# Medical Policy

**Healthcare Services Department**

| Policy Name | Policy Number | Scope |
|---|---|---|
| Tarlatamab-dlle (Imdelltra) | MP-RX-FP-171-25 | ☒ MMM MA ☒ MMM Multihealth |

## Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

## Service Description

This document addresses the use of Tarlatamab-dlle (Imdelltra) , a drug approved by the Food and Drug Administration (FDA) for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) on or after platinum-based chemotherapy.

**Background Information**
Imdelltra was 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.

I**mdelltra has a black box warning regarding cytokine release syndrome (CRS**), including serious or life-threatening reactions, can occur in patients receiving Imdelltra. It is recommended to use step-up dosing in order to reduce the incidence and severity of CRS. The black box warning also contains warnings about neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). It is recommended that individuals with signs or symptoms of neurologic toxicity receive prompt treatment. Imdelltra should be held until ICANS resolves or permanently discontinue based on severity.

**Definitions and Measures**

Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.

Non-small cell lung cancer: A group of lung cancers that are named for the kinds of cells found in the cancer and how the cells look under a microscope. The three main types of non-small cell lung cancer are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma.

Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.

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## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS | Description |
|---|---|
| J9026 | Injection, tarlatamab-dlle, 1 mg [Imdelltra] |

| ICD-10 | Description |
|---|---|
| C33 | Malignant neoplasm of trachea |
| C34.00-C34.92 | Malignant neoplasm of bronchus and lung |

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## Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

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

## Tarlatamab-dlle (Imdelltra)

**A. Criteria For Initial Approval**

i. Individual has a diagnosis of extensive stage small cell lung cancer (ES-SCLC); **AND**
ii. Individual has experienced disease progression on or after platinum-based chemotherapy

**B. Criteria For Continuation of Therapy**

i. MMM considers continuation of **Tarlatamab-dlle (Imdelltra)** therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of an unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:
   a. A current oncology note documenting the patient's response to treatment showing no progression of disease.
   b. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results

**C. Authorization Duration**

a. Initial Approval Duration: 12 months
b. Reauthorization Approval Duration: 12 months

D. **Conditions Not Covered**

*Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):*

i. Requests for **Tarlatamab-dlle (Imdelltra)** may not be approved when the above criteria are not met and for all other indications.

## Limits or Restrictions

A. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

| Dosing schedule | Day | Dose of IMDELLTRA | Recommended Monitoring |
|---|---|---|---|
| Step Dosing Schedule Day 1 | Day 1[a] | Step up dose 1mg | Monitor patients from the start of the IMDELLTRA infusion for 22 to 24 hours on Cycle 1 Day 1 and Cycle 1 Day 8 in an appropriate healthcare setting.<br><br>Recommend that patients remain within 1-hour of an appropriate healthcare setting for a total of 48 hours from start of the infusion with IMDELLTRA, accompanied by a caregiver. |
| | Day 8[a] | 10mg | |
| | Day 15 | 10mg | Observe patients for 6-8 hours post IMDELLTRA infusion. |
| Cycle 2 | Day 1 and 15 | 10mg | Observe patients for 6-8 hours post IMDELLTRA infusion. |
| Cycle 3 and 4 | Day 1 and 15 | 10mg | Observe patients for 3-4 hours post IMDELLTRA infusion. |
| Cycle 5 and subsequent infusions | Day 1 and 15 | 10mg | Observe patients for 2 hours post IMDELLTRA infusion. |

a. Administer concomitant medications as recommended. drug label recommends administering 8 mg of intravenous dexamethasone (or equivalent) within 1 hour prior to **Tarlatamab-dlle (Imdelltra)** administration on Cycle 1 Day 1 and Day 8 to reduce the risk of cytokine release syndrome (CRS).

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## Reference Information


1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.


## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | MPCC Approval Date |
|---|---|---|---|
| Policy Inception 6/9/2025 | Elevance Health's Medical Policy adoption. | 7/17/2025 | 8/8/2025 |