PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Trogarzo (ibalizumab-uiyk)
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.

DATE	ACTION/DESCRIPTION
11/03/2020	New policy for Trogarzo created.
04/25/2022	Transferred to new template. Updated references. Removed adherence attestation. Added infectious disease specialist
02/21/2023	Updated references. Removed adherence attestation from reauthorization criteria. Removed requirement of anti-retroviral agent availability.
01/19/2024	Added IV push dosing option; simplified trial requirement wording; updated references.

References:

1. Trogarzo [package insert]. Montréal, Québec Canada; Theratechnologies: 2023.
2. 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. 2023. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed January 19, 2024.
3. Emu B, Fessel J, Schrader S, et al. Phase 3 Study for Ibalizumab for Multidrug-Resistant HIV-1. *N Engl J Med.* 2018 Aug 16;379(7):645-654.

Effective date: 07/01/2024
Revised date: 01/19/2024