SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Imlygic™ (talimogene laherparepvec) (J9325) (Medical)

NDC(s)
❑ Imlygic 10^6 (1 million) PFU per mL is light green, single-use vial (NDC 55513-0078-01)
❑ Imlygic 10^8 (100 million) PFU per mL is royal blue, single-use vial (NDC 55513-0079-01)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Dosage and/or Quantity Limits:

A. **Quantity Limit (max daily/weekly dose) [NDC unit]:**
   a. Imlygic 10^6 (1 million) PFU per mL: 4 mL one time only
   b. Imlygic 10^8 (100 million) PFU per mL: 4 mL three weeks after initial treatment, then 4 mL every two weeks

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B. **Max Units (per dose and over time) [HCPCS Unit]:**
   a. Initial treatment: 4 billable units
   b. Second treatment: 400 billable units occurring 3 weeks after initial treatment
   c. All subsequent treatments: 400 billable units occurring 2 weeks after previous treatment

C. **Talimogene laherparepvec, 1 million plaque forming units (PFU)**: 1 billable unit = 10^6 (1 million) PFU

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization Approval: 6 Months

- ❑ Member is 18 years of age or older

AND

- ❑ Prescribed by or in consultation with a hematologist/oncologist

AND

- ❑ **For female members** of reproductive potential, pregnancy has been excluded before initiation of treatment; acceptable methods of contraception will be used during treatment and pregnancy status will be monitored monthly

AND

- ❑ Member is not immunocompromised (i.e., patients with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy)

AND

- ❑ Treatment (i.e., talimogene laherparepvec) will only be administered via intralesional injection

AND

- ❑ The member has a diagnosis of Melanoma with cutaneous, subcutaneous, and/or nodal lesions which are visible, palpable, or detectable by ultrasound (must submit recent chart notes/progress notes recording the diagnosis workup and current status, lesion(s) size, etc.)

AND

- ❑ The member's diagnosis meets one of the following disease statuses (must submit recent chart notes/progress notes recording the current status of diagnosis):
  - ❑ Unresectable, distant metastatic disease; **OR**
  - ❑ Unresectable or incomplete resection of nodal recurrence: **OR**
  - ❑ Limited resectable or unresectable stage III disease with clinical satellite or in-transit metastases; **OR**
  - ❑ Limited resectable or unresectable disease with local satellite and/or in-transit recurrence

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AND

- ❑ The provider will limit the intralesional injectable volume to a maximum of 4mL per treatment visit

AND

- ❑ The provider will follow the recommended maximum intralesional volume dose that correlates to lesion size and indicates that below (must submit recent chart notes/progress notes which includes assessment of lesion size):
  - ❑ If the lesion size is >5 cm, inject up to 4 mL
  - ❑ If the lesion size is >2.5 cm to 5 cm, inject up to 2 mL
  - ❑ If the lesion size is >1.5 cm to 2.5 cm, inject up to 1 mL
  - ❑ If the lesion size is >0.5 cm to 1.5 cm, inject up to 0.5 mL
  - ❑ If the lesion size is ≤0.5 cm, inject up to 0.1 mL

Reauthorization Approval: 6 Months: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Patient continues to have injectable lesions to treat meeting criteria in the initial approval section (must submit recent chart notes/progress notes which includes assessment of lesion size)

AND

- ❑ The member is not experiencing unacceptable toxicity from the drug. [Examples of unacceptable toxicity include: herpetic infection, injection site complications (necrosis, ulceration, cellulitis and systemic bacterial infection), immune-mediated events, plasmacytoma at injection site, obstructive airway disorder, etc.]

AND

- ❑ Disease response has been observed with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread (must submit recent chart notes/progress notes recording the member's medical status, lesion(s) size, etc.)

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee**: 11/18/2021
REVISED/UPDATED: 2/4/2022