

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

Summary

Trogarzo, a CD4-directed post-attachment HIV-1 inhibitor, in combination with other



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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.