BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Talimogene Laherparepvec (Imlygic™)

File Name:	talimogene_laherparepvec_(imlygic)
Origination:	2/2016
Last CAP Review:	8/2019
Next CAP Review:	8/2020
Last Review:	12/2019

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.

Use of talimogene laherparepvec (Imlygic) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, (see Policy Guidelines); **OR**

- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

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) is considered investigational when used for:

1. Non-cancer indications; **OR**

2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under "When Talimogene Laherparepvec (Imlygic) is covered."

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.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standard from nationally recognized compendia.

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. 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

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

Specialty Matched Consultant Advisory Panel 8/2019

Medical Director review 12/2019

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 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)

10/1/19 Specialty Matched Consultant Advisory Panel review 8/21/2019. No change to policy statement. (krc)

12/31/19 Added the following statement to "When Covered" section: "Use of talimogene laherparepvec (Imlygic) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either: In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); OR In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform

consensus of clinical appropriateness has been reached." Under "When Not Covered" section, added the statement: "Talimogene laherparepvec (Imlygic) is considered investigational when used for: 1) Non-cancer indications; OR 2) When criteria are not met regarding FDA labeling OR strong endorsement/ support by nationally recognized compendia, as stated under "When Talimogene Laherparepvec (Imlygic) is covered." Added the following statements under "Policy Guidelines" section: 1) Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy, Investigational (Experimental) Services." 2) Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia. Medical Director review 12/2019. (krc)