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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 31, 2024
Subject:	Imdelltra	**Page:**	1 of 4

Last Review Date: March 7, 2025

Imdelltra

Description

Imdelltra (tarlatamab-dlle)

Background
Imdelltra (tarlatamab-dlle) is a bispecific T-cell engager that binds to delta-like ligand 3 (DLL3) expressed on the surface of cells, including tumor cells, and CD3 expressed on the surface of T-cells. Imdelltra causes T-cell activation, release of inflammatory cytokines, and lysis of DLL3-expressing cells (1).

Regulatory Status
FDA-approved indications: Imdelltra is a bispecific DLL3-directed CD3 T-cell engager 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 (1).

Imdelltra contains a boxed warning regarding cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). Imdelltra should be initiated using the step-up dosing schedule to reduce the incidence and severity of CRS. Patients should also be monitored for signs and symptoms of neurologic toxicity, including ICANS, during treatment and treated promptly (1).

Imdelltra should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reaction such as CRS and neurologic toxicity, including ICANS. Concomitant medications should also be administered as recommended to reduce the risk of CRS (1).

Other warnings for Imdelltra include cytopenias, infections, hepatotoxicity, and hypersensitivity reactions (1).

Imdelltra may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with Imdelltra and for 2 months after the last dose (1).

The safety and effectiveness of Imdelltra in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Imdelltra may be considered **medically necessary** if the conditions indicated below are met.

Imdelltra may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Extensive-stage small cell lung cancer (ES-SCLC)
    a. Patient has had disease progression on or after platinum-based chemotherapy

AND ALL of the following:

a. Prescriber agrees to initiate treatment using the step-up dosing schedule to reduce the incidence and severity of cytokine release syndrome (CRS)

b. Prescriber agrees to monitor for signs and symptoms of neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS)
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Imdelltra and for 2 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Extensive-stage small cell lung cancer (ES-SCLC)

AND ALL of the following:
a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor for signs and symptoms of neurologic toxicity, including ICANS
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Imdelltra and for 2 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Imdelltra 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. It contains a boxed warning regarding CRS and neurologic toxicity, including ICANS. Imdelltra should be administered using the step-up dosing schedule. The safety and effectiveness of Imdelltra in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Imdelltra while maintaining optimal therapeutic outcomes.

References

1. Imdelltra [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2024.
2. NCCN Drugs & Biologics Compendium® Tarlatamab-dlle 2025. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2025.

Policy History

Date	Action
May 2024	Addition to PA
September 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.