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5.01.045

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Anti-Infective Agents	**Original Policy Date:**	April 13, 2018
Subject:	Trogarzo	**Page:**	1 of 4

Last Review Date: June 13, 2024

Trogarzo

Description

Trogarzo (ibalizumab-uiyk)

Background
Trogarzo (ibalizumab-uiyk) is a recombinant humanized monoclonal antibody that blocks HIV-1 from infecting $CD4^+$ T-cells. This medication blocks the HIV-1 virus from entering the host cell by interfering with post-attachment steps required for the entry of HIV-1 virus that occurs via cell fusion. The binding specificity of ibalizumab-uiyk to domain 2 of CD4 allows ibalizumab-uiyk to block viral entry into host cells without causing immunosuppression (1).

Regulatory Status
FDA-approved indication: Trogarzo, a CD4-directed post-attachment HIV-1 inhibitor, 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 (1).

Immune reconstitution inflammatory syndrome has been reported in one patient treated with Trogarzo in combination with other antiretrovirals. During the initial phase of combination antiretroviral therapies, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment (1).

Phenotypic and genotypic test results revealed no evidence of cross-resistance between ibalizumab-uiyk and any of the approved classes of anti-retroviral drugs (CCR5 co-receptor

antagonists, gp41 fusion inhibitors, integrase strand transfer inhibitors [INSTIs], non-nucleos(t)ide reverse transcriptase inhibitors [NNRTIs], nucleos(t)ide reverse transcriptase inhibitors [NRTIs], or protease inhibitors [PIs]). Ibalizumab-uiyk is active against HIV-1 resistant to all approved antiretroviral agents and exhibits antiretroviral activity against R5-tropic, X4-tropic, and dual-tropic HIV-1 (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies
Cabenuva

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Trogarza may be considered **medically necessary** if the conditions indicated below are met.

Trogarza may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

HIV-1 infection

AND ALL of the following:

1. Inadequate response to 6 months of treatment with anti-retroviral therapy (ART) and have failed therapy within the last 8 weeks
2. Viral load (VL) greater than 1,000 copies/mL
3. Have multidrug resistant HIV-1 infection including documented resistance to at least **ONE** medication from **EACH** of the following classes as measured by resistance testing:
    a. Protease inhibitor (PI)

b. Nucleoside reverse transcriptase inhibitors (NRTI)
c. Non-nucleoside reverse transcriptase inhibitors (NNRTI)

4. Physician agrees to start an optimized background regimen (OBR) of anti-retroviral therapy (ART)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

HIV-1 infection

AND ALL of the following

1. Decrease in viral load from baseline
2. Patient continues to take an optimized background regimen (OBR) of anti-retroviral therapy (ART) throughout Trogarzo therapy

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Trogarzo, a CD4-directed post-attachment HIV-1 inhibitor, 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. Immune reconstitution inflammatory syndrome has been reported in one patient treated with Trogarzo in combination with other antiretrovirals. During the initial phase of combination antiretroviral therapies, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Trogarzo while maintaining optimal therapeutic outcomes.

References

1. Trogarzo [package insert]. Montreal, Canada: Theratechnologies, Inc.; December 2024.

Policy History

Date	Action
March 2018	Addition to PA
June 2018	Annual editorial review
December 2019	Annual review
December 2020	Annual review and reference update
June 2021	Annual review
December 2022	Annual review and reference update. Changed policy number to 5.01.045
June 2023	Annual review
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.