Effective October 1, 2025

IMDELLTRA® has been granted New Technology Add-On Payment (NTAP)

What is a New Technology Add-on Payment (NTAP)?[1,2]

Effective October 1, 2025, hospitals may be eligible for additional separate payment when IMDELLTRA® is administered to Medicare beneficiaries on an inpatient basis. This additional payment is called the New Technology Add-on Payment or NTAP. NTAP supports Medicare beneficiary access to certain new and innovative medical technologies, drugs, or devices that are used in an inpatient setting. NTAP generally allows for an additional payment of up to 65% of the cost of a new technology and is applied only if the cost of a given inpatient case, as reported by the hospital on the claim, exceeds the MS-DRG payment under the IPPS for that case.

CMS granted IMDELLTRA® NTAP status for FY 2026 October 1, 2025 – September 30, 2026. The maximum NTAP amount for IMDELLTRA® in FY 2026 is $7,117.50.

The actual amount a hospital may receive for a given IMDELLTRA® administration will vary based on the applicable MS-DRG for the patient and the reported costs for the case.

Specific ICD-10-PCS codes must be included on Medicare inpatient claim forms to receive the NTAP payment for IMDELLTRA®.

Summary of New Technology Add-on Payment for IMDELLTRA®[1,2]	
ICD-10-PCS	**XW033NA:** Introduction of tarlatamab-dlle antineoplastic into peripheral vein, percutaneous approach, new technology group 10
	XW043NA: Introduction of tarlatamab-dlle antineoplastic into central vein, percutaneous approach, new technology group 10
Eligible Facilities	Inpatient settings at acute care hospitals reimbursed under IPPS
Qualified Patients	Medicare beneficiaries only. Those for whom the cost of an inpatient stay involving the use of IMDELLTRA® exceeds the applicable MS-DRG payment
Maximum Add-on Payment	The maximum NTAP amount for a case involving IMDELLTRA® is $7,117.50 for FY 2026. The actual payment will vary based on the costs reported and may be less than the maximum NTAP amount
Effective Dates	IMDELLTRA®'s NTAP is effective from **October 1, 2025 – September 30, 2026 with the potential for CMS to grant a second year of NTAP the following fiscal year** Claims prior to October 1, 2025 **do not** qualify for NTAP

Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage, reimbursement parameters, and appropriate coding for his/her own patients and procedures. This information does not guarantee 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.

CMS, Centers for Medicare & Medicaid Service; FY, Fiscal Year; ICD-10-PCS, International Classification of Diseases, 10th Revision, Procedure Coding System; IPPS, Inpatient Prospective Payment System; MS-DRG, Medicare Severity Diagnosis Related Group.

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, throughout.

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

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 accompanying IMDELLTRA® full Prescribing Information, including BOXED WARNINGS.

References: 1. Centers for Medicare & Medicaid Services. New Medical Services and New Technologies. https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies. Accessed July 31, 2025. **2.** Centers for Medicare & Medicaid Services. Final Rule. https://public-inspection.federalregister.gov/2025-14681.pdf. Accessed August 5, 2025.

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