Imlygic® (talimogene laherparepvec)
Intralesional

Document Number: IC-0274

Last Review Date: 05/04/2023
Date of Origin: 04/26/2016
Dates Reviewed: 04/25/2017, 04/2018, 05/2019, 05/2020, 05/2021, 05/2022, 05/2023

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 single-use vial: 4 mL one time only
- Imlygic 10^8 (100 million) PFU per mL single-use vial: 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 at least 18 years of age; **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 will be administered via intralesional injection; **AND**

Cutaneous Melanoma † ‡ Φ

- Used for unresectable recurrent disease †; **OR**

- Used as primary treatment for unresectable or borderline resectable stage III disease with clinically positive node(s); **OR**
- Used for oligometastatic disease with accessible lesions; **OR**
- Used for widely disseminated distant metastatic disease with limited extracranial lesions; **OR**
- Patient has limited resectable or unresectable disease; **AND**
    - Used for stage III disease with clinical satellite/in-transit metastases; **OR**
    - Used for local satellite/in-transit recurrence

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

IV. Renewal Criteria[1,2]

Coverage may be renewed based upon the following criteria:

- Patient 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**
- Patient continues to have injectable lesions; **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., necrosis, ulceration, cellulitis, systemic bacterial infection, etc.), immune-mediated events, plasmacytoma at injection site, obstructive airway disorder, etc.

V. Dosage/Administration[1]

Indication	Dose
Melanoma	**Initial Treatment** • Imlygic 10^6 (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 • Imlygic 10^8 (100 million) PFU per mL • Administer 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 reinitiation) • Imlygic 10^8 (100 million) PFU per mL • Administer 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.
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

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 single-use vial: 55513-0078-xx
- Imlygic 10^8 (100 million) PFU per mL single-use vial: 55513-0079-xx

VII. References

1. Imlygic [package insert]. Thousand Oaks, CA; Amgen Inc.; February 2023. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for talimogene laherparepvec. National Comprehensive Cancer Network, 2023. 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 March 2023.
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
C43.111	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
Z85.820	Personal history of malignant melanoma of skin

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: https://www.cms.gov/medicare-coverage-database/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