

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	NA	X	NA	NA	X	NA	X	NA	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Trogarzo (ibalizumab-uiyk)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Trogarzo (ibalizumab-uiyk) Injection

### 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 (HIC) 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 (FDA Summary, 2018); **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. 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**
- II. Individuals being treated for an acute infection secondary to HIV infection (NCT00784147).

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.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	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](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761065Orig1s000SumR.pdf). Accessed: October 18, 2018.

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