



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 3, 2018 May 23, 2018, August 6, 2018

TROGARZO™ (ibalizumab-uiyk)

LENGTH OF AUTHORIZATION: SIX MONTHS

INDICATION: Trogarzo, a CD4-directed post-attachment human immunodeficiency virus (HIV-1) inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

REVIEW CRITERIA:

Initial Therapy:

Multi-drug resistant HIV-1 in patients who meet ALL of the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of HIV-1 infection.
- Trogarzo must be prescribed or in consultation with an infectious diseases specialist or a physician who specializes in the treatment of HIV.
- Patient has heavily treated multi-drug resistant HIV-1 infection;
 - Patient has been compliant to current antiretroviral medications for at least six months and recently failed therapy; AND
 - Patient has documented viral resistance to at least one antiretroviral medication from each of three classes of antiretroviral medication with submitted documentation confirming resistance testing (e.g. phenotype and genotype).
- The patient has a RNA viral load greater than 200 copies/mL (submission of viral load required).
- Trogarzo is used in combination with antiretroviral therapy that includes at least one drug to which the individual's virus is susceptible.

Continuation of Therapy:

- Patient has previously received treatment with Trogarzo™.
- Disease response as indicated by a decrease in viral load.
- Physician confirms that the patient will continue to take the prescribed antiretroviral regimen in combination with Trogarzo™.

DOSING

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