

# 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. IMLYGIC® has not been shown to improve overall survival or have an effect on visceral metastases.

Item	Coding Information (HCPCS <sup>1</sup> /CPT <sup>2</sup> /ICD-10-CM <sup>3</sup> )	Notes
IMLYGIC®	J9999, not otherwise classified, antineoplastic drugs <b>OR</b> J3490, unclassified drugs; <b>OR</b> J3590, unclassified biologics; <b>OR</b> another unclassified drug/supply code, as required by a given payer	Billing requirements for unclassified or miscellaneous codes may vary by payer; however, payers commonly require providers to list product name, route of administration, dosage, and NDC in box 19 (or corresponding field for electronic claims*). <ul style="list-style-type: none"> <li>The NDC numbers for IMLYGIC® in the 11-digit format, are as follows<sup>4</sup>: <ul style="list-style-type: none"> <li>1 million PFU per 1 mL vial (10<sup>6</sup> PFU/mL) for the initial dose only: 55513-0078-01</li> <li>100 million PFU per 1 mL vial (10<sup>8</sup> PFU/mL) for the second and subsequent doses: 55513-0079-01</li> </ul> </li> </ul>
Administration	96405, chemotherapy administration; intralesional, up to and including 7 lesions <b>OR</b> 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 <sup>†,‡</sup>	See payer guidelines
Diagnosis/Condition	Appropriate ICD-10-CM code(s) for patient condition	<b>Examples of ICD-10-CM codes:</b> C43.0 – C43.9 Malignant melanoma

\*Note that the reporting field for electronic claims (SV101-7) is limited to 80 characters; however, some payers may allow to utilize Loop 2400 NTE 02 if additional space is needed.

<sup>†</sup>Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

<sup>‡</sup>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 Assist® at 1-888-4ASSIST for assistance.  
www.AmgenAssistOnline.com

## IMPORTANT SAFETY INFORMATION

- 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 5.



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

# PHYSICIAN OFFICE – SAMPLE CMS 1500 FOR THE INITIAL DOSE OF IMLYGIC® (talimogene laherparepvec)



## HEALTH INSURANCE CLAIM FORM

### PRODUCT INFO (Box 19)

Billing requirements for unclassified or miscellaneous codes may vary by payer; however, payers commonly require providers to list product name, route of administration, dosage, and NDC.\*

**Potential Examples for the INITIAL DOSE (1 million PFU per 1 mL vial [10<sup>6</sup> PFU/mL]):**

Number of Vials	Product Info Documentation†
1 vial	Talimogene laherparepvec NDC 55513-0078-01 1 million PFU (1 vial)
2 vials	Talimogene laherparepvec NDC 55513-0078-01 2 million PFU (2 vials)
3 vials	Talimogene laherparepvec NDC 55513-0078-01 3 million PFU (3 vials)
4 vials	Talimogene laherparepvec NDC 55513-0078-01 4 million PFU (4 vials)

\* Note that the reporting field for electronic claims (SV101-7) is limited to 80 characters; however, some payers may allow to utilize Loop 2400 NTE 02 if additional space is needed.

† Note that depending on the total injection volume required for a given treatment visit, a patient might not need the full dose provided in a single-use 1 mL vial. Payer requirements for documenting discarded drug amount might vary.

Check with payer or Amgen Assist® for additional guidance.

### PRODUCT CODE (Box 24D)

Use J9999, not otherwise classified, antineoplastic drugs;  
**OR** J3490, unclassified drugs;  
**OR** J3590, unclassified biologics;  
**OR** another unclassified drug/supply code, as required by a given payer

### 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

### 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.

### SERVICE UNITS (Box 24G)

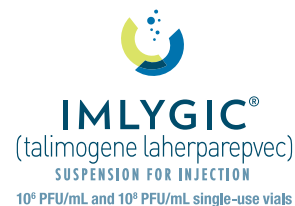
Unclassified or miscellaneous codes do not have "unit values" and are generally reported as 1 unit.

Check with payer or Amgen Assist® for additional guidance.

The form is a standard CMS 1500 Health Insurance Claim Form. Key sections include:

- Section 1:** Insured's ID Number, Name, Address, City, State, ZIP Code, Telephone.
- Section 2:** Insured's Policy Group or PECA Number, Date of Birth, Sex, Other Claim ID, Insurance Plan Name.
- Section 3:** Name of Referring Provider or Other Source, Additional Claim Information (NDC: Talimogene laherparepvec intralesional NDC 55513-0078-01 X million PFU (X vials)), Diagnosis or Nature of Illness or Injury (ICD-10-CM: C43.X).
- Section 4:** Table of Services with columns for Date of Service, Service Code (CPT/HCPCS: 96405 OR 96406), Diagnosis Pointer, Charges, Days or Units (1), and Rendering Provider ID.

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.



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



## HEALTH INSURANCE CLAIM FORM

### PRODUCT INFO (Box 19)

Billing requirements for unclassified or miscellaneous codes may vary by payer; however, payers commonly require providers to list product name, route of administration, dosage, and NDC.\*

**Potential Examples for the SECOND & SUBSEQUENT DOSES (100 million PFU per 1 mL vial [10<sup>8</sup> PFU/mL]):**

Number of Vials	Product Info Documentation†
1 vial	Talimogene laherparepvec NDC 55513-0079-01 100 million PFU (1 vial)
2 vials	Talimogene laherparepvec NDC 55513-0079-01 200 million PFU (2 vials)
3 vials	Talimogene laherparepvec NDC 55513-0079-01 300 million PFU (3 vials)
4 vials	Talimogene laherparepvec NDC 55513-0079-01 400 million PFU (4 vials)

\* Note that the reporting field for electronic claims (SV101-7) is limited to 80 characters; however, some payers may allow to utilize Loop 2400 NTE 02 if additional space is needed.

† Note that depending on the total injection volume required for a given treatment visit, a patient might not need the full dose provided in a single-use 1 mL vial. Payer requirements for documenting discarded drug amount might vary.

Check with payer or Amgen Assist® for additional guidance.

### PRODUCT CODE (Box 24D)

Use J9999, not otherwise classified, antineoplastic drugs;  
**OR** J3490, unclassified drugs;  
**OR** J3590, unclassified biologics;  
**OR** another unclassified drug/supply code, as required by a given payer

### 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

### 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)

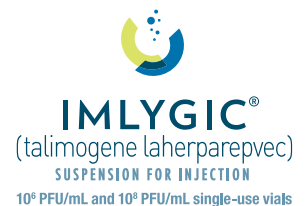
Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

### SERVICE UNITS (Box 24G)

Unclassified or miscellaneous codes do not have "unit values" and are generally reported as 1 unit.

Check with payer or Amgen Assist® 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.



# CODING AND BILLING CONSIDERATIONS FOR IMLYGIC® (talimogene laherparepvec)

## Billing System

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

- Miscellaneous product codes that may apply to IMLYGIC®
- 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 versus subsequent doses of IMLYGIC®
- Conversion for PFU-based dosing into billing units for miscellaneous product codes
- Coding and billing requirements for ultrasound guidance

## Claim Submission

### Contact Amgen Assist® or call local payer to check specific coding and billing requirements.

#### Consider the following:

- Miscellaneous product code required for IMLYGIC®
- Information required in box 19 of the CMS 1500 Form (or corresponding electronic field) for claims with a miscellaneous code
- Billing documentation requirements for discarded volume of IMLYGIC®

#### Confirm appropriate documentation in 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

- Centers for Medicare & Medicaid Services. 2016 Alpha-Numeric HCPCS File. Available at: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2016-Alpha-Numeric-HCPCS-File.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>. Accessed March 8, 2016.
- American Medical Association. Current Procedural Terminology [CPT®] copyright 2014 American Medical Association. 2015. All Rights Reserved.
- Centers for Medicare & Medicaid Services. 2016 ICD-10 Codes Table and Index. Available at: <https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html>. Accessed March 8, 2016.
- IMLYGIC® (talimogene laherparepvec) Prescribing Information, BioVex, Inc., a subsidiary of Amgen Inc.

The information provided in this Billing and Coding Considerations sheet 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.



# 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.

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 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 ( $\geq 25\%$ ) 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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**IMLYGIC®**  
(talimogene laherparepvec)  
SUSPENSION FOR INJECTION  
10<sup>6</sup> PFU/mL and 10<sup>8</sup> PFU/mL single-use vials