Medical Drug Clinical Criteria

Subject:	Imdelltra (tarlatamab-dlle)		
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Overview

This document addresses the use of Imdelltra (tarlatamab-dlle). Imdelltra is a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager primarily used to treat adult patients with extensive stage small cell lung cancer (ES-SCLC) on or after platinum-based chemotherapy.

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.

The National Comprehensive Cancer Network (NCCN) does not currently address the use of Imdelltra.

Imdelltra 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.

Clinical Criteria

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.

Imdelltra (tarlatamab-dlle)

Requests for Imdelltra (tarlatamab-dlle) may be approved if the following criteria are met:

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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9999	Not otherwise classified, antineoplastic drugs (Imdelltra)
C9399	Unclassified drugs or biologics (Imdelltra)

ICD-10 Diagnosis

All diagnoses pend.

Document History

New: 06/10/2024
Document History:

- 06/10/2024 – Annual Review: New criteria for Imdelltra. Coding Reviewed: New document. Added HCPCS J9999, C9399. All diagnoses pend.

References

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. Accessed on May 22, 2024.
    A. Small Cell Lung Cancer. V2.2024. Revised November 21, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.