

## Corporate Medical Policy

### Talimogene Laherparepvec (Imlygic™)

<b>File Name:</b>	talimogene_laherparepvec_(imlygic)
<b>Origination:</b>	2/2016
<b>Last CAP Review:</b>	8/2018
<b>Next CAP Review:</b>	8/2019
<b>Last Review:</b>	8/2018

#### Description of Procedure or Service

---

Talimogene laherparepvec (Imlygic™) is an oncolytic viral therapy for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in individuals with melanoma recurrent after initial surgery.

Talimogene laherparepvec (Imlygic™) is a live, attenuated herpes simplex virus type 1 (HSV-1) that has been genetically modified to replicate within tumors and express granulocyte macrophage colony-stimulating factor (GM-CSF), an immunostimulatory protein. The administration of talimogene laherparepvec (Imlygic™) causes cell lysis of tumors, followed by the release of tumor-derived antigens. The antigens along with the virally derived GM-CSF may promote an anti-tumor immune response.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Policy

---

**BCBSNC will provide coverage for talimogene laherparepvec (Imlygic™) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.**

#### Benefits Application

---

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

#### When Talimogene Laherparepvec (Imlygic) is covered

---

Talimogene laherparepvec (Imlygic™) is considered medically necessary for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

#### When Talimogene Laherparepvec (Imlygic) is not covered

---

Talimogene Laherparepvec (Imlygic) is considered not medically necessary and therefore not covered when above criteria are not met.

This treatment is contraindicated for immunocompromised and pregnant patients.

# Talimogene Laherparepvec (Imlygic™)

## Policy Guidelines

---

Talimogene laherparepvec (Imlygic) is administered via direct injection into the recurrent, unresectable melanoma lesions.

The recommended dose for initial treatment with talimogene laherparepvec (Imlygic™) is up to 4mL at a concentration of  $10^6$  (1 million) plaque-forming units (PFU) per mL.

The recommended dose for subsequent administrations of talimogene laherparepvec (Imlygic™) is up to 4mL at a concentration of  $10^8$  (100 million PFU) per mL. The second treatment is to be performed three weeks after the initial treatment and all subsequent treatments are to be performed two weeks after the previous treatment.

## Billing/Coding/Physician Documentation Information

---

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: C9399, J3490, J3590, J9325, J9999*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

---

US Food and Drug Administration (FDA). Center for Biologics Evaluation and Research. Imlygic™. Available at:  
<http://www.fda.gov/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/ucm469411.htm>.

Accessed January 29, 2016.

US Food and Drug Administration (FDA). Available at:  
<http://www.fda.gov/downloads/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/ucm469575.pdf>

Accessed January 29, 2016.

[http://pi.amgen.com/united\\_states/imlygic/imlygic\\_pi.pdf](http://pi.amgen.com/united_states/imlygic/imlygic_pi.pdf)

Senior Medical Director review 2/2016

Specialty Matched Consultant Advisory Panel 8/2016

Specialty Matched Consultant Advisory Panel 8/2017

Specialty Matched Consultant Advisory Panel 8/2018

## Policy Implementation/Update Information

---

2/29/16 New policy issued. Talimogene laherparepvec (Imlygic™) is considered medically necessary for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients

# Talimogene Laherparepvec (Imlygic™)

with melanoma recurrent after initial surgery. Notification given 2/29/2016 for effective date 4/29/2016. Senior medical director review 2/2016. (lpr)

4/29/16 Added HCPCS code C9472 to Billing/Coding section. (lpr)

9/30/16 Specialty Matched Consultant Advisory Panel review 8/31/2016. No change to policy statement. (lpr)

11/22/16 Deleted C9472 and added HCPCS code J9325 to Billing/Coding section. No change to policy statement. (lpr)

9/29/17 Specialty Matched Consultant Advisory Panel review 8/30/2017. No change to policy statement. (lpr)

10/12/18 Specialty Matched Consultant Advisory Panel review 8/22/2018. No change to policy statement. (krc)

---

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.