Tudriqev™ (vusolimogene oderparepvec)
(Intratumor)

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I. Length of Authorization [1]

- Initial: Prior authorization validity will be provided initially for 4 months (120 days) for 8 doses.
- Renewal: Prior authorization validity may be renewed every 4 months (120 days) for an additional 8 doses thereafter up to a maximum lifetime total (i.e., initial plus subsequent doses) of 24 doses*.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Initial treatment:

- 10^6 plaque-forming units (PFU)/mL at Week 1 followed by 10^7 PFU/mL every two weeks for 8 total doses (Maximum injection volume is 10 mL per dose across all lesions treated)

Subsequent treatment*:

- 10^7 PFU/mL every two weeks for 16 additional doses (Maximum injection volume is 10 mL per dose across all lesions treated)

III. Initial Approval Criteria [1,2]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity will be provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria

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- Member will be monitored for signs and symptoms of visceral injury (e.g., pneumothorax, etc.), herpetic infection/reactivation, or immune-mediated events (e.g., colitis, hepatitis, myocarditis, neuropathy, capillary leak syndrome, dermatitis, vitiligo, etc.) and will be treated as clinically warranted; **AND**
- Pregnancy status of women of reproductive potential will be verified prior to the start of therapy (*Note: Women of childbearing potential and men should be advised to use an effective method of contraception during treatment and for 90 days after the last dose*); **AND**
- Therapy will not be used concomitantly with systemic antiviral treatment for herpetic infection and will be delayed for at least 72 hours following completion of antiviral therapy; **AND**
- Treatment will be administered as an intratumor injection *(Note: Treatment will NOT be administered into brain or spinal cord tumors or scalp tumors with moderate to extensive bone erosion, or tumors that encase, invade, or occlude major blood vessels, major nerve structures, or airways)*; **AND**
- Member has not previously been treated with, and will not be treated concurrently with, another oncolytic virus therapy; **AND**
- Member does not have untreated or uncontrolled central nervous system (CNS) metastases; **AND**
- Used in combination with nivolumab *(Note: Subsequent therapy may be used without nivolumab if nivolumab was previously discontinued due to nivolumab-related toxicity)*; **AND**

Cutaneous Melanoma † [1]

- Member has unresectable advanced disease; **AND**
- Used as subsequent therapy after disease progression on immediate prior use of a programmed death receptor-1 (PD-1)-blocking antibody-based regimen that was administered for at least 8 consecutive weeks

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2]

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Member continues to have lesions (superficial, deep or visceral) suitable for injection; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: herpetic infection, injection site complications (e.g., hemorrhage, visceral injury, infection, etc.),

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immune-mediated events (e.g., colitis, hepatitis, myocarditis, neuropathy, capillary leak syndrome, dermatitis, vitiligo, etc.), etc.; **AND**

- Member has no confirmed disease progression; **AND**
  - Member will be retreated with Tudriqev at a concentration of 10^7 PFU/mL every two weeks; **AND**
  - Member has not received a maximum lifetime limit of 24 doses*

**Authorization of Tudriqev beyond the maximum lifetime limit of up to 24 total doses of treatment will be reviewed on a case-by-case basis.*

V. Dosage/Administration [1,5]

Indication	Dose
Cutaneous Melanoma	• The recommended dosage of Tudriqev 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 intratumoral (IT) injections of Tudriqev every 2 weeks for 8 consecutive doses starting at a concentration of 10^6 PFU/mL at Week 1 followed by 10^7 PFU/mL for subsequent weeks**. - Members with no confirmed disease progression may receive up to 16 additional doses of Tudriqev at a concentration of 10^7 PFU/mL every two weeks (maximum lifetime total of 24 doses*).
***Administer nivolumab as intravenous injection starting at Week 3. Refer to the nivolumab prescribing information for the dosage and administration information including dose modifications, preparation, and administration.*	

VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified antineoplastic drugs

NDC(s):

- Tudriqev 10^6 (1 million) PFU per mL single-use vial: 83616-0106-xx
- Tudriqev 10^7 (10 million) PFU per mL single-use vial: 83616-0107-xx

VII. References

1. Tudriqev [package insert]. Woburn, MA; Replimune Inc.; August 2026. Accessed August 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for visolimogene oderparepvec. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2026.
3. ClinicalTrials.gov. NCT06264180. Randomized, Ph3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination With Nivolumab Vs Treatment of Physician's Choice in Patients

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With Advanced Melanoma That Progressed on Anti-PD-1 and Anti-CTLA-4 Containing Treatment. | ClinicalTrials.gov.
4. Luke JJ, Kong G, Gullo G, Robert C. A randomized, controlled, multicenter, phase 3 study of vusolimogene oderparepvec (VO) combined with nivolumab vs treatment of physician's choice in patients with advanced melanoma that has progressed on anti–PD-1 and anti–CTLA-4 therapy (IGNYTE-3). JCO 42, TPS9604-TPS9604(2024). DOI:10.1200/JCO.2024.42.16_suppl.TPS9604.
5. Wong MK, Milhem MM, Sacco JJ, et al. RP1 combined with nivolumab in advanced anti-PD-1-failed melanoma (IGNYTE). J Clin Oncol. 2025;43(33):3589-3599. doi:10.1200/JCO-25-01346.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face

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ICD-10	ICD-10 Description
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	Wellpoint Federal
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	Wellpoint Federal
15	KY, OH	CGS Administrators, LLC

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