UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Imdelltra Utilization Management Medical Policy
- Imdelltra™ (tarlatamab-dlle intravenous infusion – Amgen)

REVIEW DATE: 05/07/2025

OVERVIEW

Imdelltra, a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager, is indicated for the treatment of **extensive stage small cell lung cancer** (ES-SCLC) with disease progression on or after platinum-based chemotherapy in adults.[1] 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).

Guidelines

The National Comprehensive Cancer Network (NCCN) Small Cell Lung Cancer guidelines (version 4.2025 – January 13, 2025) recommend Imdelltra as a single agent for the subsequent treatment of extensive stage small cell lung cancer with disease progression on or after platinum-based chemotherapy for primary progressive disease or relapse following complete or partial response or stable disease with primary treatment (category 2A).[2,3] Imdelltra is a "Preferred Regimen" if the chemotherapy-free interval (CTFI) is ≤ 6 months and an "Other Recommended Regimen" if the CTFI is > 6.[2,3]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Imdelltra. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Imdelltra as well as the monitoring required for adverse events and long-term efficacy, approval requires Imdelltra to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Imdelltra is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has primary progressive, relapsed, or refractory extensive stage disease; AND
   - **C)** Patient has previously received platinum-based chemotherapy; AND
     Note: Examples of platinum medications include cisplatin and carboplatin.

D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimens (A and B):
A) Step-up dosing (i, ii, and iii):
- **i.** Dose 1: Approve 1 mg given by intravenous infusion on Day 1; AND
- **ii.** Dose 2: Approve 10 mg given by intravenous infusion 7 days after Dose 1; AND
- **iii.** Dose 3: Approve 10 mg given by intravenous infusion 14 days after Dose 1.

B) Approve 10 mg given by intravenous infusion no more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Imdelltra is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Imdelltra intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; May 2024.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 10, 2025. Search term: tarlatamab.
3. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – January 13,, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 10, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	New Policy.	05/22/2024
Selected Revision	**Small Cell Lung Cancer**: Patient is ≥ 18 years of age added as an additional requirement.	06/19/2024
Annual Revision	**Small Cell Lung Cancer:** Added "primary progressive" disease as an option for approval.	05/07/2025