

Imlygic™ (talimogene laherparepvec) Intralesional

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- Imlygic 10^6 (1 million) PFU per mL: 4 mL one time only
- Imlygic 10^8 (100 million) PFU per mL: 4 mL three weeks after initial treatment followed by 4 mL every two weeks thereafter

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

Initial treatment: 4 billable units

Second treatment: 400 billable units occurring 3 weeks after initial treatment

All subsequent treatments: 400 billable units occurring 2 weeks after previous treatment

III. Initial Approval Criteria^{1,2}

Coverage is provided in the following conditions:

- Patient is 18 years of age or older; **AND**

Universal Criteria

- Patient is not pregnant (*Note: Women of childbearing potential should be advised to use an effective method of contraception to prevent pregnancy during treatment*); **AND**
- Patient is not immunocompromised (i.e., patients with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy); **AND**
- Treatment (i.e., talimogene laherparepvec) will only be administered via intralesional injection; **AND**

Melanoma †/Φ

- Patient has one of the following:
 - Unresectable, distant metastatic disease; **OR**
 - Unresectable or incomplete resection of nodal recurrence; **OR**
 - Limited resectable or unresectable stage III disease with clinical satellite or in-transit metastases; **OR**
 - Limited resectable or unresectable disease with local satellite and/or in-transit recurrence

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

IV. Renewal Criteria^{1,2}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: herpetic infection, injection site complications (necrosis, ulceration, cellulitis and systemic bacterial infection), immune-mediated events, plasmacytoma at injection site, obstructive airway disorder, etc.; **AND**
- Patient continues to have injectable lesions to treat; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

V. Dosage/Administration¹

Indication	Dose
Melanoma	Initial Treatment <ul style="list-style-type: none">• Imlygic 10⁶ (1 million) PFU per mL• Inject largest lesion(s) first• Prioritize injection of remaining lesion(s) based on lesion size until maximum injection volume is reached or until all injectable lesion(s) have been treated
	Second Treatment <ul style="list-style-type: none">• Imlygic 10⁸ (100 million) PFU per mL• 3 weeks after initial treatment• Inject any new lesion(s) (lesions that have developed since initial treatment) first.• Prioritize injection of remaining lesion(s) based on lesion size until maximum injection volume is reached or until all injectable lesion(s) have been treated.
	All subsequent treatments (including re-initiation) <ul style="list-style-type: none">• Imlygic 10⁸ (100 million) PFU per mL

	<ul style="list-style-type: none"> • 2 weeks after previous treatment • Inject any new lesion(s) (lesions that have developed since previous treatment) first. • Prioritize injection of remaining lesion(s) based on lesion size until maximum injection volume is reached or until all injectable lesion(s) have been treated.
<p><i>The total injection volume for each treatment visit should not exceed 4 mL for all injected lesions combined. It may not be possible to inject all lesions at each treatment visit or over the full course of treatment. Previously injected and/or uninjected lesion(s) may be injected at subsequent treatment visits.</i></p>	

Lesion size (longest dimension)	Intralesional Injection Volume
> 5 cm	up to 4 mL
> 2.5 cm to 5 cm	up to 2 mL
> 1.5 cm to 2.5 cm	up to 1 mL
> 0.5 cm to 1.5 cm	up to 0.5 mL
≤ 0.5 cm	up to 0.1 mL

- Store and transport at -90°C to -70°C (-130°F to -94°F), thaw immediately prior to administration.
- Protect from light, store in the carton until use.

VI. Billing Code/Availability Information

HCPCS code:

- J9325 - Injection, talimogene laherparepvec, per 1 million plaque forming units; 1 billable unit = 10^6 (1 million) PFU

NDC(s):

- Imlygic 10^6 (1 million) PFU per mL is light green, single-use vial (NDC 55513-0078-01)
- Imlygic 10^8 (100 million) PFU per mL is royal blue, single-use vial (NDC 55513-0079-01)

VII. References

1. Imlygic [package insert]. Thousand Oaks, CA; Amgen Inc; October 2019. Accessed April 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for talimogene laherparepvec. National Comprehensive Cancer Network, 2021. 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 April 2021.
3. Andtbacka RHI, Kaufman HL, Collichio F, et al. Talimogene laherparepvec improves durable response rate in patients with advanced melanoma. *J Clin Oncol.* 2015;33:2780-2788.

4. Andtbacka RHI, Kaufman HL, Collichio F, et al. Talimogene laherparepvec improves durable response rate in patients with advanced melanoma. J Clin Oncol. 2015;33 (suppl Clinical Study Protocol):doi:10.1200/JCO.2014.58.3377.

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
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)

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered 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	National Government Services, Inc. (NGS)
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC