Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Ibalizumab-uiyk (Trogarzo®)	MP-RX-FP-95-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of Ibalizumab-uiyk (Trogarzo®) , a CD4-directed post-attachment HIV-1 inhibitor approved by the Food and Drug Administration (FDA) for the treatment of human immunodeficiency virus type 1 (HIV-1) in combination with other antiretroviral agents.

Background Information

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 type 1 infection (HIV-1) in heavily treatment-experienced adults with multidrug resistant HIV-1 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

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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 log10 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.

Approved Indications

A. In combination with other antiretroviral(s) 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.

Other Uses

i. N/A

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

ICD-10	Description
B20	Human immunodeficiency virus [HIV] disease

Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria

Ibalizumab-uiyk (Trogarzo®)

A. Criteria for Initial Approval

Initial 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.

B. Criteria for Continuation of Therapy

i. MMM considers continuation of Trogarzo therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:
   A. Progress notes or clinical documentation of the patient's safety and clinical response to treatment.

C. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Trogarzo (ibalizumab-uiyk) may not be approved for the following:
   A. Individual who has received immunomodulating therapy within 12 weeks of initiating treatment with Trogarzo (for example, interferon, systemic steroids or systemic chemotherapy) (NCT00784147);

   OR

   B. Individual is being treated for an acute infection secondary to HIV infection (NCT00784147);

   OR

   C. May not be approved when the above criteria are not met and for all other indications.

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D. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Trogarzo (ibalizumab-uiyk) 200 mg/1.33 mL vial	8 vials per 28 days
Exceptions	
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.	

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Reference Information

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.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Choose an item.		Click or tap to enter a date.	Click or tap to enter a date.
Annual Review. 08/18/2024	Added sections: approved indications, other uses, criteria for continuation requests, approval duration, and limits and restrictions (quantity limits table). Add wording to specify Trogarzo use for HIV-1. Update wording and formatting. Coding reviewed: no changes.	3/14/2025	4/2/2025
Policy Inception 8/18/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023