

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

*FHK- Florida Healthy Kids

Trogarzo (ibalizumab-uiyk)

DRUG.00096

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Trogarzo (ibalizumab-uiyk) Injection

APPROVAL CRITERIA

Requests for Trogarzo (ibalizumab-uiyk) may be approved for the treatment of multidrug-resistant HIV in combination with other antiretroviral(s) if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a viral load of ≥ 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. Documented resistance to at least one antiretroviral medication from each of the following three named classes as measured by resistance testing
 1. non-nucleoside reverse transcriptase inhibitors (NNRTIs); **AND**
 2. nucleoside reverse transcriptase inhibitors (NRTIs), **AND**
 3. protease inhibitors (PIs); **AND**
- VI. Documentation of full viral sensitivity/susceptibility to at least one antiretroviral agent, other than ibalizumab-uiyk, as determined by resistance tests.

Trogarzo (ibalizumab-uiyk) may **not** be approve when the criteria above are not met and for all other indications, including but not limited to:

- I. Individuals who have received immunomodulating therapy within the 12 weeks preceding initiation of treatment with ibalizumab ibalizumab-uiyk (for example, interferon, systemic steroids or systemic chemotherapy); **OR**
- II. Individuals being treated for an acute infection secondary to HIV infection.

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New Program Date 04/30/2018

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.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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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. Department of Health and Human Services (DHHS). AIDSinfo. Ibalizumab. Updated on September 01, 2016. Available at: <https://aidsinfo.nih.gov/drugs/511/ibalizumab/0/professional>. Accessed on June 21, 2018.
2. Department of Health and Human Services (DHHS). Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. Updated on May 30, 2018. Available at: <https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>. Accessed on June 21, 2018.
3. Ibalizumab. In: DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated March 16, 2018. Available at: <http://www.micromedexolutions.com>. Accessed on June 21, 2018.
4. Trogarzo™ [Product Information Label], Irvine, CA. TaiMed Biologics, Inc. Revised March 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/7610651b1.pdf. Accessed June 21, 2018.
5. Theratechnologies Inc. Ibalizumab plus optimized background regimen in patients with multi-drug resistant HIV. NLM Identifier: NCT02475629. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT02475629>. Accessed on June 21, 2018.

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