

Trogarzo™ (ibalizumab-uiyk) (Intravenous)

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Dates Reviewed: 04/2018, 08/2018, 08/2019

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Trogarzo 200 mg single-dose vial: 10 vials initially followed by 4 vials every 14 days thereafter.

B. Max Units (per dose and over time) [Medical Benefit]:

- Load: 200 billable units one time only
- Maintenance: 80 billable units every 14 days

III. Initial Approval Criteria

Site of care specialty infusion program requirements are met (refer to [OHSU Health Services Site of Care Policy](#)).

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Human Immunodeficiency Virus Type-1 (HIV-1) †

- Patient has heavily treated multi-drug resistant disease, confirmed by resistance testing, to at least one drug in at least three classes (see table below); **AND**
- Patient has a baseline viral load > 1,000 copies/mL; **AND**
- Patient is failing on their current anti-retroviral regimen; **AND**

Used in combination with highly active antiretroviral therapy (HAART) for which, via resistance testing, the patient's disease is known to be sensitive/susceptible

Class	Examples (not all-inclusive)
Nucleoside reverse transcription inhibitor (NRTI)	Emtricitabine, lamivudine, stavudine, zidovudine
Non-nucleoside reverse transcription inhibitor (NNRTI)	Efavirenz, rilpivirine, nevirapine, etravirine, doravirine
Protease inhibitor (PI)	Atazanavir, fosamprenavir, ritonavir

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include immune reconstitution inflammatory syndrome (IRIS), etc.; **AND**
- Disease response as indicated by a decrease in viral load from pretreatment baseline
 - Note: increases in viral load from nadir and/or less than anticipated reduction from baseline should prompt resistance testing for susceptibility and optimization of the background regimen

V. Dosage/Administration

Indication	Dose
HIV-multidrug resistant	Infuse, intravenously, 2000 mg as a one-time dose, followed by a maintenance dose of 800 mg every 2 weeks, thereafter. <ul style="list-style-type: none"> • If a maintenance dose (800 mg) is missed by 3 days or longer beyond the scheduled dosing day, a loading dose (2,000 mg) should be administered as early as possible. Resume maintenance dosing (800 mg) every 14 days thereafter.

VI. Billing Code/Availability Information

Jcode:

- J1746 – Injection, ibalizumab-uiyk, 10 mg; 1 billable unit = 10 mg

NDC:

Trogarzo 200 mg/1.33 mL single-dose vial: 62064-0122-xx

VII. References

1. Trogarzo [package insert]. Montreal, Quebec Canada; Theratechnologies, Inc.; May 2018. Accessed June 2019.
2. Emu B, Fessel J, Schrader S, et al. Phase 3 Study of Ibalizumab for Multidrug-Resistant HIV-1. N Engl J Med. 2018 Aug 16;379(7):645-654.
3. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed 6/17/19

Appendix 1 – Covered Diagnosis Codes

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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC