IMDELLTRA®: Access and Reimbursement

A guide to billing, coding, and coordination of care considerations for IMDELLTRA®
01/2025

Please note that the information in this resource is intended to be educational and is not a guarantee of reimbursement. Coverage, coding, and billing requirements vary by health plan, so be sure to check with individual payers for detailed guidance. Actual codes and/or modifiers used are at the sole discretion of the treating physician and/or facility.

IMDELLTRA® J-Code: J9026, Injection, tarlatamab-dlle, 1 mg

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. This information is not a guarantee of coverage or reimbursement.

INDICATION

IMDELLTRA® (tarlatamab-dlle) is indicated for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving IMDELLTRA®. Initiate treatment with IMDELLTRA® using the step-up dosing schedule to reduce the incidence and severity of CRS. Withhold IMDELLTRA® until CRS resolves or permanently discontinue based on severity.**
- **Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including serious or life-threatening reactions, can occur in patients receiving IMDELLTRA®. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment and treat promptly. Withhold IMDELLTRA® until ICANS resolves or permanently discontinue based on severity.**

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

IMDELLTRA® (tarlatamab-dlle) for injection 1 mg & 10 mg single-use vials

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This resource provides example codes to support accurate reimbursement and information to help you coordinate care between inpatient and outpatient settings. In each care setting, coordination helps to ensure patients receive their medicine in a timely manner

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Treatment initiation and care coordination

Begin the coordination-of-care process by evaluating patient benefits and determining coverage for available care options prior to treatment initiation.

Administer IMDELLTRA® as a 1-hour IV infusion as an initial step-up dosing schedule to reduce the incidence and severity of CRS, and then every 2 weeks (Q2W) thereafter until disease progression or unacceptable toxicity. All IMDELLTRA® infusions and monitoring should take place in an appropriate healthcare setting. Prior to administration of IMDELLTRA®, evaluate complete blood count, liver enzymes, and bilirubin before each dose, and as clinically indicated. Ensure patients are well hydrated prior to administration of IMDELLTRA®.[1]

Dosing Schedule[1]	Day[1]	Administration[1] 1-Hour IV Infusion	Patient Monitoring[1]
Step-up Dosing Schedule Cycle 1	Day 1	1 mg Step-up dose	Monitor patients from the start of the IMDELLTRA® infusion for **22 to 24 hours** on Cycle 1 Day 1 and Cycle 1 Day 8 in an appropriate healthcare setting. Recommend patients remain within 1 hour of an appropriate healthcare setting for a total of 48 hours from start of the IMDELLTRA® infusion, accompanied by a caregiver.
	Day 8	10 mg	
	Note: Patient treatment journeys may vary. Early discharge planning is an important factor in a patient's transition to different sites of care. **After Day 8, continuing treatment may be transitioned to an outpatient clinic.**		
	Day 15	10 mg	Observe patients for **6–8 hours** post IMDELLTRA® infusion.*
	Some patients may receive their Cycle 1 doses in the inpatient setting and may not transition for administration in the outpatient setting until later cycles/doses.		
Cycle 2	Day 1 and 15	10 mg	Observe patients for **6–8 hours** post IMDELLTRA® infusion.*
Cycles 3 and 4	Day 1 and 15	10 mg	Observe patients for **3–4 hours** post IMDELLTRA® infusion.*
Cycle 5 and subsequent infusions	Day 1 and 15	10 mg	Observe patients for **2 hours** post IMDELLTRA® infusion.*

In the DeLLphi-300 and DeLLphi-301 pooled safety population, 55% of patients who received IMDELLTRA® experienced CRS and 47% experienced neurologic toxicity, including ICANS. ICANS occurred in 9% of IMDELLTRA®-treated patients.† IMDELLTRA® should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity, including ICANS.[1]

For additional information, please see the IMDELLTRA® Dosing, Administration & Pharmacy Guide. Please refer to the full Prescribing Information for important Dosing, Administration, and Monitoring information

*Extended monitoring in a healthcare setting is not required unless the patient experiences Grade ≥ 2 CRS, ICANS, or neurological toxicity during prior treatments.[1] See the IMDELLTRA® full Prescribing Information for monitoring recommendations.

†Based on the pooled safety population of 187 patients enrolled in DeLLphi-300 and DeLLphi-301 who received IMDELLTRA® 1 mg on Cycle 1 Day 1 followed by 10 mg on Days 8, 15, and then Q2W until disease progression or intolerable toxicity.[1]

CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; IV, intravenous.

IMDELLTRA® (tarlatamab-dlle) for injection 1 mg & 10 mg single-use vials

Reimbursement across sites of care

Patients treated with IMDELLTRA® may transition through multiple sites of care. See below for payer coverage and reimbursement details.

Components of Care	FFS Medicare	FFS Medicaid	Commercial
Hospital — inpatient status			
IMDELLTRA® & administration services	MS-DRG payment typically includes drug covered by Part A[2,3] Hospital may be eligible for outlier payment[4] Reimbursement varies for PPS-exempt cancer hospitals[5] Physician services may be separately covered and reimbursed according to MPFS by Part B	APR-DRG–based payment typically includes drug[6,7] Reimbursement varies by state Physician services may be separately covered and paid outside the bundle	MS-DRG–based payments may apply; however, reimbursement varies by contract between IDN/hospitals and payer[8,9] Some IDN/hospitals have separate cancer care arrangements with payers. Check with payer Physician services may be covered outside of the bundled payment. Check with payer
Hospital — outpatient status (may include hospital stay < 2 midnights in addition to hospital outpatient department)			
IMDELLTRA®	Covered under Medicare Part B Pass-through status under OPPS (effective October 1, 2024)[10] Typically reimbursed based on ASP + 6% (with 2% sequestration reduction)[11,12]	Reimbursement may be similar to Medicare OR Rates vary by state May require prior authorization	Reimbursed based on the contracted rates; methods vary[13] Examples: ASP + X%; WAC + X%; AWP – X% May require prior authorization
Administration services (including observation care)	Covered under Medicare Part B Reimbursement varies for PPS-exempt cancer hospitals[5] Physician services may be separately covered and reimbursed according to MPFS by Part B	Reimbursement based on fee schedule Rates vary by state	Reimbursed based on contracted rate
Physician's office/non-hospital infusion clinic			
IMDELLTRA®	Covered under Medicare Part B Typically reimbursed based on ASP + 6% (with 2% sequestration reduction)[11,12]	Reimbursement may be similar to Medicare OR Rates vary by state May require prior authorization	Reimbursed based on the contracted rates; methods vary[13] Examples: ASP + X%; WAC + X%; AWP – X% May require prior authorization
Administration services (including observation care)	Covered under Medicare Part B Physician services may be separately covered and reimbursed according to MPFS by Part B	Physician services may be covered Reimbursement based on fee schedule Rates vary by state	Reimbursed based on contracted rate

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. This information is not a guarantee of coverage or reimbursement.

APR-DRG, All Patient Refined Diagnosis Related Groups; ASP, average sales price; AWP, average wholesale price; FFS, fee-for-service; IDN, integrated delivery network; MPFS, Medicare Physician Fee Schedule; MS-DRG, Medicare Severity Diagnosis Related Groups; OPPS, Outpatient Prospective Payment System; PPS, Prospective Payment System; WAC, wholesale acquisition cost.

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Hospital — inpatient status site of service

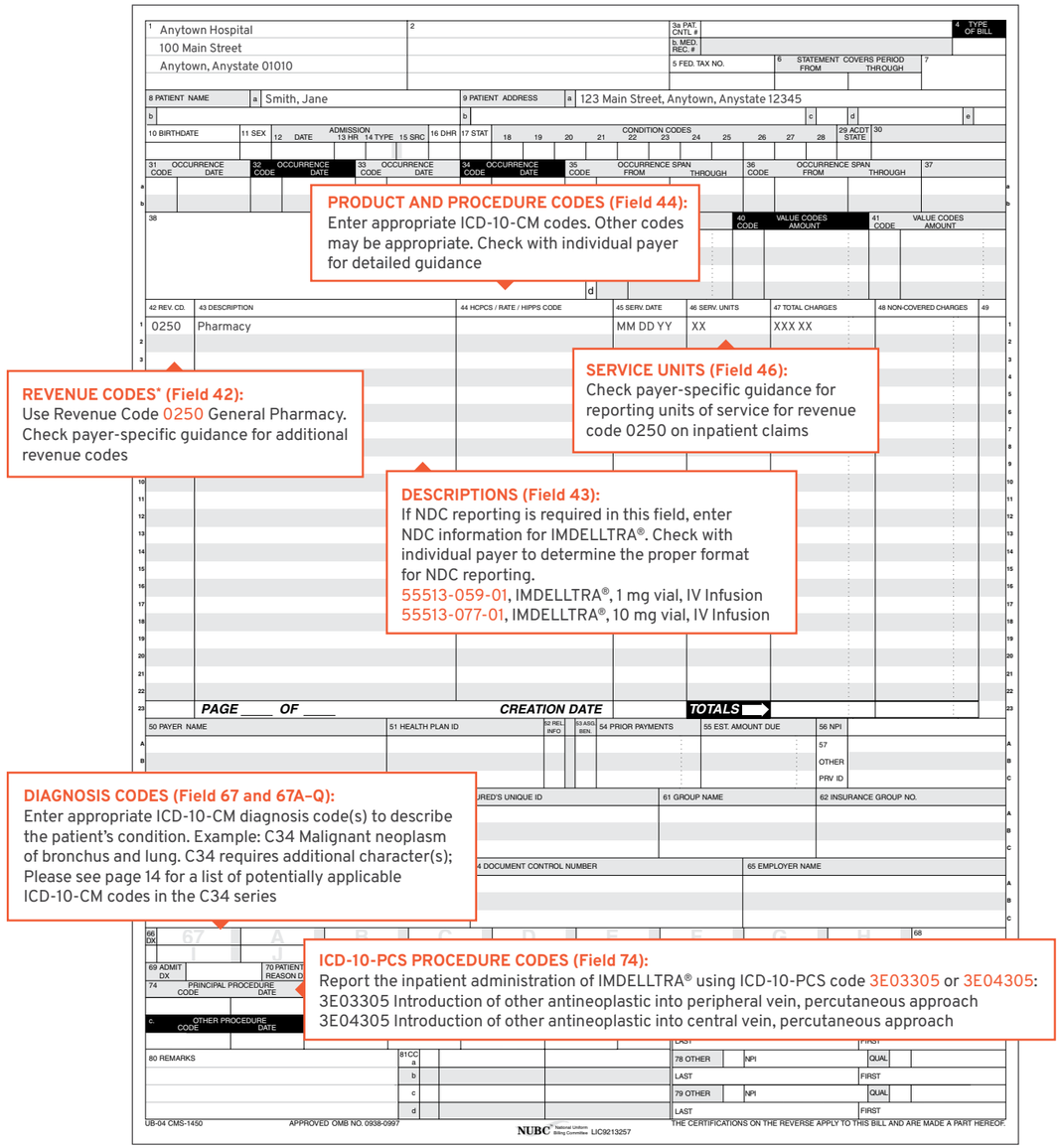
Multiple payers (Medicare and non-Medicare)

Item	Revenue Code*	Coding Information (ICD-10-CM, ICD-10-PCS, NDC)	Notes
Diagnosis/ condition	—	Appropriate ICD-10-CM code(s) for patient condition	Examples of ICD-10-CM codes: C34.0–C34.9: Malignant neoplasm of the bronchus and lung. Please see page 14 for a list of ICD-10-CM codes in the C34 series. Include any additional metastasis codes C39.0 Malignant neoplasm of upper respiratory tract, part unspecified C39.9 Malignant neoplasm of lower respiratory tract, part unspecified
IMDELLTRA®	**0250**, general pharmacy	**NDC:** 55513-059-01, IMDELLTRA® 1 mg vial; **NDC:** 55513-077-01, IMDELLTRA® 10 mg vial	Some payers may require NDC reporting. When reporting the NDC on claims, use the 11-digit NDC in the 5-4-2 format
Procedure: Administration	—	**3E03305:** Introduction of other antineoplastic into peripheral vein, percutaneous approach **3E04305:** Introduction of other antineoplastic into central vein, percutaneous approach	ICD-10-PCS codes are used to report procedures on inpatient claims. Hospitals can report the inpatient administration of IMDELLTRA® using ICD-10-PCS code 3E03305 or 3E04305

*This is not an all-inclusive list of revenue codes; revenue codes will vary by institution. Revenue codes are only required on the CMS-1450.

ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; ICD-10-PCS, International Classification of Diseases, 10th Revision, Procedure Coding System; NDC, National Drug Code.

Sample UB-04 (CMS 1450) form: Hospital — inpatient status site of service



PRODUCT AND PROCEDURE CODES (Field 44):
Enter appropriate ICD-10-CM codes. Other codes may be appropriate. Check with individual payer for detailed guidance

REVENUE CODES* (Field 42):
Use Revenue Code 0250 General Pharmacy. Check payer-specific guidance for additional revenue codes

SERVICE UNITS (Field 46):
Check payer-specific guidance for reporting units of service for revenue code 0250 on inpatient claims

DESCRIPTIONS (Field 43):
If NDC reporting is required in this field, enter NDC information for IMDELLTRA®. Check with individual payer to determine the proper format for NDC reporting.
55513-059-01, IMDELLTRA®, 1 mg vial, IV Infusion
55513-077-01, IMDELLTRA®, 10 mg vial, IV Infusion

DIAGNOSIS CODES (Field 67 and 67A–Q):
Enter appropriate ICD-10-CM diagnosis code(s) to describe the patient's condition. Example: C34 Malignant neoplasm of bronchus and lung. C34 requires additional character(s); Please see page 14 for a list of potentially applicable ICD-10-CM codes in the C34 series

ICD-10-PCS PROCEDURE CODES (Field 74):
Report the inpatient administration of IMDELLTRA® using ICD-10-PCS code 3E03305 or 3E04305:
3E03305 Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04305 Introduction of other antineoplastic into central vein, percutaneous approach

*This is not an all-inclusive list of revenue codes; revenue codes will vary by institution. Revenue codes are only required on the CMS-1450.

This sample form is intended as a reference for coding and billing for products 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.

CMS, Centers for Medicare & Medicaid Services; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; ICD-10-PCS, International Classification of Diseases, 10th Revision, Procedure Coding System; IV, intravenous; NDC, National Drug Code; UB, uniform billing.

Hospital — outpatient status

Hospital outpatient status applies to observation care received as part of an outpatient hospital admission, as well as care received in a hospital outpatient department (may include a hospital stay < 2 midnights in addition to hospital outpatient department)

Multiple payers (Medicare and non-Medicare)

Item	Revenue Code*	Coding Information (HCPCS, CPT, ICD-10-CM, NDC)	Notes
Diagnosis/ condition	—	Appropriate ICD-10-CM code(s) for patient condition	Examples of ICD-10-CM codes: C34.0–C34.9: Malignant neoplasm of the bronchus and lung. Please see page 14 for a list of ICD-10-CM codes in the C34 series. Include any additional metastasis codes C39.0 Malignant neoplasm of upper respiratory tract, part unspecified C39.9 Malignant neoplasm of lower respiratory tract, part unspecified
IMDELLTRA®	**Medicare: 0636**, drugs requiring detailed coding **Other Payers: 0250**, general pharmacy OR **0636**, if required by a given payer	**J9026:** Injection, tarlatamab-dlle, 1 mg (effective January 1, 2025) **JZ:** Zero drug amount discarded/not administered to any patient **JW:** Drug amount discarded/ not administered to any patient **TB:** Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes **NDC:** 55513-059-01, IMDELLTRA® 1 mg vial **NDC:** 55513-077-01, IMDELLTRA® 10 mg vial	For dates of service on or after January 1, 2025, IMDELLTRA® must be reported with J-code J9026, which has a billing unit of 1 mg† Under Medicare's discarded drug policy, claims for drugs from single-dose containers require use of the JZ modifier (Zero drug amount discarded/not administered to any patient) or JW modifier (Drug amount discarded/not administered to any patient). Discarded drug reporting policies for payers other than Medicare may vary Some payers may require NDC reporting. When reporting the NDC on claims, use the 11-digit NDC in the 5-4-2 format
Procedure: Administration	—	**96413:** Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug **96417:** Chemotherapy administration, IV infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour. Must be listed separately in addition to code for primary procedure	The CPT code for the IMDELLTRA® administration procedure should reflect the actual service performed

*This is not an all-inclusive list of revenue codes; revenue codes will vary by institution. Revenue codes are only required on the CMS-1450.

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. This information is not a guarantee of coverage or reimbursement.

†For dates of service prior to January 1, 2025, hospital outpatient coding for IMDELLTRA® will vary. Medicare OPPS: Report IMDELLTRA® using C9170 (dates of service from 10/1/2024–12/31/2024); C9399 (dates of service through 9/30/2024). Other payers: Report IMDELLTRA® using an unclassified J-code (eg, J9999, J3590, or J3490).

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous; NDC, National Drug Code.

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Hospital — outpatient status (cont'd)

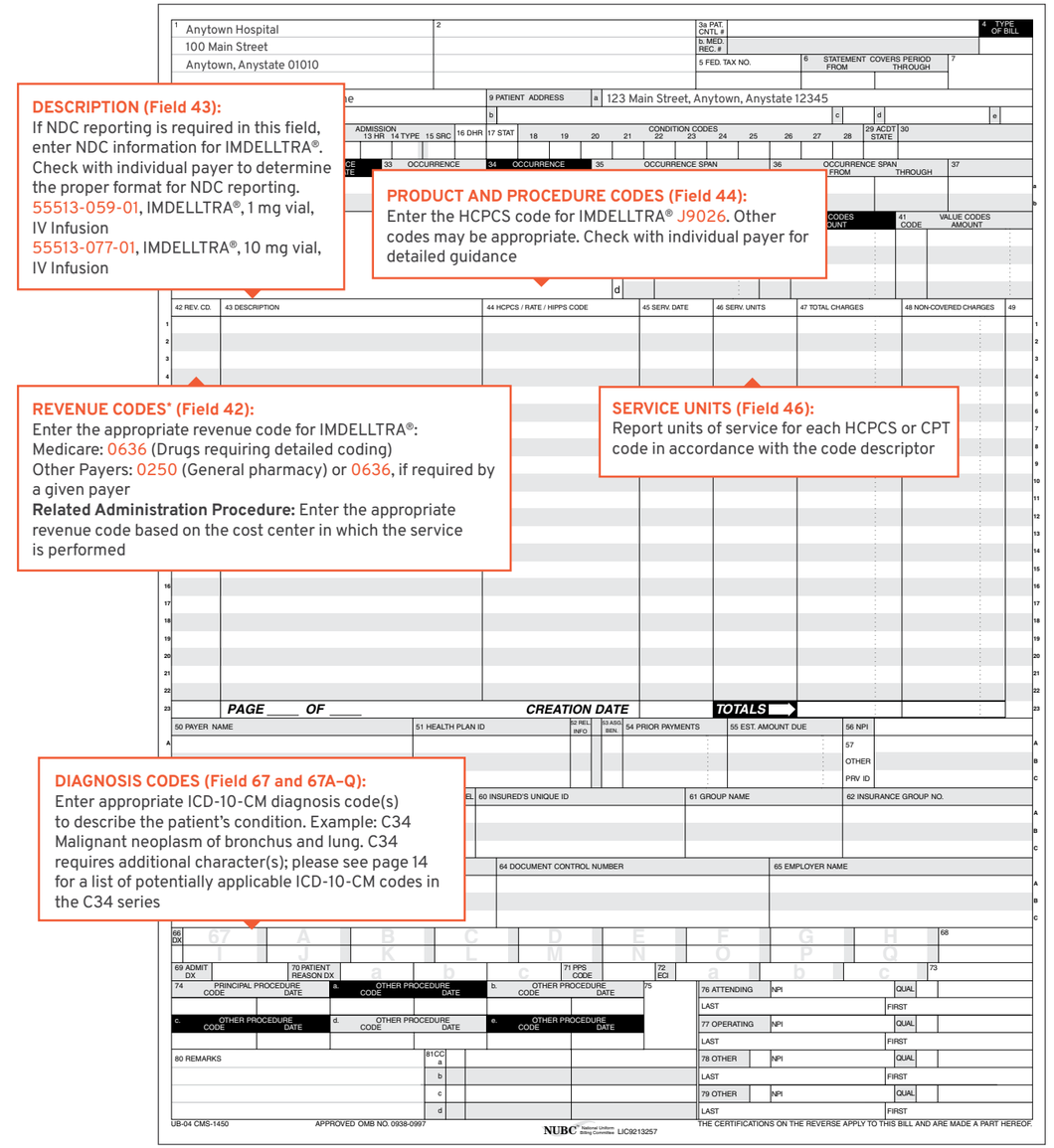
Item	Revenue Code	Coding Information (HCPCS, CPT, ICD-10-CM, NDC)	Notes
Observation care	–	**Hospital billing (CMS-1450 claim form):** **G0378:** Hospital observation service, per hour; **G0379:** Direct admission of patient for hospital observation care **G0463:** Hospital outpatient clinic visit for assessment and management of a patient **Physician billing (CMS-1500 claim form):** **99221–99223:** Initial hospital inpatient or observation care, per day, for E/M of patient. Code will be different based on time or level of medical decision-making **99231–99233** Subsequent hospital inpatient or observation care, per day, for E/M of patient. Code will be different based on time or level of medical decision-making **99234–99236** Hospital inpatient or observation care, for E/M of patient including admission and discharge on the same date. Code will be different based on time or level of medical decision-making **99238, 99239** Hospital inpatient or observation discharge day management. Code will be different based on time or level of medical decision-making **99418:** Prolonged inpatient or observation E/M services (not recognized by Medicare) **G0316:** Prolonged inpatient or observation E/M services (recognized by Medicare instead of CPT code 99418)	Use appropriate revenue code for cost center in which service is performed Coding and payment policy for observation care varies by payer. For example, Medicare requires hospitals and physicians to use different codes to bill for observation care in the hospital setting, but other payers may not.* As a result, providers should consult the pertinent payer regarding coding and payment for observation services The descriptions for the codes listed at left are abbreviated. Physicians should consult a current CPT manual to review all available E/M codes, complete descriptions, and applicable CPT guidelines to determine which E/M code (if any) is most appropriate for a specific patient encounter. In addition, physicians should review the billing information in CMS's Evaluation and Management Services Guide

*Medicare billing instructions for observation services can be found in section 290 of Chapter 4 of the Medicare Claims Processing Manual.

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. This information is not a guarantee of coverage or reimbursement.

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; E/M, evaluation and management; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code.

Sample UB-04 (CMS 1450) form: Hospital — outpatient status



DESCRIPTION (Field 43):
If NDC reporting is required in this field, enter NDC information for IMDELLTRA®. Check with individual payer to determine the proper format for NDC reporting.
55513-059-01, IMDELLTRA®, 1 mg vial, IV Infusion
55513-077-01, IMDELLTRA®, 10 mg vial, IV Infusion

PRODUCT AND PROCEDURE CODES (Field 44):
Enter the HCPCS code for IMDELLTRA® J9026. Other codes may be appropriate. Check with individual payer for detailed guidance

REVENUE CODES* (Field 42):
Enter the appropriate revenue code for IMDELLTRA®:
Medicare: 0636 (Drugs requiring detailed coding)
Other Payers: 0250 (General pharmacy) or 0636, if required by a given payer
Related Administration Procedure: Enter the appropriate revenue code based on the cost center in which the service is performed

SERVICE UNITS (Field 46):
Report units of service for each HCPCS or CPT code in accordance with the code descriptor

DIAGNOSIS CODES (Field 67 and 67A–Q):
Enter appropriate ICD-10-CM diagnosis code(s) to describe the patient's condition. Example: C34 Malignant neoplasm of bronchus and lung. C34 requires additional character(s); please see page 14 for a list of potentially applicable ICD-10-CM codes in the C34 series

*This is not an all-inclusive list of revenue codes; revenue codes will vary by institution. Revenue codes are only required on the CMS-1450.

This sample form is intended as a reference for coding and billing for products 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.

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous; NDC, National Drug Code; UB, uniform billing.

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Physician's office/non-hospital infusion clinic

Multiple payers (Medicare and non-Medicare)

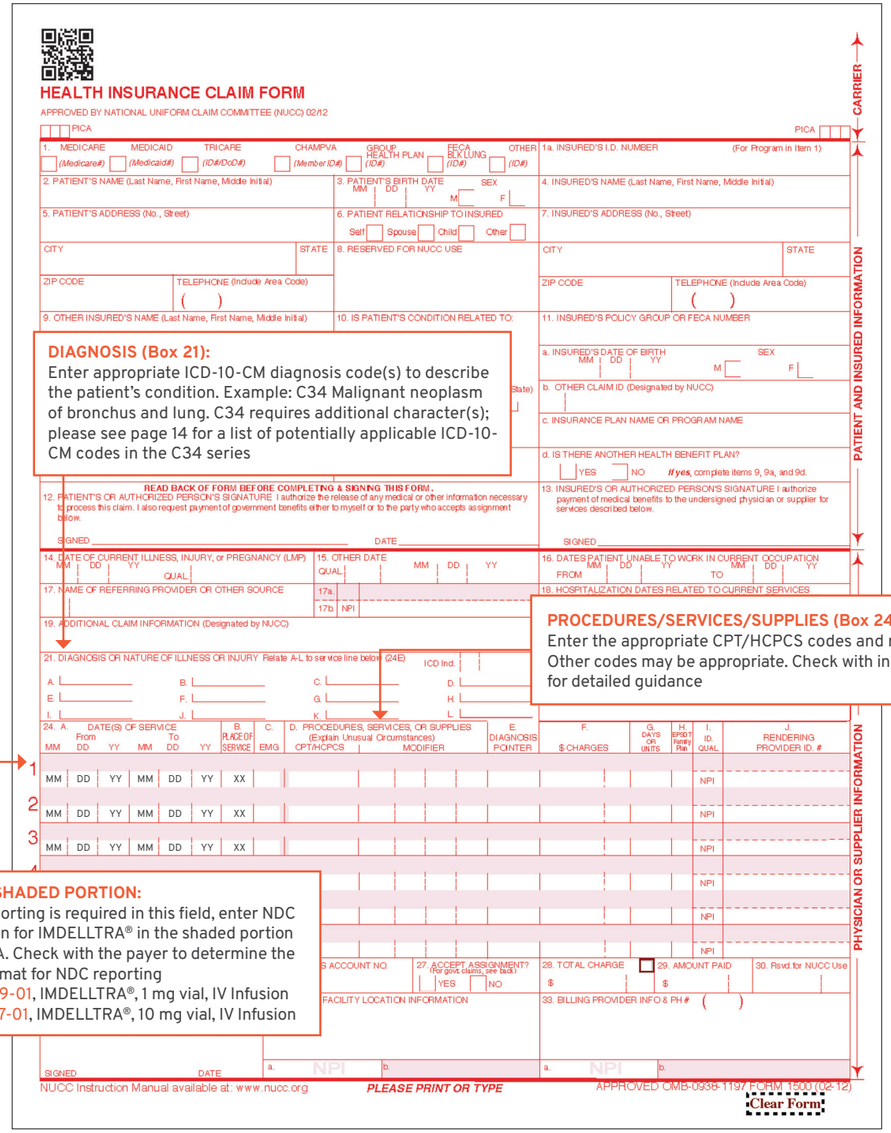
Item	Coding Information (HCPCS, CPT, ICD-10-CM, NDC)	Notes
Diagnosis/ condition	Appropriate ICD-10-CM code(s) for patient condition Example: C34: Malignant neoplasm of bronchus and lung	Examples of ICD-10-CM codes: C34.0–C34.9: Malignant neoplasm of the bronchus and lung. Please see page 14 for a list of ICD-10-CM codes in the C34 series. Include any additional metastasis codes C39.0: Malignant neoplasm of upper respiratory tract, part unspecified C39.9: Malignant neoplasm of lower respiratory tract, part unspecified
IMDELLTRA®	**J9026:** Injection, tarlatamab-dlle, 1 mg (effective January 1, 2025) **JZ:** Zero drug amount discarded/not administered to any patient **JW:** Drug amount discarded/not administered to any patient **NDC:** 55513-059-01, IMDELLTRA® 1 mg vial **NDC:** 55513-077-01, IMDELLTRA® 10 mg vial	For dates of service on or after January 1, 2025, IMDELLTRA® must be reported with J-code J9026, which has a billing unit of 1 mg* Under Medicare's discarded drug policy, claims for drugs from single-dose containers require use of the JZ modifier (Zero drug amount discarded/not administered to any patient) or JW modifier (Drug amount discarded/not administered to any patient). Discarded drug reporting policies for payers other than Medicare may vary Some payers may require NDC reporting. When reporting the NDC on claims, use the 11-digit NDC in the 5-4-2 format
Procedure: Administration	**96413:** Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug **96417:** Chemotherapy administration, IV infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour. Must be listed separately in addition to code for primary procedure	The CPT code for the IMDELLTRA® administration procedure should reflect the actual service performed

*For dates of service prior to January 1, 2025, physician offices should report IMDELLTRA® using an unclassified J-code (eg, J9999, J3590, or J3490).

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. This information is not a guarantee of coverage or reimbursement.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous; NDC, National Drug Code.

Sample CMS-1500 form: Physician office — multiple payers (Medicare and non-Medicare)



This sample form is intended as a reference for coding and billing for products 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.

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code; IV, intravenous..

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Additional billing codes

Current Procedural Terminology

Procedure

Code	Description
96413	Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug
96417	Chemotherapy administration, IV infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour. Must be listed separately in addition to code for primary procedure

Observation: Hospital

Category	CPT Code	Description
Initial inpatient or observation care	99221	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and **straightforward or low level of medical decision-making**. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded
	99222	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and **moderate level of medical decision-making**. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded
	99223	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and **high level of medical decision-making**. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded
Subsequent inpatient or observation care	99231	Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and **straightforward or low level of medical decision-making**. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded
	99232	Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and **moderate level of medical decision-making**. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded
	99233	Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and **high level of medical decision-making**. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded

CPT, Current Procedural Terminology; IV, intravenous.

Observation: Hospital (cont'd)

Category	CPT Code	Description
Inpatient or observation care (same day admission and discharge)	99234	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and **straightforward or low level of medical decision-making**. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded
	99235	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and **moderate level of medical decision-making**. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded
	99236	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and **high level of medical decision-making**. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded
Inpatient or observation discharge day management	99238	Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter
	99239	Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter
Each additional 15 minutes	99418	Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time (List separately in addition to the code of the inpatient and observation Evaluation and Management service)

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. This information is not a guarantee of coverage or reimbursement.

CPT, Current Procedural Terminology; IV, intravenous.

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Additional billing codes (cont'd)

Diagnosis codes

ICD-10-CM

Code	Description
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C39.0	Malignant neoplasm of upper respiratory tract, part unspecified
C39.9	Malignant neoplasm of lower respiratory tract, part unspecified

The ICD-10-CM diagnosis codes listed above are provided only as examples of potentially relevant codes. Providers should consult a current ICD-10-CM manual and always select the most appropriate diagnosis code(s) with the highest level of specificity to describe a patient's actual condition.

ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

Other codes

Place of service codes

Code	Location	Description
11	**Office**	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the healthcare professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis
19	**Off campus:** outpatient hospital	A portion of an off-campus hospital provider–based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
21	**Inpatient hospital**	A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions
22	**On campus:** outpatient hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization

Revenue codes

Code	Description
0258	IV solutions (pharmacy series 25x)
0263	IV therapy/drug/supply delivery (IV therapy 26x)
0636	Drugs requiring detailed coding (drugs requiring specific identification series 63x)

IMDELLTRA® is indicated for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

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. This information is not a guarantee of coverage or reimbursement.

IV, intravenous.

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Benefits verification

Prior to initiating therapy, check your patient's insurance coverage, requirements, and available options.

Amgen® SupportPlus can assist with benefits investigations and check your patient's plan coverage details. To get started, download the Insurance Verification form.

Visit **AmgenSupportPlus.com** to learn more.

Checklists

Prior authorization (PA)

Information for navigating IMDELLTRA® health plan PA requirements*

When submitting a PA, consider the following steps:

☐ **Fill out the PA form completely, being sure to include:**

- Patient information and date of birth
- Patient insurance information, including member ID and policy number (certain payers may request a photocopy of the insurance card)
- Provider and facility information
- Provider NPI and Tax ID number
- Date of service
- Clinical diagnosis with appropriate ICD-10-CM and relevant procedure codes
- Product NDC:[14]
  - NDC: 55513-059-01, IMDELLTRA® 1 mg vial
  - NDC: 55513-077-01, IMDELLTRA® 10 mg vial
- Setting of care

☐ **Some payers may require:**

- Patient-specific notes detailing relevant clinical diagnosis
- Previously given treatments/therapies, including chemotherapy, and initial diagnosis
- Letter of Medical Necessity
- IMDELLTRA® Prescribing Information

☐ **Sign all necessary forms**

☐ **Check to ensure the applicable PA form is completed correctly and all required documentation is included with the submission**

☐ **PA requirements vary by health plan. Verify with the health plan to ensure all information and documentation was received and is clear for a timely review**

☐ **Prior to the PA submission, document dates and methods of correspondence (phone, email, and written), including names of insurance contacts and reviewers with whom you speak**

Appeals

If your patient is denied a claim or PA, use this checklist as a guide for the appeals process.

1. Understand why the PA was rejected

☐ Review the denial to determine reason for rejection

- If the denial was for **clerical reasons**, resubmit the request with the proper information
- If the denial was for **clinical reasons**, determine what additional information is required to demonstrate medical necessity
- If the denial was because **a payer coverage policy is not in place**, you can contact the payer to ask whether a medical exception might be granted and what criteria will be required (eg, no out-of-network benefits provided but the only experienced provider is out of network)

2. Complete the appeal form

☐ Use the appeal form recommended by the health plan

☐ Make sure you complete and submit the form within the required time period

3. Write the appeal letter

☐ Utilize an example appeal letter template. Samples can be found on AmgenSupportPlus.com

☐ Customize the sample letter of appeal based on the reason for rejection

4. Gather supporting documentation

☐ Possible documentation may include:

- Date of initial diagnosis
- Previous therapies and response
- Any relevant comorbidities
- History prior to your care, if applicable
- Supporting literature and peer-reviewed journal articles
- Applicable guidelines
- Chart notes
- IMDELLTRA® Prescribing Information

5. Submit and follow up

☐ Some plans may require the provider and/or patient signature on the appeal letter

☐ Confirm all appropriate documentation has been provided and is accurate and complete

- Some plans may provide multiple appeals. You can also request a "peer-to-peer" review

If no decision is received within a timely manner:

Follow up with the health plan. Confirm that the appeal letter was received and ask about its status. If the coverage denial is upheld, you will need to contact the payer directly to determine next steps. You can ask for a Peer-to-Peer Medical Review with the payer to discuss the denial.

*Specific plan requirements may vary.

ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code; NPI, National Provider Identifier.

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Coordination of care considerations

To enable timely discharge when transitioning patients between different sites of care, it is important to consider the following:

Before treatment

Collaborate with key stakeholders across a multidisciplinary team to appropriately support your patient between care sites:

- **Evaluate patient benefits and determine coverage for available care options**
- **This may require a prior authorization detailing initial and ongoing clinical care**

- **Upon approval of prior authorization, confirm where your patient will continue IMDELLTRA® following initial infusions (hospital/outpatient or physician's office/non-hospital infusion clinic)**
- Review coverage determination information with the patient to confirm they understand additional costs associated with treatment initiation and transition to an outpatient facility
- Amgen® SupportPlus is available to assist with issues around patient coverage, prior authorizations, co-pay programs, and more

Before discharge

- Before discharge, coordinate follow-up care with the hospital/outpatient or physician's office/non-hospital infusion clinic to schedule the patient's next treatment
- Amgen SupportPlus provides access support and helpful resources across Amgen therapies

Upon completion of infusion and observation:

- On Day 1 and Day 8 of Cycle 1, recommend patients remain within 1 hour of an appropriate healthcare setting for a total of 48 hours from the start of the IMDELLTRA® infusion, accompanied by a caregiver[1]
- Provide the patient and caregiver with the appropriate contact information for questions regarding potential adverse events

Continuing care

- Confirm the follow-up site of care (hospital/outpatient or physician's office/non-hospital infusion clinic) has received insurance authorization or reauthorization for treatment with IMDELLTRA® before scheduling Cycle 1 Day 15 (or subsequent) infusions

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Product information

1 mg package
(NDC 55513-059-01)[2]

- One single-dose 1 mg vial of IMDELLTRA® (NDC 55513-103-01)[1,14]
- **Two 7 mL vials of IV Solution Stabilizer (IVSS)** (NDC 55513-068-01)[1,14]

10 mg package
(NDC 55513-077-01)[2]

- One single-dose 10 mg vial of IMDELLTRA® (NDC 55513-069-01)[1,14]
- **Two 7 mL vials of IV Solution Stabilizer (IVSS)** (NDC 55513-068-01)[1,14]

Package NDC[1]	Strength[1]	IMDELLTRA® for injection is a sterile, preservative free, white to slightly yellow, lyophilized powder in a single-dose vial supplied in package as follows:[1]
55513-059-01	1 mg	• One single-dose 1 mg vial of IMDELLTRA® (NDC 55513-103-01)[1,14] • Two 7 mL vials of IVSS (NDC 55513-068-01)[1,14]
55513-077-01	10 mg	• One single-dose 10 mg vial of IMDELLTRA® (NDC 55513-069-01)[1,14] • Two 7 mL vials of IVSS (NDC 55513-068-01)[1,14]

Do not use IVSS for reconstitution of IMDELLTRA®. The IVSS is used to coat the IV bag prior to addition of reconstituted IMDELLTRA® to prevent adsorption of IMDELLTRA® to IV bags and IV tubing.[1]

Product expiration/ shelf life

The expiration date is printed on each dispensing pack and vial label.

Storage and handling of IMDELLTRA® and IVSS vials

- Store IMDELLTRA® and IVSS vials refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. Do not freeze[1]
- IMDELLTRA® and IVSS vials may be kept at room temperature between 20°C to 25°C (68°F to 77°F) for up to 24 hours in the original carton to protect from light[1]

Product returns

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at **1-800-28-AMGEN** (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

Supplied and marketed by Amgen Inc. (1-800-282-6436) www.amgen.com

IMDELLTRA® specialty distribution

Specialty Distributor	Phone Number	Website
ASD Healthcare	800-746-6273	www.asdhealthcare.com
Oncology Supply	800-633-7555	www.oncologysupply.com
Cardinal Health SPD–Hospital & SP's	855-855-0708	www.cardinalhealth.com
Cardinal Health SPD–Clinics	877-453-3972	www.cardinalhealth.com
Cardinal Health Puerto Rico 120, Inc.	787-625-4100	www.cardinalhealth.pr
McKesson Plasma and Biologics	877-625-2566	connect.mckesson.com
McKesson Specialty Care Distribution	855-477-9800	mscs.mckesson.com/CustomerCenter
CuraScript Specialty Distribution	877-599-7748	www.curascript.com
BioCareSD	800-304-3064	biocare-us.com

For questions on coverage, co-pay assistance, and reimbursement:

Amgen SupportPlus: 1-866-264-2778 or AmgenSupportPlus.com

IV, intravenous; NDC, National Drug Code; SP, specialty pharmacy; SPD, specialty pharmaceutical distribution.

IMDELLTRA® (tarlatamab-dlle) for injection 1 mg & 10 mg single-use vials

AMGEN® Support+

We're right here, right when you need us

Personalized support that you and your patients can count on across Amgen therapies

HCP Support Center

Our Amgen SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

Benefits Verification

- Verify patient's insurance plan coverage details

Prior Authorization Requirements

- Provide payer-specific prior authorization forms

Amgen SupportPlus Customer Portal

- A tool for managing patient benefits verification and more
- Submit, store, and retrieve benefit verifications electronically

Visit **myAmgenPortal.com** to register and submit forms online.

Amgen® Patient Navigator

A single point of contact to help answer questions about access and reimbursement, navigating treatment logistics, and to provide supplemental resources as your patients transition from hospital to outpatient care.

Amgen Patient Navigators can help with:

- Benefits verification and understanding coverage
- Prior authorization process
- Reimbursement and access resources

The Amgen Patient Navigator is not part of a patient's treatment team and does not provide medical advice or case management services. The Amgen Patient Navigator does not administer Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

HCP, healthcare professional.

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

Financial Support

We know every patient has unique needs. And we're here to provide financial support information and resources, regardless of their current financial situation or what type of insurance they have.

What if my patient doesn't have private or commercial insurance? Amgen SupportPlus can provide your patients with information about independent nonprofit foundations that may be able to help.*

Learn more about how Amgen SupportPlus can help your patients access their prescribed medication. Visit **AmgenSupportPlus.com** to learn more.

*Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

Amgen Therapy Locator™

AMGEN THERAPY LOCATOR™

Use this searchable database to locate alternative injection sites where IMDELLTRA® can be administered to your patients.†

Visit Amgen Therapy Locator™ at **AmgenTherapyLocator.com**

†The information on this website is self-reported by independent third-party sites that administer treatment to patients or dispense product. It is not a comprehensive list of all sites that provide the therapies listed, and Amgen does not confirm the accuracy or otherwise endorse any of the sites on this list, which is subject to change. The information provided is not a guarantee of coverage, reimbursement, or availability of a product.

Note: 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. This information is not a guarantee of coverage or reimbursement.

Call **Amgen SupportPlus** at **(866) 264-2778**, Monday–Friday 9:00 AM–8:00 PM ET.
Visit **AmgenSupportPlus.com** to learn how Amgen can help.

References: 1. IMDELLTRA® (tarlatamab-dlle) prescribing information, Amgen. **2.** CMS. Drug coverage under different parts of Medicare. https://cmsnationaltrainingprogram.cms.gov/sites/default/files/shared/11315-P%20Drug-Coverage-Parts-Medicare.pdf. Accessed November 4, 2024. **3.** Danzon PM. Pricing and reimbursement of biopharmaceuticals and medical devices in the USA. *Encyclopedia of Health Economics*. 2014;3:127-135. **4.** CMS. Outlier payments. https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/outlier-payments. Accessed November 4, 2024. **5.** GAO. Payment methods for certain cancers should be revised to promote efficiency. https://www.gao.gov/assets/gao-15-199.pdf. Accessed November 4, 2024. **6.** Iowa State Government. IAC Ch 78. https://www.legis.iowa.gov/docs/iac/rule/441.78.3.pdf. Accessed November 4, 2024. **7.** MACPAC. State Medicaid payment policies for inpatient hospital services. https://www.macpac.gov/publication/macpac-inpatient-hospitalpayment-landscapes/. Accessed November 4, 2024. **8.** KFF. Comparing private payer and Medicare payment rates for select inpatient hospital services. https://www.kff.org/report-section/comparing-private-payer-and-medicare-payment-rates-for-select-inpatient-hospital-services-methods/. Accessed November 4, 2024. **9.** Congressional Budget Office. The prices that commercial health insurers and Medicare pay for hospitals' and physicians' services. https://www.cbo.gov/system/files/2022-01/57422-medical-prices.pdf. Accessed November 4, 2024. **10.** CMS. October 2024 Update of the Hospital Outpatient Prospective Payment System (OPPS). https://www.cms.gov/files/document/r12816cp.pdf. Accessed November 4, 2024. **11.** CMS. Hospital Outpatient Prospective Payment System (OPPS). https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/opps#:~:text=The. Accessed November 4, 2024. **12.** Congressional Research Service. Medicare and budget sequestration. https://crsreports.congress.gov/product/pdf/R/R45106. Accessed November 4, 2024. **13.** Johnson D. How pharmacy reimbursement methods have evolved. Washington Healthcare News. http://www.wahcnews.com/newsletters/wa-djohnson1110.pdf. Accessed November 4, 2024. **14.** Data on file, Amgen; 2024.

IMDELLTRA® (tarlatamab-dlle) for injection 1 mg & 10 mg single-use vials

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving IMDELLTRA®. Initiate treatment with IMDELLTRA® using the step-up dosing schedule to reduce the incidence and severity of CRS. Withhold IMDELLTRA® until CRS resolves or permanently discontinue based on severity.**
- **Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including serious or life-threatening reactions, can occur in patients receiving IMDELLTRA®. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment and treat promptly. Withhold IMDELLTRA® until ICANS resolves or permanently discontinue based on severity.**

WARNINGS AND PRECAUTIONS

- **Cytokine Release Syndrome (CRS):** IMDELLTRA® can cause CRS including serious or life-threatening reactions. In the pooled safety population, CRS occurred in 55% of patients who received IMDELLTRA®, including 34% Grade 1, 19% Grade 2, 1.1% Grade 3 and 0.5% Grade 4. Recurrent CRS occurred in 24% of patients, including 18% Grade 1 and 6% Grade 2.

  Most events (43%) of CRS occurred after the first dose, with 29% of patients experiencing any grade CRS after the second dose and 9% of patients experiencing CRS following the third dose or later. Following the Day 1, Day 8, and Day 15 infusions, 16%, 4.3% and 2.1% of patients experienced ≥ Grade 2 CRS, respectively. The median time to onset of all grade CRS from most recent dose of IMDELLTRA® was 13.5 hours (range: 1 to 268 hours). The median time to onset of ≥ Grade 2 CRS from most recent dose of IMDELLTRA® was 14.6 hours (range: 2 to 566 hours).

  Clinical signs and symptoms of CRS included pyrexia, hypotension, fatigue, tachycardia, headache, hypoxia, nausea, and vomiting. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

  Administer IMDELLTRA® following the recommended step-up dosing and administer concomitant medications before and after Cycle 1 IMDELLTRA® infusions as described in Table 3 of the Prescribing Information (PI) to reduce the risk of CRS. Administer IMDELLTRA® in an appropriate health care facility equipped to monitor and manage CRS. Ensure patients are well hydrated prior to administration of IMDELLTRA®.

  Closely monitor patients for signs and symptoms of CRS during treatment with IMDELLTRA®. At the first sign of CRS, immediately discontinue IMDELLTRA® infusion, evaluate the patient for hospitalization and institute supportive care based on severity. Withhold or permanently discontinue IMDELLTRA® based on severity. Counsel patients to seek medical attention should signs or symptoms of CRS occur.
- **Neurologic Toxicity, Including ICANS:** IMDELLTRA® can cause serious or life-threatening neurologic toxicity, including ICANS. In the pooled safety population, neurologic toxicity, including ICANS, occurred in 47% of patients who received IMDELLTRA®, including 10% Grade 3. The most frequent neurologic toxicities were headache (14%), peripheral neuropathy (7%), dizziness (7%), insomnia (6%), muscular weakness (3.7%), delirium (2.1%), syncope (1.6%), and neurotoxicity (1.1%).

  ICANS occurred in 9% of IMDELLTRA®-treated patients. Recurrent ICANS occurred in 1.6% of patients. Most patients experienced ICANS following Cycle 2 Day 1 (24%). Following Day 1, Day 8, and Day 15 infusions, 0.5%, 0.5% and 3.7% of patients experienced ≥ Grade 2 ICANS, respectively. The median time to onset of ICANS from the first dose of IMDELLTRA® was 29.5 days (range: 1 to 154 days). ICANS can occur several weeks following administration of IMDELLTRA®. The median time to resolution of ICANS was 33 days (range: 1 to 93 days).

  The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

  Patients receiving IMDELLTRA® are at risk of neurologic adverse reactions and ICANS resulting in depressed level of consciousness. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, in the event of any neurologic symptoms until they resolve.

  Closely monitor patients for signs and symptoms of neurologic toxicity and ICANS during treatment. At the first sign of ICANS, immediately evaluate the patient and provide supportive therapy based on severity. Withhold IMDELLTRA® or permanently discontinue based on severity.
- **Cytopenias:** IMDELLTRA® can cause cytopenias including neutropenia, thrombocytopenia, and anemia. In the pooled safety population, decreased neutrophils occurred in 12% including 6% Grade 3 or 4 of IMDELLTRA®-treated patients. The median time to onset for Grade 3 or 4 neutropenia was 29.5 days (range: 2 to 213). Decreased platelets occurred in 33% including 3.2% Grade 3 or 4. The median time to onset for Grade 3 or 4 decreased platelets was 50 days (range: 3 to 420). Decreased hemoglobin occurred in 58% including 5% Grade 3 or 4. Febrile neutropenia occurred in 0.5% of patients treated with IMDELLTRA®.

  Monitor patients for signs and symptoms of cytopenias. Perform complete blood counts prior to treatment with IMDELLTRA®, before each dose, and as clinically indicated. Based on the severity of cytopenias, temporarily withhold, or permanently discontinue IMDELLTRA®.
- **Infections:** IMDELLTRA® can cause serious infections, including life-threatening and fatal infections.

  In the pooled safety population, infections, including opportunistic infections, occurred in 41% of patients who received IMDELLTRA®. Grade 3 or 4 infections occurred in 13% of patients. The most frequent infections were COVID-19 (9%, majority during the COVID-19 pandemic), urinary tract infection (10%), pneumonia (9%), respiratory tract infection (3.2%), and candida infection (3.2%).

  Monitor patients for signs and symptoms of infection prior to and during treatment with IMDELLTRA® and treat as clinically indicated. Withhold or permanently discontinue IMDELLTRA® based on severity.
- **Hepatotoxicity:** IMDELLTRA® can cause hepatotoxicity. In the pooled safety population, elevated ALT occurred in 42%, with Grade 3 or 4 ALT elevation occurring in 2.1%. Elevated AST occurred in 44% of patients, with Grade 3 or 4 AST elevation occurring in 3.2%. Elevated bilirubin occurred in 15% of patients; Grade 3 or 4 total bilirubin elevations occurred in 1.6% of patients. Liver enzyme elevation can occur with or without concurrent CRS. Monitor liver enzymes and bilirubin prior to treatment with IMDELLTRA®, before each dose, and as clinically indicated. Withhold IMDELLTRA® or permanently discontinue based on severity.
- **Hypersensitivity:** IMDELLTRA® can cause severe hypersensitivity reactions. Clinical signs and symptoms of hypersensitivity may include, but are not limited to, rash and bronchospasm. Monitor patients for signs and symptoms of hypersensitivity during treatment with IMDELLTRA® and manage as clinically indicated. Withhold or consider permanent discontinuation of IMDELLTRA® based on severity.
- **Embryo-Fetal Toxicity:** Based on its mechanism of action, IMDELLTRA® may cause fetal harm when administered to a pregnant woman. Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IMDELLTRA® and for 2 months after the last dose.

ADVERSE REACTIONS

- The most common (> 20%) adverse reactions were CRS (55%), fatigue (51%), pyrexia (36%), dysgeusia (36%), decreased appetite (34%), musculoskeletal pain (30%), constipation (30%), anemia (27%), and nausea (22%). The most common (≥ 2%) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes (57%), decreased sodium (16%), increased uric acid (10%), decreased total neutrophils (6%), decreased hemoglobin (5%), increased activated partial thromboplastin time (5%), decreased potassium (5%), increased aspartate aminotransferase (3.2%), decreased white blood cells (3.8%), decreased platelets (3.2%), and increased alanine aminotransferase (2.1%).
- Serious adverse reactions occurred in 58% of patients. Serious adverse reactions in > 3% of patients included CRS (24%), pneumonia (6%), pyrexia (3.7%), and hyponatremia (3.6%). Fatal adverse reactions occurred in 2.7% of patients including pneumonia (0.5%), aspiration (0.5%), pulmonary embolism (0.5%), respiratory acidosis (0.5%), and respiratory failure (0.5%).

DOSAGE AND ADMINISTRATION: Important Dosing Information

- Administer IMDELLTRA® as an intravenous infusion over one hour.
- Administer IMDELLTRA® according to the step-up dosing schedule in the IMDELLTRA® PI (Table 1) to reduce the incidence and severity of CRS.
- For Cycle 1, administer recommended concomitant medications before and after Cycle 1 IMDELLTRA® infusions to reduce the risk of CRS reactions as described in the PI (Table 3).
- IMDELLTRA® should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity including ICANS.
- Due to the risk of CRS and neurologic toxicity, including ICANS, monitor patients from the start of the IMDELLTRA® infusion for 22 to 24 hours on Cycle 1 Day 1 and Cycle 1 Day 8 in an appropriate healthcare setting.
- Recommend that patients remain within 1 hour of an appropriate healthcare setting for a total of 48 hours from start of the infusion with IMDELLTRA® following Cycle 1 Day 1 and Cycle 1 Day 8 doses, accompanied by a caregiver.
- Prior to administration of IMDELLTRA®, evaluate complete blood count, liver enzymes, and bilirubin before each dose, and as clinically indicated.
- Ensure patients are well hydrated prior to administration of IMDELLTRA®.

Please see IMDELLTRA® full Prescribing Information, including BOXED WARNINGS.

IMDELLTRA® (tarlatamab-dlle) for injection 1 mg & 10 mg single-use vials

AMGEN Support+

We're right here, right when you need us

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- Verify patient's insurance plan coverage details

Prior Authorization Requirements
- Provide payer-specific prior authorization forms

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- A tool for managing patient benefits verification and more
- Submit, store, and retrieve benefit verifications electronically

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A single point of contact to help answer questions about access and reimbursement, navigating treatment logistics, and to provide supplemental resources as your patients transition from hospital to outpatient care.

Amgen Patient Navigators can help with:
- Benefits verification and understanding coverage
- Prior authorization process
- Reimbursement and access resources

The Amgen Patient Navigator is not part of a patient's treatment team and does not provide medical advice or case management services. The Amgen Patient Navigator does not administer Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

AMGEN Support+ | **Co-Pay Program**

Helping eligible patients save on out-of-pocket costs

The Amgen SupportPlus Co-Pay Program may help eligible patients with private or commercial insurance lower their out-of-pocket costs.
- Pay as little as $0* out-of-pocket for each dose
- Can be applied to deductible, co-insurance, and co-payment*
- No income eligibility requirement

Encourage your patients with private or commercial insurance to check eligibility and enroll.

*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

What if my patient doesn't have private or commercial insurance?

Amgen SupportPlus can provide your patients with information about independent nonprofit foundations that may be able to help.†

†Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

Call **Amgen SupportPlus** at **(866) 264-2778**, Monday–Friday 9:00 AM–8:00 PM ET.
Visit **AmgenSupportPlus.com** to learn how Amgen can help.

Visit IMDELLTRAhcp.com to learn more

HCP, healthcare professional.

Please see additional Important Safety Information, including BOXED WARNINGS, on pages 22–23.

AMGEN

IMDELLTRA® (tarlatamab-dlle) for injection 1 mg & 10 mg single-use vials