Talimogene Laherparepvec (Imlygic™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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

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

- Melanoma
- Merkel Cell Carcinoma

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

COVERAGE CRITERIA

Melanoma

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

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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Imlygic [package insert]. Thousand Oaks, CA: Amgen Inc.; November 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: 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.

EFFECTIVE DATE 7/31/2026

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