

**Generic:** ibalizumab-uiyk (FDA approved 3/6/18 )

**Company:** TaiMed Biologics

**Agent for:** Multi-drug-resistant Human Immunodeficiency Virus Type 1 (HIV-1) Infection

**Indications:** Indicated for patients who have tried HIV medications in the past and whose infections cannot be successfully treated with other currently available treatments due to multi-drug-resistance. Used concurrently with other antiretroviral treatments.

**Mechanism of Action:** CD-4 directed post-attachment HIV-1 inhibitor. Trogarzo blocks the infection from binding to T-cells and interferes with the attachment steps needed for the virus to enter the host cells, which prevents transmission.

**COMPARABLE DRUGS:** None, first in its class. Other HIV medications include Triumeq, Juluca, Genvoya, Descovy, Tivicay, and Prezista.

#### COST PER MONTH (WAC)

TROGARZO: \$2,270.00

BIKTARVY: \$2,945.65

TRIUMEQ: \$ 2,805.20

JULUCA: \$2,579.00

GENVOYA: \$2,945.65

DESCOVY: \$1,675.79

TIVICAY 50MG: \$1,657.61

PREZISTA 800MG: \$1,580.64

#### ADVANTAGES:

- New type of antiretroviral medication for patients who have limited options
- No drug-drug interactions or cross-resistance with other antiretroviral therapies
- Doses are bi-weekly

#### DISADVANTAGES:

- Must be administered by trained professional
- Not a complete treatment on its own

**MOST IMPORTANT RISKS/ADVERSE EVENTS:** Most important adverse risk is immune reconstitution syndrome where the patient's immune system may develop an inflammatory response.

**MOST COMMON ADVERSE EVENTS:** Common side effects include diarrhea, dizziness, nausea and rash.

**USUAL DOSAGE:** Trogarzo is administered intravenously once every 14 days. The first dose is a single loading dose of 2,000 mg (10 vials). The maintenance doses are 800 mg (4 vials) every 2 weeks. Both doses must be diluted in 250mL of 0.9% normal saline. Duration of loading dose should be around 30 minutes. Duration of maintenance doses can be decreased to 15 minutes if no adverse reactions occur during loading dose. After the dose is completed, flush with 30 mL of 0.9% normal saline. If a maintenance dose is missed by three or more days, a loading dose should be administered as soon as possible and normal maintenance doses should be administered every 14 days after.

**PRODUCT:** Product comes as a 200 mg/ 1.33 mL solution in a single-dose 2 mL vial. The solution is colorless to slightly yellow and clear. It should be administered immediately once diluted. If not, it can be stored at room temperature for 4 hours or refrigerated for 24 hours. If refrigerated, let the product sit at room temperature for at least 30 minutes but no more than 4 hours prior to administration. The vials should be stored in a refrigerator at 2 to 8°C (36-46 °F).

**COMMENTS:** HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). HIV is transmitted through contact with infected body fluids. It targets the immune system and invades T-cells, which normally fight infection. The virus replicates and destroys the immune system. There is no known cure for HIV. The current medications help manage HIV by preventing it from replicating. Medications do not prevent the spread of HIV. Up to 25,000 Americans with HIV are multidrug resistant and half have detectable viral loads, making the virus transmittable. In the clinical trial, Trogarzo reduced the viral load within 7 days and maintained the response when combined with another active antiretroviral therapy. 43% of patients achieved undetectable viral loads after 24 weeks during the clinical trials. An increase in the mean number of CD4+ T-cells was also seen at the end of the clinical trials. However, the trial size was only 40 patients.