Trogarzo (Ibalizumab-uiyk)

Definitions

Trogarzo (Ibalizumab-uiyk), a recombinant humanized monoclonal antibody, blocks 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), 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.

Dosing

Administer intravenously as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks.

Guideline

Trogarzo (Ibalizumab-uiyk) is considered medically necessary for the treatment of HIV-1 infection when the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient is diagnosed with HIV-1 infection; AND
- Patient has a documented baseline viral load of greater than 1,000 copies/ml; AND
• Patient must have been treated with antiretrovirals for at least 6 months and be failing or had recently failed (i.e., in the last 8 weeks) therapy; **AND**

• Documented resistance to ONE antiretroviral medication from each of the following three classes of antiretroviral medications:
  - Protease inhibitor (PI)
  - Nucleoside reverse transcriptase inhibitor (NRTI)
  - Non-nucleoside reverse transcriptase inhibitor (NNRTI)); **AND**

• Patient will be using Trogarzo in combination with antiretroviral treatment drugs.

Coverage for Trogarzo (ibalizumab-uiyk) may be renewed when the following criteria are met:

• Patient demonstrates a decreased viral load indicating clinically significant disease response and improvement to achieve <200 copies/mL; **AND**

• Absence of unacceptable toxicity from the drug (i.e. immune reconstitution inflammatory syndrome (IRIS), etc.)

**Limitations/Exclusions**

• Initial approval will be granted for 6 months and may be renewed

• Renewed approvals will be granted for 6 months

**Revisions**

<table>
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<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>12/3/2018</td>
<td>Added J1746 and removed J3590 from Applicable Procedure Codes.</td>
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**Applicable Procedure Codes**

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<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1746</td>
<td>Injection, ibalizumab-uiyk, 10mg</td>
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**Applicable Diagnosis Codes**

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<tr>
<td>B20</td>
<td>Human immunodeficiency virus (HIV) disease</td>
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**References**

1. TROGARZO [package insert], Montreal, Quebec Canada; Thera technologies; 2018.