Reference number(s)
4468-A

STANDARD MEDICARE PART B 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
Local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery

B. Compendial Uses
1. Limited resectable or unresectable stage III melanoma with clinical satellite/in-transit metastases or with nodal lesions
2. Widely disseminated distant metastatic melanoma
3. Limited resectable or unresectable local satellite/in-transit recurrence of melanoma
4. In combination with ipilimumab for metastatic or unresectable disease as subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy

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

II. CRITERIA FOR INITIAL APPROVAL

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

III. 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:
1. The member is currently receiving therapy with the requested medication
2. The requested medication is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy. Benefit is defined as:

i. No evidence of unacceptable toxicity while on the current regimen, and
ii. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

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

1. The prescribing information for Imlygic.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Cutaneous melanoma

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:

1. Limited resectable or unresectable stage III melanoma with clinical satellite/in-transit metastases or with nodal lesions
2. Widely disseminated distant metastatic melanoma
3. Limited resectable or unresectable local satellite/in-transit recurrence of melanoma
4. In combination with ipilimumab for metastatic or unresectable disease as subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy

V. 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 section IV 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).

VI. REFERENCES

1. Imlygic [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2022.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 1, 2022.