



## MEDICAL COVERAGE POLICY

**SERVICE:** Talimogene Laherparepvec

**Policy Number:** 245

**Effective Date:** 07/01/2019

**Last Review:** 04/25/2019

**Next Review Date:** 04/25/2020

### Important note

Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

**SERVICE:** Talimogene Laherparepvec (Imlygic®)

**PRIOR AUTHORIZATION:** **Required.** This policy provides guidelines for medical review when that review is NOT performed by vendor Oncology Analytics.

### POLICY:

SWHP may consider oncolytic virus therapy, talimogene laherparepvec (e.g. Imlygic®), in the treatment of metastatic melanoma cancer, medically necessary for adults 18 years and older, in the following situations:

As intralesional therapy for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery; OR

As intralesional therapy for the treatment of patients with melanoma when used for:

- Primary and/or second-line treatment of unresectable stage III disease with clinical satellite or in-transit metastases; or
- Unresectable distant metastatic disease (extracranial lesions); or
- Primary and/or second-line treatment of unresectable local, satellite and/or in-transit recurrence; or
- Unresectable or incomplete resection of nodal recurrence.

Talimogene laherparepvec (Imlygic®) is considered experimental, investigational and/or unproven for all other indications.

**OVERVIEW:** Talimogene laherparepvec is a genetically modified herpes simplex virus 1 (HSV) oncolytic virus which selectively replicates in and lyses tumor cells. Tumor cells are destroyed either through the natural cytotoxic effect of replicative viral infection or through the expression of endogenous or exogenous gene products. Talimogene is injected directly into cutaneous, subcutaneous, or nodal lesions that are visible, palpable, or accessible using ultrasound guidance.

The results of a large randomized controlled trial suggest that talimogene therapy increases the durable response rate and may lengthen overall survival compared with single-agent granulocyte-macrophage colony-stimulating factor treatment in patients with unresectable melanoma.



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Therapy for the conditions listed in this policy has a National Comprehensive Cancer Network (NCCN) recommendation of Category 1.

**CODES:**

**Important note:**

*CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

CPT Codes:	
CPT Not Covered:	
HCPCS Covered:	J9325 Injection, talimogene laherparepvec
HCPCS Not Covered:	
ICD-10:	C43.0 - C43.9 Malignant melanoma of skin (unresectable cutaneous, subcutaneous, and nodal lesions)

**CMS:** There are no NCDs or LCDs related to this coverage.

**POLICY HISTORY:**

Status	Date	Action
New	03/13/2018	New policy
Reviewed	04/25/2019	No changes aside for review process

**REFERENCES:**

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Andtbacka RH, Kaufman HL, Collichio F, et al. Talimogene laherparepvec improves durable response rate in patients with advanced melanoma. J Clin Oncol. 2015;33(25):2780-2788.
2. National Cancer Institute (NCI). Melanoma treatment – for health professionals. Updated January 19, 2018. Available at: <http://www.cancer.gov/types/skin/hp/melanoma-treatment-pdq#section/all>. Accessed March 12, 2018.
3. Senzer NN, Kaufman HL, Amatruda T, et al. Phase II clinical trial of a granulocyte-macrophage colony-stimulating factor-encoding, second-generation oncolytic herpesvirus in patients with unresectable metastatic melanoma. J Clin Oncol. 2009;27(34):5763-5771.
4. Scott LJ. Nivolumab: a review in advanced melanoma. Drugs. 2015;75(12):1413-1424
5. Amgen Inc. Imlygic (talimogene laherparepvec) - prescribing information