Clinical Policy: Ibalizumab-uiyk (Trogarzo)

Reference Number: PA.CP.PHAR.378
Effective Date: 04.17.19
Last Review Date: 05.19

Coding Implications
Revision Log

Description
Ibalizumab-uiyk (Trogarzo™) is a CD4-directed post-attachment human immunodeficiency virus type 1 (HIV-1) inhibitor.

FDA Approved Indication(s)
Trogarzo is indicated for the treatment of HIV-1 infection, in combination with other antiretroviral(s), in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

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

It is the policy of health plans affiliated with PA Health and Wellness® that Trogarzo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. HIV-1 Infection (must meet 1 or 2)**:**

1. Request meets the following (must meet all):
   a. Diagnosis of multidrug resistant HIV-1 infection;
   b. Prescribed by or in consultation with an infectious disease or HIV specialist;
   c. Age ≥ 18 years;
   d. Documentation of resistance to at least 1 antiretroviral agent from each of 4 classes (NRTI, NNRTI, PI, INSTI), unless contraindicated or clinically significant adverse effects are experienced;
   e. Current (within the past 30 days) HIV ribonucleic acid viral load of ≥ 200 copies/mL;
   f. Prescribed concurrently with additional antiretroviral agents to which member is susceptible, if available;
   g. Dose does not exceed 2,000 mg (10 vials) IV loading dose* and/or 800 mg (4 vials) IV every 14 days.
   **A loading dose may be repeated if the member misses scheduled maintenance dose by 3 days or more.*
2. Member is currently receiving Trogarzo.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. HIV-1 Infection (must meet all)**:**
1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2,000 mg (10 vials) IV loading dose* and/or 800 mg (4 vials) IV every 14 days.
   **A loading dose may be repeated if the member misses scheduled maintenance dose by 3 days or more.*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
HIV-1: human immunodeficiency virus type 1
INSTI: integrase strand transfer inhibitors
NNRTI: non-nucleoside reverse transcriptase inhibitor
NRTI: nucleos(t)ide reverse transcriptase inhibitor
PI: protease inhibitor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Nucleos(t)ide reverse transcriptase inhibitors (NRTIs) (e.g., abacavir, tenofovir disoproxil fumarate, Emtriva®)	Refer to prescribing information	Refer to prescribing information

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g., efavirenz, nevirapine, Edurant®)	Refer to prescribing information	Refer to prescribing information
Integrase strand transfer inhibitors (INSTIs) (e.g., Tivicay®, Isentress®)	Refer to prescribing information	Refer to prescribing information
Protease inhibitors (PIs) (e.g., atazanavir, fosamprenavir, Invirase®, Viracept®)	Refer to prescribing information	Refer to prescribing information
Fixed-dose combinations (e.g., Genvoya®, Stribild®, Odefsey®, Descovy®, Truvada®)	Refer to prescribing information	Refer to prescribing information

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HIV-1 infection	A single loading dose of 2,000 mg IV, followed by a maintenance dose of 800 mg every 2 weeks. If a maintenance dose is missed by 3 days or longer beyond the scheduled dosing day, a loading dose of 2,000 mg should be administered as early as possible prior to resuming maintenance dosing of 800 mg every 2 weeks thereafter.	A loading dose of 2,000 mg up to every 17 days* A maintenance dose of 800 mg every 14 days

**Frequency of every 17 days was calculated from frequency of maintenance dose (every 14 days) plus minimum number of days that the dose is missed to qualify for another loading dose (3 days).*

VI. Product Availability

Injection in single-dose vial: 200 mg/1.33 mL (150 mg/mL)

VII. References

1. Trogarzo Prescribing Information. Irvine, CA: TaiMEd Biologics USA Corp.; May 2018. Available at: https://www.trogarzo.com. Accessed January 23, 2019.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. US Department of Health and Human Services. Last updated October 25, 2018. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed January 23, 2019.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	Injection, ibalizumab, 200 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.17.19	