IMLYGIC®
(talimogene laherparepvec)
SUSPENSION FOR INJECTION
10^6 PFU/mL and 10^8 PFU/mL single-use vials

IMLYGIC® FACT SHEET

INDICATION

IMLYGIC® is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

Limitations of use: IMLYGIC® has not been shown to improve overall survival or have an effect on visceral metastases.[1]

PRODUCT INFORMATION

NDC		Description	Vial Size	Quantity
55513-078-01		10^6 (1 million) PFU/mL single-use vial	1 mL	One vial per carton
55513-079-01		10^8 (100 million) PFU/mL single-use vial	1 mL	One vial per carton

PFU = plaque forming units.

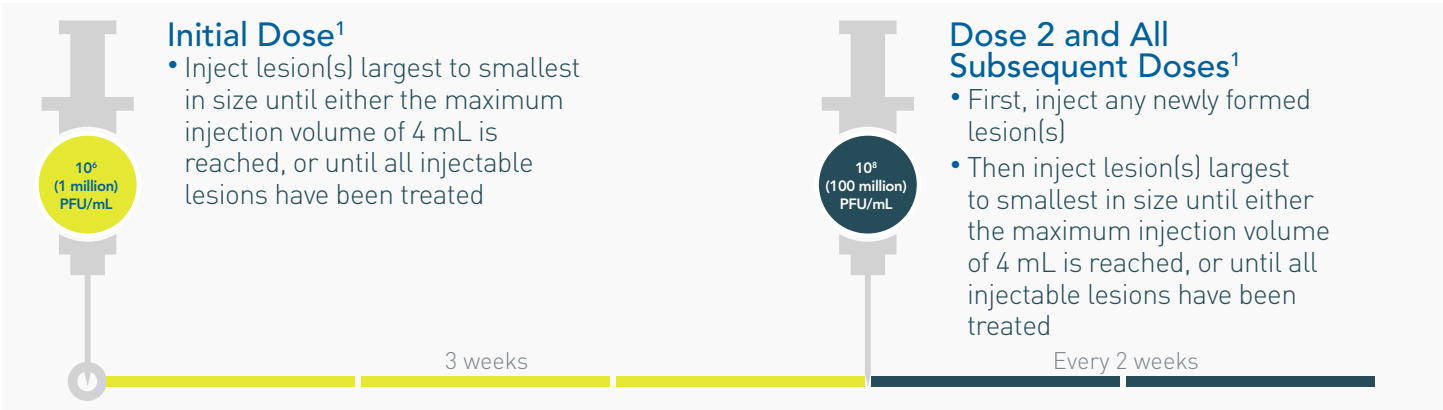
DOSAGE AND ADMINISTRATION

IMLYGIC® is administered by intralesional injection into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance.

There is no limit on the number of lesions that may be injected until the maximum cumulative dose of 4 mL per visit is reached.[1]

It may not be possible to inject all lesions at each treatment visit or over the full course of treatment.

Figure 1: Recommended Dosing Schedule
Please see full prescribing instructions for vial thawing, storage and handling information.



Continue IMLYGIC® treatment for at least 6 months unless other treatment is required or until there are no injectable lesions to treat.[1]

Reinitiate IMLYGIC® treatment if new unresectable cutaneous, subcutaneous, or nodal lesions appear after a complete response.[1]

IMPORTANT SAFETY INFORMATION

Contraindications

- Do not administer IMLYGIC® to immunocompromised patients, including those 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, due to the risk of life-threatening disseminated herpetic infection.
- Do not administer IMLYGIC® to pregnant patients.

Please see Important Safety Information on page 4.

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PRODUCT EXPIRATION

The expiration date is printed on each product carton and vial label.

SUPPLIED AND MARKETED BY

Amgen USA Inc.
www.amgen.com

PRODUCT ORDERING

Please contact one of the following authorized distributors:

- ASD Healthcare
- Cardinal Health Specialty Distribution
- M&D Specialty Distribution, LLC
- McKesson Plasma and Biologics
- McKesson Specialty Health
- Oncology Supply
- Smith Medical Partners

STORAGE AND HANDLING REQUIREMENTS

Storage: IMLYGIC® vials must be stored and transported frozen at –90°C to –70°C (–130°F to –94°F). IMLYGIC® should be protected from light. IMLYGIC® should be stored in the carton until use. IMLYGIC® should only be thawed immediately prior to administration. IMLYGIC® should not be drawn into a syringe until immediately prior to administration. Please refer to the full Prescribing Information for specific instructions for product handling and preparation.

Shelf Life: 4 years, if stored as directed. Discard after expiry date printed on vial label.

Please see Important Safety Information on page 4.

SHIPMENT INFORMATION

IMLYGIC® (talimogene laherparepvec) will be shipped in a time-sensitive storage container with dry ice. Please read entire instruction card included in the shipment before opening the container.

Figure 2: IMLYGIC® Storage Container

For more information about IMLYGIC®, Ordering, or Returns, please:
Call **1-866-IMLYGIC** (465-9442)
Visit: **www.IMLYGIC.com**

For billing and reimbursement assistance, please:
Contact Amgen Assist® at **1-888-4ASSIST**
Visit: www.AmgenAssistOnline.com

Please see Important Safety Information on page 4.

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- Do not administer IMLYGIC® to pregnant patients.

Warnings and Precautions

- **Accidental exposure to IMLYGIC®** may lead to transmission of IMLYGIC® and herpetic infection, including during preparation and administration. Health care providers, close contacts, pregnant women, and newborns should avoid direct contact with injected lesions, dressings, or body fluids of treated patients. The affected area in exposed individuals should be cleaned thoroughly with soap and water and/or a disinfectant.
- Caregivers should wear protective gloves when assisting patients in applying or changing occlusive dressings and observe safety precautions for disposal of used dressings, gloves, and cleaning materials. Exposed individuals should clean the affected area thoroughly with soap and water and/or a disinfectant.
- To prevent possible inadvertent transfer of IMLYGIC® to other areas of the body, patients should be advised to avoid touching or scratching injection sites or occlusive dressings.
- **Herpetic infections:** Herpetic infections (including cold sores and herpetic keratitis) have been reported in IMLYGIC®-treated patients. Disseminated herpetic infection may also occur in immunocompromised patients. Patients who develop suspicious herpes-like lesions should follow standard hygienic practices to prevent viral transmission.
- Patients or close contacts with suspected signs or symptoms of a herpetic infection should contact their health care provider to evaluate the lesions. Suspected herpetic lesions should be reported to Amgen at 1-855-IMLYGIC (1-855-465-9442). Patients or close contacts have the option of follow-up testing for further characterization of the infection.
- IMLYGIC® is sensitive to acyclovir. Acyclovir or other antiviral agents may interfere with the effectiveness of IMLYGIC®. Consider the risks and benefits of IMLYGIC® treatment before administering antiviral agents to manage herpetic infection.
- **Injection Site Complications:** Necrosis or ulceration of tumor tissue may occur during IMLYGIC® treatment. Cellulitis and systemic bacterial infection have been reported in clinical studies. Careful wound care and infection precautions are recommended, particularly if tissue necrosis results in open wounds.
- Impaired healing at the injection site has been reported. IMLYGIC® may increase the risk of impaired healing in patients with underlying risk factors (eg, previous radiation at the injection site or lesions in poorly vascularized areas). If there is persistent infection or delayed healing of the injection site, consider the risks and benefits of continuing treatment.
- **Immune-Mediated events** including glomerulonephritis, vasculitis, pneumonitis, worsening psoriasis, and vitiligo have been reported in patients treated with IMLYGIC®. Consider the risks and benefits of IMLYGIC® before initiating treatment in patients who have underlying autoimmune disease or before continuing treatment in patients who develop immune-mediated events.
- **Plasmacytoma at the Injection Site:** Plasmacytoma in proximity to the injection site has been reported in a patient with smoldering multiple myeloma after IMLYGIC® administration in a clinical study. Consider the risks and benefits of IMLYGIC® in patients with multiple myeloma or in whom plasmacytoma develops during treatment.
- **Obstructive Airway Disorder:** Obstructive airway disorder has been reported following IMLYGIC® treatment. Use caution when injecting lesions close to major airways.

Adverse Reactions

- The most commonly reported adverse drug reactions (≥ 25%) in IMLYGIC®-treated patients were fatigue, chills, pyrexia, nausea, influenza-like illness, and injection site pain. Pyrexia, chills, and influenza-like illness can occur at any time during IMLYGIC® treatment, but were more frequent during the first 3 months of treatment.
- The most common Grade 3 or higher adverse reaction was cellulitis.

Please click here to see full **Prescribing Information** and **Medication Guide**.

Reference: 1. IMLYGIC® (talimogene laherparepvec) Prescribing Information, BioVex, Inc., a subsidiary of Amgen, Inc.

AMGEN®

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