



5.21.66

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Subsection:	Antineoplastic Agents	Original Policy Date:	December 11, 2015
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Last Review Date: June 16, 2022

Imlygic

Description

Imlygic (talimogene laherparepvec)

Background

Imlygic is a genetically modified live oncolytic herpes virus therapy, used to treat melanoma lesions in the skin and lymph nodes that cannot be removed completely by surgery. Imlygic is injected directly into the melanoma lesions, where it replicates inside cancer cells and causes the cells to rupture and die (1).

Regulatory Status

FDA-approved indication: Imlygic is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery (1).

Limitations of Use:

Imlygic has not been shown to improve overall survival or have an effect on visceral metastases (1).

Imlygic is a live, attenuated herpes simplex virus and may cause a disseminated herpetic infection in patients who are immunocompromised. Do not administer this drug to immunocompromised patients, including those with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy. Patients who develop herpetic infections should be advised to follow standard hygienic practices to prevent

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viral transmission. Disseminated herpetic infection may also occur in immunocompromised patients (1).

Adequate and well-controlled studies have not been conducted in pregnant women. Women of childbearing potential should be advised to use an effective method of contraception to prevent pregnancy during treatment with this drug. Do not administer Imlygic to pregnant patients (1). Imlygic treatment should be continued for at least 6 months unless other treatment is required or until there are no injectable lesions to treat (1).

Imlygic should not be used in pregnant women (1).

Imlygic is sensitive to acyclovir. Acyclovir or other antiherpetic viral agents may interfere with the effectiveness of Imlygic. Therefore, consider the risks and benefits of Imlygic treatment before administering antiviral agents to manage herpetic infection (1).

Safety and effectiveness of Imlygic have not been established in pediatric patients (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Imlygic may be considered **medically necessary** in patients 18 years of age or older with melanoma and if the conditions indicated below are met.

Imlygic may be considered **investigational** in patients below the age of 18 or for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Melanoma

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- a. Presence of unresectable cutaneous, subcutaneous, and/or nodal lesions that is recurrent after initial surgery

AND NONE of the following:

1. Concurrent treatment with acyclovir or other antiherpetic viral agents
2. Immune deficiencies, including history of:
 - a. Primary or acquired immunodeficient states
 - b. Leukemia
 - c. Lymphoma
 - d. AIDS or other clinical manifestations of infection with human immunodeficiency viruses
3. Concurrent treatment with an immunosuppressive therapy
4. Females who are pregnant

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Melanoma
 - a. Presence of unresectable cutaneous, subcutaneous, and/or nodal lesions

AND NONE of the following:

1. Concurrent treatment with acyclovir or other antiherpetic viral agents
2. Immune deficiencies, including history of:
 - a. Primary or acquired immunodeficient states
 - b. Leukemia
 - c. Lymphoma
 - d. AIDS or other clinical manifestations of infection with human immunodeficiency viruses
3. Concurrent treatment with an immunosuppressive therapy
4. Females who are pregnant

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Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 18 months

Rationale

Summary

Imlygic is a genetically modified live oncolytic herpes virus therapy, is used to treat melanoma lesions that cannot be removed completely by surgery. Imlygic is injected directly into the melanoma lesions, where it replicates inside cancer cells and causes the cells to rupture and die. Do not administer this drug to immunocompromised patients, including those with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Imlygic while maintaining optimal therapeutic outcomes.

References

1. Imlygic [package insert]. Thousand Oaks, CA: Amgen; December 2021.
2. NCCN Drugs & Biologics Compendium[®] Talimogene laherparepvec 2022. National Comprehensive Cancer Network, Inc. Accessed on April 18, 2022.

Policy History

Date	Action
December 2015	Addition to PA
June 2016	Annual editorial review and reference update Policy number change from 5.04.66 to 5.21.66
June 2017	Annual review

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June 2018	Annual editorial review and reference update
June 2019	Annual review and reference update
June 2020	Annual review and reference update
June 2021	Annual review and reference update
June 2022	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.