

TROGARZO™ (IBALIZUMAB-UIYK)

Policy Number: PHARMACY 307.3 T2

Effective Date: January 1, 2019

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Related Policy
<ul style="list-style-type: none"> Specialty Medication Administration – Site of Care Review Guidelines

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

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

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General Benefits Package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes ¹
Precertification with Medical Director Review Required	Yes ^{1,2}
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	All ²
Special Considerations	¹ Precertification with review by a Medical Director or their designee is required. ² Additional precertification requirements apply to requests for hospital outpatient facility infusion of Trogarzo. Refer to the policy titled Specialty Medication Administration - Site of Care Review Guidelines .

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Trogarzo (ibalizumab-uiyk) is proven and/or medically necessary for¹ the treatment of multi-drug resistant human immunodeficiency virus (HIV) in patients who meet ALL of the following criteria:

- 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.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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.

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

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 may apply.

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

ICD-10 Diagnosis Code	Description
B20	Human immunodeficiency virus [HIV] disease
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

CLINICAL EVIDENCE

A single arm, 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/ μ L and 30% had less than 10 CD4+ T cells/ μ 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 ≥ 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/ μ L after 24 weeks of treatment. Patients with baseline CD4+ T cells lower than 50 cells/ μ L (17 patients) had an increase of 9 cells/ μ L, those with CD4+ T cells between 50 and 200 cells/ μ L (10 patients) had an increase of 75 cells/ μ L and those with CD4+ T cells higher than 200 cells/ μ L (13 patients) had an increase of 78 cells/ μ 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.^{1,2}

REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare Pharmacy, Clinical Pharmacy Program that was researched, developed and approved by the UnitedHealth Group National Pharmacy & Therapeutics Committee. [2018D0063A]

1. Trogarzo [package insert]. X, MA: Theratechnologies, Inc, April 2018.
2. TaiMed Biologics, Inc. Ibalizumab Plus Optimized Background Regimen in Patient With Multi-Drug Resistant HIV. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2017 Feb 6]. Available from: <https://clinicaltrials.gov/show/NCT02475629> NLM Identifier: NCT02475629.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none"> Updated list of applicable HCPCS codes: <ul style="list-style-type: none"> Added J1746 (<i>annual code edit</i>) Removed J3590 Archived previous policy version PHARMACY 307.2 T2