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	APPROVAL DATE January 8, 2020	EFFECTIVE DATE January 8, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 03/23/16, 01/07/16, 01/02/18, 01/08/19, 12/11/19, 01/08/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Imlygic (Talimogene Laherparepvec) usage in the treatment of cancer.

II. DEFINITIONS

Imlygic (Talimogene Laherparepvec): is a genetically modified attenuated herpes simplex virus 1 (HSV) oncolytic virus that selectively replicates into and lyses the tumor cell via the deletion of two nonessential viral genes. Virally derived GM-CSF recruits and activates antigen-presenting cells, leading to an antitumor immune response.

Imlygic (Talimogene Laherparepvec) is FDA approved for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrent after initial surgery

Imlygic (Talimogene Laherparepvec) is available in:

1. 1,000,000 units/mL (1 mL) intralesional suspension (Initial therapy)
2. 100,000,000 units/ mL (1 mL) intralesional suspension (Subsequent doses)

III. POLICY

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

Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Imlygic (Talimogene Laherparepvec) may be considered medically necessary when any of the following selection criteria is met:

1. **Melanoma**
    a. The member has stage IIIB, IIIC, or IV melanoma and **ONE** of the following:
        i. Unresectable stage III in-transit metastases
        ii. Local/satellite and/or in-transit unresectable recurrence
        iii. Unresectable or distant metastatic disease

Exclusion Criteria: Imlygic (Talimogene Laherparepvec) is not considered medically necessary when any of the following selection criteria is met:

1. Disease progression while taking Imlygic (Talimogene Laherparepvec)
2. Max dose volume of 4mL per intralesional injection.
3. Member is immunocompromised or has any immune-mediated events.
4. Member has a Herpetic infection and on anti-herpetic treatment.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Brand (generic) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration:**
    a. Imlygic (Talimogene Laherparepvec) is intralesional injected up to a maximum volume of 4 mL at a concentration of 10^6 (1 million) PFU/mL for the initial visit
        i. Inject the largest lesions first
        ii. Priority follows the next largest lesion and so forth with the amount of inject correlating to the size of the lesion
            1. If the lesion size is >5 cm, inject up to 4 mL
            2. If the lesion size is >2.5 cm to 5 cm, inject up to 2 mL
            3. If the lesion size is >1.5 cm to 2.5 cm, inject up to 1 mL
            4. If the lesion size is >0.5 cm to 1.5 cm, inject up to 0.5 mL
            5. If the lesion size is ≤0.5 cm, inject up to 0.1 mL
    b. 3 weeks after the initial visit, a second treatment therapy may be intralesional injected up to a maximum volume of 4 mL at a concentration of 10^8 (1 million) PFU/mL
        i. First inject any new lesions which have appeared since the initial visit
        ii. Priority follows the next largest lesion and so forth with the amount of inject correlating to the size of the lesion
    c. All additional treatments may be given 2 weeks after the 2nd treatment therapy and subsequent treatments thereafter
        i. First inject any new lesions which have appeared since the initial visit
        ii. Priority follows the next largest lesion and so forth with the amount of inject correlating to the size of the lesion.
2. **Dosage Adjustments:** Dosage adjustments are not required for renal or hepatic impairment**.**
3. **Monitoring Parameters:** signs or symptoms of immunocompromised events, injection site complications, and herpetic infections such as cold sores and herpetic keratitis.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

V. ATTACHMENTS

None

VII. REFERENCES

1. PI prescribing information accessed on 1/8/19: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208434s000lbl.pdf
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs . Bethesda, MD. 2020.