Reference number(s)
1680-A

SPECIALTY GUIDELINE MANAGEMENT

IMLYGIC (talimogene laherparepvec)

POLICY

I. 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.

A. FDA-Approved Indication
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.

B. Compendial Uses
1. Limited resectable or unresectable stage III melanoma with clinical satellite/in-transit metastases
2. Unresectable distant metastatic melanoma (extracranial lesions)
3. Limited resectable or unresectable local satellite/in-transit recurrence of melanoma
4. Unresectable or incomplete resection of nodal occurrence in patients with melanoma

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

II. CRITERIA FOR INITIAL APPROVAL

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

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Imlygic [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2019.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed November 5, 2020.