Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Trogarzo (ibalizumab-uiyk)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Trogarzo (ibalizumab-uiyk) Injection	8 vials per 28 days*

*Initiation of therapy with Trogarzo (ibalizumab-uiyk): May approve up to 6 additional vials in the first 28 days of treatment.

APPROVAL CRITERIA

Requests for Trogarzo (ibalizumab-uiyk) may be approved if the following criteria are met:

I. Individual is using to treat human immunodeficiency virus (HIV) infection; **AND**
II. Individual has a viral load of $\geq$ 1000 copies/mL; **AND**
III. Individual has a history of at least 6 months on antiretroviral treatment; **AND**
IV. Individual is receiving a failing antiretroviral regimen or has failed and is off therapy; **AND**
V. Individual has documented resistance to at least one antiretroviral agent from three different classes as measured by resistance testing; **AND**
VI. Individual is using in combination with other antiretroviral agents and has documentation of full viral sensitivity/susceptibility to at least one antiretroviral agent (other than Trogarzo) as determined by resistance testing.

Trogarzo (ibalizumab-uiyk) may **not** be approved for the following:

I. All other indications not included above; **OR**
II. Individuals who has received immunomodulating therapy within the 12 weeks of initiating treatment with Trogarzo (for example, interferon, systemic steroids or systemic chemotherapy) (NCT00784147); **OR**
III. Individuals being treated for an acute infection secondary to HIV infection (NCT00784147).

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. A Phase 2b, Randomized, Double-Blinded, 48-Week, Multicenter, Dose-Response Study of Ibalizumab Plus an Optimized Background Regimen in Treatment-Experienced Patients Infected With HIV-1(Amended to 24-Weeks). Last Update: May 5, 2104. ClinicalTrials.gov Identifier: NCT00784147. Available at: https://clinicaltrials.gov/ct2/show/study/NCT00784147?term=ibalizumab&rslt=With&rank=1&sect=X70156. Accessed: October 18, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 18, 2018.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Emu B, Fessel J, Schrader S, et. al. Phase 3 Study of Ibalizumab for Multidrug-Resistant HIV-1. *N Engl J Med.* 2018; 379(7): 645-654.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
7. Ibalizumab FDA Summary Review. March 4, 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761065Orig1s000SumR.pdf. Accessed: October 18, 2018.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.