CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Tudriqev Utilization Management Medical Policy
- Tudriqev™ (vusolimogene oderparepvec-wtpg suspension for intratumor injection – Replimmune)

REVIEW DATE: 09/02/2026; selected revision 09/30/2026

OVERVIEW

Tudriqev is a genetically modified oncolytic viral therapy indicated in combination with Opdivo® (nivolumab intravenous [IV] infusion) for the treatment of adults with unresectable advanced cutaneous **melanoma** who experienced disease progression with a programmed death receptor-1 (PD-1) blocking antibody-based regimen.[1]

This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response.[1] Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).

Dosing Information

Tudriqev is for intratumor injection only; it should not be administered by IV infusion.[1] The recommended dose is 1 mL/cm of the largest dimension of the tumor for a maximum of 10 mL across all lesions treated with each dose. Administer Tudriqev every two weeks for eight consecutive doses starting at a concentration of 10^6 PFU/mL at Week 1, followed by 10^7 PFU/mL for subsequent weeks. The size of injectable lesions should be assessed on each treatment day to determine the required Tudriqev volume. If multiple tumors are present, prioritize the most rapidly growing and largest new or existing lesions suitable for injection. Patients with no confirmed disease progression could be retreated with Tudriqev at a concentration of 10^7 PFU/mL every two weeks. Opdivo is administered, in combination with Tudriqev, by IV infusion starting at Week 3.

Guidelines

Tudriqev has been addressed in National Comprehensive Center Network (NCCN) guidelines for cutaneous melanoma; it is recommended under Other Recommended Options in the second-line and subsequent treatment setting (category 1).[2]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Tudriqev. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication(s). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tudriqev as well as the monitoring required for adverse events and long-term efficacy, approval requires Tudriqev to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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Coverage of Tudriqev is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Melanoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable or metastatic disease; AND
   - **C)** Patient has been treated with a programmed death receptor-1 (PD-1) blocking antibody or a programed death ligand-1 (PD-L1) blocking antibody; AND
     Note: Examples of PD-1/PD-L1 blocking antibodies include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion) and Tecentriq (atezolizumab intravenous infusion).
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** Tudriqev is being used or will be used in combination with Opdivo; OR
     - **ii.** According to the prescriber, Opdivo has been discontinued due to an unacceptable adverse event, toxicity, or intolerance, and Tudriqev will be continued as monotherapy; AND
   - **E)** If the patient is BRAF V600 mutation positive, the patient has been treated with a BRAF inhibitor with or without a MEK inhibitor; AND
     Note: Examples of BRAF inhibitors include Braftovi (encorafenib capsules), Zelboraf (vemurafenib tablets), and Tafinlar (dabrafenib capsules).
   - **F)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 10 mL per dose as an intratumor injection given not more frequently than once every two weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tudriqev is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tudriqev™ intravenous infusion [prescribing information]. Framingham, MA: Replimmune; August 2026.
2. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (Version 3.2026 – September 2, 2026). © 2026 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 2, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/02/2026
Selected Revision	**Melanoma**. The requirement for unresectable advanced disease was changed to unresectable or metastatic disease. An option was added that Tudriqev may be continued as monotherapy for a patient who, according to the prescriber, has experienced an unacceptable adverse event, toxicity, or intolerance to Opdivo. A requirement was added that for a patient who is BRAF V600 mutation positive to have been treated with a BRAF inhibitor with or without a MEK inhibitor; a Note of examples of BRAF inhibitors was also added.	09/30/2026

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