

Trogarzo™ (ibalizumab-uiyk)
Effective 06/01/2019

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Trogarzo (ibalizumab-uiyk) is a CD4-directed post-attachment 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.

Coverage Guidelines

Trogarzo may be approved if the member meets all the following criteria and documentation has been submitted:

1. Member is diagnosed with HIV-1 infection
2. Member is 18 years of age or older
3. Prescriber is an infectious disease or HIV specialist experienced in the use of this treatment
4. Documentation that the member has exhausted oral and injectable treatments available for HIV and requires Trogarzo to achieve effective antiretroviral combination therapy, optimized with at least 1 and preferably 2 fully active agents with demonstrated full viral sensitivity /susceptibility
5. Member is currently using other antiretrovirals
6. Documentation of resistance to at least one antiretroviral medication from each of these antiretroviral medication classes (including combination agents):
 - a. NRTI (Combivir, Viread, Epivir, etc.)
 - b. NNRTI (Edurant, Intelence, Sustiva, etc.)
 - c. PI (Prezista, Eviataz, Aptivus, etc.)
7. Recent HIV ribonucleic acid viral load (within last 8 weeks) of > 200 copies/mL persisting after at least 6 months of antiretroviral therapy.

Limitations

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 12 months

References

1. Trogarzo (ibalizumab-uiyk) [prescribing information]. Irvine, CA: TaiMed Biologics USA Corp; May 2018.
2. Lewis S, Fessel J, Emu B, et al. Long-acting ibalizumab in patients with multi-drug resistant HIV-1: A 24-week study. Presented at CROI 2017. 13-17 February 2017, Seattle. Abstract #449LB.
3. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. US Department of Health and Human Services. Last updated October 2018. Accessed on December 28, 2018.
4. Saag MS, Benson CA, Gandhi RT, et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2018 Recommendations of the International Antiviral Society-USA Panel. *JAMA* 2018; 320:379.
5. Jacobson JM, Kuritzkes DR, Godofsky E, et al. Safety, pharmacokinetics, and antiretroviral activity of multiple doses of ibalizumab (formerly TNX-355), an anti-CD4 monoclonal antibody, in human immunodeficiency virus type 1-infected adults. *Antimicrob Agents Chemother*. 2009;53(2):450-457.
6. Emu B, Fessel J, Schrader S., et al., Phase 3 study of ibalizumab for multidrug-resistant HIV-1, *N Engl J Med* 2018 Aug 16; 379(7):645-654.

Review History

02/20/2019 – Reviewed

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

