Blue Cross Blue Shield Blue Care Network of Michigan

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.

P&T Date: 10/08/2026

Tudriqev™ (vusolimogene oderparepvec-wtpg)

HCPCS: J3590

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 indication
   b. FDA approved age
   c. Prescribed by or in consultation with an oncologist
   d. Must have progressive disease following use of a programmed cell death protein ligand-1 (PD-1) inhibitor
   e. Must have at least one measurable and injectable lesion greater than or equal to 1 cm in diameter
   f. Must not have any of the following:
      i. ECOG performance status > 1
      ii. Active infection (e.g. viral, bacterial, fungal) such as HIV, active hepatitis B or active hepatitis C
      iii. Symptomatic and/or untreated brain metastases
   g. Have not received prior treatment with Tudriqev or any other oncolytic viral therapy
   h. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM
   i. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the BCBSM Pharmacy and Therapeutics Committee
   h. 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: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
   c. Renewal Criteria: Treatment may be continued until unacceptable toxicity or disease progression for a total of up to 16 weeks of therapy

***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.

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.

Background Information:

- Tudriqev is a genetically modified oncolytic viral therapy indicated in combination with nivolumab for the treatment of adult patients with unresectable advanced cutaneous melanoma who experienced disease progression with a programmed death receptor-1 (PD-1)-blocking antibody-based regimen.

- Safety and efficacy were evaluated in the IGNYTE trial, an open-label, multicenter, phase II study of 91 patients with stage IIIB, IIIC, or IV unresectable advanced melanoma who had previously been treated with at least eight consecutive weeks of immediate prior anti-PD-1-based therapy and experienced disease progression while being on the anti-PD-1-based therapy. Patients must have had at least one measurable and injectable lesion greater than or equal to 1 cm in diameter. The study excluded patients who had received prior oncolytic virus therapy, uncontrolled or untreated central nervous system (CNS) metastasis, an active or history of hepatitis B, hepatitis C, HIV infection, prior severe complications from HSV-1 infection, and patients requiring chronic systemic corticosteroids. Patients received Tudriqev via intratumor injection every 2 weeks for 8 consecutive injections, starting at a concentration of 10^6 PFU/mL at week 1 followed by Tudriqev at a concentration of 10^7 PFU/mL for the remaining doses. Starting with the second dose of Tudriqev, nivolumab was administered at a dose of 240 mg by intravenous infusion every 2 weeks for 16 weeks followed by nivolumab single agent at a dose of 480 mg by intravenous infusion every 4 weeks for up to a total of 24 months. Patients could receive up to 16 additional doses of Tudriqev at a concentration of 10^7 PFU/mL every 2 weeks either in combination with nivolumab or as monotherapy if nivolumab was previously stopped due to toxicity related to nivolumab. The primary endpoint was objective response rate (ORR). The ORR was 24.2% with a median duration of response of 14.1 months.

- There are no studies to support use of Tudriqev following failure. NCCN treatment guidelines also do not recommend use of Tudriqev or other oncolytic viral therapy following a previous failure.

- A provider portal is used to capture clinical outcome information for patients on select high-cost treatments, such as gene and cellular therapies. If a patient meets medical necessity as defined by this policy and is approved for treatment, the requesting physician must attest to providing clinical outcome information within the appropriate provider portal at the requested cadence.

References:

1. Tudriqev [prescribing information]. Woburn, MA: Replimune, Inc.; August 2026.
2. Wong MK, Milhem MM, Sacco JJ, et al. RP1 combined With nivolumab in advanced anti–PD-1–failed melanoma (IGNYTE). J Clin Oncol. 2025 July 8; 43 (23): 3589 – 99.
3. National Comprehensive Cancer Network. Melanoma: cutaneous (Version 2.2026). 2026 April 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed on August 10, 2026.

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<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.2</td><td>Effective Date: 10/08/2026</td><td>New Policy</td></tr>
<tr><td>1.1</td><td>Effective Date: 09/01/2026</td><td>UM medical management system update for MAPPO and BCNA
<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>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.0</td><td>Effective Date: 08/24/2026</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>
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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.*

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Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form

Blue Cross Blue Shield Blue Care Network of Michigan

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This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. 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
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
2. Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
3. Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
   ☐ Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
   ☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
4. Please specify location of administration if hospital outpatient infusion: _____
5. Please specify location of administration if hospital inpatient infusion: _____
6. Please provide the NPI number for the place of administration: _____
7. **Initiation AND Continuation of therapy:**
   a. What is the patient's diagnosis? _____
   b. What other medication has the patient received for their condition? Please list_____
      i. Please describe the response to previous therapies:
      _____
   c. Will the patient be receiving any other treatment for the listed condition while on this medication? Please list:
      _____
   d. Please list any labs values important for diagnosing or monitoring this patient's condition:
      _____
8. **Continuation of therapy:**
   a. Has the patient progressed while on this medication? ☐ yes ☐ no
   b. How has the patient's condition changed while on this medication?
      ☐ Improved: Please describe: _____
      ☐ Stable: please describe: _____
      ☐ Worsened; Please describe: _____
      ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review **(required)**

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**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021