

PHARMACY POLICY STATEMENT

Ohio Medicaid

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 to at least one antiretroviral from the three drug classes or have failed at least 3 drug classes for HIV treatment due to intolerance or contraindication; 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:** 2000mg IV for loading dose followed by 800mg IV infusion every 2 weeks for maintenance dose. 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.

References:

1. Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed October 10, 2020.
2. 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.
3. Trogarzo [package insert]. Montréal, Québec Canada; Theratechnologies. October 2022.
4. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
5. 29. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
6. 30. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

Effective date: 03/01/2024

Revised date: 02/21/2023