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5.21.066

Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 11, 2015
Subject:	Imlygic	**Page:**	1 of 5

Last Review Date: June 11, 2026

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

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** if the conditions indicated below are met.

Imlygic may be considered **investigational** for all other indications.

Prior-Approval 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 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

Policy Guidelines

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; November 2024.
2. NCCN Drugs & Biologics Compendium® Talimogene laherparepvec 2026. National Comprehensive Cancer Network, Inc. Accessed on April 21, 2026.

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
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
June 2023	Annual review and reference update. Changed policy number to 5.21.066
June 2024	Annual review and reference update
June 2025	Annual review and reference update
June 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.