Effective Date: 12/01/2019
Reviewed: 9/2019, 8/2020, 4/2021, 2/2022, 3/2023, 12/2023, 01/2024 Pharmacy Scope: Medicaid Medical Scope: Medicaid, Commercial

Trogarzo™ (ibalizumab-uiyk)
(Intravenous)

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. Summary of Evidence

Trogarzo (ibalizumab-uiyk) is a CD4-directed post-attachment human immunodeficiency virus type I (HIV-1) inhibitor used in combination with other antiretrovirals for the treatment of HIV-1 infection in heavily treatment experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen. Trogarzo carries warnings of hypersensitivity reactions, immune reconstitution inflammatory syndrome (IRIS), and embryo-fetal toxicity. The most common adverse events that occur with Trogarzo use include diarrhea, dizziness, nausea, and rash. The efficacy of Trogarzo was established in a single-arm, multicenter clinical trial conducted in 40 heavily treatment-experienced HIV-infected subjects with multidrug resistance HIV-1. The primary efficacy endpoint was the proportion of subjects achieving a ≥ 0.5 log10 decrease in viral load from the beginning to the end of the "Functional Monotherapy Period" (Day 7 to Day 13) as compared to the proportion of subjects achieving a ≥ 0.5 log10 decrease from the beginning to the end of the "Control Period" (Day 0 to Day 6) At the end of the control period 3% (95% CI: 0.06%, 13%) of subjects achieved a ≥ 0.5 log10 decrease in viral load. At the end of the functional monotherapy period 83% (95% CI: 67%, 93%) of subjects achieved a ≥ 0.5 log10 decrease in viral load. At week 25, viral load < 50 and < 200 HIV-1 RNA copies/mL was achieved in 43% and 50% of subjects, respectively.

IV. Initial Approval Criteria

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)	Abacavir, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, zidovudine
Non-nucleoside reverse transcription inhibitor (NNRTI)	Delaviridine, efavirenz, rilpivirine, nevirapine, etravirine, doravirine
Protease inhibitor (PI)	Atazanavir, darunavir, fosamprenavir, nelfinavir, ritonavir, tipranavir

† FDA Approved Indication(s)

V. 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

VI. Dosage/Administration

Indication	Dose
HIV-multidrug resistant	2000 mg as a one-time dose, followed by a maintenance dose of 800 mg every 2 weeks, thereafter. • 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.
***Loading dose must be given as an IV infusion. Maintenance doses may be given as an IV infusion or undiluted IV push**	

VII. 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

VIII. References

1. Trogarzo [package insert]. Montreal, Quebec Canada; Theratechnologies, Inc.; October 2022. Accessed November 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 9/21/2022. Accessed 3/9/2029

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

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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

Policy Rationale:

Trogarzo was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Trogarzo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.