Updated: 03/2020
DMMA Approved: 03/2020

Request for Prior Authorization for Trogarzo (Ibalizumab-uiyk)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Trogarzo (Ibalizumab-uiyk) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Trogarzo (Ibalizumab-uiyk) Prior Authorization Criteria:

Grandfathering provision: members that are stable on the medication and new to Highmark Health Options will be maintained on therapy

Coverage may be provided with a diagnosis of multidrug resistant HIV-1 infection and the following criteria is met:

- Must be at least 18 years of age
- Must provide lab result confirming documented resistance to at least one antiretroviral (ART) medication from each of the three following classes of antiretroviral medications as measured by resistance testing:
  - Protease inhibitor (PI)
  - Nucleoside reverse transcriptase inhibitor (NRTI)
  - Non-nucleoside reverse transcriptase inhibitors (NNRTI)
- Must be adherent to current ART regimen for at least 6 months as verified by pharmacy claims and physician attestation member is failing or recently failed (i.e. in the last 8 weeks) therapy
- Must have a viral load (HIV RNA level) greater than 1,000 copies/mL
- Must use in combination with an optimized background regimen containing at least one ART medication that demonstrates sensitivity/susceptibility
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - Documentation of a decrease in viral load or sustained reduction as a result of treatment
  - Continues to use in combination with an optimized background antiviral regimen containing at least one ART medication
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

Highmark Delaware
HEALTH OPTIONS

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TROGARZO (IBALIZUMAB-UIYK)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE: _____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Multidrug resistant HIV-1 ☐ Other: _____ ICD-10 Code: _____

Does the member have documented resistance to at least one antiretroviral (ART) medication from each of the following classes: PI, NRTI, NNRTI? *Documentation must be provided* ☐ Yes, see attached fax ☐ No

Has the member been adherent to their current ART regimen for at least 6 months? ☐ Yes ☐ No

Does the member have a viral load greater than 1,000 copies/ml? ☐ Yes ☐ No

Will this be used in combination with an optimized background antiviral regimen? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a decrease in viral load or sustained the reduction as a result of this treatment? ☐ Yes ☐ No

Is this being used in combination with an optimized background antiviral regimen? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date