

Clinical Policy: Telisotuzumab Vedotin-tllv (Emrelis)

Reference Number: PA.CP.PHAR.733

Effective Date: 08/2025

Last Review Date: 07/2026

Description

Telisotuzumab vedotin-tllv (Emrelis™) is a c-Met-directed antibody and microtubule inhibitor conjugate.

FDA Approved Indication(s)

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 [$\geq 50\%$ 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).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Emrelis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of NSCLC;
2. Disease is recurrent, locally advanced, or metastatic;
3. Disease has all of the following characteristics (a, b and c):
 - a. Non-squamous;
 - b. High c-Met/MET protein overexpression defined as $\geq 50\%$ of tumor cells with strong (3+) immunohistochemistry staining (IHC 3+)
 - c. Epidermal growth factor receptor (EGFR) wild-type;
4. Prescribed by or in consultation with an oncologist;
5. Age ≥ 18 years;
6. Member has received prior systemic therapy for NSCLC (*see Appendix B*);
7. Request is for single agent therapy;
8. Request meets one of the following (a or b):
 - a. Dose does not exceed 1.9 mg/kg, up to a maximum of 190 mg, every 2 weeks;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Non-Small Cell Lung Cancer (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
 - a. New dose does not exceed 1.9 mg/kg, up to a maximum of 190 mg, every 2 weeks;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DOR: duration of response

EGFR: epidermal growth factor receptor

FDA: Food and Drug Administration

IHC: immunohistochemistry staining

ORR: overall response rate

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of systemic therapy for advanced or metastatic NSCLC: • Keytruda®/carboplatin/pemetrexed • Keytruda/cisplatin/pemetrexed	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Libtayo[®]/pemetrexed/(carboplatin or cisplatin) • Tecentriq[®]/carboplatin/paclitaxel/bevacizumab • Tecentriq/carboplatin/albumin-bound paclitaxele • Opdivo[®]/Yervoy[®] • Opdivo/Yervoy/pemetrexed/(carboplatin or cisplatin) • Imjudo[®]/Imfinfzi[®]/carboplatin/albumin-bound paclitaxel • Imjudo/Imfinfzi/(carboplatin or cisplatin)/pemetrexed • Bevacizumab/carboplatin/paclitaxel • Bevacizumab/carboplatin/pemetrexed • Bevacizumab/cisplatin/pemetrexed • Carboplatin-combination therapy ◦ Combination options include: albumin-bound paclitaxel, docetaxel, etoposide, gemcitabine, paclitaxel, or pemetrexed • Cisplatin-combination therapy ◦ Combinations options include: docetaxel, etoposide, gemcitabine, paclitaxel, or pemetrexed • Gemcitabine/docetaxel • Gemcitabine/vinorelbine • Albumin-bound paclitaxel • Docetaxel • Gemcitabine • Paclitaxel • Pemetrexed		

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	1.9 mg/kg IV every 2 weeks until disease progression or unacceptable toxicity	190 mg every 2 weeks

VII. Product Availability

Lyophilized powder in single-dose vials: 20 mg, 100 mg

VIII. References

1. Emrelis Prescribing Information. North Chicago, IL : AbbVie, Inc.; May 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761384s000lbl.pdf. Accessed April 16, 2026.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 7, 2026.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 5.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed May 7, 2026.
4. Camidge DR, Bar J, Horinouchi H, et al. Telisotuzumab Vedotin Monotherapy in Patients With Previously Treated c-Met Protein-Overexpressing Advanced Nonsquamous *EGFR*-Wildtype Non-Small Cell Lung Cancer in the Phase II LUMINOSITY Trial. *J Clin Oncol*. 2024 Sep 1; 42(25): 3000-3011.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPSC Codes	Description
J9326	Injection, telisotuzumab vedotin-tllv, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	07/2025
3Q 2026 annual review: no significant changes; modified initial approval duration from 6 to 12 months; HCPSC added [J9326], removed [C9399, J9999]; references reviewed and updated.	07/2026