Clinical Policy: Ibalizumab-uiyk (Trogarzo)
Reference Number: ERX.SPA.236
Effective Date: 04.17.18
Last Review Date: 05.18

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Trogarzo™ is a CD4-directed post-attachment human immunodeficiency virus type 1 (HIV-1) inhibitor.

FDA Approved Indication(s)
Trogarzo is indicated for the treatment of HIV-1 infection, in combination with other antiretroviral(s), in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Trogarzo is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. HIV-1 Infection (must meet all):
      1. Diagnosis of multidrug resistant HIV-1 infection;
      2. Prescribed by or in consultation with an infectious disease or HIV specialist;
      3. Age ≥ 18 years;
      4. Documentation of resistance to at least 1 antiretroviral agent from each of 4 classes (NRTI, NNRTI, PI, INSTI), unless contraindicated or clinically significant adverse effects are experienced;
      5. Failure of Fuzeon, unless resistant, contraindicated, or clinically significant adverse effects are experienced;
      6. Failure of Selzentry, if CCR5-tropic, unless resistant, contraindicated, or clinically significant adverse effects are experienced;
      7. Current (within the past 30 days) HIV ribonucleic acid viral load of ≥ 200 copies/mL;
      8. Prescribed concurrently with additional antiretroviral agents to which member is susceptible, if available;
      9. Dose does not exceed 2,000 mg (10 vials) IV loading dose* and/or 800 mg (4 vials) IV every 14 days.
         *A loading dose may be repeated if the member misses scheduled maintenance dose by 3 days or more.
   Approval duration: 6 months

   B. Other diagnoses/indications
      1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. HIV-1 Infection (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Trogarzo for a covered indication and has received this medication for at least 30 days;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed 2,000 mg (10 vials) IV loading dose* and/or 800 mg (4 vials) IV every 14 days.
         *A loading dose may be repeated if the member misses scheduled maintenance dose by 3 days or more.
   Approval duration: 12 months
B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy. 
      Approval duration: Duration of request or 6 months (whichever is less); or 
   2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   FDA: Food and Drug Administration 
   HIV-1: human immunodeficiency virus type 1
   INSTI: integrase strand transfer inhibitors
   NNRTI: non-nucleoside reverse transcriptase inhibitor
   NRTI: nucleos(t)ide reverse transcriptase inhibitor
   PI: protease inhibitor

   Appendix B: Therapeutic Alternatives
   This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nucleos(t)ide reverse transcriptase inhibitors (NRTIs) (e.g., abacavir, tenofovir disoproxil fumarate, Emtriva®, etc.)</td>
<td>Refer to prescribing information</td>
<td>Refer to prescribing information</td>
</tr>
<tr>
<td>Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g., efavirenz, nevirapine, Edurant®, etc.)</td>
<td>Refer to prescribing information</td>
<td>Refer to prescribing information</td>
</tr>
<tr>
<td>Integrase strand transfer inhibitors (INSTIs) (e.g., Tivicay®, Isentress®)</td>
<td>Refer to prescribing information</td>
<td>Refer to prescribing information</td>
</tr>
<tr>
<td>Protease inhibitors (PIs) (e.g., atazanavir, fosamprenavir, Invirase®, Viracept®, etc.)</td>
<td>Refer to prescribing information</td>
<td>Refer to prescribing information</td>
</tr>
</tbody>
</table>
   | Fuzeon® (enfuvirtide, T-20)                   | Refer to prescribing information       | Adults: 180 mg/day  
Children 6 years and older: 4 mg/kg/day |
   | Selzentry® (maraviroc, MVC)                   | Refer to prescribing information       | 600 mg/day; 1200 mg/day if taking a potent CYP3A inducer |

   Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

   Appendix C: Contraindications
   Not applicable

V. Dosage and Administration
<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 infection</td>
<td>A single loading dose of 2,000 mg IV, followed by a maintenance dose of 800 mg every 2 weeks.</td>
<td>2,000 mg every 17 days*</td>
</tr>
</tbody>
</table>
**Indication** | **Dosing Regimen** | **Maximum Dose**
--- | --- | ---
If a maintenance dose is missed by 3 days or longer beyond the scheduled dosing day, a loading dose of 2,000 mg should be administered as early as possible prior to resuming maintenance dosing of 800 mg every 2 weeks thereafter.

*Frequency of every 17 days was calculated from frequency of maintenance dose (every 14 days) plus minimum number of days that the dose is missed to qualify for another loading dose (3 days).*

**VI. Product Availability**

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

**VII. References**


**Reviews, Revisions, and Approvals**

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created</td>
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**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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