Trogarzo® (Ibalizumab-Uiyk) (for Louisiana Only)

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➲ Instructions for Use

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Application

This Medical Benefit Drug Policy only applies to the state of Louisiana.

Prior authorization is not required for Trogarzo.

Coverage Rationale

Trogarzo (ibalizumab) 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
    - Physician attestation that the patient has multi-drug resistant HIV-1 infection; **and**
  - **Physician confirms that the patient has been prescribed an optimized background antiretroviral regimen, containing at least one antiretroviral agent that demonstrates full viral sensitivity/susceptibility;** ~~**Physician confirms that the patient has been prescribed and will continue to take an optimized background antiretroviral regimen, containing at least one antiretroviral agent that demonstrates full viral sensitivity/susceptibility;**~~ **and**
  - Ibalizumab initial and maintenance dosing is in accordance with the U.S. Food and Drug Administration prescribing information~~: A single loading dose of 2,000mg intravenously (IV) followed by a maintenance dose of 800mg IV every two weeks thereafter~~; **and**
  - Initial authorization is for no more than 6 months
- For **continuation of therapy**, **all** of the following:
  - Patient has previously received treatment with ibalizumab; **and**
  - Physician confirms that the patient has achieved a clinically significant viral response to ibalizumab therapy; **and**
  - Physician confirms that the patient will continue to take an optimized background antiretroviral regimen in combination with ibalizumab; **and**

- Ibalizumab maintenance dosing is in accordance with the U.S. Food and Drug Administration prescribing information~~; Maintenance dosing of 800mg IV every two weeks;~~ **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

Ibalizumab is a humanized monoclonal antibody for the treatment of MDR HIV-1 infection. Ibalizumab 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. Ibalizumab 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 CD4+ T 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]

In December 2019, the United States Department of Health and Human Services published their updated guidelines for the use of antiretroviral agents in adults and adolescents with HIV. The guidelines list 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.

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, **April 2020**~~March 2018~~.
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 December **29, 2020**~~18, 2019~~. Available at: https://aidsinfo.nih.gov/guidelines. Accessed January 1**5, 2021**~~7, 2020~~.

Policy History/Revision Information

Date	Summary of Changes
	Annual review. Updated dosing in coverage rationale. Updated references.

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 MCG™ Care Guidelines, 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.