## Clinical Policy: Talimogene laherepvec (Imlygic)

Reference Number: PA.CP.PHAR.542
Effective Date: 10/2021
Last Review Date: 07/2023

Coding Implications
Revision Log

**Description**
Talimogene laherepvec (Imlygic™) is genetically modified oncolytic viral therapy.

**FDA Approved Indication(s)**
Imlygic is indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

Limitation(s) of use: Imlygic has not been shown to improve overall survival or have an effect on visceral metastases.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Imlygic is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Melanoma** (must meet all)**:**

1. Diagnosis of unresectable or limited resectable melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as one of the following (a or b):
   a. As a single agent;
   b. For low burden of disease and injectable lesions, in combination with Yervoy (ipilimumab) as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy;
5. Documentation of both the following (a and b):
   a. Lesions are cutaneous, subcutaneous, or nodal;
   b. Quantity and sizes of lesions;
6. Request meets one of the following (a or b):
   a. Both of the following (i or ii):
      i. For initial dose: Dose does not exceed 4 mL of $10^6$ plaque-forming units (PFU)/mL (*see Appendix E*);
      ii. For all subsequent doses (starting 3 weeks after initial dose) and reinitiation: Dose does not exceed 4 mL of $10^8$ PFU/mL every 2 weeks (*see Appendix E*);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## II. Continued Therapy

**A. Melanoma** (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Documentation supports quantity and sizes of lesions that remain to be treated;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 4 mL of $10^8$ PFU/mL every 2 weeks (*see Appendix E*);
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer NetworkPFU: plaque-forming units

*Appendix B: Therapeutic Alternatives*
*Not applicable*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): immunocompromised patients, pregnancy
- Boxed warning(s): none

*Appendix D: Determination of Imlygic Injection Volume Based on Lesion Size*

| Lesion Size (longest dimension) | Injection Volume |
|---|---|
| > 5 cm | up to 4 mL |

| Lesion Size (longest dimension) | Injection Volume |
|---|---|
| > 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 |

When lesions are clustered together, they should be injected together as a single lesion according to this table.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Melanoma | Recommended starting dose for injection into cutaneous, subcutaneous, and/or nodal lesions is up to 4 mL at a concentration of $10^6$ (1 million) PFU per mL, followed by up to 4 mL of $10^8$ (100 million) PFU/mL administered 3 weeks later; thereafter, subsequent doses (including reinitiation) of up to 4 mL of $10^8$ PFU/mL are administered every 2 weeks | 4 mL at a concentration of $10^8$ PFU/mL per treatment (all lesions combined) |

## VI. Product Availability

Single-use vials: $10^6$ (1 million) PFU per mL, $10^8$ (100 million) PFU/mL

## VII. References

1. Imlygic Prescribing Information. Thousand Oaks, CA: Amgen; February 2023. Available at: https://www.imlygic.com/. Accessed May 9, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed May 9, 2023.
3. National Comprehensive Cancer Network. Melanoma: Cutaneous Version 02.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed May 9, 2023.

## Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J9325 | Injection, talimogene laherparepvec, per 1 million plaque forming units |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 10/2021 | |
| 3Q 2022 annual review: no significant changes; references reviewed and updated. | 07/2022 | |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 3Q 2023 annual review: updated dosing in initial approval criteria so that member meets both initial and subsequent dosing; added reinitiation dose in initial approval criteria to align with dosing section in prescriber information; references reviewed and updated. | 07/2023 | |