Medical Policy:

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

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.221	January 2, 2024	2018

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® [enfuviritide 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. 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 $\log_{10}$ 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	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: Theratechnologies; October 2022.