Medical Policy:

Emrelis (telisotuzumab vedotin) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.438	August 1, 2025	August 1, 2025

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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 [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.
This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Length of Authorization

Initial: Prior authorization will be provided initially for 6 months.

Renewal: Prior authorization may be renewed every 6 months thereafter

Dosing Limits [Medical Benefit]

1.9 mg/kg (maximum dose: 190 mg [in patients weighing ≥100 kg]) once every 2 weeks; continue until disease progression or unacceptable toxicity

Max Units (per dose and over time) [HCPCS Unit]:

• 200 mg every 14 days

Guideline

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient will be monitored for all of the following signs and symptoms:
  Ocular surface disorders during treatment and will receive an ophthalmic examination (and treatment, if required) for Grade ≥2 ocular toxicity; **AND**
  -Interstitial lung disease and/or pneumonitis; **AND**
  -New or worsening peripheral neuropathy such as hypoesthesia, hyperesthesia, paresthesia, a burning sensation, neuropathic pain, or muscle weakness; **AND**
  -Severe infusion related reactions; **AND**
- Used as single agent therapy; **AND**

Non-Small Cell Lung Cancer (NSCLC) †

- Patient has a diagnosis of locally advanced or metastatic disease; **AND**
- Used as subsequent therapy; **AND**
- Patient has high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved or CLIA-compliant test, unless otherwise specified❖; **AND**
- Patients are epidermal growth factor receptor (EGFR) mutation negative (wild-type); **AND**
- Patient disease has non-squamous cell histology

Renewal Criteria

Prior authorization validity may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Initial Criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: peripheral neuropathy, severe interstitial lung disease and pneumonitis, severe ocular surface disorders, severe infusion related reactions, etc.

❖If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics
† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

Applicable Procedure Codes

Code	Description
J9399	Unclassified drugs or biologicals
J9999	Not otherwise classified, antineoplastic drugs

Applicable NDCs

Code	Description

00074-1044-01	Emrelis 20mg
00074-1055-01	Emrelis 100mg

ICD-10 Diagnoses

Code	Description
C33	Malignant Neoplasm Of Trachea
C34.00	Malignant Neoplasm Of Unspecified Main Bronchus
C34.01	Malignant Neoplasm Of Right Main Bronchus
C34.02	Malignant Neoplasm Of Left Main Bronchus
C34.10	Malignant Neoplasm Of Upper Lobe, Unspecified Bronchus Or Lung
C34.11	Malignant Neoplasm Of Upper Lobe, Right Bronchus Or Lung
C34.12	Malignant Neoplasm Of Upper Lobe, Left Bronchus Or Lung
C34.2	Malignant Neoplasm Of Middle Lobe, Bronchus Or Lung
C34.30	Malignant Neoplasm Of Lower Lobe, Unspecified Bronchus Or Lung
C34.31	Malignant Neoplasm Of Lower Lobe, Right Bronchus Or Lung
C34.32	Malignant Neoplasm Of Lower Lobe, Left Bronchus Or Lung
C34.80	Malignant Neoplasm Of Overlapping Sites Of Unspecified Bronchus And Lung
C34.81	Malignant Neoplasm Of Overlapping Sites Of Right Bronchus And Lung
C34.82	Malignant Neoplasm Of Overlapping Sites Of Left Bronchus And Lung
C34.90	Malignant Neoplasm Of Unspecified Part Of Unspecified Bronchus Or Lung
C34.91	Malignant Neoplasm Of Unspecified Part Of Right Bronchus Or Lung
C34.92	Malignant Neoplasm Of Unspecified Part Of Left Bronchus Or Lung

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/1/2025	New Policy

References

1. Emrelis™ intravenous infusion [prescribing information]. North Chicago, IL: AbbVie; May 2025.