Updated: 03/2019
PARP Approved: 04/2019

Prior Authorization Criteria

Trogarzo (Ibalizumab-uiyk)

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

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 or physician attestation and are failing or recently failed 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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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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 Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 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:
Gateway 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:

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