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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 6, 2025
Subject:	Emrelis	**Page:**	1 of 5

Last Review Date: September 19, 2025

Emrelis

Description

Emrelis (telisotuzumab vedotin-tllv)

Background
Emrelis (telisotuzumab vedotin-tllv) is a c-Met-directed antibody drug conjugate (ADC). The antibody is a humanized IgG1κ directed against c-Met, the cell surface receptor for hepatocyte growth factor. The small molecule, MMAE, is a microtubule-disrupting agent, attached to the antibody via a protease cleavable linker. Following binding to c-Met-expressing cells, Emrelis undergoes internalization and intracellular cleavage of MMAE. MMAE disrupts the microtubule network of actively dividing cells, subsequently inducing cell cycle arrest and apoptotic cell death (1).

Regulatory Status
FDA-approved indication: Emrelis is a c-Met-directed antibody and microtubule inhibitor conjugate 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 [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy (1).

Select patients for treatment with Emrelis based on the presence of high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining] in patients with non-squamous NSCLC (1).

Emrelis has warnings regarding the following: peripheral neuropathy, interstitial lung disease (ILD)/pneumonitis, ocular surface disorders, and infusion-related reactions (IRR). Withhold, reduce the dose or permanently discontinue EMRELIS based on severity. (1).

Emrelis can cause fetal harm when administered in pregnant women. Females of reproductive potential should be advised to use effective contraception during treatment with Emrelis and for 2 months after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Emrelis and for 4 months after the last dose (1).

The safety and effectiveness of Emrelis 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.

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

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

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC)
    a. High c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test

b. Patient has received a prior systemic therapy

AND ALL of the following:

1. Prescriber agrees to monitor for signs and symptoms of peripheral neuropathy, interstitial lung disease/pneumonitis, and ocular surface disorders
2. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Emrelis and for 2 months after the last dose
3. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Emrelis and for 4 months after the last dose

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC)
   a. **NO** disease progression or unacceptable toxicity

AND ALL of the following:

1. Prescriber agrees to monitor for signs and symptoms of peripheral neuropathy, interstitial lung disease/pneumonitis, and ocular surface disorders
2. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Emrelis and for 2 months after the last dose
3. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Emrelis and for 4 months after the last dose

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 12 vials (6 IV infusions) per 84 days

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Emrelis is a c-Met-directed antibody and microtubule inhibitor conjugate indicated for the treatment of locally advanced or metastatic non-squamous NSCLC with high c-Met protein overexpression. Emrelis has warnings regarding the following: peripheral neuropathy, interstitial lung disease (ILD)/pneumonitis, ocular surface disorders, and infusion-related reactions (IRR). The safety and effectiveness of Emrelis in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Emrelis [package insert]. North Chicago, IL: AbbVie; May 2025.
2. NCCN Drugs & Biologics Compendium® Telisotuzumab vedotin-tllv 2025. National Comprehensive Cancer Network, Inc. Accessed on August 5, 2025.

Policy History

Date	Action
June 2025	Addition to PA
September 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.