Clinical Policy: Tarlatamab-dlle (Imdelltra)

Reference Number: PA.CP.PHAR.685
Effective Date: 08/2024
Last Review Date: 07/2025

Description
Tarlatamab-dlle (Imdelltra™) is a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager.

FDA Approved Indication(s)
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).*

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Imdelltra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of extensive stage small cell lung cancer (ES-SCLC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease has progressed on or after receiving platinum based therapy;
5. Request meets one of the following (a or b):
   a. Dose does not exceed (i and ii):
      i. Cycle 1, step-up dose: 1 mg on Day 1, and 10 mg on Day 8 and Day 15;
      ii. Cycle 2 and beyond: 10 mg on Day 1 and Day 15 of each cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Small Cell Lung Cancer (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 10 mg on Days 1 and 15 of each cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DLL3: bispecific delta-like ligand 3
ES-SCLC: extensive stage small cell lung cancer
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Platinum-containing regimens	Examples include: • Carboplatin, etoposide, and atezolizumab • Carboplatin, etoposide, and durvalumab • Cisplatin, etoposide, and durvalumab • Carboplatin and etoposide • Cisplatin and etoposide • Carboplatin and irinotecan	Dose varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	• Cisplatin and irinotecan	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
• Boxed warning: cytokine release syndrome and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ES-SCLC	Step-up dosing schedule cycle 1: Day 1: 1 mg, day 8: 10 mg, day 15: 10mg Cycle 2 and beyond: Day 1 and day 15: 10 mg	10 mg

VI. Product Availability
Single dose vial for reconstitution: 1 mg, 10 mg

VII. References
1. Imdelltra Prescribing Information. Thousand Oaks, CA: Amgen Inc; May 2024. Available at: www.imdelltra.com. Accessed May 6, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 6, 2025.
3. National Comprehensive Cancer Network. Small Cell Lung Cancer Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed May 6, 2025.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9026	Injection, tarlatamab-dlle, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	07/2024

Reviews, Revisions, and Approvals	Date
3Q 2025 annual review: no significant changes; HCPCS code added [J9026] and removed codes [J3590, C9399]; references reviewed and updated.	07/2025