

Trogarzo™ (ibalizumab-uiyk) (Intravenous)

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I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

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) [HCPCS Unit]:

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

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

Patient is required to meet Site of Service specialty infusion program requirements (refer to the [Medica Site of Service Policy](#)).

- Patient is at least 18 years of age; AND

Universal Criteria ¹

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

Human Immunodeficiency Virus Type-1 (HIV-1) † ‡ Φ ¹⁻⁴

- 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 ≥ 200 copies/mL; AND
- Patient is failing on their current anti-retroviral regimen

**Class ⁴	Examples (not all-inclusive) ⁴
Nucleoside reverse transcriptase inhibitor (NRTI)	Abacavir, emtricitabine, lamivudine, tenofovir disoproxil fumarate, zidovudine
Non-nucleoside reverse transcriptase inhibitor (NNRTI)	Doravirine, efavirenz, etravirine, nevirapine, rilpivirine
Protease inhibitor (PI)	Atazanavir, darunavir, fosamprenavir, ritonavir, tipranavir
Fusion Inhibitor	Enfuvirtide
CCR5 Antagonist	Maraviroc
Integrase Strand Transfer Inhibitor (INSTI)	Cabotegravir, dolutegravir, raltegravir

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹⁻³

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions including infusion-related reactions and anaphylactic reactions, 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 ¹

Indication	Dose
Multidrug Resistant HIV	<p>Administer 2000 mg as a single loading* dose, followed by a maintenance* dose of 800 mg every 2 weeks thereafter.</p> <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.
*Both the loading dose and maintenance doses may be administered as an IV infusion or undiluted IV push by a trained medical professional.	

VI. Billing Code/Availability Information

HCPSC code:

- 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.; October 2022. Accessed October 2023.
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 <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv>. Last updated 03/23/2023. Accessed 10/30/2023.
4. HIV Overview. FDA-Approved HIV Medicines. Department of Health and Human Services. Available at <https://hivinfo.nih.gov/understanding-hiv/fact-sheets/fda-approved-hiv-medicines>. Last updated 03/23/2023. Accessed 10/26/2023.

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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/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)

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