

## Trogarzo™ (ibalizumab-uiyk) (Intravenous)

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Dates Reviewed: 04/2018, 08/2018

### 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 (2000 mg) one time only
- Maintenance: 80 billable units (800 mg) 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 (e.g., NRTI, PI, NNRTI, etc.); AND
- Used in combination with anti-retroviral therapy (ART); AND
- Patient is failing on their current anti-retroviral regimen

† FDA Approved Indication(s)

### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria in section III; AND
- Disease response as indicated by a decrease in viral load; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include immune reconstitution inflammatory syndrome (IRIS), etc.

## 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. *If a maintenance dose (800mg) is missed by 3 days or longer beyond the scheduled dosing day, a loading dose (2,000mg) should be administered as early as possible. Resume maintenance dosing (800mg) every 14 days thereafter.

## VI. Billing Code/Availability Information

### Jcode:

- J1746 – Injection, ibalizumab-uiyk, 10 mg: 1 billable unit = 10 mg (effective 1/1/19)
- J3590 - Unclassified biologics

### NDC:

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

## VII. References

1. Trogarzo [package insert]. Montreal, Irvine, California; TaiMed Biologics; May 2018. Accessed July 2018.

## 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)

## Medicare Part B Administrative Contractor (MAC) Jurisdictions

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 Government Benefit Administrators, 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