Medical Necessity Criteria

Trogarzo™ (Ibalizumab-uiyk) is considered medically necessary when ALL of the following criteria are met:

• Documentation of multidrug-resistant HIV infection
• Used in combination with other antiretroviral(s)

Initial and reauthorization is up to 12 months.

Trogarzo (Ibalizumab-uiyk) is not covered for any other uses because it is considered experimental, investigational or unproven.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.
FDA Approved Indication
Trogarzo, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

Recommended Dosing

FDA Recommended Dosing
Trogarzo is available in a single-dose, 2 mL vial containing 150 mg/mL of ibalizumab-uiyk. Each vial delivers approximately 1.33 mL containing 200 mg of ibalizumab-uiyk.

Trogarzo is administered intravenously (IV), after diluting the appropriate number of vials in 250 mL of 0.9% Sodium Chloride Injection, USP. Patients should receive a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks.

Dose modifications of Trogarzo are not required when administered with any other antiretroviral or any other treatments.

Drug Availability
Supplied as 200 mg/1.33 mL (150 mg/mL) in a single-dose 2 mL vial.

Background

Professional Societies/Organizations
Department of Health and Human Services (DHHS) Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV recommend ibalizumab be considered for individuals with treatment failure and who have inadequate treatment options to design a suppressive regimen. (DHHS, 2018)

American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative:
No recommendations are available for ibalizumab.

Centers for Medicare & Medicaid Services - National Coverage Determinations (NCDs):
There are no CMS National Coverage Determinations for ibalizumab.

Off label uses:
The American Hospital Formulary Service currently supports no off-label uses of Ibalizumab. (AHFS, 2018)

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered medically necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1746</td>
<td>Injection, ibalizumab-uiyk, 10 mg</td>
</tr>
</tbody>
</table>

References