PHYSICIAN OFFICE – BILLING INFORMATION SHEET FOR IMLYGIC® (talimogene laherparepvec)

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.

Item	Coding Information (HCPCS[1]/CPT[2]/ICD-10-CM[3])	Notes
IMLYGIC®	J9325 injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	• Code effective for dates of service on or after 1/1/2017 • National Drug Code (NDC) billing requirements may vary by payer • The NDC numbers for IMLYGIC® in the 11-digit format, are as follows[4]: - 1 million PFU per 1 mL vial (10^6 PFU/mL) for the initial dose only: 55513-0078-01 - 100 million PFU per 1 mL vial (10^8 PFU/mL) for the second and subsequent doses: 55513-0079-01
Administration	96405, chemotherapy administration; intralesional, up to and including 7 lesions **OR** 96406, chemotherapy administration; intralesional, more than 7 lesions	If ultrasound guidance is used, the following administration code may also be appropriate: 76942, ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation.
Office visit	Relevant Evaluation and Management (E&M) code*,†	See payer guidelines
Diagnosis/Condition	Appropriate ICD-10-CM code(s) for patient condition	**Examples of ICD-10-CM codes:** C43.0 – C43.9 Malignant melanoma

*Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

†Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this section be considered a guarantee of coverage or reimbursement for any product or service.

Contact Amgen SupportPlus at 866-AMG-ASST (1-866-264-2778) or visit www.amgenassist.com/copay

IMPORTANT SAFETY INFORMATION

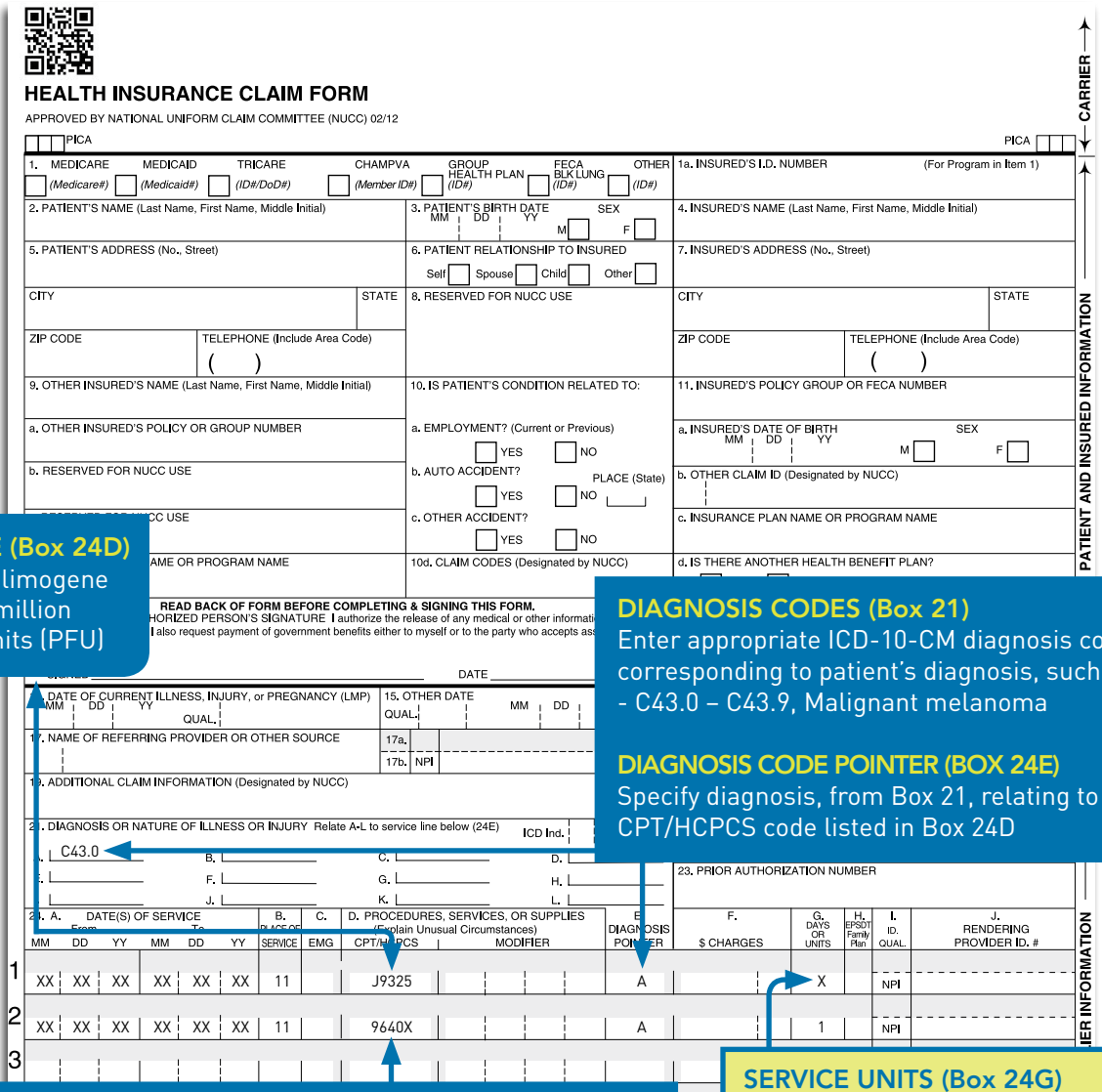
Contraindications

- 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 additional Important Safety Information on page 5.

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

PHYSICIAN OFFICE – SAMPLE CMS 1500 FOR THE INITIAL DOSE OF IMLYGIC®



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code)

ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN?

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

DATE

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. C43.0 B. C. D. E. F. G. H. I. J. K. L.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	XX	XX	XX	XX	XX	XX	11		J9325		A		X		NPI
2	XX	XX	XX	XX	XX	XX	11		9640X		A		1		NPI
3															

28. TOT $

33. BILL

a.

PATIENT AND INSURED INFORMATION

CARRIER

IER INFORMATION

PRODUCT CODE (Box 24D)
J9325 injection, talimogene laherparepvec, 1 million plaque forming units (PFU)

DIAGNOSIS CODES (Box 21)
Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, such as:
- C43.0 – C43.9, Malignant melanoma

DIAGNOSIS CODE POINTER (BOX 24E)
Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D

PROCEDURE CODE (Box 24D)
Use CPT code representing procedure performed, such as:
- 96405, chemotherapy administration; intralesional, up to and including 7 lesions

OR

- 96406, chemotherapy administration; intralesional, more than 7 lesions

Note: If ultrasound guidance is used, the following administration code might be also appropriate:
- 76942, ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation

SERVICE UNITS (Box 24G)
For J9325: Report units of service; 1 unit corresponds to 1 million PFU of IMLYGIC®

Examples of Billing Units for J9325 for the INITIAL DOSE (1 million PFU per 1 mL vial [10^6 PFU/mL]):

Number of Vials	Billing Units	11-digit NDC
1 vial	1	55513-0078-01
2 vials	2	
3 vials	3	
4 vials	4	

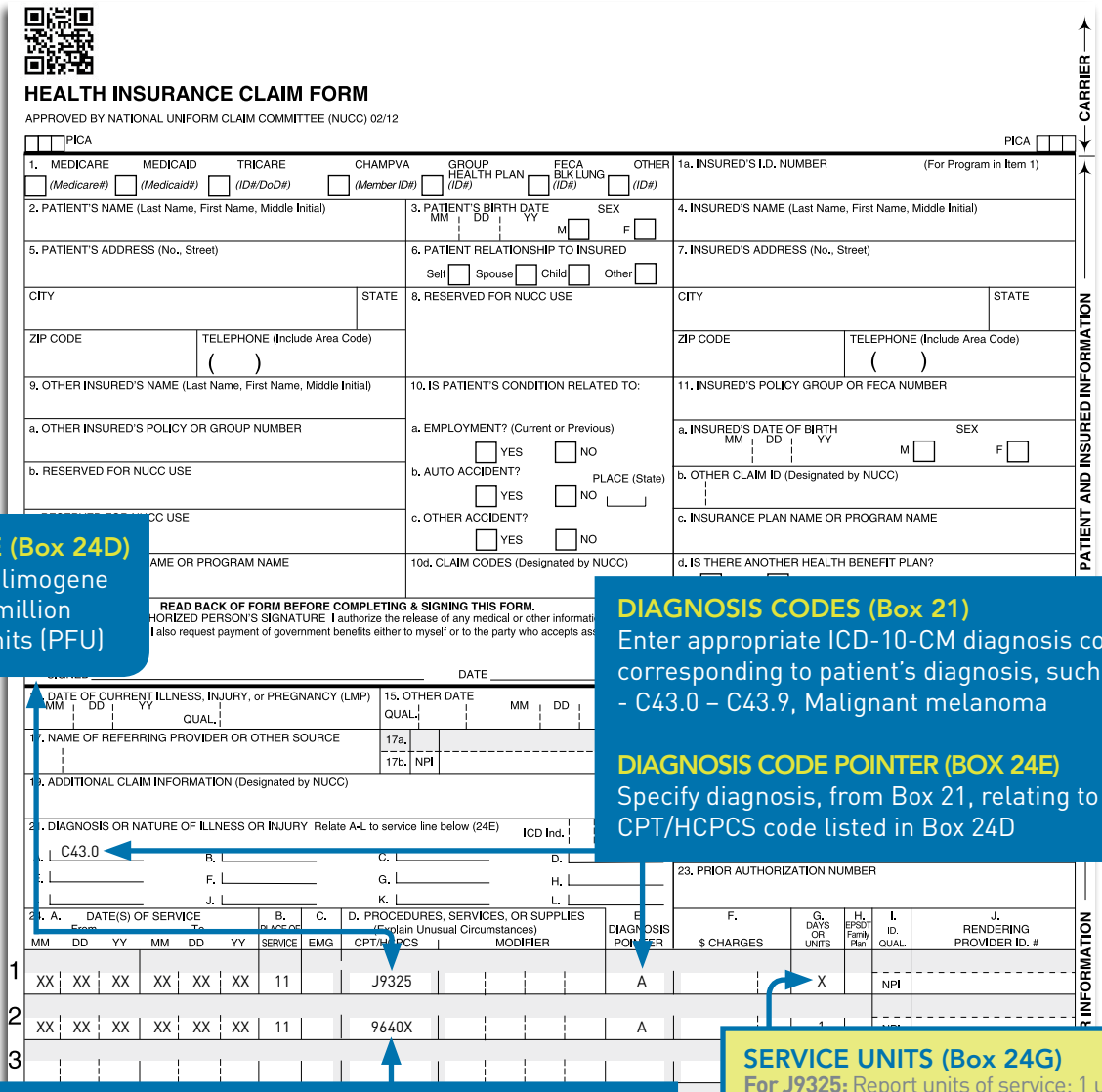
Check with payer or Amgen SupportPlus for additional guidance.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

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

Please see Important Safety Information on page 5.

PHYSICIAN OFFICE – SAMPLE CMS 1500 FOR THE SECOND & SUBSEQUENT DOSES OF IMLYGIC®



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APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

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CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

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11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

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b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN?

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

DATE

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

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23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 XX XX XX	XX XX XX	11		J9325		A		X		NPI	
2 XX XX XX	XX XX XX	11		9640X		A		1			
3											

28. TOTAL $

33. BILLING

a.

PATIENT AND INSURED INFORMATION

CARRIER

INFORMATION

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SERVICE UNITS (Box 24G)
For J9325: Report units of service; 1 unit corresponds to 1 million PFU of IMLYGIC®

Examples of Billing Units for J9325 for the SECOND & SUBSEQUENT DOSES (100 million PFU per 1 mL vial [10^8 PFU/mL]):

Number of Vials	Billing Units	11-digit NDC
1 vial	100	55513-0079-01
2 vials	200	
3 vials	300	
4 vials	400	

Check with payer or Amgen SupportPlus for additional guidance.

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10^6 PFU/mL and 10^8 PFU/mL single-use vials

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CODING AND BILLING CONSIDERATIONS FOR IMLYGIC®

Billing System

Update billing systems with appropriate billing codes, which may include:

- Updating billing software with the new HCPCS code and appropriate billing unit
- NDC numbers for both dosing concentrations of IMLYGIC®
- CPT codes for intralesional injections
- CPT code for ultrasonic guidance for needle placement

Consider establishing a process for integrating billing systems with additional clinical information, including:

- Number of lesions injected with IMLYGIC® during the visit to help select an appropriate CPT code (ie, ≤7 vs >7 injections)
- Volume of IMLYGIC® used during the visit to help identify appropriate billing units and to document unused drug, if required by payer (ie, volume injected vs volume discarded)

Information that may help billing staff includes:

- Billing considerations for initial vs subsequent doses of IMLYGIC®
- Coding and billing requirements for ultrasound guidance

Claim Submission

Contact Amgen SupportPlus or call the local payer to check specific coding and billing requirements. Consider the following:

- Confirm payer(s) have updated their system with the new HCPCS code
- Billing documentation requirements for discarded volume of IMLYGIC®

Confirm appropriate documentation in the patient's medical record, which may include:

- Clinical documentation to support appropriate E&M code
- Number and location of lesions injected with IMLYGIC® during the visit
- Time of injection(s) for IMLYGIC® and corresponding clinician's signature

References
1. Centers for Medicare & Medicaid Services. 2020 Alpha-Numeric HCPCS File. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File Accessed August 22, 2022. **2.** American Medical Association. Current Procedural Terminology (CPT®) copyright 2016 American Medical Association. 2016. All Rights Reserved. **3.** Centers for Medicare & Medicaid website. ICD-10-CM tabular list of diseases and injuries. https://www.cms.gov/files/zip/2022-code-tables-tabular-and-index-updated-02012022.zip. Accessed September 1, 2022.
4. IMLYGIC® (talimogene laherparepvec) Prescribing Information. Amgen.

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INDICATION AND IMPORTANT SAFETY INFORMATION

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.

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Contraindications

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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 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.
- 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 to see full Prescribing Information and Medication Guide for IMLYGIC®.

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AMGEN
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One Amgen Center Drive
Thousand Oaks, CA 91320-1799