Drug Policy:

Imlygic™ (talimogene laherparepvec)

POLICY NUMBER UM ONC_1282	SUBJECT Imlygic™ (talimogene laherparepvec)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 03/23/16, 01/07/16, 01/02/18, 01/08/19, 12/11/19, 01/08/20, 11/11/20, 10/13/21, 11/15/21, 05/11/22, 10/12/22, 01/11/23, 03/08/23, 05/10/23, 01/10/24	APPROVAL DATE January 10, 2024	EFFECTIVE DATE January 26, 2024	COMMITTEE APPROVAL DATES 03/23/16, 01/07/16, 01/02/18, 01/08/19, 12/11/19, 01/08/20, 11/11/20, 10/13/21, 11/15/21, 05/11/22, 10/12/22, 01/11/23, 03/08/23, 05/10/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Imlygic (talimogene laherparepvec) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
3. Additional medication(s) are not being added to the continuation request.

B. Melanoma

1. Imlygic (talimogene laherparepvec) may be used as a single agent (as an intra-lesional injection) for unresectable cutaneous, subcutaneous, and nodal lesions, in members with melanoma recurrence after prior surgery OR
2. Imlygic (talimogene laherparepvec) may be used as a single agent as neo-adjuvant (preoperative) therapy for resectable stage IIIB-IVM1a melanoma.

3. NOTE: Imlygic (talimogene laherparepvec) in combination with Yervoy (ipilimumab) is not supported by Evolent Medical Policy for the treatment of advanced or unresectable melanoma. This policy position is based on the lack of Level 1 Evidence (randomized clinical trials and/or meta-analyses) to show superior outcomes compared to the Evolent recommended alternative agents/regimens, including but not limited to regimens at (http://pathways.newcenturyhealth.com).

III. EXCLUSION CRITERIA

A. Disease progression while on Imlygic (talimogene laherparepvec).

B. Use of Imlygic (talimogene laherparepvec) for visceral lesions or for a lack of injectable lesions that are not visible and palpable.

C. Concurrent use with checkpoint inhibitors (e.g., ipilimumab, nivolumab, and pembrolizumab).

D. Max dose volume of 4mL per intralesional injection.

E. Investigational use of Imlygic (talimogene laherparepvec) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Chesney J, et al. Randomized, Open-Label Phase II Study Evaluating the Efficacy and Safety of Talimogene Laherparepvec in Combination With Ipilimumab Versus Ipilimumab Alone in Patients With Advanced, Unresectable Melanoma. J Clin Oncol. 2018 Jun 10;36(17):1658-1667.

B. Dummer R, et al. Neoadjuvant talimogene laherparepvec plus surgery versus surgery alone for resectable stage IIIB-IVM1a melanoma: a randomized, open-label, phase 2 trial. Nat Med. 2021 Oct;27(10):1789-1796.

C. Dummer R, et al. Final 5-year results of the phase II, multicenter, randomized, open-label trial of talimogene laherparepvec (T-VEC) neoadjuvant treatment (Tx) plus surgery vs immediate surgery in patients (pts) with resectable stage IIIB-IVM1a melanoma (MEL). Ann Oncol. 2022;33(suppl 7).

D. Chesney JA, et al. Randomized, Double-Blind, Placebo-Controlled, Global Phase III Trial of Talimogene Laherparepvec Combined with Pembrolizumab for Advanced Melanoma. J Clin Oncol. 2022 Aug 23:JCO2200343.

E. Andtbacka RHI, et al. Final analyses of OPTiM: a randomized phase III trial of talimogene laherparepvec versus granulocyte-macrophage colony-stimulating factor in unresectable stage III-IV melanoma. J Immunother Cancer. 2019 Jun 6;7(1):145.

F. Andtbacka RH, et al. Patterns of Clinical Response with Talimogene Laherparepvec (T-VEC) in Patients with Melanoma Treated in the OPTiM Phase III Clinical Trial. Ann Surg Oncol. 2016 Dec;23(13):4169-4177.

G. Imlygic prescribing information. Amgen Inc Thousand Oaks, CA 2022.

H. Clinical Pharmacology Elsevier Gold Standard 2023.

I. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

J. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

K. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2023.

L. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

M. NCQA UM 2023 Standards and Elements.