

## ibalizumab-uiyk (Trogarzo)

### Commercial Medical Benefit Drug Policy

#### Place of Service

Home Infusion Administration  
Hospital Administration  
Infusion Center Administration  
Office Administration  
Outpatient Facility Administration

### Drug Details

**USP Category:** ANTIVIRALS

**Mechanism of Action:** CD4-directed post-attachment HIV-1 inhibitor

#### HCPCS:

J1746:Injection, ibalizumab-uiyk, 10 mg

#### How Supplied:

200 mg/1.33 mL (150 mg/mL) single-dose vial

### Condition(s) listed in policy *(see coverage criteria for details)*

- Multidrug Resistant HIV-1 Infection

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

### Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct) may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

## CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

*MCG Care Guidelines, 19th edition, 2015*

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is starting new therapy with this drug (allowed for the first dose). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
2. Patient is being re-initiated on this drug after being off therapy for at least 6 months (allowed for the first dose). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
3. Additional clinical monitoring is required during administration as evidenced by one of the following:
  - a. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.
  - b. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
  - c. Patient is clinically unstable based on documentation submitted.
  - d. Patient is physically or cognitively unstable based on documentation submitted

### **Coverage Criteria**

**The following condition(s) require Prior Authorization/Preservice.**

#### **Multidrug Resistant HIV-1 Infection**

**Meets medical necessity if all the following are met:**

1. Prescribed by or in consultation with an Infectious Disease or HIV specialist
2. Patient's HIV-1 isolate has documented resistance to at least one (1) antiretroviral medication from three (3) separate drug classes of antiretroviral medications
3. Confirmation that Trogarzo will be taken in combination with an optimized background antiretroviral regimen which contains at least one other partially or fully active antiretroviral medication

#### **Covered Doses:**

Not to exceed 2000 mg given intravenously for one loading dose, followed by up to 800 mg every 14 days

#### **Coverage Period:**

Yearly, based on continued response to therapy

#### **ICD-10:**

B20

## References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Trogarzo (ibalizumab-uiyk) Prescribing Information. Theratechnologies Inc., Montreal, Quebec, Canada:12/2023.

## Review History

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*