Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2021**
Policy Number:	**Effective Date: 10/2021** **Revision Date: 10/2021**
Policy Name:	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Talimogene laherepvec (Imlygic)

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

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 health plans affiliated with 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. Administered as single agent;
5. Documentation of 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, b, or c):*
   a. For initial dose: Dose does not exceed 4 mL of 10^6 plaque-forming units (PFU)/mL (*see Appendix E*);
   b. For all subsequent doses (starting 3 weeks after initial dose): Dose does not exceed 4 mL of 10^8 PFU/mL every 2 weeks (*see Appendix E*);
   c. 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: 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
PFU: 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
> 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 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 per mL

VII. References

1. Imlygic Prescribing Information. Thousand Oaks, CA: Amgen; October 2019. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/imlygic/imlygic_pi.pdf. Accessed May 25, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed May 25, 2021.
3. National Comprehensive Cancer Network. Cutaneous Melanoma Version 02.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed May 25, 2021.

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	