LifeWise
Health Plan of Washington

PHARMACY / MEDICAL POLICY – 5.01.562

Imlygic (talimogene laherparepvec)

Effective Date:	June 1, 2024	RELATED MEDICAL POLICIES:	
Last Revised:	May 24, 2024	5.01.534	Multiple Receptor Tyrosine Kinase Inhibitors
Replaces:	N/A	5.01.540	Miscellaneous Oncology Drugs

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Imlygic is a drug that uses a genetically altered virus to treat melanoma. This type of treatment is known as oncolytic viral therapy. This drug uses the herpes simplex 1 virus—the virus that can cause cold sores around the mouth—that has been changed to include a specific gene. This gene stimulates the immune system to create certain other cells that attack cancer. The modified virus can enter normal cells, but normal cells are able to kill the virus. Cancer cells can't. When the modified virus enters a cancer cell, it begins to grow and reproduce. The growing virus causes the cancer cells to burst and die. The dying cells then release a number of substances which then stimulate the body's immune system to further attack the cancer cells. This policy describes when Imlygic may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Imlygic (talimogene laherparepvec)	**Imlygic (talimogene laherparepvec) may be considered medically necessary for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in individuals with melanoma recurrent after initial surgery.**

Drug	Investigational
Imlygic (talimogene laherparepvec)	**Use of Imlygic (talimogene laherparepvec) for all other indications is considered investigational.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Imlygic (talimogene laherparepvec) may be approved up to 6 months.**
Re-authorization criteria	**Future re-authorization of Imlygic (talimogene laherparepvec) may be approved up to 12 months as long as the drug-specific coverage criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history and physical evaluation

Coding

Code	Description
HCPCS	
J9325	Injection, talimogene laherparepvec (Imlygic), per 1 million plaque forming units

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

This policy is managed through the medical benefit.

Evidence Review

Description

Imlygic (talimogene laherparepvec) is a first-in-class oncolytic viral therapy. It is a herpes simplex 1 virus genetically modified to express human granulocyte-macrophage colony-stimulating factor (GM-CSF), indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in individuals with melanoma recurrent after initial surgery.

Melanoma

Melanoma accounts for a small (<5%) proportion of all skin cancers but, because it is more likely to metastasize than squamous cell or basal cell cancers, it causes a disproportionately high amount of skin cancer mortality. If recognized and treated early, it is almost always curable. Approximately 84% of melanomas are diagnosed at a localized stage with 5-year survival of 98%. However, the 5-year survival for the 4% of individuals with metastatic disease at diagnosis is 15%.

Incidence rates for melanoma have been rising for at least 30 years. The risk of melanoma increases as people age and the average age of people when it is diagnosed is 65. The American Cancer Society estimates that approximately 99,780 new cases of melanoma will be diagnosed in the United States (US) in 2022 and an estimated 7,650 people will die of melanoma (about 5,080 men and 2,570 women). The lifetime risk of melanoma is about 2.6% for Caucasians, 0.6% for Hispanics, and 0.1% for African Americans. Major risk factors for melanoma include atypical nevi (moles), more than 50 benign or atypical nevi, giant congenital nevus, and a personal or family history of melanoma. Other risk factors for all skin cancer types include: sun sensitivity, defined as easily sun burning, freckling, tanning with difficulty, or having naturally blond or red

hair, history of excessive sun exposure, including sunburns, use of tanning booths and immune-deficiency states (e.g., immunosuppressive chemotherapy, post-transplant immunosuppression, HIV/AIDS).

Rationale

One open-label, phase 3 Randomized Controlled Trial (RCT) has been published: The OPTiM study showed a significantly higher durable response rate in the talimogene laherparepvec (T-VEC) arm: (16.3% vs. 2.1% for GM-CSF, $P<0.001$). Overall, response rate was 26.4% for T-VEC vs. 5.7% for GM-CSF ($P<0.001$); 10.8% in the T-VEC arm had a Complete Remission (CR) compared to <1% in the GM-CSF arm, while 15.6% of the T-VEC arm achieved a Partial Response (PR) compared to 5.0% of the GM-CSF arm. There was no statistically significant difference in overall survival (OS) between the T-VEC and the GM-CSF arms. The median OS in the overall study population was 22.9 months in the T-VEC arm and 19.0 months in the GM-CSF arm ($P=0.116$).

Most common adverse events with T-VEC were fatigue (50% vs. 36% with GM-CSF), chills (49% vs. 9% with GM-CSF), pyrexia (43% vs. 9% with GM-CSF), nausea (36% vs. 20% with GM-CSF), flu-like illness (30% vs. 15% with GM-CSF), and injection-site pain (28% vs. 6% with GM-CSF).

Subgroup analyses found that differences in Durable Response Rate (DRR) between the T-VEC and GM-CSF arms were more pronounced in individuals with stage IIIB or IIIC and IVM1a disease than in individuals with stage IVM1b and IVM1c disease. Differences in DRR were also more pronounced in individuals with treatment-naïve metastatic melanoma than in those receiving second-line or greater therapy. Similar patterns were seen for Overall Response Rate (ORR) and OS.

2017 Update

Search of recent literature found no new information that would modify this policy.

2018 Update

Search of recent literature from October 1, 2017, to October 31, 2018, found no new information that would modify this policy. Updated references.

2019 Update

Reviewed Imlygic (talimogene laherparepvec) prescribing information and conducted a literature search from November 1, 2018, through November 30, 2019. No new information was identified that would require changes to this policy.

2020 Update

Reviewed Imlygic (talimogene laherparepvec) prescribing information and conducted a literature search from December 1, 2019, through September 30, 2020. No new information was identified that would require changes to this policy.

2021 Update

Reviewed Imlygic (talimogene laherparepvec) prescribing information and conducted a literature search on the management of melanoma. No new information was identified that would require changes to this policy.

2022 Update

Reviewed Imlygic (talimogene laherparepvec) prescribing information. In June 2022 a new warning and precaution was added regarding transcutaneous intrahepatic route of administration. The prescribing information stated that in clinical studies, cases of hepatic hemorrhage resulting in hospitalization and death have been reported in individuals receiving transcutaneous intrahepatic Imlygic injections and that Imlygic is not indicated for transcutaneous intrahepatic route of administration. No new information was identified that would require changes to this policy.

2023 Update

Reviewed Imlygic (talimogene laherparepvec) prescribing information and conducted a literature search on the management of melanoma. No new information was identified that would require changes to this policy.

2024 Update

Reviewed Imlygic (talimogene laherparepvec) prescribing information and conducted a literature search on the management of melanoma. No new information was identified that would require changes to this policy.

References

1. Imlygic (talimogene laherparepvec) [package insert]. Thousand Oaks, CA; BioVex, Inc (subsidiary of Amgen); Revised February 2023. Available at: **http://pi.amgen.com/united_states/imlygic/imlygic_pi.pdf** Accessed May 1, 2024.
2. Rothermel LD, Zager JS. Engineered oncolytic viruses to treat melanoma: where are we now and what comes next? Expert Opin Biol Ther. 2018 Nov 4. doi: 10.1080/14712598.2018.1544614.
3. Seremet T, Planken S, Schwarze JK, Successful treatment with intralesional talimogene laherparepvec in two patients with immune checkpoint inhibitors refractory advanced melanoma. Melanoma Res. 2018 Sep 11. doi: 10.1097/CMR.0000000000000501.
4. Collins JM, Redman JM, Gulley JL. Combining vaccines and immune checkpoint inhibitors to prime, expand, and facilitate effective tumor immunotherapy. Expert Rev Vaccines. 2018 Aug;17(8):697-705. doi: 10.1080/14760584.2018.1506332. Epub 2018 Aug 22.

History

Date	Comments
05/01/16	New Policy, approved April 12, 2016. Add to Prescription Drug section. Imlygic may be considered medically necessary for labeled indication. Reviewed by Pharmacy and Therapeutics Committee, February 25, 2016.
01/01/17	Coding update; added new HCPCS code J9325 effective 1/1/17.
06/01/17	Coding update; removed HCPCS codes J3490, J3590, and J9999.
10/01/17	Annual Review, approved September 5, 2017. A literature search was conducted from 04/13/16 to 8/18/17. No new studies were found that would require changes to this policy.
12/01/18	Annual Review, approved November 21, 2018. Literature search found no new information that would modify this policy. Updated references.

Date	Comments
01/01/20	Annual Review, approved December 10, 2019. No changes to policy statement.
12/01/20	Annual Review, approved November 3, 2020. No changes to policy statement.
10/01/21	Annual Review, approved September 23, 2021. No changes to policy statement.
11/01/22	Annual Review, approved October 10, 2022. No changes to policy statement. Changed the wording from "patient" to "individual" throughout the policy for standardization.
12/01/23	Annual Review, approved November 20, 2023. No changes to policy statement. Removed coverage from the pharmacy benefit to align with current benefit coverage.
06/01/24	Annual Review, approved May 24, 2024. No changes to policy statement.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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Language Assistance

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