



Nonprofit corporations and independent licensees  
of the Blue Cross and Blue Shield Association

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 led 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 log<sub>10</sub> 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 log<sub>10</sub> viral load reduction after seven days of treatment than at baseline (83% vs. 3%, respectively). A decrease of at least 0.5 log<sub>10</sub> 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 consists 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, fostemsavir, 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-adolescentary.pdf> Accessed August 17<sup>th</sup>, 2023.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

Policy History												
#	Date	Change Description										
1.7	Effective Date: 10/12/2023	Annual review – no changes to the criteria										
1.6	Effective Date: 10/06/2022	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										
1.5	Effective Date: 10/07/2021	Annual review – no changes to the criteria										
1.4	Effective Date: 08/13/2020	Annual review of criteria was performed, updated criteria to include trial or preferred statement										
1.3	Effective Date: 02/01/2019	UM medical management system update for BCNA and MAPPO <table border="1" data-bbox="485 638 1365 848"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <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> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	No	MAPPO	Yes	BCNA	Yes
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BCBS	Yes											
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1.2	Effective Date: 10/01/2018	UM medical management system update for BCBS and BCN <table border="1" data-bbox="485 930 1365 1140"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <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> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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1.1	Effective Date: 08/09/2018	Full Drug Review										
1.0	Effective Date: 05/03/2018	Preliminary Drug Review <table border="1" data-bbox="485 1283 1365 1493"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <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> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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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>.

**Blue Cross Blue Shield/Blue Care Network of Michigan**  
**Medication Authorization Request Form**  
**Trogarzo™ (ibalizumab-ulyk injection) HCPCS CODE: J1746**



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This form is to be used by participating physicians to obtain coverage for Trogarzo™. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
<b>Name</b>	<b>Name</b>
<b>ID Number</b>	<b>Specialty</b>
<b>D.O.B.</b> <input type="checkbox"/> Male <input type="checkbox"/> Female	<b>Address</b>
<b>Diagnosis</b>	<b>City /State/Zip</b>
<b>Drug Name</b>	<b>Phone/Fax: P: (     )     -     F: (     )     -</b>
<b>Dose and Quantity</b>	<b>NPI</b>
<b>Directions</b>	<b>Contact Person</b>
<b>Date of Service(s)</b>	<b>Contact Person Phone / Ext.</b>

**STEP 1: DISEASE STATE INFORMATION**

1. Initiation or continuation of treatment?  Initiation  Continuation *Date patient started therapy:* \_\_\_\_\_
2. Site of administration?  Provider office/Home infusion  Other: \_\_\_\_\_  
 Hospital outpatient facility (go to #3) *Reason for Hospital Outpatient administration:* \_\_\_\_\_
3. Please specify location of administration if hospital outpatient infusion: \_\_\_\_\_
4. Please provide the NPI number for the place of administration: \_\_\_\_\_
5. **Initiation and Continuation:**
  - a. Primary Indication:  HIV-1  Other \_\_\_\_\_
  - b. Will Trogarzo be used in combination with other antiretroviral therapy?  Yes  No, Why? \_\_\_\_\_  
 i. If yes please list the name of antiretroviral therapy: \_\_\_\_\_
  - c. Is the patient heavily treatment experienced with multidrug resistant HIV-1 infection, resistant to at least one antiretroviral medication from 3 different classes of drugs (MUST PROVIDE LAB RESULTS TO SUPPORT RESISTANCE)?  Yes  No, Comment: \_\_\_\_\_
  - d. Has the patient failed their current antiretroviral regimen?  Yes  No, Comment: \_\_\_\_\_
6. **Continuation:** How has the patient responded since beginning Trogarzo therapy? **Trogarzo start date:** \_\_\_\_\_  
 a.  Yes  No, Comment: \_\_\_\_\_

**Please add any other supporting medical information necessary for our review**

**Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.**

Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

	Physician's Name	Physician Signature	Date
<b>Step 2 Checklist</b>	<input type="checkbox"/> Form Completely Filled Out <input type="checkbox"/> Attached Chart Notes	<input type="checkbox"/> Attach RNA viral load <input type="checkbox"/> Documentation of resistance (Include lab results)	
<b>Step 3 Submit</b>	<b>By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979</b>	<b>By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320</b>	

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