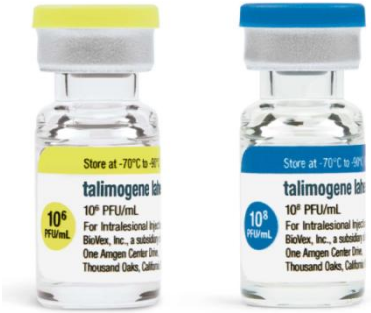
Imlygic

(talimogene laherparepvec)



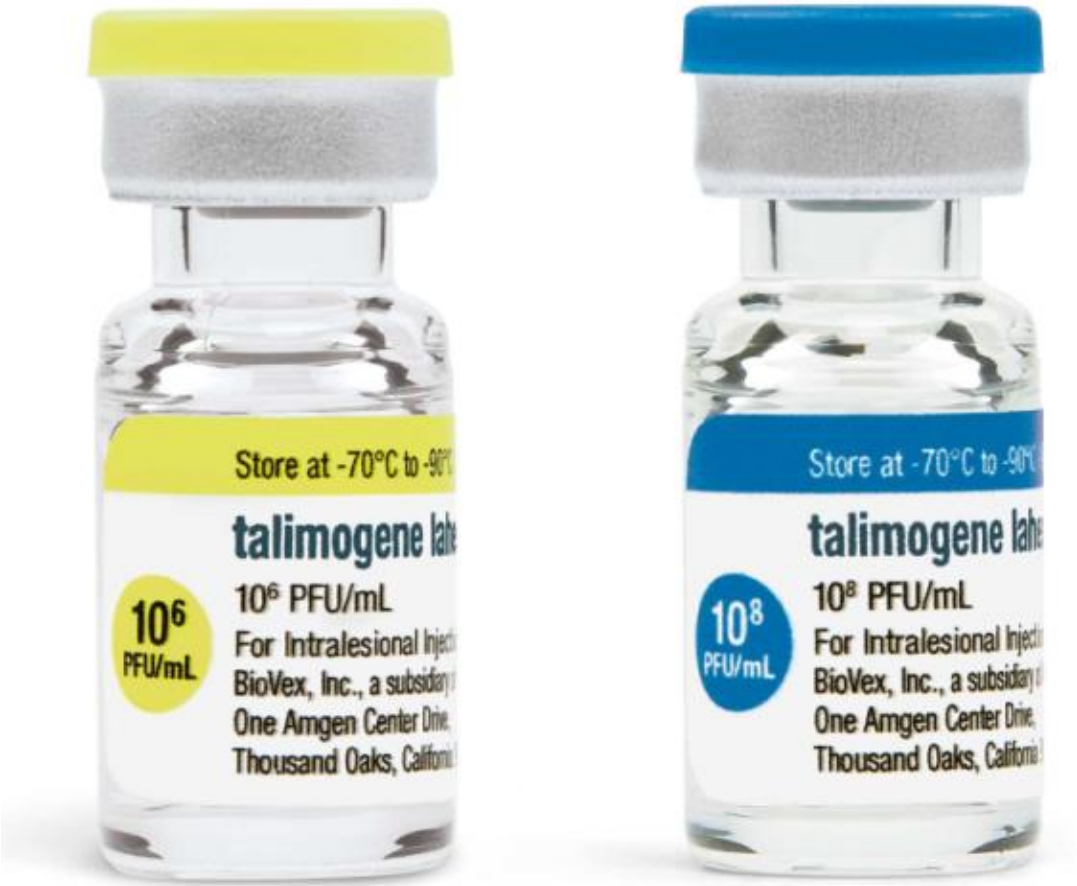
New Product Slideshow

MPR

Introduction

- **Brand name:** Imlygic
- **Generic name:** Talimogene laherparepvec
- **Pharmacological class:** Genetically modified oncolytic viral therapy
- **Strength and Formulation:** 10^6 (1 million) PFU/mL, 10^8 (100 million) PFU/mL; susp for intralesional inj; preservative-free
- **Manufacturer:** Amgen
- **How supplied:** Single-use vial (1mL)—1
- **Legal Classification:** Rx

IMLYGIC


Store at -70°C to -90°
talimogene lahe
10⁶ PFU/mL
10⁶ PFU/mL
For Intralesional Inject
BioVex, Inc., a subsidiary
One Amgen Center Drive,
Thousand Oaks, California
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Indications

- Treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with **melanoma** recurrent after initial surgery
- **Limitations of use:** not shown to improve overall survival or have an effect on visceral metastases

Dosage & Administration

- See full labeling
- Inject intralesionally into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance
- Total inj volume per treatment visit: max 4mL for all injected lesions combined
- **Initial dose:** up to 4mL of 10^6 (1 million) PFU/mL
- **2nd dose:** up to 4mL of 10^8 (100 million) PFU/mL given 3 weeks later

Dosage & Administration

- **All subsequent doses (including reinitiation):** up to 4mL of 10^8 (100 million) PFU/mL given 2 weeks apart
- Continue for ≥6 months unless other treatment required or until no injectable lesions to treat; reinitiate if new lesions appear after a complete response

Considerations for Special Populations

- **Pregnancy:** See Contraindications
- **Nursing mothers:** Not recommended
- **Pediatric:** Not established
- **Geriatric:** No overall differences observed

Contraindications

- Immunocompromised or pregnant patients

Warnings/Precautions

- For intralesional injection only
- **Avoid** accidental exposure (esp. skin, eyes, mucous membranes) and direct contact with patient's injected lesions, dressings, or body fluids
- Advise patients to **avoid** inadvertent transfer of drug to other areas of the body (eg, touching/scratching inj sites or occlusive dressings)

Warnings/Precautions

- Evaluate lesions if suspected herpetic infection occurs
- Inj site complications (eg, necrosis or ulceration of tumor tissue, cellulitis, systemic bacterial infection)
- Persistent infection or delayed healing of inj site
- Underlying autoimmune disease
- Multiple myeloma or plasmacytoma
- Women of childbearing potential should use effective method of contraception

Interactions

- **Acyclovir** or other antiherpetic viral agents may interfere with efficacy

Adverse Reactions

- Fatigue
- Chills
- Pyrexia
- Nausea
- Influenza-like illness
- Injection site pain
- Immune-mediated events

Mechanism of Action

- Imlygic has been genetically modified to replicate within tumors and to produce GM-CSF
- Imlygic causes **tumor lysis** followed by release of tumor-derived antigens, which together with virally derived GM-CSF may promote an antitumor immune response

Clinical Trials

- The safety and efficacy of intralesional Imlygic vs. subcutaneous GM-CSF was evaluated in a multicenter, open-label, randomized clinical study in 436 patients with stage IIIB, IIIC, and IV melanoma that was considered not surgically resectable
- Patients were randomized to receive either Imlygic (n=295) or GM-CSF (n=141) for at least 6 months or until no injectable lesions

Clinical Trials

- After 6 months, patients were to continue treatment until clinically relevant disease progression, up to 12 months
- Patients with a response at 12 months after starting treatment could continue for another 6 months unless there were no remaining injectable lesions or disease progression
- All patients were followed for survival status for at least 36 months

Clinical Trials

- The major efficacy outcome was **durable response rate (DRR)**, defined as the percent of patients with complete response (CR) or partial response (PR) maintained continuously for a minimum of 6 months

Clinical Trials

- Study data showed **DRR** was 16.3% in the Imlygic arm vs. 2.1% in the GM-CSF arm in the overall study population
- The unadjusted relative risk was 7.6 (95% CI: 2.4, 24.1; *P*<0.0001)
- The median time to response was 4.1 months in the Imlygic arm

Clinical Trials

- No statistically significant difference in overall survival (OS) was seen between the Imlygic and GM-CSF arms
- The median **OS** in the overall study population was 22.9 months in the Imlygic arm vs. 19.0 months in the GM-CSF arm (*P*=0.116)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/imlygic/drug/34546/