CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Antibody-Drug Conjugate – c-Met) – Emrelis Utilization Management Medical Policy
- Emrelis® (telisotuzumab vedotin-tllv intravenous infusion – AbbVie)

REVIEW DATE: 05/21/2025

OVERVIEW

Emrelis, a c-Met-directed antibody and microtubule inhibitor conjugate, is indicated for the following use:[1]

- **Non-small cell lung cancer (NSCLC),** in locally advanced or metastatic non-squamous disease with high c-Met protein overexpression (≥ 50% of tumor cells with strong [3+] staining), as determined by an FDA-approved test in adults who have received prior systemic therapy.

Guidelines

Emrelis is not addressed in the National Comprehensive Cancer Network (NCCN) non-small cell lung cancer guidelines (version 3.2025 – January 14, 2025).[2] Guidelines note the following as therapy options for advanced or metastatic adenocarcinoma in patients without contraindications to programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitors, and without actionable mutations. The "Preferred" therapies include Keytruda® (pembrolizumab intravenous infusion) combination with carboplatin or cisplatin and pemetrexed and Libtayo® (cemiplimab-rwlc intravenous infusion) in combination with cisplatin or carboplatin and pemetrexed (all category 1). "Other Recommended" therapies include Opdivo® (nivolumab intravenous infusion) + Yervoy® (ipilimumab intravenous infusion), Opdivo + Yervoy + pemetrexed + carboplatin or cisplatin, Tecentriq® (atezolizumab intravenous infusion) + carboplatin + paclitaxel + bevacizumab, Tecentriq + carboplatin + Abraxane® (albumin-bound paclitaxel intravenous infusion), Libtayo + pacliltaxel + carboplatin or cisplatin, Imjudo® (tremelimumab-actl intravenous infusion) +Imfinzi® (durvalumab intravenous infusion) + carboplatin or cisplatin + pemetrexed or Abraxane. All therapies listed above are category 1, except for Tecentriq + carboplatin + Abraxane and Opdivo + Yervoy, both of which are category 2A recommended therapies. Other single agent chemotherapies (e.g., gemcitabine, docetaxel, paclitaxel) and combination chemotherapy regimens without PD-1/PD-L1 agents are recommended for patients with contraindications to PD-1or PD-L1 inhibitors or in patients with actionable mutations.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Emrelis. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of specialized skills required for evaluation and diagnosis of patients treated with Emrelis as well as the monitoring required for adverse events and long-term efficacy, approval requires Emrelis to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Emrelis is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic, non-squamous disease; AND
   - **C)** The tumor has high c-Met protein overexpression, defined as a ≥ 50% of tumor cells with strong [3+] staining, as determined by an approved test; AND
   - **D)** Patient has received at least one prior systemic therapy; AND
     Note: Examples are cisplatin, carboplatin, pemetrexed, Keytruda (pembrolizumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion).
   - **E)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve if each dose does not exceed 1.9 mg/kg (up to a maximum of 190 mg for patients ≥ 100 kg), administered as an intravenous infusion not more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Emrelis is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Emrelis™ intravenous infusion [prescribing information]. North Chicago, IL: AbbVie; May 2025.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 15, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/21/2025