

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 Indications¹

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 Uses²

- Melanoma
 - metastatic
 - limited resectable
 - borderline resectable

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

Reference number(s)
1680-A

Coverage Criteria

Melanoma¹⁻²

Authorization of 12 months may be granted for treatment of unresectable, limited resectable, borderline resectable, or metastatic cutaneous, subcutaneous, and nodal lesions in melanoma.

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.; February 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed November 12, 2024.