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

Emrelis™ Support Services

BILLING & REIMBURSEMENT

HOW TO BILL FOR EMRELIS™ USING A MISCELLANEOUS J-CODE

- Until a permanent J-code is available for EMRELIS, claims for EMRELIS can use an unclassified/miscellaneous HCPCS code
  – A permanent EMRELIS J-code is anticipated by January 1, 2026
- Miscellaneous J-codes are used for the drug portion of a physician-administered therapy if no drug-specific code is available (where permissible under payer rules)
- When using J3490 for EMRELIS, bill as 1 unit for Medicare

NOTE: For J3490, always check with the payer regarding units to be billed. Some payers have reduced rates for miscellaneous codes.

UNCLASSIFIED/MISCELLANEOUS HCPCS CODES FOR EMRELIS[1,2]

HCPCS Code	Description
J3490	Unclassified drug
J3590	Unclassified biologics
J9999	Antineoplastic drugs that are not otherwise classified
C9399	Unclassified drugs or biologics

HCPCS = Healthcare Common Procedure Coding System; **HOPD** = hospital outpatient department.

JW Modifier: Effective January 1, 2017, Medicare requires providers to use the JW modifier (drug amount discarded/not administered to any patient) for all claims with unused drugs or biologicals from single-use vials that are appropriately discarded, and to document the discarded drug or biological in the patient's medical record.*

JZ Modifier: Effective July 1, 2023, Medicare requires the use of the JZ modifier to indicate there were no units of a drug discarded.*

*For more information on the JW and JZ modifiers, visit https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.

Modifier requirements for payers other than Medicare may vary—providers should check with their specific plans about policies.

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).

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.

Please see additional Important Safety Information for EMRELIS on page 2.

Please see accompanying full Prescribing Information, or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf

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NATIONAL DRUG CODE (NDC)[3]

- For drugs without a permanent HCPCS code, payers often require inclusion of the drug's NDC in the claim
- While the FDA provides NDCs as 10-digit codes, payers frequently require 11-digit formats
  - Contact each payer for its specific requirements, as they vary by payer

	Strength	FDA-Specified 10-Digit NDC (4-4-2 format)	11-Digit NDC (5-4-2 format)
EMRELIS™	20 mg/vial	0074-1044-01	00074-1044-01
EMRELIS™	100 mg/vial	0074-1055-01	00074-1055-01

NDC ON CLAIM FORMS FOR THE PLACE OF SERVICE (POS)

Claim Form (or Electronic Equivalent)	Place of Service	Additional Information
CMS-1500 claim form	Physician office setting	Information required in boxes 19 and 24 (commercial payers may also require additional information in box 19; may vary by payer)
UB-04 (CMS-1450) claim form	HOPD setting	Information required in box 43 (may vary by payer). May be important to note additional information in box 80

MISCELLANEOUS CLAIM SUBMISSION

Payers May Require Additional Information and/or Documentation, Including:

- Drug name/strength
- Dosing
- Administration
- NDC
- Prescribing Information
- FDA approval letter
- Medical necessity documentation
- Drug purchase invoice

IMPORTANT SAFETY INFORMATION (cont'd)

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 additional Important Safety Information for EMRELIS on page 1.

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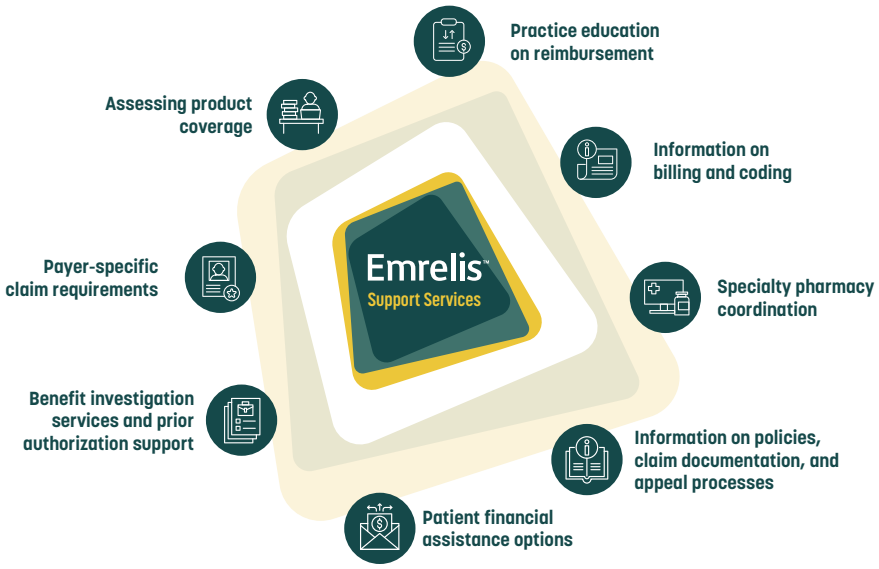
TIPS THAT MAY HELP WITH TIMELY REIMBURSEMENT

Payers May Require Additional Information and/or Documentation

- **Help prevent delays in processing claims by:**
  - Ensuring proper coding
  - Including appropriate documentation
  - Including payer-specific required information (check payer contracts for language around miscellaneous J-codes or C-codes)
  - Submitting payer-required clinical notes and invoice along with your billing
- **Timing:** Miscellaneous J-code or C-code claims typically require a manual review by payers, so the payment may be delayed
- **Common reasons for claim denial:** Incorrect patient information, invalid codes (CPT, HCPCS, or ICD-10), and missing information (eg, NDC, number of units, or place-of-service mismatch)

PROVIDER AND PATIENT REIMBURSEMENT SUPPORT FOR EMRELIS™

EMRELIS Support Services as well as your Field Reimbursement Manager (FRM) provide access and reimbursement education for healthcare professionals and office staff throughout the reimbursement continuum to help patients access EMRELIS.



For more information, visit EMRELIShcp.com

or call: 1-844-859-5760, **Monday to Friday**, 8 AM to 8 PM ET.

DISCLAIMER: This guide is for informational purposes only and is not intended to provide reimbursement or legal advice. The information presented here does not guarantee payment or coverage. The coding, coverage, and payment information included in this guide is subject to change in accordance with frequently changing laws, regulations, rules, and policies. Reimbursement policies will vary by payer and state. You should check the current laws, regulations, and payer coverage policies to confirm current coding, coverage, and billing requirements for EMRELIS. AbbVie encourages healthcare providers to submit claims with accurate and appropriate codes, charges, and modifiers for the services rendered. It is always the provider's responsibility to determine medical necessity and the proper site for delivery of any services, and to submit the appropriate codes. Healthcare professionals are ultimately responsible for all aspects of reimbursement. Codes must accurately reflect the patient's condition, procedure performed, and products used.

Please see Important Safety Information for EMRELIS on pages 1 and 2.

Please see accompanying full Prescribing Information, or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf

References: 1. Centers for Medicare and Medicaid Services. Billing and coding: hospital outpatient drugs and biologicals under the Outpatient Prospective Payment System (OPPS). Accessed May 13, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55913. 2. American Academy of Professional Coders. HCPCS Code for Not otherwise classified, antineoplastic drugs. Accessed May 13, 2025. https://www.aapc.com/codes/hcpcs-codes/J9999#:~:text=HCPCS%20code%20J9999%20for%20Not,CMS%20falls%20under%20Chemotherapy%20Drugs.
3. EMRELIS [package insert]. AbbVie, Inc. 2025.

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