Emrelis™
(telisotuzumab vedotin-tllv)
injection for intravenous use 20 mg | 100 mg

Emrelis™
Support Services

SAMPLE Letter of Medical Necessity

This is intended as a TEMPLATE Letter of Medical Necessity

<Date>

<Prescriber name>
<Address>
<City, state ZIP>
<Phone number>
<Tax ID number>
<DEA number>
<Name of Rx plan>
<Address of Rx plan>

Re: Authorization for EMRELIS™ (telisotuzumab vedotin-tllv) use for <Patient name>
Member ID: <XX>
Group #: <XX>
Rx BIN #: <XX>
Date of birth: <XX>

To Whom It May Concern,

I am writing to document the medical necessity of EMRELIS (telisotuzumab vedotin-tllv) for my patient, <Patient name>. The enclosed documentation provides information about the patient's medical history, diagnosis information, and my treatment rationale. EMRELIS was approved by the US Food and Drug Administration on May 14, 2025, 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).[1]

<Patient name> was diagnosed with <diagnosis and ICD code> on <Month Day, Year>, and has tried other treatment options. <Patient name> has been in my care since <Month Day, Year>.

Please see Indication and Important Safety Information on the following pages.

Please see full Prescribing Information at https://www.rxabbvie.com/pdf/emrelis_pi.pdf

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I plan to treat <Patient name> with EMRELIS™. <Include the rationale supporting the use of EMRELIS. The statement could include a brief description of the patient's diagnosis, the severity of the patient's condition, prior treatments (and duration), the rationale for discontinuation, your professional opinion of your patient's likely prognosis or disease progression without treatment, as well as other factors that impacted your treatment decision>.

In my professional opinion, EMRELIS is medically necessary and is the appropriate treatment for my patient at this time. Please refer to the enclosed supporting documents for further details, and please don't hesitate to contact me at <Insert telephone number> if you have any further questions.

<Doctor's name>, <MD>

cc: <Patient name>

<Optional enclosures: FDA Approval Letter, EMRELIS Prescribing Information, and medical records.>

INDICATION

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).

IMPORTANT SAFETY INFORMATION

Peripheral Neuropathy

EMRELIS can cause peripheral neuropathy, including peripheral sensory neuropathy and peripheral motor neuropathy. In the safety population, peripheral neuropathy occurred in 51% of patients treated with EMRELIS, including Grade 3 in 11%. These adverse reactions included peripheral sensory neuropathy in 45% of patients and peripheral motor neuropathy in 9%. The median time to onset of peripheral neuropathy was 105 days (range: 1 to 472 days). Peripheral neuropathy led to permanent discontinuation of EMRELIS in 13% of patients. The median time to onset of peripheral neuropathy leading to treatment discontinuation was 249 days (range: 57 to 519 days). Of the 7 patients with motor neuropathy ongoing as of their last dose of EMRELIS, 6 had persistent Grade 1 or 2 symptoms 30 days after their last dose.

Monitor patients for signs and symptoms of new or worsening peripheral neuropathy such as hypoesthesia, hyperesthesia, paresthesia, a burning sensation, neuropathic pain, or muscle weakness. Withhold, reduce the dose, or permanently discontinue EMRELIS based on severity.

Interstitial Lung Disease/Pneumonitis

EMRELIS can cause severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis. In the safety population, ILD/pneumonitis occurred in 10% of patients treated with EMRELIS, including Grade 3 in 3% and Grade 4 in 0.6%. There were 3 fatal cases of ILD/pneumonitis in patients who received EMRELIS. The median time to onset of ILD/pneumonitis was 48 days (range: 23 to 85 days). ILD/pneumonitis led to permanent discontinuation of EMRELIS in 7% of patients. The median time to onset of ILD/pneumonitis leading to treatment discontinuation was 46 days (range: 23 to 85 days).

Please see additional Important Safety Information on the following page.

Please see full Prescribing Information at https://www.rxabbvie.com/pdf/emrelis_pi.pdf

IMPORTANT SAFETY INFORMATION (cont'd)

Interstitial Lung Disease/Pneumonitis (cont'd)

Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD/pneumonitis. Withhold or permanently discontinue EMRELIS based on severity.

Ocular Surface Disorders

EMRELIS can cause ocular surface disorders, including blurred vision, visual impairment, keratitis, and dry eye. In the safety population, ocular surface disorders occurred in 25% of patients treated with EMRELIS. The most common ocular surface disorders were blurred vision (15%), keratitis (11%), and dry eye (5%). Grade 3 ocular surface disorders occurred in 1.2% of patients [blurred vision (1.2%), and keratitis (0.6%)]. The median time to onset of ocular surface disorders was 47 days (range: 1 to 319 days).

Monitor patients for ocular surface disorders during treatment with EMRELIS. Withhold EMRELIS and refer patients to an eye care professional for an ophthalmic examination and treatment for patients who develop Grade ≥2 ocular toxicity. Withhold or permanently discontinue EMRELIS based on severity.

Infusion-Related Reactions

EMRELIS can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, chills, nausea, chest discomfort, and hypotension. The median time to onset of IRR was 28 days (range: 1 to 43 days). In the safety population, IRR occurred in 3% of patients treated with EMRELIS, including Grade 3 in 1.2% and Grade 4 in 0.6%. IRR led to permanent discontinuation of EMRELIS in 0.6% of patients.

Monitor patients for signs and symptoms of infusion reactions during EMRELIS infusion. Withhold, reduce the rate of infusion, or permanently discontinue EMRELIS based on severity. For patients who experience IRR, administer premedications prior to subsequent infusions.

Embryo-Fetal Toxicity

Based on the mechanism of action and findings in animals, EMRELIS can cause fetal harm when administered to a pregnant woman. The small molecule component of EMRELIS, monomethyl auristatin E (MMAE), administered to rats caused adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities, at exposures similar to those occurring clinically at the recommended dose.

Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with EMRELIS and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with EMRELIS and for 4 months after the last dose.

Adverse Reactions

Serious adverse reactions occurred in 35% of patients. The most common adverse reactions (≥20%) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, increased glucose, increased alanine aminotransferase, increased gamma glutamyl transferase, decreased phosphorus, decreased sodium, decreased hemoglobin, and decreased calcium.

Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with EMRELIS may increase the area under the curve of MMAE. Monitor for increased risk of adverse reactions to EMRELIS.

Use in Specific Populations

Severe or Moderate Hepatic Impairment: Avoid the use of EMRELIS.

Lactation: Advise lactating women not to breastfeed during treatment with EMRELIS and for 1 month after the last dose.

Infertility: Based on findings from animal studies, EMRELIS may impair fertility in females and males.

Please see full Prescribing Information at https://www.rxabbvie.com/pdf/emrelis_pi.pdf

Reference: 1. EMRELIS [package insert]. AbbVie, Inc., 2025.