

## Imlygic™ (talimogene laherparepvec)

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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) [Pharmacy Benefit]:

- 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) [Medical Benefit]:

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

Coverage is provided in the following conditions:

- Patient is 18 years of age or older; AND
- Patient is not pregnant; AND
- Patient is not immunocompromised; AND
- Imlygic must be administered intralesionally; AND

Melanoma †

- Patient has one of the following:
  - Unresectable, distant metastatic disease; OR
  - Unresectable or incomplete resection of nodal recurrence; OR
  - Used as first or second line therapy; AND
    - Unresectable stage III with clinical satellite or in-transit metastases; OR
    - Local/satellite and/or in-transit unresectable recurrence; OR

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria 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/Administration

Indication	Dose
Melanoma	Initial Treatment <ul style="list-style-type: none"> <li>• Imlygic <math>10^6</math> (1 million) PFU per mL</li> <li>• Inject largest lesion(s) first</li> <li>• 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</li> </ul>
	Second Treatment <ul style="list-style-type: none"> <li>• Imlygic <math>10^8</math> (100 million) PFU per mL</li> <li>• 3 weeks after initial treatment</li> <li>• Inject any new lesion(s) (lesions that have developed since initial treatment) first.</li> <li>• 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.</li> </ul>
	All subsequent treatments (including re-initiation) <ul style="list-style-type: none"> <li>• Imlygic <math>10^8</math> (100 million) PFU per mL</li> <li>• 2 weeks after previous treatment</li> <li>• Inject any new lesion(s) (lesions that have developed since previous treatment) first.</li> <li>• 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.</li> </ul>
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.	

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
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- 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

### Jcode:

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

### NDC(s):

- Imlygic 10<sup>6</sup> (1 million) PFU per mL is light green, single-use vial (NDC 55513-0078-01)
- Imlygic 10<sup>8</sup> (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; December 2018. Accessed April 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for talimogene laherparepvec. National Comprehensive Cancer Network, 2019. 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 2019.

## 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
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left 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

ICD-10	ICD-10 Description
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