Talimogene laherparepvec (Imlygic®; T-VEC) is a first-in-class oncolytic viral immunotherapy recently approved by the Food and Drug Administration (FDA) as intralesional treatment of unresectable cutaneous, subcutaneous, and/or nodal melanoma recurrent after initial surgery.

This document is part of an overall nursing toolkit intended to assist nurses in optimizing the care of melanoma in patients receiving newer anti-melanoma therapies.

**PREPARATION AND HANDLING**

T-VEC is a live, attenuated virus. Consequently, there are exposure and transmission risks to healthcare personnel and family members/caregivers.

- Healthcare providers who are immunocompromised or pregnant should not prepare or administer T-VEC and should avoid direct contact with the T-VEC injection site, dressings, or body fluids of treated patients.

- Those preparing and/or administering T-VEC should wear protective clothing and avoid accidental exposure.

- Clean all surfaces that may have come into contact with T-VEC and treat all T-VEC spills with a virucidal agent and blot using absorbent materials. Dispose contaminated materials as biohazardous waste.

- Similarly, caregivers/family members should be instructed to wear protective gloves when assisting patients to apply or change occlusive dressings and should put used dressings, gloves, and cleaning materials in a sealed plastic bag and dispose of the bag in the regular trash.
**STORAGE AND DRUG-DOSING/ADMINISTRATION**

- T-VEC can be kept in stock but must be stored in a freezer to maintain temperature at -90 °C to 70 °C. If an ultra-low freezer is not available, Amgen can provide access to one (1-866-IMLYGIC).

- For more immediate procurement, you can also use the IMLYGIC just-in-time delivery system. This allows you to keep T-VEC in the original shipping container for up to 96 hours after it is sealed for delivery.

- Thawing of T-VEC vials requires about 30–45 minutes. Ideally, IMLYGIC should be thawed immediately prior to administration. The lower dose of T-VEC can be refrigerated for up to 12 hours; the higher dose can be refrigerated for up to 48 hours.

- T-VEC is administered by intraleisional injection into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound.

- T-VEC is available in single-use vials of 1 mL that contain either 106 (1 million) or 108 (100 million) PFU/mL.

◊ The lower T-VEC concentration (106 PFU/mL) is used for the initial dose. The higher T-VEC concentration (108 PFU/mL) should be used for the second and all subsequent treatments. The second treatment occurs 3 weeks after initial treatment and all subsequent lesions occur 2 weeks after previous treatment.

◊ Inject lesion(s) from largest to smallest until either all lesions are injected or a maximum injection volume of 4 mL is reached for the treatment session. The volume per lesion size is shown the table at right (you may not be able to inject every lesion at each treatment session).

◊ At the first treatment session, lesions are injected in size order from largest to smallest or until the maximum dose is reached. Thereafter, the HCP should treat any new lesions first, then inject in size order starting with the largest lesion.

<table>
<thead>
<tr>
<th>Lesion size (longest dimension)</th>
<th>Injection volume</th>
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<tbody>
<tr>
<td>&gt; 5 cm</td>
<td>Up to 4 mL</td>
</tr>
<tr>
<td>&gt; 2.5 cm to 5 cm</td>
<td>Up to 2 mL</td>
</tr>
<tr>
<td>&gt; 1.5 cm to 2.5 cm</td>
<td>Up to 1 mL</td>
</tr>
<tr>
<td>&gt; 0.5 cm to 1.5 cm</td>
<td>Up to 0.5 mL</td>
</tr>
<tr>
<td>≤ 0.5 cm</td>
<td>Up to 0.1 mL</td>
</tr>
</tbody>
</table>

Closely clustered lesions can be measured as a single lesion.
STORAGE AND DRUG-DOSING/ADMINISTRATION

(Continued)

- Using a single insertion point, the injection should be made on multiple radial tracks, rotating and pulling the needle back to achieve even and complete dispersion (see diagram).

![Diagram 1: Injection administration for cutaneous lesions](image1)
![Diagram 2: Injection administration for subcutaneous lesions](image2)
![Diagram 3: Injection administration for nodal lesions](image3)

- To reduce risk of over- or under-injecting, prepare individual syringes with the exact amount of T-VEC to be injected into each lesion.

- To prevent drug leakage, securely attach the needle to syringe prior to injection and slowly withdraw the needle after T-VEC is fully injected.

- Slow and steady pressure should be applied to the syringe. This helps if the lesion is difficult to inject or prone to drug leakage.
SIDE EFFECTS AND THEIR MANAGEMENT

Management strategies for preventing and managing T-VEC–related adverse events are outlined in the Care Step Pathway below. The most commonly reported adverse events include constitutional or administration site symptoms (fatigue, chills, pyrexia, influenza-like illness, and injection site pain) and gastrointestinal disorders (nausea and vomiting). Herpetic infections (cold sores and ocular herpetic infection) have also been reported in T-VEC–treated patients. The most commonly reported grade 3 adverse event is cellulitis, with an incidence of 2%.

• T-VEC is contraindicated in immunocompromised or pregnant patients.

• Nurses should contact patients 1–2 days after the first T-VEC injection to assess treatment tolerability and provide counsel about AE recognition and management. Follow-up phone calls and/or visits are important for continued monitoring and management of potential drug-related adverse events.

• If the patient reports pain with injection after topical anesthetic, ice packs may be applied to the site for 5 to 10 minutes. If the pain persists, injection of 1% lidocaine around the lesion periphery may be considered.

◊ Local anesthetic should NOT be injected into the lesion itself, as this may affect T-VEC stability and efficacy.
**Management of AEs**

*Prevention of AEs*

- Suggest use of a heating blanket/multipurpose blanket. The night of treatment to reduce the impact of chills
- Issue access to an immediate nurse to take the night of treatment if necessary. The following morning and on an as-needed basis
- Advised parent to keep periods and get some light exercise daily (the week after MTH 99) to combat fatigue
- Any change in vision, even small
- Stress importance of keeping infection site covered for 1 week and avoiding touching or scratching injection sites or dressing
- Suggest premedication with ibuprofen/acetaminophen prior to injection and the evening of/next morning after injection (to reduce the impact of fever/chills)
- Review potential AEs with the patient

*Care Step Pathway – Adverse Events (AEs) After T-VEC*

- Signs of cellulitis (edema or tender cellulitis)
- Signs of infection (fever/chills)
- Presence of tender lesions
- Complaints/forward vomit

**Patient Evaluation/Nursing Assessment**

- Look:
  - Is there excessive swelling?
  - Is there the infection site red, warm, or edematous?
  - Is the dressing dry?
  - Does the patient appear dehydrated?
  - Does the patient appear uncomfortable?

- Note:
  - Early signs of ocular herpes
  - Neck pain
  - Canker sores, cold sores, any tingling skin lesions
  - Symptoms, like welling
  - Persistent fever (>101.0°F; 38.3°C), chills, nausea/vomiting, aches, pains
  - Current febrile?
  - Onset and duration of fevers, chills, malaise, or joint pain
  - Listen:
    - Patient discomfort level
    - How the patient has been managing the injection site
    - Whether the patient has been taking enough fluids
    - Eating habits, any nausea or vomiting
    - Medications taken for fevers (acetaminophen, NSAIDS)
  - Feel/chills
  - Fever/chills
  - Elevation, ice
  - Acetaminophen, NSAIDS
  - Warm packs, blankets
  - -

- Important Nursing Interventions:
  - Consider testing herpetic lesions to determine if they are
  - Refer patients with vision changes to an ophthalmologist
  - Oral antiemetics
  - Consider hospitalization for intravenous antibiotics if oral antibiotics fail or the patient develops weakness
  - Avoid compression because it may
  - Re-evaluate
  - Any change in vision, even small

- Important Observations:
  - Antivirals such as acyclovir
  - Acetaminophen
  - -
  - Cough
  - -
  - S/P

- Important Patient Education:
  - How the patient has been managing the injection site
  - Whether the patient has been taking enough fluids
  - Eating habits, any nausea or vomiting
  - Medications taken for fevers (acetaminophen, NSAIDS) and how often
  - Possible adverse effects
  - Pain at the injection site
  - Suggest premedication with ibuprofen/acetaminophen prior to injection and the evening of/next morning after injection (to reduce the impact of fever/chills)
  - Review potential AEs with the patient

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Q. What should I tell a patient who is concerned about sharing a shower, toothbrush, dishes, or laundry facilities with other people? Is there a transmission risk?

A. Advise the patient that there is not a risk unless he/she has uncovered, draining lesions or leaves used dressing materials where others could come in contact with them. All lesions must be covered with an airtight and watertight dressing for 1 week after injection. Draining lesions must remain covered with an airtight and watertight dressing until they are no longer draining. Dressing should be changed once a week.

Q. What should I tell a patient to do if the lesion is oozing? Is this a transmission risk?

A. There is little risk of transmission as long as the lesions remain covered and no one who is pregnant or has a weakened immune system comes into contact with the lesions. Draining lesions must remain covered with an airtight and watertight dressing until they are no longer draining. Dressing should be changed once a week.

Q. How do I advise a patient who is concerned when a lesion leaks on a counter surface or a bandage with drainage touches the bathroom vanity? How should the patient clean it up?

A. You can advise the patient to put on gloves and wipe down the surface with a 1:10 bleach solution. Instructions on how to make such a solution are available at https://www.verywell.com/make-your-own-disinfectant-solution-998274. Advise the patient to use disposable materials for wiping, place them in a sealed plastic bag, and throw them in the household trash.
RESOURCES

Financial Assistance
Amgenassistonline.com
or call 1-888-4ASSIST

Additional Information Resources
AIM at Melanoma Foundation (Nurse on Call, patient symposia, drug resources, etc)
http://www.AIMatMelanoma.org

Additional resources


• Seery V. Intralesional therapy: consensus statements for best practices in administration from the Melanoma Nursing Initiative. *Clin J Oncol Nurs.* 2017; 21(Suppl. 4):76-86.