| Reference number(s) |
| --- |
| 6987-A |

# Standard Medicare Part B Management Emrelis

## 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 |
| --- | --- |
| Emrelis | telisotuzumab vedotin-tllv |

## 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 Indication[1]

Emrelis is indicated for the treatment of adult patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression [greater than or equal to 50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.

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.

## Documentation

The following documentation must be available, upon request, for all initial requests: c-Met protein expression status.


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# Coverage Criteria

## Non-Small Cell Lung Cancer (NSCLC)[1]

Authorization of 12 months may be granted for treatment of locally advanced or metastatic non-squamous NSCLC with high c-Met protein overexpression [greater than or equal to 50% of tumor cells with strong (3+) staining], for members who have received a prior systemic therapy.

# 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 section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

# Summary of Evidence

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

- The prescribing information for Emrelis.
- 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

# Explanation of Rationale

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

# References

1. Emrelis [package insert]. North Chicago, IL: AbbVie Inc.; May 2025.


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