Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

**OVERVIEW**
Trogarzo® (ibalizumab-uiyk) is an injectable monoclonal antibody approved by the FDA for use in combination with other antiretroviral therapies 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 is administered as an intravenous (IV) solution and is the first biologic approved by the FDA for the treatment of HIV infection. It works by preventing HIV from infecting CD4+ immune cells to reduce the amount of HIV in the body. FDA approval was based on a clinical trial that demonstrated that 43% of patients with MDR HIV-1 infection treated with Trogarzo in combination with other antiretroviral medications achieved HIV RNA suppression.

**POLICY STATEMENT**
This policy involves the use of Trogarzo® (ibalizumab-uiyk). Prior authorization is recommended for medical benefit coverage of Trogarzo® (ibalizumab-uiyk). Approval is recommended for those who meet the conditions of coverage in the Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics for the diagnosis provided. The requirement that the patient meet the Criteria for coverage of the requested medication applies to the initial authorization only. Waste Management applies for all covered conditions. Conditions Not Recommended for Approval are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Trogarzo® (ibalizumab-uiyk) as well as the monitoring required for AEs and long-term efficacy, initial approval requires Trogarzo® (ibalizumab-uiyk) be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

**RECOMMENDED AUTHORIZATION CRITERIA**
Coverage of Trogarzo® (ibalizumab-uiyk) is recommended in those who meet the following criteria:
Food and Drug Administration (FDA)-Approved Indications

1. **Multi-drug Resistant HIV-1 Infection.**

   **Criteria.** *The patient must meet the following criteria (a, b, c, d AND e):*
   
   a) The patient is at least 18 years of age; AND  
   b) Trogarzo is prescribed by or in consultation with an infectious diseases physician or a physician who specializes in the treatment of HIV infections; AND  
   c) The patient has been diagnosed with multi-drug resistant HIV-1 infection and meets the following criteria (i and ii):  
      i. Patient has been adherent to treatment with antiretrovirals for at least 6 months and are failing or recently failed therapy; AND  
      ii. Patient has documented resistance to at least one antiretroviral medication from each of three classes of antiretroviral medications (NRTI, NNRTI, and PI) as measured by resistance testing (i.e. genotype and phenotype) [documentation required]; AND  
   d) The patient has a RNA viral load greater than 1,000 copies/mL [documentation required]; AND  
   e) Trogarzo will be used in combination with other antiretroviral medications.

   **Dosing in Multi-drug Resistant HIV-1 Infection.** *Dosing must meet the following:*

   Trogarzo is administered intravenously (IV) as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks after dilution in 250 mL of 0.9% Sodium Chloride Injection, USP.

   **Initial Approval/ Extended Approval.**
   
   A) *Initial Approval: 6 months*
   
   B) *Extended Approval: 6 months in patients achieving a decrease in viral load or sustained viral load reduction from Trogarzo [documentation required].*

   **Duration of Therapy in Multi-drug Resistant HIV-1 Infection.** Indefinite or until the patient develops resistance to Trogarzo.

   **Labs/Diagnostics.** ART resistance testing; RNA viral load.

   **Waste Management for All Indications.**

   Trogarzo is available in a single-dose, 2 mL vial containing 150 mg/mL of ibalizumab-uiyk.
   
   **Recommended Trogarzo Dose and Number Vials Per Administration:**

<table>
<thead>
<tr>
<th>Trogarzo Dose</th>
<th>Trogarzo Vials (total volume to be withdrawn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loading dose of 2,000 mg</td>
<td>10 vials (13.3 mL)</td>
</tr>
<tr>
<td>Maintenance dose of 800 mg</td>
<td>4 vials (5.32 mL)</td>
</tr>
</tbody>
</table>
CONDITIONS NOT RECOMMENDED FOR APPROVAL
Trogarzo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes J3490, J3590, C9399

†When unclassified drugs (J3490) or unclassified biologics (J3590) or unclassified drugs or biologics (C9399) is determined to be Trogarzo.

REFERENCES

| HCPCS Code(s): | 
|----------------|------------------|
| J3490          | Unclassified drugs |
| J3590          | Unclassified biologics |
| C9399          | Unclassified drugs or biologics |