Imdelltra™ (tarlatamab-dlle)
(Intravenous)

Document Number: IC-0756

Last Review Date: 06/04/2024
Date of Origin: 06/04/2024
Dates Reviewed: 06/2024

I. Length of Authorization [1]

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Imdelltra 1 mg powder for injection single-dose vial: 1 vial on day 1 only
- Imdelltra 10 mg powder for injection single-dose vial: 2 vials every 14 days

B. 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
- Cycle 2 and subsequent:
  - 10 billable units on day 1 and 15

III. Initial Approval Criteria [1]

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 [1-4]

- Patient has extensive stage disease (ES-SCLC); **AND**
- Used as subsequent therapy following disease progression on or after platinum-based chemotherapy

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

IV. Renewal Criteria [1]

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 [1]

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>SCLC</td><td>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:
<table>
<tr><th>Dosing Schedule</th><th>Day</th><th>Dose</th><th>Recommended Monitoring</th></tr>
<tr><td rowspan="3">Cycle 1</td><td>Day 1 (Step-up)</td><td>1 mg</td><td rowspan="2">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.</td></tr>
<tr><td>Day 8</td><td>10 mg</td></tr>
<tr><td>Day 15</td><td>10 mg</td><td>Observe patients for 6-8 hours post infusion.</td></tr>
<tr><td>Cycle 2</td><td>Day 1 & 15</td><td>10 mg</td><td>Observe patients for 6-8 hours post infusion.</td></tr>
<tr><td>Cycles 3 & 4</td><td>Day 1 & 15</td><td>10 mg</td><td>Observe patients for 3-4 hours post infusion.</td></tr>
<tr><td>Cycle 5 and subsequent infusions</td><td>Day 1 & 15</td><td>10 mg</td><td>Observe patients for 2 hours post infusion.</td></tr>
</table>
</td></tr>
<tr><td colspan="2">

Administer Imdelltra according to the step-up dosing schedule to reduce the incidence and severity of cytokine release syndrome (CRS).
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).
Due to the risk of CRS and neurologic toxicity, including ICANS, monitor patients from the start of the 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 following Cycle 1 Day 1 and Cycle 1 Day 8 doses, accompanied by a caregiver.

</td></tr>
</table>

VI. Billing Code/Availability Information

HCPCS Code:

- J9026 – Injection, tarlatamab-dlle, 1 mg; 1 billable unit = 1 mg *(Effective 01/01/2025)*

- J9999 – not otherwise classified, antineoplastic drugs *(Discontinue use on 01/01/2025)*
- C9170 – Injection, tarlatamab-dlle, 1 mg; 1 billable unit = 1 mg *(Discontinue use on 01/01/2025)*

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

1. Imdelltra [package insert]. Thousand Oaks, CA; Amgen, Inc; May 2024. Accessed May 2024.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) tarlatamab. National Comprehensive Cancer Network, 2024. 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 May 2024.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Small Cell Lung Cancer. Version 2.2024. National Comprehensive Cancer Network, 2024. 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 January 2024.
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.

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

ICD-10	ICD-10 Description
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