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Next Review Due By: 01/2025
Policy Number: C14522-A

Trogarzo (ibalizumab-uiyk)

PRODUCTS AFFECTED

Trogarzo (ibalizumab-uiyk)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Multidrug resistant HIV-1 infection

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. MULTI-DRUG RESISTANT HIV1 INFECTION:
1. Documented diagnosis of HIV-1
   AND
2. Documentation of current HIV RNA viral load of greater than 1,000 copies/mL (within the past 30

days) [DOCUMENTATION REQUIRED]
AND

3. Prescriber attestation of member adherence to highly active antiretroviral therapy for at least 6 months AND member is failing, or has recently failed therapy within the past 8 weeks [MOLINA REVIEWER NOTE: Please verify historical claims unless benefit is not managed by Molina]
AND
4. Documentation that the member has been prescribed and will continue to take an optimized background antiretroviral regimen (OBR), containing at least one antiretroviral agent that demonstrates full viral sensitivity/susceptibility, in combination with Trogarzo (ibalizumab-uiyk).
AND
5. Documented viral resistance to at least ONE agent from EACH of the following THREE classes of HIV antiretroviral medication (as single agent products or combination products), unless contraindicated or clinically significant adverse effects are experienced. Documented resistance as measured by resistance testing, completed while member is current to therapy or within 4 weeks if possible. [DOCUMENTATION REQUIRED]
    a. Protease inhibitor (PI)
    b. Nucleoside reverse transcriptase inhibitor (NRTI)
    c. Non-nucleoside reverse transcriptase inhibitor (NNRTI)

CONTINUATION OF THERAPY:

A. MULTI-DRUG RESISTANT HIV-1 INFECTION:

1. Documentation of decreased viral load < 200 copies/mL indicating clinically significant disease response and improvement as a result of treatment [DOCUMENTATION REQUIRED]
AND
2. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)
AND
3. Documentation member continues to take an optimized background regimen (OBR) of antiretroviral therapy in combination with Trogarzo (ibalizumab-uiyk) (review Rx history for compliance)
AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified infectious disease or HIV specialist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Loading dose: 2,000 mg (10 vials) once
Maintenance Dose: 800 mg (4 vials) every 14 days

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Trogarzo. For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Antiretroviral CD4 Directed Post-Attachment Inhibitor

FDA-APPROVED USES:
Indicated for the treatment of human immunodeficiency virus type 1 (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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Trogarzo (Ibalizumab-uiyk), a recombinant humanized monoclonal antibody, blocks HIV-1 from infecting CD4+ T cells by binding to domain 2 of CD4 and interfering with post-attachment steps required for the entry of HIV-1 virus particles into host cells and preventing the viral transmission that occurs via cell-cell fusion. Trogarzo (Ibalizumab-uiyk), 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. There are no data yet on the activity of ibalizumab against HIV-2. Trogarzo (Ibalizumab-uiyk) is the first antiretroviral that does not require daily dosing, and the first anti-HIV therapy with a novel mechanism to be introduced in a decade.

Trogarzo (Ibalizumab-uiyk) reduced viral loads in heavily treatment-experienced patients with multidrug-resistant infection in one single-arm trial. Use should be combined with an optimized anti-HIV regimen. Its long-term efficacy and safety remain to be determined. No cross-resistance between ibalizumab and other FDA-approved antiretroviral drugs has been observed to date. There is currently no commercially available resistance test for the CD4 T lymphocyte post-attachment inhibitor ibalizumab.

Safety and efficacy were evaluated in a clinical trial among 40 heavily treatment-experienced patients with MDR HIV-1 who continued to have high levels of HIV RNA in their blood despite many having previously been treated with 10 or more antiretroviral drugs. The majority of participants experienced a significant decrease in HIV RNA levels one week after ibalizumab-uiyk was added to their failing antiretroviral regimens. After 24 weeks of ibalizumab-uiyk plus other antiretroviral drugs,43% of trial participants achieved HIV RNA suppression.

The loading dose of TROGARZO is administered as a diluted intravenous infusion (IV infusion) or an undiluted IV push. Maintenance doses of TROGARZO may be administered as a diluted IV infusion or undiluted intravenous push (IV push). If a maintenance dose (800 mg) of TROGARZO is missed by 3 days or longer beyond the scheduled dosing day, a loading dose (2,000 mg) should be administered as early as possible. Resume maintenance dosing (800mg) every 14 days thereafter.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Trogarzo (ibalizumab-uiyk) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Trogarzo (ibalizumab-uiyk) include: prior hypersensitivity reaction to TROGARZO or any components of the product, resistance to Trogarzo (ibalizumab-uiyk) therapy as indicated by Prescriber notes/lab report(s)/documentation.

OTHER SPECIAL CONSIDERATIONS:
Use is not recommended in antiretroviral therapy-naïve patients. CD4 count, HIV RNA plasma levels, infusion-related reactions should be monitored. Virologic failure may be defined as not achieving a viral load of <200 copies/mL within 6 months (24 weeks) of initiating antiretroviral therapy. For individuals who were initially able to suppress their viral load, virologic failure is defined as a recurrence of viremia to >200 copies/mL on two consecutive measurements taken approximately one month apart.

If a maintenance dose (800 mg) of TROGARZO is missed by 3 days or longer beyond the scheduled dosing day, a loading dose (2,000 mg) should be administered as early as possible. Resume maintenance dosing (800mg) every 14 days thereafter.

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

HCPCS CODE	DESCRIPTION
J1746	Injection, ibalizumab-uiyk, 10 mg

AVAILABLE DOSAGE FORMS:
Trogarzo SOLN 200MG/1.33ML single-dose vial

REFERENCES

1. Trogarzo (ibalizumab-uiyk) [prescribing information]. Montreal, Quebec, Canada: Theratechnologies Inc; December 2023.
2. Lewis S, Fessel J, Emu B, et al. Long-acting ibalizumab in patients with multi-drug resistant HIV-1: a 24-week study. Poster presented at: Conference on Retroviruses and Opportunistic Infections (CROI); February 13-16, 2017; Seattle, WA.
3. TaiMed Biologics, Inc. Ibalizumab Plus Optimized Background Regimen in Member With Multi- Drug Resistant HIV. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2017 Feb 6]. Available from: https://clinicaltrials.gov/show/NCT02475629. NLM Identifier: NCT02475629.
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5. Emu B, Fessel WJ, Schrader S, et al. Forty-eight-week safety and efficacy on–treatment analysis of ibalizumab in patients with multi-drug resistant HIV-1 [abstract 1686]. Open Forum Infect Dis. 2017;4(suppl 1):S38-S39.
6. Department of Health and Human Services. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. AIDS info website. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0. Updated March 27, 2018.
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7. Panel on Antiretroviral Guidelines for Adults and Adolescents: Guidelines for the use of antiretroviral

agents in HIV-1-infected adults and adolescents. AIDS info, Department of Health and Human Services. Rockville, MD. 2012. Available from URL: http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed July 2018.
8. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed 31 October 2022.
9. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed 4 December 2023.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Continuation of Therapy Drug Class Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Background Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file