CareSource

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Trogarzo (ibalizumab-uiyk)
BILLING CODE	J1746
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT – for loading dose 10 vials and for maintenance dose 8 vials/month
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Trogarzo (ibalizumab-uiyk) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with the following disease states and meet their individual criteria as stated.

MULTIDRUG-RESISTANT HIV-1 INFECTION

For **initial** authorization:

1. Member must be at least 18 years of age or older; AND
2. The medication must be prescribed by or in consultation with an HIV specialist; AND
3. Member must have documented resistance to at least one antiretroviral from 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 RNA count > 200 copies/mL; AND
5. Member has at least 1 anti-retroviral agent available to add to Trogarzo (ibalizumab-uiyk); AND
6. Member is NOT using Trogarzo (ibalizumab-uiyk) as monotherapy. Provider must include documentation of the entire anti-retroviral regimen; AND
7. Member/prescriber attestation to be adherent to treatment regimen and appointments for maintenance doses.
8. **Dosage allowed:** 2000mg IV for loading dose followed by 800mg IV infusion every 2 weeks for maintenance dose.

If member meets all the requirements listed above, the medication will be approved for 6 months

For **reauthorization**:

1. Trogarzo (ibalizumab-uiyk) 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 RNA load < 200 copies/mL; OR
   b) Decrease in HIV RNA load from initial authorization; AND
3. Member is adherent to antiretroviral regimen as prescribed proven through chart notes, or prescriber/member attestation.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Trogarzo (ibalizumab-uiyk) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
11/03/2020	New policy for Trogarzo (ibalizumab-uiyk) created.

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. April 2020.

Effective date: 04/01/2021
Revised date: 11/03/2020