Washington Early Intervention Program (EIP)
Prior Authorization for Trogarzo™ (Ibalizumab-uiyk)
For Insured and Uninsured Members
TELEPHONE: 888-311-7632 FAX: 800-848-4241

APPLICATION INFORMATION

Ramsell is the contracted Pharmacy Benefit Manager for Washington EIP. Requests for prior authorization for Trogarzo™ will be reviewed and approved by the Ramsell Clinical Department.

Please complete the attached supplemental form and fax to Ramsell at 800-848-4241. The prescriber must confirm medical necessity for Trogarzo™ use by checking the appropriate boxes and signing the Prior Authorization form where indicated. The request must include all of the supporting lab results and chart documentation for approval. For additional questions, call the Ramsell help desk at 888-311-7632.

ELIGIBILITY

Patients must have current EIP eligibility. Copayments can be covered for insured members and full pay for uninsured members.

Approval Period:

Initial coverage will be provided for **6 months** when all of the following criteria are met:

- Patient is at least 18 years old
- Patient is diagnosed with HIV-1
- Patient is heavily treatment experienced
- Patient is experiencing antiretroviral treatment failure documented by the inability to achieve or maintain viral suppression at an HIV RNA level of <200 copies/ml
- Patient has documented multidrug resistant HIV-1 infection
- Trogarzo treatment will be combined with other antiretroviral(s)

Renewal Guideline: Coverage will be renewed for an additional **6 months** when all of the following criteria are met:

- Patient demonstrates a disease response by a decrease in viral load from start of therapy; AND
- Absence of unacceptable toxicity from the drug (i.e. immune reconstitution inflammatory syndrome (IRIS), etc.)

Limits: Approval of this application is dependent on availability of WA EIP funding.

Approval notification: Clinicians will be notified of the approval decision via fax.

MEDICAL ELIGIBILITY

All supporting laboratory results and chart notes are **REQUIRED**:

- ☐ CD4 count (within the last 6 months)
- ☐ HIV viral load (within the last 6 months)
- ☐ Proof of documented multidrug resistance

If the requesting renewal, please provide documentation to demonstrate a disease response by a decrease in viral load from baseline; AND absence of unacceptable toxicity from the drug (i.e. immune reconstitution inflammatory syndrome etc)

References: TROGARZO [package insert], Montreal, Quebec Canada; Thera technologies; 2018.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761065lbl.pdf
https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0

WA EIP Distribution network for Trogarzo - Accredo & Walgreens (Alliance Rx Specialty Pharmacy)

Washington Early Intervention Program (EIP)
Supplemental/Prior Authorization Form for Trogarzo™ ((Ibalizumab-uiyk)
TELEPHONE: 888-311-7632 FAX: 800-848-4241
Please complete the ALL sections below for determination of treatment authorization

Trogarzo™ (Ibalizumab-uiyk), a CD4-directed post-attachment HIV-1 inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV -1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

Prescriber Name and Signature must be included. Please fax completed application to Ramsell at 800-848-4241.For additional information, call the Ramsell Help Desk at: 1-888-311-7632.

Medical Justification - Completion of all questions with documentation is REQUIRED for approval

Section 1 Patient Name: DOB: EIP ID #:

Latest CD4 count & Viral Load _____/_____ Date of Results

Section 2

Planned Trogarzo™ treatment regimen and duration (check all that apply):

☐ Loading Dose: 2,000 mg (13.3 ml **OR** 10 vials) X 1 **(Dosed Once)**
☐ Maintenance Dose: 800 mg (5.32ml or 4 vials) every 2 weeks

Dosage Form: Injection: 200 mg/1.33 mL (150 mg/mL) in a single-dose vial.

YES NO Check ALL that apply)

☐ ☐ 1. New Start patient: Requesting a loading dose ONLY

☐ ☐ 2. Maintenance Dose: This patient is continuing treatment with Trogarzo™ that was initiated with a loading dose at the prescriber's office on (*Insert date of loading dose*) _____
Name & Phone number of pharmacy that dispensed the initial loading dose is included for confirmation purposes:
Pharmacy Name: _____
Pharmacy phone #: _____

☐ ☐ 3. Trogarzo™ is being used as therapy in a treatment-experienced patient with multidrug resistant HIV-1
Medications tried/failed include_____

For ALL (NOTE: Failure to answer any of the questions below will result in a denial)

☐ ☐ 4. I have reviewed the clinical information on the proposed prescription for possible drug-drug interactions with other medications currently prescribed to the patient

☐ ☐ 5. I confirm that this patient is HIV -1 infected, heavily treatment-experienced with multidrug resistant HIV-1 infection and is failing their current antiretroviral regime *(Provide supporting documentation)*

☐ ☐ 6. Patient will receive the following other antiretroviral(s):

Date: **To the best of my knowledge, I certify that the above is accurate and true.**

Prescriber Name Prescriber Signature

Phone # Fax #

Pharmacy Name Pharmacy Phone # Fax #

REQUIRED DOCUMENTATION - Please submit ALL required clinical notes/ lab reports in reference to this request. Failure to provide documentation will delay decision process.

☐ CD4 count (within the last 6 months) ☐ HIV viral load (within the last 6 months) ☐ Proof of documented multidrug resistance.