

## PHARMACY POLICY STATEMENT

### Marketplace

<b>DRUG NAME</b>	<b>Trogarzo (ibalizumab-uiyk)</b>
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Trogarzo is a CD4-directed post-attachment HIV inhibitor initially approved by the FDA in 2018. It is approved, in combination with other antiretroviral(s), for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen. Trogarzo works by blocking HIV-1 from infecting CD4+ T cells by binding to domain 2 of CD4 and interfering with post-attachment steps required for the entry of HIV-1 virus particles into host cells and preventing the viral transmission that occurs via cell-cell fusion.

Trogarzo (ibalizumab-uiyk) will be considered for coverage when the following criteria are met:

#### Multidrug-Resistant HIV-1 Infection

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an infectious disease or HIV specialist; AND
3. Member must have documented resistance, intolerance or contraindication to at least **ONE** antiretroviral from three different drug classes; AND
4. Member is failing current regimen as evidenced by HIV viral count > 200 copies/mL; AND
5. Member is NOT using Trogarzo as monotherapy. Provider must include documentation of entire anti-retroviral regimen.
6. **Dosage allowed/Quantity limit:** Administer a 2000 mg IV loading dose followed by 800 mg IV infusion or IV push every 2 weeks. Quantity Limit: Loading dose 10 vials per 30 days; maintenance dose 8 vials per 30 days.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Trogarzo is not being used as monotherapy; AND
2. Chart notes have been provided that show the member has demonstrated improvement as evidenced by **ONE** of the following:
  - a) HIV viral load < 200 copies/mL; OR
  - b) Decrease in HIV RNA load from initial authorization.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Trogarzo (ibalizumab-uiyk) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

