Reference number(s)
6501-A

Standard Medicare Part B Management Imdelltra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Imdelltra	tarlatamab-dlle

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Extensive Stage Small Cell Lung Cancer[1]

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Authorization of 12 months may be granted for treatment of extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy as a single agent.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on current regimen AND
    - No evidence of disease progression while on current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Imdelltra.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Small Cell Lung Cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Imdelltra are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Imdelltra [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2024.

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