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 has at least 1 anti-retroviral agent available to add to Trogarzo; AND
6. Member is NOT using Trogarzo as monotherapy. Provider must include documentation of entire anti-retroviral regimen; AND
7. **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; AND
3. Member is adherent to antiretroviral regimen as prescribed proven through chart notes, or prescriber/member attestation.

*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.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/03/2020</td>
<td>New policy for Trogarzo created.</td>
</tr>
<tr>
<td>04/25/2022</td>
<td>Transferred to new template. Updated references. Removed adherence attestation.</td>
</tr>
<tr>
<td></td>
<td>Added infectious disease specialist</td>
</tr>
</tbody>
</table>

References:


Effective date: 10/01/2022
Revised date: 04/25/2022