Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 10/12/2023

Trogarzo™ (ibalizumab-ulyk)

HCPCS: J1746

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age.
   b. Will be used in combination with other anti-retroviral therapy for the treatment of human immunodeficiency virus type 1 (HIV-1)
   c. Patient is heavily treatment-experienced with multidrug resistant HIV-1 infection based on the following:
      i. Documented resistance to at least one antiretroviral medication from three different classes of drugs.
   d. Failing their current antiretroviral regimen
   e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing.
   b. Authorization Period: One year at a time.
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information

- Trogarzo is indicated for use in combination with other ARTs 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. It is a humanized IgG4 monoclonal antibody that blocks the entry of HIV-1 through binding to CD4.

- The indication, along with specific criteria on defining treatment resistance and failure, reflects the patient population that was included in the clinical trial that lead to its approval. Therefore, use outside of this specific patient population is not recommended as the safety and efficacy has not been established.

- The evidence of efficacy for Trogarzo is based on one small, open-label, phase 3 trial in 40 patients. The primary outcome evaluated was the proportion of patients obtaining at least a 0.5 log10 reduction in HIV-1 RNA viral load compared to baseline. There was a statistically significant greater proportion of patients achieving at least a 0.5 log10 viral load reduction after seven days of treatment than at baseline (83% vs. 3%, respectively). A decrease of at least 0.5 log10 HIV-1 RNA viral load is considered clinically significant in MDR HIV-1 as this delays clinical progression.

- More than 25 approved antiretroviral drugs in multiple classes are available to design combination antiretroviral treatment (ART) regimens. Treatment always consist of drugs from multiple categories. Viral failure can occur for many reasons including development of drug resistance, suboptimal adherence and drug intolerance/toxicity prompting a new antiretroviral regimen to be designed.

- Guidelines from the U.S. Department of Health and Human Services (2022) and International Antiviral Society–USA Panel (2022) states:

    - Virologic failure is a viral load that is persistently greater than or equal to 200 copies/mL because this level of viremia often leads to drug resistance

    - In patients with virologic failure, it is crucial to provide continuous adherence support before and after ART regimen changes.

    - Designing a new regimen for patients who are experiencing treatment failure should always be guided by ART history and results from current and past resistance testing.

    - Patients with MDR HIV-1 who have few treatment options their new regimen should include at least two, and preferably three, fully active agents, including those with novel mechanisms of action (ex: ibalizumab, fosternsavir, lenacapavir). If less than 3 fully active drugs, include as many fully active drugs as possible, along with potentially partially active drugs.

References:

1. Emu B, Fessel J, Schrader S, et al. Phase 3 Study of Ibalizumab for Multidrug-Resistant HIV-1. N Engl J Med. 2018;379(7):645-654.
2. Trogarzo [package insert]. Forest City, CA. Gilead Sciences Inc.; April 2021.
3. Gandhi RT, Bedimo R, Hoy JF, et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2022 Recommendations of the International Antiviral Society–USA Panel. JAMA. 2023;329(1):63–84. doi:10.1001/jama.2022.22246
4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescentarv.pdfAccessed August 17th,2023.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.7</td><td>Effective Date: 10/12/2023</td><td>Annual review – no changes to the criteria</td></tr>
<tr><td>1.6</td><td>Effective Date: 10/06/2022</td><td>Updated to remove specific prescriber requirement per NCQA recommendations and loosen requirement to allow for documented resistance of at least one antiretroviral medication from three different classes without specifying which classes must be trialed</td></tr>
<tr><td>1.5</td><td>Effective Date: 10/07/2021</td><td>Annual review – no changes to the criteria</td></tr>
<tr><td>1.4</td><td>Effective Date: 08/13/2020</td><td>Annual review of criteria was performed, updated criteria to include trial or preferred statement</td></tr>
<tr><td>1.3</td><td>Effective Date: 02/01/2019</td><td>UM medical management system update for BCNA and MAPPO
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.2</td><td>Effective Date: 10/01/2018</td><td>UM medical management system update for BCBS and BCN
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.1</td><td>Effective Date: 08/09/2018</td><td>Full Drug Review</td></tr>
<tr><td>1.0</td><td>Effective Date: 05/03/2018</td><td>Preliminary Drug Review
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*