RXADVANCE
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Clinical Policy Title:	ibalizumab-uiyk
Policy Number:	RxA.524
Drug(s) Applied:	Trogarzo®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

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 human immunodeficiency virus type 1 (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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ibalizumab-uiyk (Trogarzo®)	HIV-1 infection	A single loading dose of 2,000 mg intravenous, 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).*

Dosage Forms

- 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 of age or older;

4. Documentation of resistance to at least one (1) antiretroviral agent from each of the four (4) classes (NRTI, NNRTI, PI, INSTI), unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of enfuviritide (Fuzeon®), unless resistant, contraindicated or clinically significant adverse effects are experienced;
6. If CCR5-tropic, failure of maraviroc (Selzentry®), unless resistant, contraindicated or clinically significant adverse effects are experienced;
7. Current (within the past 30 days) HIV ribonucleic acid viral load of at least 200 copies/mL;
8. Prescribed concurrently with antiretroviral agents to which member is susceptible, if available;
9. Dose does not exceed 2,000 mg IV loading dose* and/or 800 mg IV every 14 days.
   **A loading dose may be repeated if the member misses scheduled maintenance dose by 3 days or more.*

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving ibalizumab-uiyk 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 IV loading dose* and/or 800 mg IV every 14 days.
   **A loading dose may be repeated if the member misses scheduled maintenance dose by 3 days or more.*

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HIV-1: Human Immunodeficiency Virus type 1
IV: Intravenous/intravenously
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

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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
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
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 reaction to ibalizumab-uiyk or any components of the product.

- Boxed Warning(s):
  - None

APPENDIX D: General Information

- Hypersensitivity reactions including infusion-related reactions and anaphylactic reactions have been reported following infusion of ibalizumab-uiyk during post-approval use. Symptoms may include dyspnea, angioedema, wheezing, chest pain, chest tightness, cough, hot flush, nausea and vomiting. If signs and symptoms of an anaphylactic or other clinically significant hypersensitivity reaction occur, immediately discontinue administration of ibalizumab-uiyk and initiate appropriate treatment.

References

1. Trogarzo® Prescribing Information. Irvine, CA: TaiMEd Biologics USA Corp.; April 2020. Available at: https://www.trogarzo.com. Accessed September 24, 2020.
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.
3. 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 July 10, 2019. Available at: https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines. Accessed September 24, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. APPENDIX D: General Information was updated to include the detailed information regarding hypersensitivity reaction during treatment. 6. APPENDIX B verbiage was rephrased. 7. References were updated.	09/24/2020	12/07/2020