

# Specialty Guideline 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<sup>1</sup>

Imlygic is indicated for the 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<sup>2,3</sup>

- Melanoma
- Merkel Cell Carcinoma

All other indications are considered experimental/investigational and not medically necessary.

Reference number(s)
1680-A

# Coverage Criteria

## Melanoma<sup>1-3</sup>

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.

## Merkel Cell Carcinoma<sup>2</sup>

Authorization of 12 months may be granted for palliative treatment of 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

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria when there is no evidence of unacceptable toxicity or disease progression while on the current 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. <https://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.