Clinical Policy: Talimogene laherepvec (Imlygic)

Reference Number: LA.PHAR.542
Effective Date: 09.29.23
Last Review Date: ~~05.01.23~~04.05.24
Line of Business: Medicaid

Coding Implications
Revision Log

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

Please note: This policy is for medical benefit

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 Louisiana Healthcare Connections® 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~~Prescribed as a single agent;
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~~, b,~~ or ~~c~~b):*
   a. Both of the following (i and ii):
      ~~a.~~i. For initial dose: Dose does not exceed 4 mL of 10^6 plaque-forming units (PFU)/mL (*see Appendix D*);
      ~~b.~~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 D*);
   ~~c.~~b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

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

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit, 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 (*see Appendix D*);
   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

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

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 – LA.PMN.53 for Medicaid 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
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 (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/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~~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/.~~https://www.nccn.org/professionals/drug_compendium/content/. Accessed ~~April 13, 2022~~May 9, 2023.

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3. National Comprehensive Cancer Network. Melanoma: Cutaneous Version ~~03.2022~~02.2023. Available at: ~~https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf.~~https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed ~~April 13, 2022~~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~~/LDH Approval Date
Policy created	05.01.23	~~04.23~~08.28.23
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.	04.05.24	

Important Reminder

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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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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