

# Trogarzo® (Ibalizumab-Uiyk)

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[➔ Instructions for Use](#)

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<b>Related Commercial Policy</b>
<ul style="list-style-type: none"> <li><a href="#">Provider Administered Drugs – Site of Care</a></li> </ul>
<b>Community Plan Policy</b>
<ul style="list-style-type: none"> <li><a href="#">Trogarzo® (Ibalizumab-Uiyk)</a></li> </ul>

## Coverage Rationale

[➔ See Benefit Considerations](#)

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

- 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; and
  - Ibalizumab initial and maintenance dosing is in accordance with the US 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 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 US 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 the member specific benefit plan document 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.<sup>1</sup>

## Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. See the Policy and Procedure addressing the treatment of serious rare diseases.

## 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/ $\mu$ L and 30% had less than 10 CD4+ T cells/ $\mu$ L. 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  $\geq 0.5$  log<sub>10</sub> 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 log<sub>10</sub>) and 50% of patients had a viral load lower than 200 copies/mL. 83% of patients achieved a  $\geq 0.5$  log<sub>10</sub> 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 log<sub>10</sub> over the 24 week treatment period with more than 48% of patients experiencing a viral load reduction of more than 2.0 log<sub>10</sub>. Patients experienced a mean increase in CD4+ T cell of 48 cells/ $\mu$ L after 24 weeks of treatment. Patients with baseline CD4+ T cells lower than 50 cells/ $\mu$ L (17 patients) had an increase of 9 cells/ $\mu$ L, those with CD4+ T cells between 50 and 200 cells/ $\mu$ L (10 patients) had an increase of 75 cells/ $\mu$ L and those with CD4+ T cells higher than 200 cells/ $\mu$ L (13 patients) had an increase of 78 cells/ $\mu$ L. 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.<sup>1,2</sup>

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.

## Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for Trogarzo® (ibalizumab-uiyk). Local Coverage Determinations (LCDs) do not exist at this time.

In general, Medicare may cover outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the [Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals](#). (Accessed January 17, 2020)

## References

1. Trogarzo [package insert]. Montreal, Quebec, Canada: Theratechnologies, Inc. May 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 18, 2019. Available at: <https://aidsinfo.nih.gov/guidelines>. Accessed January 17, 2020.

## Policy History/Revision Information

Date	Summary of Changes
08/01/2020	<b>Template Update</b> <ul style="list-style-type: none"><li>● Reformatted policy; transferred content to new template</li></ul>
04/01/2020	<b>Template Update</b> <ul style="list-style-type: none"><li>● Relocated <i>Background</i> and <i>FDA</i> sections</li></ul> <b>Supporting Information</b> <ul style="list-style-type: none"><li>● Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li><li>● Archived previous policy version 2019D0063D</li></ul>

## Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. 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.