Reference number(s)
4468-A

Standard Medicare Part B Management Imlygic

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Imlygic	talimogene laherparepvec

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

Limitations of Use

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

Compendial Uses[2,3]

- Melanoma
- Merkel cell carcinoma

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Reference number(s)
4468-A

Coverage Criteria

Melanoma[1-3]

Authorization of 12 months may be granted for the treatment of metastatic, unresectable, limited resectable, or borderline resectable cutaneous, subcutaneous, and nodal lesions in melanoma, when used as a single agent.

Authorization of 12 months may be granted for subsequent treatment of progressed, unresectable, or metastatic cutaneous melanoma or if the member has an intolerance to BRAF-targeted therapy, when used in combination with ipilimumab (Yervoy).

Merkel Cell Carcinoma[2]

Authorization of 12 months may be granted for palliative treatment of metastatic or nodal Merkel cell carcinoma, as a single agent, when the following criteria is met:

- The member has a contraindication to or the disease has progressed on anti-PD-L1 or anti-PD-1 therapy.
- Curative surgery and/or radiation therapy are not feasible.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, AND
    - No evidence of disease progression while on the current regimen.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Imlygic.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Cutaneous melanoma
- NCCN Guideline: Merkel cell carcinoma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Imlygic are covered in addition to the following:

- Limited resectable or unresectable stage III melanoma with clinical satellite/in-transit metastases or with nodal lesions
- Oligometastatic melanoma
- Widely disseminated distant metastatic melanoma
- Limited resectable or unresectable/ borderline resectable local satellite/in-transit recurrence of melanoma
- In combination with ipilimumab for metastatic or unresectable disease as subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy
- Merkel cell carcinoma

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Imlygic to treat the clinical scenarios listed in the summary of evidence can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Imlygic [package insert]. Thousand Oaks, CA: Amgen Inc.; November 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 3, 2025.
3. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. http://online.lexi.com. Accessed November 7, 2025.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.