Trogarzo® (Ibalizumab-Uiyk)

Policy Number: CS2023D0063M
Effective Date: July 1, 2023

Instructions for Use

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Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Trogarzo® (Ibalizumab-Uiyk) (for Indiana Only)
Kansas	Refer to the state's Medicaid clinical policy
Louisiana	None
New Jersey	None
North Carolina	None
Ohio	Trogarzo® (Ibalizumab-Uiyk) (for Ohio Only)
Pennsylvania	Refer to the state's Medicaid clinical policy
Texas	Refer to drug specific criteria found within the Texas Medicaid Provider Procedures Manual

Coverage Rationale

Trogarzo (ibalizumab-uiyk) is proven and medically necessary for the treatment of multi-drug resistant human immunodeficiency virus (HIV) in patients who meet all of the following criteria:[1]

- For **initial therapy**, **all** of the following:
  - Both of the following:
    - Diagnosis of HIV-1 infection.
    - Provider attestation that the patient has multi-drug resistant HIV-1 infection.

    and
  - Provider confirms that the patient has been prescribed an optimized background antiretroviral regimen, containing at least one antiretroviral agent that demonstrates full viral sensitivity/susceptibility; **and**
  - Trogarzo (ibalizumab-uiyk) initial and maintenance dosing is in accordance with the U.S. Food and Drug Administration prescribing information; **and**
  - Initial authorization is for no more than 12 months.

- For **continuation of therapy**, **all** of the following:
  - Patient has previously received treatment with Trogarzo (ibalizumab-uiyk); **and**
  - Provider confirms that the patient has achieved a clinically significant viral response to Trogarzo (ibalizumab-uiyk) therapy; **and**
  - Provider confirms that the patient will continue to take an optimized background antiretroviral regimen in combination with Trogarzo (ibalizumab-uiyk); **and**
  - Trogarzo (ibalizumab-uiyk) maintenance dosing is in accordance with the U.S. Food and Drug Administration prescribing information; **and**
  - Authorization is for no more than 12 months.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

Diagnosis Code	Description
B20	Human immunodeficiency virus [HIV] disease
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

Background

Trogarzo (ibalizumab-uiyk) is a humanized monoclonal antibody for the treatment of MDR HIV-1 infection. Trogarzo (ibalizumab-uiyk) binds primarily to the second extracellular domain of the CD4 + T cell receptor, away from major histocompatibility complex II molecule binding sites. It prevents HIV from infecting CD4 + immune cells while preserving normal immunological function. Trogarzo (ibalizumab-uiyk) is active against HIV-1 resistant to all approved antiretroviral agents.[1]

Clinical Evidence

A single arm, multicenter, 24-week study examined the efficacy and safety of ibalizumab plus an optimized background regimen (OBR) in treatment-experienced patients infected with multidrug resistant HIV-1. The primary objective of this study was to demonstrate the antiviral activity of ibalizumab seven days after the first dose of ibalizumab. Enrolled patients were already receiving failing antiretroviral therapy (ART), or no therapy. Patients had a mean HIV-1 viral load of 100,287 copies/mL, with 18% having viral loads above 100,000 copies/mL. The median CD4 + T cell count was 73 cells/µL and 30% had less than 10 CD4 + T cells/µL. Patients received a single loading dose of 2,000 mg of ibalizumab, intravenously (IV), in addition to their current therapy, and continued dosing at 800 mg IV every two weeks through 24 weeks. The primary efficacy endpoint was the proportion of patients achieving a ≥ 0.5 log10 decrease in HIV-1 RNA seven days after initiating ibalizumab therapy, day 14 of the study. After the single loading dose, patients experienced a significant decrease in viral load. Viral load decreases were maintained during the 24-week trial. At the end of the treatment period, the proportion of study participants with undetectable viral load (HIV-1 < 50 copies/mL) was 43% (mean viral load reduction of 3.1 log10) and 50% of patients had a viral load lower than 200 copies/mL. 83% of patients achieved a ≥ 0.5 log10 decrease in viral load from baseline seven days after the single loading dose of 2000 mg of ibalizumab (primary endpoint) and a mean reduction in viral load of 1.6 log10 over the 24 week treatment period with more than 48% of patients experiencing a viral load reduction of more than 2.0 log10. Patients experienced a mean increase in CD4 + T cell of 48 cells/ µL after 24 weeks of treatment. Patients with baseline CD4 + T cells lower than 50 cells/µL (17 patients) had an increase of 9 cells/µL, those with CD4T cells between 50 and 200 cells/µL (10 patients) had an increase of 75 cells/µL and those with CD4 + T cells higher than 200 cells/µL (13 patients) had an increase of 78 cells/µL. No serious adverse events were considered to be related to ibalizumab. Most treatment-emergent adverse events

reported were mild to moderate in severity. No notable trends in laboratory abnormalities were observed. Additionally, no anti-ibalizumab antibodies were detected in blood samples from patients.[1,2]

Since 2019, the United States Department of Health and Human Services guidelines for the use of antiretroviral agents in adults and adolescents with HIV has listed ibalizumab as an antiretroviral component "not recommended as initial therapy", due to its efficacy and safety being studied in a very small number of patients with virologic failure, requiring intravenous therapy, and its high cost. The guidelines state that patients with ongoing detectable viremia who do not have sufficient treatment options for a fully suppressive regimen may be candidates for ibalizumab. In regards to HIV-2 infection, there is currently no evidence to support the activity of ibalizumab against HIV-2.[3]

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Trogarzo (ibalizumab-uiyk) is a CD4-directed post-attachment HIV-1 inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multi-drug resistant HIV-1 infection failing their current antiretroviral regimen.

References

1. Trogarzo [package insert]. Montreal, Quebec, Canada: Theratechnologies, Inc, October 2022.
2. Emu B, Fessel J, Schrader S, et al. Phase 3 Study of Ibalizumab for Multidrug-Resistant HIV-1. N Engl J Med. 2018 Aug 16;379(7):645-654.
3. U.S. Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Updated March 23, 2023. Available at: https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines. Accessed April 4, 2023.

Policy History/Revision Information

Date	Summary of Changes
07/01/2023	**Application** ***Texas*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Texas**; refer to the drug-specific criteria found within the *Texas Medicaid Provider Procedures Manual* **Coverage Rationale** • Revised language pertaining to initial authorization duration; replaced "no more than ***6*** months" with "no more than ***12*** months" **Supporting Information** • Updated *Background* and *References* sections to reflect the most current information • Archived previous policy version CS2023D0063L

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.