



Trogarzo (Ibalizumab-uiyk)

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Number: MG.MM.PH.50v2

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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

12/3/2018 – Added J1746 and removed J3590 from Applicable Procedure Codes.

Applicable Procedure Codes

J1746	Injection, ibalizumab-uiyk, 10mg
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Applicable Diagnosis Codes

B20	Human immunodeficiency virus (HIV) disease
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References

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