Talimogene laherparepvec (Imlygic®)	Place of Service Office Administration Outpatient Facility Administration HCPCS: J9325 per 1 million plaque forming units (PFU)

Condition listed in policy (*see criteria for details*)

- Melanoma: cutaneous

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Genetically modified oncolytic viral therapy

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Imlygic® (talimogene laherparepvec) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Melanoma

1. Diagnosis of recurrent, stage III or stage IV melanoma with cutaneous, subcutaneous, and/or nodal lesions suitable for direct or ultrasound guided injection

Covered Doses

Initial: Up to 4 mL (10^6 PFU per mL) total volume injected intra-tumorally per treatment visit (all lesions combined); followed by up to 4 mL (10^8 PFU per mL) total volume injected intratumorally per treatment visit THREE weeks after initial treatment.

Subsequent doses: up to 4 mL (10^8 PFU per mL) total injected intra-tumorally among melanoma lesions per treatment visit TWO weeks after previous treatment.

Coverage Period

Initial: 1 year
Reauthorize: Yearly if patient has demonstrated at least stable response or better, but still has remaining lesions suitable for treatment.

ICD-10:

C43.0, C43.10-C43.12, C43.20-C43.22, C43.30, C43.31, C43.39, C43.4, C43.51, C43.52, C43.59-C43.62, C43.70-C43.72, C43.8, C43.9, Z85.820

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Imlygic® (talimogene laherparepvec) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 10^6 (1 million) PFU/ mL (single-use vial)
- 10^8 (100 million) PFU/ mL (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Imlygic® (talimogene laherparepvec) [Prescribing information]. Thousand Oaks, CA: Amgen, Inc.; 2/2023.
- National Comprehensive Cancer Network Drugs and Compendium (2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Melanoma: Cutaneous (Version 2.2023). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee