COMMUNITY HEALTH CHOICE

Trogarzo® (ibalizumab-uiyk)

Effective Date: 5/1/2024
Medical Care Management Committee Approval: 2/15/2024

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Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Trogarzo® (ibalizumab-uiyk) product:

HCPCS Code	Description	Maximum Dosage per Administration
J1746	Injection, ibalizumab-uiyk, 10 mg	2,000 mg loading dose; 800 mg maintenance dose

Diagnosis Specific Criteria

Trogarzo® (ibalizumab-uiyk) will be considered medically necessary for members meeting ALL of the following criteria:

Initial authorization: Approve for 6 months

1. Patient is ≥18 years of age; AND
2. Diagnosis of Human Immunodeficiency Virus (HIV)-1 infection; AND
3. Evidence of HIV-1 RNA > 1,000 copies/mL within the past 30 days (documentation required); AND
4. Evidence of resistance to at least one antiretroviral medication from each of the following drug classes: Nucleoside/tide Reverse Transcriptase Inhibitor (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) and Protease Inhibitor (PI) via resistance testing (documentation required); AND
5. Prescriber attestation of member adherence to highly active antiretroviral therapy (HAART) for at least 6 months and treatment is failing or recently failed (within previous 8 weeks); AND

6. Attestation that member will continue an optimized background antiretroviral regimen in combination with Trogarzo (ibalizumab-uiyk)

Continuation of Therapy: Approve for 12 months

1. Member has experienced significant clinical response to Trogarzo as evidenced with viral load < 200 copies/mL; AND
2. Prescriber attestation that member has been adherent to prescribed HIV medications; AND
3. Attestation that member will continue an optimized background antiretroviral regimen in combination with Trogarzo (ibalizumab-uiyk); AND
4. Member has not experienced intolerable side effects or drug toxicity from Trogarzo

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Diagnosis specific criteria above is also required to be met.

HCPCS Code	Description
J1746	Injection, ibalizumab-uiyk, 10 mg

Diagnosis Code	Description
B20	Human Immunodeficiency virus (HIV) disease
Z16.33	Resistance to antiviral drug(s)
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

Policy Revision History

Status	Effective Date	Description
Baseline	TBD	Initial version of Trogarzo (ibalizumab-uiyk) Diagnosis Specific Criteria