RXADVANCE
2 Park Central Drive
Southborough, MA 01772

**Clinical Policy Title:** **Ibalizumab-uiyk (Trogarzo)**
**Policy Number:** **RxA.524**
**Drug(s) Applied:** **Ibalizumab-uiyk (Trogarzo™)**
**Last Review Date:** **01/2020**
**Line of Business:** **Commercial, HIM-Medical Benefit, Medicaid**

## Background

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

| 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.<br><br>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*<br><br>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).*

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

## Clinical Policy

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

**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 4 classes (NRTI, NNRTI, PI, INSTI), unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of Fuzeon®, unless resistant, contraindicated, or clinically significant adverse effects are experienced;
6. If CCR5-tropic: Failure of Selzentry®, unless resistant, contraindicated, or clinically significant adverse effects are experienced;
7. Current (within the past 30 days) HIV ribonucleic acid viral load of ≥ 200 copies/mL;

8. Prescribed concurrently with additional antiretroviral agents to which member is susceptible, if available;
9. 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**

## II. Continued Therapy

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

1. Currently receiving medication via RxAdvance benefit, 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**

## III. Appendices

*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 |
| Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g., efavirenz, nevirapine, Edurant®) | Refer to prescribing information | Refer to prescribing information |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|

| | | |
|---|---|---|
| Integrase strand transfer inhibitors (INSTIs) (e.g., Tivicay®, Isentrss®) | 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<br>Children 6 years and older: 4 mg/kg/day |
| Selzentry® (maraviroc, MVC) | Refer to prescribing information | 600 mg/day;<br>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*
None reported

**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.

| Review/Revision History | Review/Revised Date | P&T Approval Date |
|---|---|---|
| Policy was established | 01/2020 | 03/06/2020 |