

# Imdelltra™ (tarlatamab-dlle) (Intravenous)

**-E-**

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## I. Length of Authorization <sup>1</sup>

Coverage will be provided for 6 months and may be renewed.

## II. Dosing Limits

**Max Units (per dose and over time) [HCPCS Unit]:**

- Cycle 1:
  - 1 billable unit on day 1
  - 10 billable units on day 8 and 15 in a 28-day cycle
- Cycle 2 and subsequent:
  - 20 billable units every 28 days

## III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

### Universal Criteria

- Patient will be closely monitored for signs and symptoms of Cytokine release syndrome (CRS), neurologic toxicity and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) during treatment; **AND**
- Patient does not have a clinically significant active systemic infection; **AND**
- Patient does not have untreated or symptomatic brain metastases or leptomeningeal disease; **AND**

### Small Cell Lung Cancer (SCLC) † Φ <sup>1-4</sup>

- Patient has extensive stage disease (ES-SCLC); **AND**
- Used as subsequent therapy following disease progression on or after platinum-based chemotherapy AND at least one other line of prior therapy

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

#### IV. Renewal Criteria <sup>1</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe cytopenias, severe infections, severe hepatotoxicity, severe hypersensitivity, etc.

#### V. Dosage/Administration <sup>1</sup>

Indication	Dose			
SCLC	Administer as an intravenous infusion according to the below schedule. After step-up dosing, administer biweekly (every 2 weeks) until disease progression or unacceptable toxicity:			
	Dosing Schedule (28-day cycles)	Day	Dose	Recommended Monitoring
	Cycle 1	Day 1 (Step-up)	1 mg	Monitor from the start of the infusion for 22-24 hours 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, accompanied by a caregiver.
		Day 8	10 mg	
		Day 15	10 mg	Observe patients for 6-8 hours post infusion.
	Cycle 2	Days 1 & 15	10 mg	Observe patients for 6-8 hours post infusion.
	Cycles 3 & 4	Days 1 & 15	10 mg	Observe patients for 3-4 hours post infusion.
	Cycle 5 and subsequent infusions	Days 1 & 15	10 mg	Observe patients for 2 hours post infusion.
<ul style="list-style-type: none"> <li>• Administer Imdelltra according to the step-up dosing schedule to reduce the incidence and severity of cytokine release syndrome (CRS).</li> <li>• 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 immune effector cell-associated neurotoxicity syndrome (ICANS).</li> </ul>				

## VI. Billing Code/Availability Information

### HCPCS Code:

- J9026 – Injection, tarlatamab-dlle, 1 mg; 1 billable unit = 1 mg

### NDC(s):

- Imdelltra 1 mg powder for injection single-dose vial: 55513-0059-xx
- Imdelltra 10 mg powder for injection single-dose vial: 55513-0077-xx

## VII. References (STANDARD)

1. Imdelltra [package insert]. Thousand Oaks, CA; Amgen, Inc; May 2024. Accessed March 2025.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) tarlatamab. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2025.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Small Cell Lung Cancer. Version 4.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2025.
4. Ahn MJ, Cho BC, Felip E, et al; DeLLphi-301 Investigators. Tarlatamab for Patients with Previously Treated Small-Cell Lung Cancer. N Engl J Med. 2023 Nov 30;389(22):2063-2075. doi: 10.1056/NEJMoa2307980. Epub 2023 Oct 20.

## VIII. References (ENHANCED)

- 1e. Trigo J, Subbiah V, Besse B, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. Lancet Oncol. 2020 May;21(5):645-654. doi: 10.1016/S1470-2045(20)30068-1. Epub 2020 Mar 27.
- 2e. von Pawel J, Schiller JH, Shepherd FA, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. J Clin Oncol. 1999 Feb;17(2):658-67.
- 3e. O'Brien ME, Ciuleanu TE, Tsekov H, et al. Phase III trial comparing supportive care alone with supportive care with oral topotecan in patients with relapsed small-cell lung cancer. J Clin Oncol. 2006 Dec 1;24(34):5441-7.

- 4e. Eckardt JR, von Pawel J, Pujol JL, et al. Phase III study of oral compared with intravenous topotecan as second-line therapy in small-cell lung cancer. J Clin Oncol. 2007 May 20;25(15):2086-92.
- 5e. Edelman MJ, Dvorkin M, Laktionov K, et al. Randomized phase 3 study of the anti-disialoganglioside antibody dinutuximab and irinotecan vs irinotecan or topotecan for second-line treatment of small cell lung cancer. Lung Cancer. 2022;166:135-142
- 6e. Baize N, Monnet I, Greillier L, et al. Carboplatin plus etoposide versus topotecan as second-line treatment for patients with sensitive relapsed small-cell lung cancer: an open-label, multicentre, randomised, phase 3 trial. Lancet Oncol 2020;21:1224-1233.
- 7e. Naito Y, Yamada K, Imamura Y, et al. Rechallenge treatment with a platinum-based regimen in patients with sensitive relapsed small-cell lung cancer. Med Oncol 2018;35:61.
- 8e. Genestreti G, Tiseo M, Kenmotsu H, et al. Outcomes of platinum-sensitive small-cell lung cancer patients treated with platinum/etoposide rechallenge: a multi-institutional retrospective analysis. Clin Lung Cancer 2015;16:e223-e228
- 9e. Prime Therapeutics Management. Imdelltra Clinical Literature Review Analysis. Last updated March 2025. Accessed March 2025.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
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
C7A.1	Malignant poorly differentiated neuroendocrine tumors

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC