Medical Policy:

Imlygic® (talimogene laherparepvec) Intralesional

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.150	April 1, 2025	

Definitions

Imlygic (Talimogene Laherparepvec): is a genetically modified attenuated herpes simplex virus 1 (HSV) oncolytic virus that selectively replicates into and lyses the tumor cell via the deletion of two nonessential viral genes. Virally derived GM-CSF recruits and activates antigen-presenting cells, leading to an antitumor immune response.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

Treatment schedule	Dosage and frequency
First treatment	4 billable units
Second treatment	400 billable units 3 weeks after first treatment

Subsequent treatments	400 billable units 2 weeks after previous treatment

Guideline

I. Initial Approval Criteria

Imlygic *may be considered medically necessary when any of the following selection criteria is met:*

1. **Cutaneous Melanoma**

A. Used for unresectable recurrent disease †; **OR**
B. Used as primary treatment for unresectable or borderline resectable stage III disease with clinically positive node(s); **OR**
C. Used for oligometastatic disease with accessible lesions; **OR**
D. Used for widely disseminated distant metastatic disease with limited extracranial lesions; **OR**
E. Patient has limited resectable or unresectable disease; **AND**
   i. Used for stage III disease with clinical satellite/in-transit metastases; **OR**
   ii. Used for local satellite/in-transit recurrence

Limitations/Exclusions

Imlygic is not considered medically necessary for when any of the following selection criteria is met:

1. Member must be 18 years of age or older
2. Member cannot be pregnant
3. Disease progression while taking Imlygic (Talimogene Laherparepvec)
4. Max dose volume of 4mL per intralesional injection.
5. Member is immunocompromised or has any immune-mediated events.
6. Member has a Herpetic infection and on anti-herpetic treatment.
7. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

Authorization coverage can be renewed if the following criteria are met:

1. Patient continues to meet INITIAL APPROVAL CRITERIA; **AND**
2. Patient continues to have injectable lesions to treat; **AND**
3. Absence of unacceptable toxicity from the drug including injection site complications, herpetic infection, immune mediated events, obstructive airway disorder, etc.; **AND**
4. Disease response with treatment as defined by decrease in tumor size or tumor spread.

Dosage/Administration

Indication	Dose
Melanoma	**First Treatment** Dose injected up to a maximum volume of 4 mL at a concentration of 10^6 (1 million) PFU/mL. Inject the largest lesions first. Priority follows the next largest lesion and so forth with the amount of inject correlating to the size of the lesion • If the lesion size is >5 cm, inject up to 4 mL • If the lesion size is >2.5 cm to 5 cm, inject up to 2 mL • If the lesion size is >1.5 cm to 2.5 cm, inject up to 1 mL • If the lesion size is >0.5 cm to 1.5 cm, inject up to 0.5 mL

	• If the lesion size is ≤0.5 cm, inject up to 0.1 mL
	Second Treatment – 3 weeks after the initial visit. Injected intralesionally up to a maximum volume of 4 ml at a concentration of 10^8 (100 million) PFU/ml. • First inject any new lesions which have appeared since the initial visit • Priority follows the next largest lesion and so forth with the amount of inject correlating to the size of the lesion
	Subsequent Treatments All additional treatments may be given 2 weeks after the 2nd treatment therapy and subsequent treatments thereafter. • First inject any new lesions which have appeared since the initial visit • Priority follows the next largest lesion and so forth with the amount of inject correlating to the size of the lesion.

Applicable Procedure Codes

Code	Description
J9325	Injection, talimogene laherparepvec, per 1 million plaque forming units

Applicable NDCs

Code	Description
55513-0078-01	Imlygic 10^6 (1 million) PFU per mL is light green
55513-0079-01	Imlygic 10^8 (100 million) PFU per mL is royal blue

ICD-10 Diagnoses

Code	Description
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder

C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/01/2025	Annual Review: Updated ICD-10 codes. No criteria changes.
EmblemHealth & ConnectiCare	2/16/2024	Annual Review: Initial Criteria: changed name to "Cutaneous "Melanoma Removed: "Patient has one of the following: Unresectable, distant metastatic disease; OR Unresectable or incomplete resection of nodal recurrence; OR Limited resectable or unresectable stage III disease with clinical satellite or in-transit metastases; OR Limited resectable or unresectable disease with local satellite and/or in-transit recurrence; OR" Added: "Used for unresectable recurrent disease †; OR Used for oligometastatic disease with accessible lesions; OR Used for widely disseminated distant metastatic disease with limited extracranial lesions; OR Patient has limited resectable or unresectable disease; AND Used for stage III disease with clinical satellite/in-transit metastases; OR Used for local satellite/in-transit recurrence"
EmblemHealth & ConnectiCare	6/23/2023	Annual Review: <u>Melanoma:</u> Initial Criteria: Removed: "a.The member has stage IIIB, IIIC, or IV melanoma and ONE of the following: i. Unresectable stage III in-transit metastases. ii. Local/satellite and/or in-transit unresectable recurrence. iii. Unresectable or distant metastatic disease." Replaced with "Patient has one of the following: a. Unresectable, distant metastatic disease; OR b. Unresectable or incomplete resection of nodal recurrence; OR c. Limited resectable or unresectable stage III disease with clinical satellite or in-transit metastases; OR d. Limited resectable or unresectable disease with local satellite and/or in-transit recurrence; OR e. Unresectable or borderline resectable stage III disease with clinically positive node(s) as primary therapy"
EmblemHealth & ConnectiCare	07/08/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	04/29/2020	Updated Exclusions/Limitations: • Member must be 18 years of age and older • Member cannot be pregnant

References

1. PI prescribing information accessed on 3/18/16: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208434s000lbl.pdf
2. Clinical Pharmacology Elsevier Gold Standard. 2017.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2017.

4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2017.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists. Bethesda, MD. 2017.
6. Lexicomp Online®, Pediatric & Neonatal Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc. 2017.