Clinical Policy: Ibalizumab-uiyk (Trogarzo)

Reference Number: ERX.SPA.236
Effective Date: 06.01.18
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Trogarzo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of multidrug resistant HIV-1 infection;
2. Prescribed by or in consultation with an infectious disease or HIV specialist;
3. Age ≥ 18 years;
4. Documentation of resistance to at least 1 antiretroviral agent from each of 3 classes (NRTI, NNRTI, PI), unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of one of the following, unless clinically significant adverse effects are experienced, both are contraindicated, or member is resistant to both: Fuzeon®, Selzentry® if CCR5 tropic;
6. Current (within the past 30 days) HIV ribonucleic acid viral load of ≥ 200 copies/mL;
7. Prescribed concurrently with additional antiretroviral agents to which member is susceptible, if available;
8. 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: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Trogarzo for multidrug resistant HIV-1 infection and has received this medication for at least 30 days;
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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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 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
Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g., efavirenz, nevirapine, Edurant®)	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
Fuzeon® (enfurvirtide, T-20)	Refer to prescribing information	Adults: 180 mg/day Children 6 years and older: 4 mg/kg/day
Selzentry® (maraviroc, MVC)	Refer to prescribing information	600 mg/day; 1,200 mg/day if taking a potent CYP3A inducer
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

- Contraindication(s): prior hypersensitivity to Trogarzo or any components of the product
- Boxed warning(s) 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 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.; April 2020. Available at: https://www.trogarzo.com. Accessed January 12, 2021.
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 December 18, 2019. Available at https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0. Accessed January 12, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.17.18	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	01.23.19	05.19
2Q 2020 annual review: modified required resistance to an agent from 4 classes to 3 classes and required trials from both Fuzeon and Selzentry to either Fuzeon or Selzentry per pivotal trial inclusion criteria and to better allow formation of a viable regimen; references reviewed and updated.	01.24.20	05.20
2Q 2021 annual review: no significant changes; updated Appendix C with hypersensitivity contraindication per updated FDA label; references reviewed and updated.	01.12.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.