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

Operational Planning Checklist

This checklist may be used by healthcare organizations developing an operational process for safe and effective handling of IMLYGIC®. **The Prescribing Information is the main source of product-handling information for IMLYGIC®. This checklist should not serve as a replacement for information within the PI.** It is intended to serve as a supplemental tool that can help healthcare organizations review selected operational considerations and related details.

It can inform institutions and practices seeking to customize their process for IMLYGIC® based on their operational capabilities and preferences.

The checklist is designed to guide pharmacy staff through decision points and related planning considerations for IMLYGIC® in four interrelated areas.

Recommended Approach to Using the Checklist

Review IMLYGIC® information

- It is important to review the following IMLYGIC® resources before using this checklist (also available at IMLYGIC.com)
  - Prescribing Information
  - Clinical Overview and Handling Instructional Guide

Review this checklist

- The checklist includes four sections: Storage, Procurement, Order Set, and Handling
  - Review of all four sections can inform effective operational planning for IMLYGIC®
  - An institution's operational process for IMLYGIC® may be based on the decisions made in each of the four sections
  - Some sections may need to be revisited based on the decisions made in other interrelated sections
- Each section of the checklist is intended to help document an institution's preferred options and answers to important planning questions
  - Key considerations and relevant IMLYGIC® resources are also highlighted in each section: Storage, Procurement, Order Set, and Handling

Implement the operational process for IMLYGIC®

- Once all four sections are completed, this checklist can serve as a roadmap for implementing the operational process for IMLYGIC® for a specific institution or practice

Please see Important Safety Information on pages 7 and 8.
Please click here for full Prescribing Information and Medication Guide.

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IMLYGIC® Vials Storage Considerations

Store frozen in a -90°C to -70°C freezer at your institution

Key Points to Consider

- IMLYGIC® should be protected from light and stored in the carton until use

Important Planning Questions

Will the -90°C to -70°C freezer be located where IMLYGIC® will be administered?

Who is responsible for freezer monitoring and maintenance at your institution?

Store frozen in the -90°C to -70°C shipping container in which IMLYGIC® was shipped

Key Points to Consider

- The shipping container in which IMLYGIC® is shipped will hold the correct storage temperatures for up to 96 hours after being sealed for delivery. This expiration time is printed on the side of the shipping container
- IMLYGIC® should be protected from light and stored in the carton until use

Important Planning Questions

Who will be responsible for monitoring expiration time on the shipping container?

Where will the shipping container be stored?

For additional IMLYGIC® resources:

- Visit IMLYGIC.com
- Call 1-866-IMLYGIC
- Speak to an Amgen representative

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IMLYGIC® Procurement Considerations

Keep in stock

Key Points to Consider

- If IMLYGIC® is intended to be administered **after** the shipping container expires (time printed on the side of the container), ordered product must be stored in a freezer that is able to maintain temperature at -90°C to -70°C *(see Storage section)*
- It is important to determine the number of IMLYGIC® vials that will be kept on hand before the order can be placed (up to 4 vials can be used per visit)

Use just-in-time ordering

Key Points to Consider

- The shipping container can be used to store IMLYGIC®, as long as the ordered product is intended for use within 96 hours after the shipment has been sealed for delivery (per expiration time on the side of the shipping container *[see Storage section]*)
- It is important to determine the number of IMLYGIC® vials that will be used (up to 4 vials per visit) before the order can be placed for just-in-time delivery *(see Order Set section)*
- To prevent treatment delays, timing of product delivery should be coordinated with scheduling of the patient visit for IMLYGIC® administration

Additional Points to Consider

- IMLYGIC® is supplied in single-use 1 mL vials (1 vial per carton), containing a sterile frozen suspension, in two different concentrations noted by distinct vial cap colors:

One-Time Initial Dose	Subsequent Doses
10^6 (1 million) PFU/mL	10^8 (100 million) PFU/mL

- The total injection volume for each treatment visit should not exceed 4 mL for all injected lesions combined. It may not be possible to inject all lesions at each treatment visit or over the full course of treatment
- Healthcare providers who are immunocompromised or pregnant should not prepare or administer IMLYGIC® and should not come into direct contact with the IMLYGIC® injection sites, dressings, or body fluids of treated patients
- Once the product container is removed from the shipment, IMLYGIC® must be placed back in the shipping container or moved to a -90°C to -70°C freezer within 60 seconds

Important Planning Questions

Who will be responsible for placing and tracking IMLYGIC® orders?

Where should IMLYGIC® orders be delivered?

Who should receive and unpack IMLYGIC® orders?

For additional IMLYGIC® resources:

- Visit IMLYGIC.com
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IMLYGIC® Order Set Considerations

Add a standard order set to the electronic prescribing database

Order on paper

Key Points to Consider

- Before creating a standard order set, it is important to determine if IMLYGIC® has been added to the electronic prescribing vendor's database and how the order set template may need to be customized

Additional Points to Consider

- The initial dose of IMLYGIC® should be flagged on the order because it requires a different concentration than the subsequent doses

One-Time Initial Dose	Subsequent Doses
10^6 (1 million) PFU/mL	10^8 (100 million) PFU/mL

- The volume of IMLYGIC® to be injected is dependent on the size of the lesion(s). Please see full Prescribing Information for determination of IMLYGIC® injection volume based on lesion size, and other important information regarding dosing, administration, and handling of IMLYGIC®
- The total injection volume for each treatment visit should not exceed 4 mL for all injected lesions combined. It may not be possible to inject all lesions at each treatment visit or over the full course of treatment
- Healthcare providers who are immunocompromised or pregnant should not prepare or administer IMLYGIC® and should not come into direct contact with the IMLYGIC® injection sites, dressings, or body fluids of treated patients
- The following information may help document a longitudinal, comprehensive view of the patient's course of treatment with IMLYGIC®:
  - » Date and time of administration
  - » Anatomical location and size of lesion (lettered or numbered on the body map image)
  - » Drug name, concentration, route
  - » Dose in mL per injected lesion
  - » Projected next treatment date

Important Planning Questions

Who will be responsible for creating the standard order set?

_____

What decision-support alerts will be built in to avoid mistakes?

_____

Important Planning Questions

What documentation will be needed to verify dosing?

_____

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IMLYGIC® Handling Considerations

Key Points to Consider

- IMLYGIC® is a live, attenuated Herpes Simplex Virus Type 1 (HSV-1); healthcare providers who are immunocompromised or pregnant should not prepare or administer IMLYGIC® and should not come into direct contact with the IMLYGIC® injection sites, dressings, or body fluids of treated patients
- Avoid accidental exposure to IMLYGIC® and follow below instructions for preparation, administration, and handling of IMLYGIC®:
  - Wear personal protective equipment (protective gown or laboratory coat, safety glasses or face shield, and gloves) while preparing or administering IMLYGIC®
  - Avoid accidental exposure to IMLYGIC®, especially contact with skin, eyes, and mucous membranes
    - Cover any exposed wounds before handling
    - In the event of an accidental occupational exposure (eg, through a splash to the eyes or mucous membranes), flush with clean water for at least 15 minutes
    - In the event of exposure to broken skin or needle stick, clean the affected area thoroughly with soap and water and/or a disinfectant
  - Clean all surfaces that may have come in contact with IMLYGIC® and treat all IMLYGIC® spills with a virucidal agent such as 1% sodium hypochlorite, or 70% isopropyl alcohol and blot using absorbent materials
  - Dispose of all materials that may have come in contact with IMLYGIC® (eg, vial, syringe, needle, cotton gauze, gloves, masks, or dressings) as biohazardous waste
  - Advise patients to place used dressings and cleaning materials into a sealed plastic bag and dispose in household waste
- IMLYGIC® is supplied in single-use 1 mL vials (1 vial per carton)
- IMLYGIC® should be thawed immediately prior to administration (Please see full Prescribing Information for thawing instructions, including instructions on preparation and administration)
- Once thawed, IMLYGIC® cannot be refrozen

For additional IMLYGIC® resources:

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IMLYGIC® Handling Considerations (*cont'd*)

Dispense as supplied in 1 mL vial(s)

Additional Points to Consider

- After thawing, administer IMLYGIC® immediately or store in its original vial and carton, as follows:
  - Thawed IMLYGIC® is stable when stored at temperatures of 2°C (36°F) up to 25°C (77°F) protected from light in its original vial and carton for the storage times specified below. Do not exceed the storage times specified below.
  - IMLYGIC® must not be refrozen once it is thawed. Discard any thawed IMLYGIC® in the vial stored longer than the specified times below.

Maximum Storage Time for Thawed IMLYGIC® in Vial

	One-Time Initial Dose	Subsequent Doses
	10^6 (1 million) PFU/mL	10^8 (100 million) PFU/mL
2°C to 8°C (36°F to 46°F)	24 hours	1 week (7 days)
up to 25°C (77°F)	12 hours	24 hours

Draw into syringe(s)

Additional Points to Consider

- IMLYGIC® should not be drawn into a syringe until immediately prior to administration

Important Planning Questions

Have the healthcare professionals who are handling IMLYGIC® read the complete Prescribing Information, including the precautionary information within?

Where will IMLYGIC® be transferred from the 1 mL vial(s) into the syringe(s)?

How will syringes be labeled?

Additional Important Planning Questions

Who will be responsible for transporting IMLYGIC® to the healthcare professional administering treatment?

Where in the institution will IMLYGIC® be administered?

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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.

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.

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 but not limited to cold sores and herpetic keratitis) and serious cases of disseminated herpetic infections have been reported in IMLYGIC®-treated patients, including fatal disseminated herpetic infection in the immunocompromised patient population. Immunocompromised patients may be at increased risk of life-threatening disseminated herpetic infection. 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.

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IMLYGIC® Important Safety Information (*cont'd*)

- 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.
- **Hepatic Hemorrhage from Transcutaneous Intrahepatic Route of Administration:** IMLYGIC® is not indicated for transcutaneous intrahepatic route of administration. In clinical studies, cases of hepatic hemorrhage resulting in hospitalization and death have been reported in patients receiving transcutaneous intrahepatic IMLYGIC® injections.

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 for Prescribing Information and Medication Guide.

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

2. Data on File, Amgen.

AMGEN®

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