Clinical Policy: Talimogene Laherepvec (Imlygic)

Reference Number: ERX.SPA.440
Effective Date: 09.01.21
Last Review Date: 08.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 both 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;
   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;
   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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or documentation supports that member is currently receiving Imlygic for a covered indication and has received this medication for at least 30 days;
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;
   b. New dose is supported by practice guideline 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

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

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/mL, followed by up to 4 mL of 10^8 (100 million) PFU/mL administered 3 weeks later;	4 mL at a concentration of 10^8 PFU/mL per treatment (all lesions combined)

Indication	Dosing Regimen	Maximum Dose
	thereafter, subsequent doses of up to 4 mL of 10^8 PFU/mL are administered every 2 weeks	

VI. Product Availability
Single-use vials: 10^6 (1 million) PFU/mL, 10^8 (100 million) PFU/mL

VII. References
1. Imlygic Prescribing Information. Thousand Oaks, CA: Amgen; December 2021. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/imlygic/imlygic_pi.pdf. Accessed April 13, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed April 13, 2022.
3. National Comprehensive Cancer Network. Cutaneous Melanoma Version 03.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed April 13, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.01.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	04.13.22	08.22

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.