

Trogarzo™ (ibalizumab-uiyk injection)

When requesting Trogarzo™ (ibalizumab-uiyk injection), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

Trogarzo, 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.

Approved Off-label Compendial use(s)

None

Coverage Guidelines

The individual must meet **all** of the following criteria for approval:

- Has human immunodeficiency virus type 1 (HIV-1) infection
- Is heavily treatment-experienced with multidrug resistance (i.e., 10 or more antiretroviral drugs)
- Trogarzo is used in combination with other antiretroviral medication(s)
- Is at least 18 years old
- For an initial authorization request, the individual has HIV RNA level greater than 1,000 copies/mL and is now failing or recently failed his/her antiretroviral therapy regimen as confirmed by drug-resistance testing (e.g., phenotypic/genotypic assays)
- For a reauthorization request, the individual is maintaining suppression of viral replication to an HIV RNA level less than 200 copies/mL

Approval duration (initial and renewal): 12 months

Dosing Recommendation

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

References

1. Trogarzo prescribing information. Irvine, California; TaiMed Biologics USA Corp. March 2018.
2. AIDSinfo. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. Available at: <https://aidsinfo.nih.gov/guidelines>, Accessed on March 17, 2018.
3. U.S. Department of Health and Human Services, Health Resources and Services Administration. Guide for
4. HIV/AIDS Clinical Care. April 2014. <https://hab.hrsa.gov/sites/default/files/hab/clinical-qualitymanagement/2014guide.pdf>. Accessed on March 19, 2018.