Trogarzo

**Description**

Trogarzo (ibalizumab-uiyk)

**Background**

Trogarzo (ibalizumab-uiyk) is a recombinant humanized monoclonal antibody that blocks HIV-1 from infecting CD4+ T-cells. This medication blocks the HIV-1 virus from entering the host cell by interfering with post-attachment steps required for the entry of HIV-1 virus that occurs via cell fusion. The binding specificity of ibalizumab-uiyk to domain 2 of CD4 allows ibalizumab-uiyk to block viral entry into host cells without causing immunosuppression (1).

**Regulatory Status**

FDA approved indication: Trogarzo, a CD4-directed post-attachment HIV-1 inhibitor, in combination with other antiretroviral(s), is indicated 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 (1).

Immune reconstitution inflammatory syndrome has been reported in one patient treated with Trogarzo in combination with other antiretrovirals. During the initial phase of combination antiretroviral therapies, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment (1).

Phenotypic and genotypic test results revealed no evidence of cross-resistance between ibalizumab-uiyk and any of the approved classes of anti-retroviral drugs (CCR5 co-receptor antagonists, gp41 fusion inhibitors, integrase strand transfer inhibitors [INSTIs], non-
nucleos(t)ide reverse transcriptase inhibitors [NNRTIs], nucleos(t)ide reverse transcriptase inhibitors [NRTIs], or protease inhibitors [PIs]). Ibalizumab-uiyk is active against HIV-1 resistant to all approved antiretroviral agents and exhibits antiretroviral activity against R5-tropic, X4-tropic, and dual-tropic HIV-1 (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Trogarzo may be considered medically necessary for patients 18 years of age or older for the treatment of HIV-1 infection and if the conditions indicated below are met.

Trogarzo may be considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

HIV-1 infection

AND ALL of the following:
1. Inadequate response to 6 months of treatment with anti-retroviral therapy (ART) and have failed therapy within the last 8 weeks
2. Viral load (VL) greater than 1,000 copies/mL
3. Have multidrug resistant HIV-1 infection including documented resistance to at least ONE medication from EACH of the following classes as measured by resistance testing:
Prior – Approval *Renewal* Requirements

**Age**
18 years of age or older

**Diagnosis**

Patient must have the following:

HIV-1 infection

**AND ALL** of the following

1. Decrease in viral load from baseline
2. Patient continues to take an optimized background regimen (OBR) of anti-retroviral therapy (ART) throughout Trogarzo therapy

### Policy Guidelines

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration**

12 months

**Prior – Approval *Renewal* Limits**

Same as above
Trogarzo, a CD4-directed post-attachment HIV-1 inhibitor, in combination with other antiretroviral(s), is indicated 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. Immune reconstitution inflammatory syndrome has been reported in one patient treated with Trogarzo in combination with other antiretrovirals. During the initial phase of combination antiretroviral therapies, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment(1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Trogarzo while maintaining optimal therapeutic outcomes.

**References**


**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.