

HOSPITAL OUTPATIENT – 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	Revenue Code	Coding Information (HCPCS ¹ /CPT ² /ICD-10-CM ³)	Notes
IMLYGIC®	<p>Medicare: 0636, drugs requiring detailed coding</p> <p>Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer</p>	J9325, injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	<ul style="list-style-type: none"> Code effective for dates of service on or after 1/1/2017 IMLYGIC® is still eligible for separate payment under Medicare under the Hospital Outpatient Prospective Payment System (OPPS) C9472 should no longer be submitted for claims with 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 follows⁴: <ul style="list-style-type: none"> - 1 million PFU per 1 mL vial (10⁶ PFU/mL) for the initial dose only: 55513-0078-01 - 100 million PFU per 1 mL vial (10⁸ PFU/mL) for the second and subsequent doses: 55513-0079-01
Administration	Appropriate revenue code for the cost center in which the service is performed	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
Diagnosis/Condition	N/A	Appropriate ICD-10-CM code(s) for patient condition	Examples of ICD-10-CM codes: C43.0 – C43.9 Malignant melanoma

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Contact Amgen Assist® at 1-888-4ASSIST or visit www.AmgenAssist.com

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.



HOSPITAL OUTPATIENT – SAMPLE CMS 1450 FOR THE INITIAL DOSE OF IMLYGIC®

For Dates of Service on or After 1/1/2017

1		2		3a PAT.		4 TYPE	
8 PATIENT NAME				9 PATIENT ADDRESS			
10 BIRTHDATE		11 SEX		12 DATE		13 ADMISSION HR	
14 TYPE		15 SRC		16 DHR		17 STAT	
18		19		20		21	
31 OCCURRENCE CODE		32 OCCURRENCE DATE		33 OCCURRENCE CODE		34 OCCURRENCE DATE	
35 CODE		36 CODE		37 CODE		38 CODE	
PRODUCT CODE (Box 44) J9325, injection, talimogene laherparepvec, per 1 million plaque forming units (PFU)							
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / PPS CODE		45 SERV. DATE	
46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
0636		Drugs/detailed coding		J9325		MMDDYY	
0510		Clinic		9640X		MMDDYY	
						X	
						1	
						XXXXX	
						XXXXX	
REVENUE CODE (Box 42) AND DESCRIPTIONS (Box 43) Product Medicare: Use revenue code 0636, drugs requiring detailed coding Other payers: Use revenue code 0250, general pharmacy for 0636, if required by a given payer) Related administration procedure Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic)							
PROCEDURE CODE (Box 44) 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							
50 PAYER NAME		51 HEALTH PLAN ID		52 REL. INFO		53 ASG. BEN.	
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID	
58 S UNIQUE ID				61 GROUP NAME		62 INSURANCE GROUP NO.	
63 DOCUMENT CONTROL NUMBER				65 EMPLOYER NAME			
DIAGNOSIS CODES (Box 67) Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, such as: - C43.0 – C43.9, Malignant melanoma							
66 DX							
C43.0							
69 ADMIT DX		70 PATIENT REASON DX		71 PPS CODE		72 ECI	
74 PRINCIPAL PROCEDURE CODE		75 OTHER PROCEDURE CODE		76 ATTENDING NPI		77 OPERATING NPI	
78 OTHER PROCEDURE CODE		79 OTHER PROCEDURE CODE		78 OTHER NPI		79 OTHER NPI	
80 REMARKS				81CC a		81CC b	
				81CC c		81CC d	

SERVICE UNITS (Box 46)
 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 [10⁶ 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 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.



HOSPITAL OUTPATIENT – SAMPLE CMS 1450 FOR THE SECOND & SUBSEQUENT DOSES OF IMLYGIC®

For Dates of Service on or After 1/1/2017

1		2		3a PAT.		4 TYPE																	
8 PATIENT NAME				9 PATIENT ADDRESS																			
10 BIRTHDATE		11 SEX		12 DATE		13 ADMISSION HR		14 TYPE		15 SRC		16 DHR		17 STAT		18		19		20			
31 OCCURRENCE CODE		32 OCCURRENCE DATE		33 OCCURRENCE CODE		34 OCCURRENCE DATE		35 OCCURRENCE CODE		36 OCCURRENCE DATE		37 OCCURRENCE CODE		38 OCCURRENCE DATE		39 OCCURRENCE CODE		40 OCCURRENCE DATE		41 OCCURRENCE CODE		42 OCCURRENCE DATE	
<p>PRODUCT CODE (Box 44) J9325, injection, talimogene laherparepvec, per 1 million plaque forming units (PFU)</p>																							
42 REV. CD.		43 DESCRIPTION				44 HCPCS / RATE / ICD-9 PS CODE				45 SERV. DATE		46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49		50		51	
0636		Drugs/detailed coding				J9325				MMDDYY		X		XXXXX									
0510		Clinic				9640X				MMDDYY		1		XXXXX									
<p>REVENUE CODE (Box 42) AND DESCRIPTIONS (Box 43) Product Medicare: Use revenue code 0636, drugs requiring detailed coding Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer) Related administration procedure Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic)</p>																							
<p>PROCEDURE CODE (Box 44) 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</p>																							
<p>DIAGNOSIS CODES (Box 67) Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, such as: - C43.0 – C43.9, Malignant melanoma</p>																							
50 PAYER NAME		51 HEALTH PLAN ID				52 REL. INFO		53 ASG. BEN.		54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID		58		59		60	
<p>TOTALS →</p>																							
66 DX		67				68				69		70		71		72		73		74		75	
C43.0																							
69 ADMIT DX		70 PATIENT REASON DX				71 PPS CODE				72 ECI		73		74		75		76		77		78	
80 REMARKS		81CC a				82				83		84		85		86		87		88		89	
		b				c				d		e		f		g		h		i		j	
		k				l				m		n		o		p		q		r		s	
		t				u				v		w		x		y		z		aa		ab	

SERVICE UNITS (Box 46)
 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 [10⁸ 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 Assist® for additional guidance.

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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 Assist® 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

- 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.
- American Medical Association. Current Procedural Terminology (CPT®) copyright 2020 American Medical Association. 2021. All Rights Reserved.
- 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.
- IMLYGIC® (talimogene laherparepvec) Prescribing Information. Amgen.

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.
- **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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IMLYGIC[®]
(talimogene laherparepvec)
SUSPENSION FOR INJECTION
10⁸ PFU/mL and 10⁹ PFU/mL single-use vials