VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Imdelltra Prior Authorization Policy
- Imdelltra™ (tarlatamab-dlle intravenous infusion – Amgen)

REVIEW DATE: 05/22/2024; selected revision 06/19/2024

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 3.2024 – June 11, 2024) 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 prescription benefit coverage of Imdelltra. 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:

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 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)** Imdelltra is prescribed by or in consultation with an oncologist.

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. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 11, 2024. Search term: tarlatamab.
3. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – June 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 11, 2024.

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