criteria included: no acquired immunodeficiency syndrome (AIDS)-defining events in the previous 3 months other than Kaposi's sarcoma or HIV wasting syndrome, a viral load of > 1000 copies/mL, documented resistance to at least one antiretroviral agent from each of three drug classes as measured by resistance testing (approved drug classes: non-nucleoside reverse transcriptase inhibitors [NNRTIs], nucleoside reverse transcriptase inhibitors [NRTIs], or protease inhibitors [PIs]) and full viral sensitivity/susceptibility to at least one antiretroviral agent other than Trogarzo. Individuals who were being treated for an acute infection secondary to HIV, were previously exposed to Trogarzo or had received immunomodulating therapy within the most recent 12 weeks were not eligible for enrollment.

The participants enrolled were a heavily treatment-experienced population with 53% reporting 10 or more antiretroviral agents in their treatment history. The first six days of the study were the control period where participants continued their failed antiretroviral regimen (or no regimen if they were not currently being treated). On day 7, the functional monotherapy period started and participants received a single loading dose of intravenous Trogarzo. The maintenance period began on day 14 and went through week 25. During the maintenance period, the background antiretroviral regimen was optimized to include at least one drug to which the individual's virus was susceptible. Participants received Trogarzo every 2 weeks during this period. Results show that 83% (33 out of 40) of participants enrolled in the study met the primary endpoint of a decrease of ≥ 0.5 $\log_{10}$ in viral load during the functional monotherapy period versus 3% during the control period ($p < 0.0001$). At study-end, only 31 of 40 participants remained enrolled in this study (23% [n=9] discontinuations); 4 died, 3 withdrew consent and 2 were lost to follow-up. At Week 25, viral load < 50 and < 200 HIV-1 RNA copies/mL was achieved in 43% and 50% of participants. Trial limitations include a lack of comparator group, lack of long-term follow-up and only 77% of participants (n=31) remained enrolled at study-end.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Trogarzo (ibalizumab-uiyk)

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 of 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. Individual who has received immunomodulating therapy within 12 weeks of initiating treatment with Trogarzo (for example, interferon, systemic steroids or systemic chemotherapy) (NCT00784147); **OR**
II. Individual is 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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1746	Injection, ibalizumab-uiyk, 10 mg [Trogarzo]

ICD-10 Diagnosis

B20	Human immunodeficiency virus [HIV] disease

Document History

Revised: 8/18/2023
Document History:

- 8/18/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/18/2022 – Annual Review: Clarify which criteria elements only apply when initiating therapy. Wording and formatting change. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/20/2020 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/15/2019 – Annual Review: Wording and formatting changes. Coding reviewed: No changes.
- 11/16/2018 – Annual Review: Initial P&T review of ING-CC-0047 Trogarzo. Remove age criteria. Remove listing of specific classes in resistance criteria. Wording updates for consistency. Add references for non-label-based criteria elements. HCPCS and ICD-10 coding update: Delete J3490, J3590. Add J1746 effective 1/1/2019.

References

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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.