

# 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. 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)

#### 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   | <p>2000 mg as a one-time dose, followed by a maintenance dose of 800 mg every 2 weeks, thereafter.</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> |
| <b>*Loading dose must be given as an IV infusion. Maintenance doses may be given as an IV infusion or undiluted IV push</b> |  |

#### 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.; October 2022. Accessed March 2023.
2. Ewu 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

Effective Date: 12/01/2019

Reviewed: 9/2019, 8/2020, 4/2021, 2/2022, 3/2023

Pharmacy Scope: Medicaid

Medical Scope: Medicaid, Commercial

## 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.                           |
| K (13 & 14)   | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS)          |
| 15  | KY, OH  | CGS Administrators, LLC                           |