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.

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

1. Patient is receiving their first infusion of Trogarzo or is being re-initiated on Trogarzo after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Trogarzo based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Trogarzo based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. 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:

Up to 2000 mg given intravenously for one loading dose, followed by up to 800 mg every 14 days

Coverage Period:

Indefinite

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]. Montreal, Quebec, Canada: Theratechnologies Inc.; 12/2023.

Review History

Date of Last Annual Review: 1Q2025
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