

## Medical Policy:

### Imlygic® (talimogene laherparepvec) Intralesional

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## 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
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## 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	<b>First Treatment</b> Dose injected up to a maximum volume of 4 mL at a concentration of 10 <sup>6</sup> (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 <ul style="list-style-type: none"> <li>• If the lesion size is &gt;5 cm, inject up to 4 mL</li> <li>• If the lesion size is &gt;2.5 cm to 5 cm, inject up to 2 mL</li> <li>• If the lesion size is &gt;1.5 cm to 2.5 cm, inject up to 1 mL</li> <li>• If the lesion size is &gt;0.5 cm to 1.5 cm, inject up to 0.5 mL</li> </ul>

	<ul style="list-style-type: none"> <li>If the lesion size is <math>\leq 0.5</math> cm, inject up to 0.1 mL</li> </ul>
	<b>Second Treatment –</b> 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. <ul style="list-style-type: none"> <li>First inject any new lesions which have appeared since the initial visit</li> <li>Priority follows the next largest lesion and so forth with the amount of inject correlating to the size of the lesion</li> </ul>
	<b>Subsequent Treatments</b> All additional treatments may be given 2 weeks after the 2nd treatment therapy and subsequent treatments thereafter. <ul style="list-style-type: none"> <li>First inject any new lesions which have appeared since the initial visit</li> <li>Priority follows the next largest lesion and so forth with the amount of inject correlating to the size of the lesion.</li> </ul>

## 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: <ul style="list-style-type: none"> <li>Member must be 18 years of age and older</li> <li>Member cannot be pregnant</li> </ul>

## References

1. PI prescribing information accessed on 3/18/16:  
[http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/208434s000lbl.pdf](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.