What is IMLYGIC® used for?
IMLYGIC® is a prescription medication used to treat a type of skin cancer called melanoma when it is on your skin or in your lymph glands.

IMLYGIC® may not help you live longer and may not shrink cancer in your organs (for example, lung or liver).

What is IMLYGIC® made from and how is it given?
- IMLYGIC® is a weakened form of Herpes Simplex Virus Type 1, which is commonly called the cold sore virus.
- Your healthcare provider will inject IMLYGIC® directly into your tumor(s) with a needle and syringe. Your healthcare provider will decide which tumor(s) to inject and may not inject every one. It is important to care for the treatment sites properly so that IMLYGIC® does not spread to other people. Your healthcare provider will show you how to do this.

Please see Important Safety Information inside and click here for Prescribing Information and Medication Guide.
WHY IMLYGIC® (talimogene laherparepvec)?

Your doctor has prescribed IMLYGIC® for treating a type of skin cancer called melanoma when it is on your skin or in your lymph glands.¹

IMLYGIC® may not help you live longer and may not shrink cancer in your organs (for example, lung or liver).¹

Normally, the body’s immune system is able to fight illnesses by attacking foreign invaders like viruses and bacteria.² Cancer cells are different—they can make themselves invisible to the immune system and avoid being recognized as an enemy.³ If the immune system cannot find the cancer cells, they may be able to grow and spread.³

IMLYGIC® is an oncolytic viral therapy that is injected directly into tumors, where it multiplies and destroys them.¹ IMLYGIC® may also trigger an immune response to help destroy cancer cells.¹ The exact way that IMLYGIC® works is not known.¹

IMPORTANT SAFETY INFORMATION

• You should not get IMLYGIC® if you are pregnant or have a weakened immune system (for example, an immune deficiency, blood or bone marrow cancer, steroid use, or HIV/AIDS).

How effective was IMLYGIC®?

IMLYGIC® was studied in a clinical trial of 436 patients with stage IIIB/C and stage IV melanoma against a control group given another medication called GM-CSF.¹

How many patients responded to treatment with IMLYGIC® during the clinical trial?¹

48 out of 295 patients (16.3%) had a durable response with IMLYGIC® compared to 3 out of 141 patients (2.1%) in the control group—meaning their tumors partially shrank or completely shrank for 6 months or longer.¹

Patient responses were complete or partial.⁴

• Of the 48 patients who achieved a durable response, 14 patients (29.1%) had a durable complete response—meaning all evidence of tumors disappeared for 6 months or longer.⁴,⁵

• Of the 48 patients who achieved a durable response, 34 patients (70.8%) had a durable partial response—meaning the size of all tumors that could be measured was reduced by 50% or more for 6 months or longer.⁴,⁵

• Of the 3 patients in the control group who achieved a durable response, all of them had a partial response.⁴,⁵

*IMLYGIC® was injected into tumors, and the control group was given GM-CSF subcutaneously (under the skin).

IMPORTANT SAFETY INFORMATION

• Common side effects of IMLYGIC® include tiredness, chills, fever, nausea, flu-like symptoms, and pain at treatment site. These are not all the side effects of IMLYGIC®.

• Tell your doctor right away if you get any of the following:
  ○ Pain, burning, or tingling in a blister around the mouth or genitals or on the fingers or ears
  ○ Eye pain, light sensitivity, discharge from the eyes, or blurry vision
  ○ Weakness in arms or legs
  ○ Extreme drowsiness
  ○ Mental confusion

• If you think you have a herpes infection, inform your healthcare provider. You or your healthcare provider should call Amgen at 1-855-IMLYGIC (1-855-465-9442) for follow-up testing, if needed.

Please see Important Safety Information inside and click here for Prescribing Information and Medication Guide.
**What should I tell my healthcare provider before I get IMLYGIC® (talimogene laherparepvec)?**

**Before getting IMLYGIC®, tell your healthcare provider if you:**

- Are taking steroids or other medicines that suppress your immune system.
- Are taking antiviral medicines to treat or prevent herpes, such as acyclovir.
- Have or ever had medical conditions such as:
  - HIV infection or AIDS
  - Blood or bone marrow cancer
  - Autoimmune disease
  - Other medical conditions that can weaken your immune system
- Have close contact with someone who has a weakened immune system or is pregnant.
- Are pregnant or plan to become pregnant.
  - IMLYGIC® may harm your unborn baby.
  - You should not become pregnant during treatment with IMLYGIC®.
  - Talk to your healthcare provider about effective birth control methods.
- Are breastfeeding or plan to breastfeed.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. IMLYGIC® may affect the way other medicines work and other medicines may affect how IMLYGIC® works.

**What should I avoid while getting IMLYGIC®?**

IMLYGIC® virus can spread to other areas of your body or to your close contacts (household members, caregivers, sex partners, or persons sharing the same bed).

Do the following to avoid spreading IMLYGIC® to other areas of your body or to your close contacts:

- Avoid direct contact between your treatment sites, dressings, or body fluids and close contacts (for example, use condoms when engaging in sexual activity, avoid kissing close contacts if either has an open mouth sore).
- Wear gloves while putting on or changing your dressings.
- Keep treatment sites covered with airtight and watertight dressings for at least 1 week after each treatment (or longer if the treatment site is weeping or oozing).
- If the dressing comes loose or falls off, replace it right away with a clean dressing.
- Place all used dressings and cleaning materials in a sealed plastic bag and throw them away in the garbage.
- Do not touch or scratch the treatment sites.

Please see Important Safety Information inside and click here for Prescribing Information and Medication Guide.
How IMLYGIC® (talimogene laherparepvec) may work

IMLYGIC® is made by modifying the virus that normally causes cold sores (herpes simplex virus type 1).¹

IMLYGIC® is the first and only FDA-approved Oncolytic Viral Therapy designed to achieve local control and may trigger a specific immune response against melanoma.¹

IMLYGIC® is injected directly into melanoma tumors, where it multiplies inside the cancer cells and destroys them.¹

Exactly how IMLYGIC® works is unknown¹; the descriptions here are meant for illustrative purposes only and are not meant to demonstrate how effectively IMLYGIC® may work.

IMPORTANT SAFETY INFORMATION

- Because IMLYGIC® may affect the way other medicines work and other medicines may affect how IMLYGIC® works, tell your doctor about all the medications you take.
- Because certain medications can affect your immune system, or affect how IMLYGIC® works, tell your doctor if you are taking steroids or are taking antiviral medications to treat or prevent herpes, like acyclovir.

Please see Important Safety Information inside and click here for Prescribing Information and Medication Guide.
What are the risks and side effects of taking IMLYGIC® (talimogene laherparepvec)?

**IMPORTANT SAFETY INFORMATION**

**What is IMLYGIC® used for?**

IMLYGIC® [talimogene laherparepvec] is a prescription medication used to treat a type of skin cancer called melanoma when it is on your skin or in your lymph glands.

IMLYGIC® may not help you live longer and may not shrink cancer in your organs (for example, lung or liver).

**What is IMLYGIC® made from and how is it given?**

- IMLYGIC® is a weakened form of Herpes Simplex Virus Type 1, which is commonly called the cold sore virus. Your healthcare provider will inject IMLYGIC® directly into your tumor(s).
- Your healthcare provider will decide which tumor(s) to inject and may not inject every one. It is important to care for the treatment sites properly so that IMLYGIC® does not spread to other people. Your healthcare provider will show you how to do this.

**Who should not get IMLYGIC®?**

You should not get IMLYGIC® if you are pregnant or have a weakened immune system (for example, an immune deficiency, blood or bone marrow cancer, steroid use, or HIV/AIDS).

**What should you tell your healthcare provider before getting IMLYGIC®?**

- Because IMLYGIC® may affect the way other medicines work and other medicines may affect how IMLYGIC® works, tell your doctor about all the medications you take.
- Because certain medications can affect your immune system, or affect how IMLYGIC® works, tell your doctor if you are taking steroids or are taking antiviral medications to treat or prevent herpes, like acyclovir.
- Tell your doctor if you have or ever had certain medical conditions like: HIV infection or AIDS, blood or bone marrow cancer, autoimmune disease, or other conditions that can weaken your immune system.
- Tell your doctor if you have close contact with someone who has a weakened immune system or is pregnant.
- IMLYGIC® may harm your unborn baby. Tell your doctor if you are pregnant or planning to become pregnant, nursing, or planning to breastfeed. Your doctor will determine whether you should receive IMLYGIC®.
- Talk with your healthcare provider about effective birth control methods.

**The IMLYGIC® virus can spread to other areas of your body or to your close contacts (household members, caregivers, sex partners, or persons sharing the same bed). Do the following to avoid spreading IMLYGIC® to other areas of your body or to your close contacts. You should share this information with them:**

- Avoid direct contact between your treatment sites, dressings, or body fluids and close contacts (for example, use condoms when engaging in sexual activity, avoid kissing close contacts if either of you has an open mouth sore).
- Don’t touch or scratch the parts of your body that have been injected with IMLYGIC®.
- Wear gloves while putting on or changing your dressings.
- Keep treatment sites covered with airtight and watertight dressings for at least 1 week after each treatment (or longer if the treatment site is weeping or oozing).
- Replace dressings right away with a clean dressing if they become loose or come off.
- Place all used dressings and cleaning materials in a sealed plastic bag, and throw them away in the garbage.

**What are the possible side effects of IMLYGIC®?**

- Common side effects of IMLYGIC® include tiredness, chills, fever, nausea, flu-like symptoms, and pain at treatment site.
- Tell your doctor right away if you get any of the following:
  - Pain, burning, or tingling in a blister around the mouth or genitals or on the fingers or ears
  - Eye pain, light sensitivity, discharge from the eyes, or blurry vision
  - Weakness in arms or legs
  - Extreme drowsiness
  - Mental confusion
- If you think you have a herpes infection, inform your healthcare provider. You or your healthcare provider should call Amgen at 1-855-IMLYGIC (1-855-465-9442) for follow-up testing, if needed.
- Tell your doctor if you have any side effect that bothers you or does not go away.
- These are not all the possible side effects of IMLYGIC®.

If you would like more information, talk with your healthcare provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please [click here to see Prescribing Information and Medication Guide](#) for more information about IMLYGIC®.
How do I get started with IMLYGIC® (talimogene laherparepvec)?

Once your doctor has prescribed IMLYGIC® here are a few things you may want to consider:

First, prepare questions for your doctor.
- To get started, you can visit IMLYGIC.com to personalize a list of questions to ask your doctor.

On the day of injection, know what to expect.
- IMLYGIC® is injected by a healthcare professional in a medical setting.¹
- The healthcare professional will inject IMLYGIC® directly into one or more tumors using a needle and syringe.¹
- The first 2 treatments of IMLYGIC® are given 3 weeks apart; after that, IMLYGIC® will be administered every 2 weeks for as long as there are injectable tumors. You can get treated for 6 months or longer.¹
- The amount of IMLYGIC® injected is based on the size of the tumors and will be determined by your doctor prior to injection of IMLYGIC®.¹
- Your healthcare provider will decide which tumor(s) to inject and may not inject every one.¹
- It is important to care for the treatment sites properly so that IMLYGIC® does not spread to other people. Your healthcare provider will show you how to do this.¹

IMLYGIC® can be injected into 3 kinds of melanoma tumors:
- Tumors on the surface of the skin, which are called cutaneous (kyoo-TANE-ee-us) lesions.¹
- Tumors just under the surface of the skin, called subcutaneous (SUB-kyoo-TANE-ee-us) lesions.¹
- Some tumors that have spread to lymph nodes, called nodal lesions, that can be seen or felt by the doctor or found by ultrasound.¹

What you might expect while you’re on IMLYGIC®

Therapy with IMLYGIC® will last at least 6 months, and possibly longer. In the clinical trial, IMLYGIC® treated patients typically saw a response by 4.1 months.¹
- Some people began to respond to treatment as early as 1.2 months, and others as late as 16.7 months.¹ It is important for your doctor to monitor your condition regularly to see how your body is responding.¹
- Existing tumors may increase in size and new tumors could appear during treatment with IMLYGIC®.¹

IMPORTANT SAFETY INFORMATION
- IMLYGIC® virus can spread to other areas of your body or to your close contacts (household members, caregivers, sex partners, or persons sharing the same bed). It is important to read the Medication Guide and talk with your healthcare provider for important precautions to take in order to avoid spreading IMLYGIC® virus.
- Common side effects of IMLYGIC® include tiredness, chills, fever, nausea, flu-like symptoms, and pain at treatment site. These are not all the side effects of IMLYGIC®.
- Tell your doctor right away if you get any of the following:
  - Pain, burning, or tingling in a blister around the mouth or genitals or on the fingers or ears
  - Eye pain, light sensitivity, discharge from the eyes, or blurry vision
  - Weakness in arms or legs
  - Extreme drowsiness
  - Mental confusion

Please see Important Safety Information inside and click here for Prescribing Information and Medication Guide.

Other questions about what to expect? Talk to your doctor, and click here to see the IMLYGIC® Medication Guide for more answers.
IMLYGIC® (talimogene laherparepvec) cost assistance

Amgen believes in the importance of patient access to your prescribed IMLYGIC®. If you have concerns about affording IMLYGIC®, Amgen may be able to help.

For eligible commercially insured patients:

**IMLYGIC FIRST STEP™ Program**

The IMLYGIC FIRST STEP™ Program can help eligible commercially insured patients meet their deductible, co-insurance, and co-payment.
- No out-of-pocket cost for the first dose.
- No income eligibility requirement.
- For subsequent doses, Amgen will pay the out-of-pocket amount in excess of $25 per dose, up to $10,000 in assistance per calendar year.

Here’s what you need to qualify:
- Must be prescribed IMLYGIC®.
- Must have private commercial health insurance that covers medication costs for IMLYGIC®.
- Must not be a participant in any federal-, state-, or government-funded healthcare program such as Medicare, Medicare Advantage, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD), or TRICARE.
- May not seek reimbursement for value received from the Amgen FIRST STEP™ Program from any third-party payers, including flexible spending accounts or healthcare savings accounts. If at any time patients begin receiving coverage under any federal-, state-, or government-funded healthcare program, patients will no longer be eligible to participate in the Amgen FIRST STEP™ Program and must call 1-888-65-STEP1 (1-888-657-8371) Monday through Friday, 9:00 AM–8:00 PM ET to stop participation. Restrictions may apply.

This is not health insurance. Program invalid where otherwise prohibited by law.

*Other restrictions apply. Not valid where prohibited by law. Amgen reserves the right to revise or terminate this program, in whole or in part, without notice at any time.

Coverage limits:
- Program covers out-of-pocket medication costs for IMLYGIC® only. Program does not cover any other costs related to office visit or administration of IMLYGIC®.
- No out-of-pocket cost for first dose or cycle; $25 out-of-pocket cost for subsequent dose or cycle; maximum benefit of $10,000 per patient per calendar year. Patient is responsible for costs above these amounts.
- Ongoing activation of the Amgen FIRST STEP™ card is contingent on the submission of the required Explanation of Benefits (EOB) form by your healthcare provider’s office within 45 days of use of the Amgen FIRST STEP™ card. Patients will be responsible for reimbursing the program for all amounts paid out if the EOB for the date of service is not received within 45 days.

For additional program details please visit [www.AmgenFIRSTSTEP.com](http://www.AmgenFIRSTSTEP.com) or call 1-888-65-STEP1 (1-888-657-8371).

For eligible Medicare and Medicaid patients:

Independent co-pay foundations

If you’re covered by Medicare or Medicaid, and need assistance with your IMLYGIC® out-of-pocket costs, you may be eligible for support from an Independent Nonprofit Co-pay Foundation*. For information about or referral to an independent co-pay foundation, visit [www.amgenassistonline.com](http://www.amgenassistonline.com), or call 1-888-4ASSIST (1-888-427-7478).

*Amgen provides donations to various nonprofit independent entities but has no influence over the distribution of the funds.

For eligible uninsured patients:

The Safety Net Foundation

The Safety Net Foundation may be able to provide IMLYGIC® at no cost to qualifying uninsured patients. For more information, visit [www.safetynetfoundation.com](http://www.safetynetfoundation.com), or call 1-888-SN-AMGEN (1-888-762-6436).
Support throughout your experience

Fighting melanoma can be a challenge. It is important to have a support network to rely on during this difficult time. There are many options—here are a few that may help.

The **AIM at Melanoma Foundation** is one organization that provides information, support, educational symposia, and more—for melanoma patients and their caregivers. Go to [www.aimatmelanoma.org](http://www.aimatmelanoma.org) for more.

**Melanoma International Foundation** offers guidance to melanoma patients and their loved ones with services that include patient outreach/support via email, a helpline, and an online forum. See [www.melanomainternational.org](http://www.melanomainternational.org) to learn more.

The **Melanoma Research Alliance (MRA)** funds research projects with the goal of making advances in the prevention, diagnosis, and treatment of melanoma. MRA partners with individuals, private foundations, and corporations on various initiatives, including public awareness campaigns. Visit [www.curemelanoma.org](http://www.curemelanoma.org) for more information.

Visitors to the **Melanoma Research Foundation** website will find resources and tools for melanoma patients, including a treatment center finder, a Phone Buddy Program, an Ask a Nurse email program, and an online patient community. To find out more visit [www.melanoma.org](http://www.melanoma.org).

These resources are provided for your information. Amgen does not endorse or control the content of the third-party patient support sites listed.

For additional resources related to melanoma support, visit IMLYGIC.com.

**REFERENCES**

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

- See the results of a clinical trial of IMLYGIC® (talimogene laherparepvec).
- Discover how IMLYGIC® works.
- Get information about the safety and side effects of IMLYGIC®.
- Information about starting treatment with IMLYGIC®.
- Get connected to financial assistance resources and support systems.

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VISIT IMLYGIC.com TO LEARN MORE

Please see Important Safety Information inside and click here for Prescribing Information and Medication Guide.