

Medical Policy:

Trogarzo® (ibalizumab-uiyk) intravenous injection for intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.221	February 10, 2025	2018

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth 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. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Trogarzo is a long-acting humanized immunoglobulin G4 monoclonal antibody indicated in combination with other antiretroviral(s) 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. Patients should receive a single intravenous loading dose of 2,000 mg followed by a maintenance dose of 800 mg once every 2 weeks. Maintenance doses of Trogarzo can be administered as a diluted intravenous (IV) infusion or undiluted IV push.

Length of Authorization

Initial- 6 months

Continuation- 12 months

Dosing Limits [Medical Benefit]

Approve the following dosing regimens (A and B):

- A. Loading dose of 2,000 mg as an intravenous infusion given one time (200 billable units one time only);

AND

Note: Approve an additional 2,000 mg loading dose if an 800-mg maintenance dose is missed by ≥ 3 days of the scheduled dosing day, with maintenance dosing (800 mg intravenously every 2 weeks) resumed thereafter.

- B. Maintenance dose of 800 mg, as an intravenous infusion or intravenous push, given every 2 weeks. (80 billable units every 14 days)

Guideline

1. Human Immunodeficiency Virus (HIV)-1. Approve for the duration outlined below if the patient meets ONE of the following conditions (A or B):

- A. **Initial Therapy.** Approve for 6 months if the patient meets ALL of the following conditions (i, ii, iii, iv, and v):
 - i. Patient is ≥ 18 years of age; **AND**
 - ii. According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; **AND**
 - iii. Patient has multiple antiretroviral drug resistance as demonstrated by resistance to at least **one** antiretroviral from at least **THREE** of the following antiviral classes (a, b, c, d, e, f):
 - a. Nucleoside reverse transcriptase inhibitor (e.g., abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine);
 - b. Non-nucleoside reverse transcriptase inhibitor (e.g., delavirdine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine);
 - c. Protease inhibitor (e.g., atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir);
 - d. Fusion inhibitor (e.g., Fuzeon[®] [enfuvirtide for injection]);
 - e. Integrase strand transfer inhibitor (e.g., raltegravir, raltegravir, dolutegravir, and elvitegravir);
 - f. CCR5-antagonist (e.g., Selzentry[®] [maraviroc tablets]); **AND**
 - iv. The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; **AND**
 - v. Patient has a baseline viral load ≥ 200 copies/mL; **AND**
 - vi. The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.
- B. **Patient is Currently Receiving Trogarzo.** Approve for 1 year if the patient meets **BOTH** of the following conditions (i and ii):
 - i. The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; **AND**
 - ii. Patient has responded (e.g., HIV-1 RNA ≥ 0.5 log₁₀ reduction from baseline in viral load) to a Trogarzo-containing regimen, as determined by the prescriber.

Applicable Procedure Codes

Code	Description
J1746	Injection, ibalizumab-uiyk, 10 mg

Applicable NDCs

Code	Description
62064-0122-01	Trogarzo 200mg/1.33mL Solution
62064-0122-02	Trogarzo 200mg/1.33mL Solution

ICD-10 Diagnoses

Code	Description
B20	Human immunodeficiency virus (HIV) disease

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/10/2025	Annual Review: Initial Criteria: added: "Patient has a baseline viral load \geq 200 copies/mL;"
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	4/5/2023	Transfer from CCUM Template to Medical CoBranded Template – retired MG.MM.PH.50
EmblemHealth & ConnectiCare	10/12/2022	Annual Revision: No criteria changes
EmblemHealth & ConnectiCare	4/6/2022	Annual Revision: Human Immunodeficiency Virus (HIV)-1. For initial therapy, the requirement that the patient is failing a current antiretroviral regimen according to the prescribing physician was changed to according to the prescriber. For the requirement of a response to therapy, according to the prescribing physician was changed to according to the prescriber.
EmblemHealth & ConnectiCare	4/07/2021	Annual Revision: No criteria changes

References

1. Trogarzo[®] injection [prescribing information]. Montreal, Quebec, Canada: Thera technologies; October 2022.