Medical Drug Clinical Criteria

Subject:	Emrelis (telisotuzumab vedotin-tllv)		
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Overview

This document addresses the use of Emrelis (telisotuzumab vedotin-tllv). Emrelis is an antibody-drug conjugate which is FDA indicated for use in the treatment of adults 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] who have received a prior systemic therapy (prior therapies in the trial included chemotherapy, tyrosine kinase inhibitors, or immune checkpoint inhibitors).

The recommended dosage of Emrelis is 1.9 mg/kg (up to a maximum of 190 mg for patients greater than or equal to 100 kg) administered as an intravenous infusion over 30 minutes every 2 weeks until disease progression or unacceptable toxicity.

Avoid use of Emrelis in patients with moderate or severe hepatic impairment (total bilirubin >1.5 x ULN and any AST). Patients with moderate or severe hepatic impairment are likely to have increased exposure to MMAE, which may increase the risk of adverse reactions. Emrelis has not been studied in patients with moderate or severe hepatic impairment. No dosage adjustment is recommended for patients with mild hepatic impairment (total bilirubin ≤ULN and AST >ULN or total bilirubin >ULN and ≤1.5 x ULN and any AST).

Definitions and Measures

Adenocarcinoma: Cancer originating in cells that line specific internal organs and that have gland-like (secretory) properties.

Disease Progression: Cancer that continues to grow or spread.

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.

- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.

Maintenance therapy: Designed to maintain a condition to prevent a relapse.

Malignant: Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Mutation: A permanent, transmissible change in genetic material.

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.

One line of therapy: Single line of therapy.

Primary refractory disease: Cancer that does not respond at the beginning of treatment; may also be called resistant disease.

Primary treatment: The first treatment given for a disease. It is often part of a standard set of treatments, such as surgery followed by chemotherapy and radiation. Also called first-line therapy, induction therapy, and primary therapy.

Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Stable disease: Cancer that is not decreasing or increasing in extent or severity.

Targeted biologic agent: A newer type of drug developed specifically to target genetic changes in cells that cause cancer. It works differently than standard chemotherapy drugs, often with different side effects.

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.

Emrelis (telisotuzumab vedotin-tllv)

Requests for Emrelis (telisotuzumab vedotin-tllv) may be approved if the following criteria are met:

I. Individual has a diagnosis of Non-small cell lung cancer (NSCLC) (Label, NCCN 2A); **AND**
II. Individual has advanced or metastatic non-squamous (EGFR wild-type) NSCLC; **AND**
III. Individual has high c-Met/MET protein expression [≥ 50% of tumor cells with strong (IHC 3+) staining]: **AND**
IV. Individual has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2; **AND**
V. Individual has received a prior systemic therapy.

Requests for Emrelis (telisotuzumab vedotin-tllv) may not be approved for the following:

I. Individual has moderate or severe hepatic impairment (total bilirubin > 1.5 x ULN and any AST); **OR**

II. When the above criteria are not met and for all other indications.

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

C9399	Unclassified drugs or biologicals [when specified as Emrelis (telisotuzumab vedotin-tllv)]
J9999	Not otherwise classified, antineoplastic drugs [when specified as Emrelis (telisotuzumab vedotin-tllv)]

ICD-10 Diagnosis

	All diagnosis pend.

Document History

New: 06/09/2025
Document History:

- 06/09/2025– Select Review: New document for Emrelis intravenous PA. Coding Reviewed: Added HCPCS NOC C9399, J9999 and all diagnosis pend for Emrelis.

References

1. Clinicaltrials.gov. National Library of Medicine. Available at: https://clinicaltrials.gov/. Accessed on May 27, 2025.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: May 27, 2025.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on May 27, 2025.
    a. Non-Small Cell Lung Cancer. V4.2025. Revised May 23, 2025.

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.