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

Emrelis™ Support Services

EMRELIS™ PATIENT ENROLLMENT FORM

Enroll your patient in EMRELIS Support Services.
Fax completed form to 1-800-222-2005.
For additional questions, call 1-844-859-5760.

PATIENT INFORMATION Please print clearly.

First Name _____ Last Name _____

Date of Birth _____ (MM/DD/YYYY) Gender M ☐ F ☐ Other ☐

Address _____ City _____ State _____ ZIP Code _____

Mobile Phone _____ Home Phone _____ Email Address _____

Preferred phone: Mobile ☐ Home ☐

Legal Representative / Caregiver Name _____

Relation to patient _____ Phone _____

Privacy Notice: For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosure to third parties, visit **https://abbv.ie/PrivacyPatient**.

Consent to process my sensitive personal information: Through my submission of the EMRELIS™ Patient Enrollment form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the **How We May Disclose Personal Data** section. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **Your Privacy Choices** on AbbVie's website.

PATIENT CONSENT (If patient is present in office; otherwise, we will attempt to get verbal consent over the phone.)

I certify that I am 18 years old or older and a resident of the United States or Puerto Rico and I am receiving care from a licensed healthcare provider authorized to prescribe, dispense, and administer prescription drugs in the United States. I am applying to enroll in EMRELIS Support Services (see full Co-Pay Terms and Conditions on page 3). I am authorizing AbbVie and its affiliated companies, vendors, agents, collaboration partners, and representatives (together, "AbbVie") to provide assistance to me. I certify that the information provided is current, complete and accurate to the best of my knowledge and I agree to notify the hub services team at 1-844-859-5760 immediately if any information provided changes. I understand that AbbVie may request additional information relevant to my eligibility or participation in the program and may review and audit any information provided to confirm its accuracy. I understand that my health information, contact information, and other information I, my Healthcare Providers, Insurers, and others share with AbbVie is collected to provide me with the assistance I request. To read the AbbVie Privacy Policy, visit https://privacy.abbvie/privacy-policies/us-privacy-policy.html.

Patient Signature: _____ Date: _____

Legal Representative/Caregiver Signature: _____ Date: _____

Please see Important Safety Information on last page.
Please see full Prescribing Information, or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf

INSURANCE INFORMATION

Primary Insurance

Medical Insurance _____

Government ☐ Commercial ☐

Policy ID # _____

Group # _____

Insurance Phone Number _____

Beneficiary/Cardholder Name _____

Beneficiary Date of Birth _____

Secondary Insurance

Medical Insurance _____

Government ☐ Commercial ☐

Policy ID # _____

Group # _____

Insurance Phone Number _____

Beneficiary/Cardholder Name _____

Beneficiary Date of Birth _____

PROVIDER INFORMATION

Prescriber

Name _____

Address _____

Phone _____ Fax _____

Prescriber NPI # _____

Tax ID _____ PTAN # _____

Primary Office Contacts

Insurance Contact:

Name _____

Phone _____

Billing/Co-Pay Contact:

Name _____

Phone _____

Prescriber Privacy Notice: For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit **https://abbv.ie/PrivacyHCP**.

DIAGNOSIS

ICD-10-CM Code _____ Select Patient Condition ☐ Non-small cell lung cancer

Patient has received 1 or more prior systemic therapies for non-small cell lung cancer Yes ☐ No ☐

LAB TESTING

Patient has tested positive with the FDA-approved test for the detection of high c-Met protein overexpression

Yes ☐ No ☐

PROVIDER CONSENT

I certify that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed EMRELIS™ to the previously identified patient and that I provided the patient with a description of EMRELIS Support Services. I authorize EMRELIS Support Services to act on my behalf for the purposes of identifying the patient's insurance coverage and pursuing coverage assistance when appropriate.

Provider Signature: _____ Date: _____

Fax 1-800-222-2005 / Phone 1-844-859-5760

The personal information collected on this form will be used for program enrollment, management, and to perform research and analytics. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit www.abbvie.com/privacy.html.

EMRELIS Co-Pay Full Terms and Conditions

Terms and Conditions apply. This benefit covers EMRELIS (telisotuzumab vedotin-tllv). Eligibility: Available only to patients with commercial insurance coverage for EMRELIS who meet eligibility criteria. The form of co-pay assistance, enrollment requirements, and processes may vary. Please call 1-844-859-5760 for additional information. Co-pay assistance program is not available to patients receiving reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law or by the patient's health insurance provider. If you live or receive treatment in certain states, you may not be eligible. If at any time a patient begins receiving prescription drug coverage under any such federal, state, or government-funded healthcare program, patient will no longer be able to use the EMRELIS Savings Card and patient must call 1-844-859-5760 to stop participation. Co-pay assistance provided under this program may not be transferred to or utilized for the benefit of third parties, including, without limitation, third-party insurance plans and/or pharmacy benefit managers and their agents. By enrolling in the co-pay assistance program, you agree that this program is intended solely for the benefit of you, the patient. Some health plans have established programs referred to as "accumulator adjustment" or "co-pay maximizer" programs. An accumulator adjustment program is one in which payments made by you that are subsidized by manufacturer assistance do not count toward your deductibles and other out-of-pocket cost sharing limitations. Co-pay maximizers are programs in which the amount of your out-of-pocket costs is increased to reflect the availability of support offered by a manufacturer assistance program. Except where prohibited by applicable state law, if your insurance company or health plan implements either an accumulator adjustment or co-pay maximizer program, you will not be eligible for, and agree not to use, co-pay assistance because these programs are inconsistent with our agreed intent that this program is solely for your benefit. You also agree that you are personally responsible for paying any amount of co-pay required after the savings card is applied. Any out-of-pocket costs remaining after the application of the savings card may not be paid by your health plan, pharmacy benefit programs, or any other program. If you learn your insurance company or health plan has implemented either an accumulator adjustment program or a co-pay maximizer program, you agree to inform AbbVie of this fact by calling 1-844-859-5760 to discuss alternative options that may be available to support you. Subject to all other terms and conditions, the maximum annual benefit that may be available solely for the patient's benefit under the co-pay assistance program is $25,000 per calendar year. The actual application and use of the benefit available under the co-pay assistance program may vary on a monthly, quarterly, and/or annual basis depending on each individual patient's plan of insurance and other prescription drug costs. This co-pay assistance program is subject to change, reduction in monetary amount, or discontinuation without any notice. AbbVie in its sole discretion may unilaterally reduce or discontinue the maximum annual benefit for any reason. Patients may not seek reimbursement for value received from the EMRELIS Savings Card Program from any third-party payers, including insurance plans, flexible spending plans or health savings accounts. Co-pay support made available under this program may not be used with any other coupon, discount, prescription savings card, free trial, or other offer (including any program offered by a third-party insurance plan or pharmacy benefit manager, or an agent of either, that adjusts patient cost-sharing obligations). Restrictions, including monthly maximums, may apply. This assistance offer is not health insurance. The failure to enforce any provision of these Terms and Conditions does not constitute a waiver by AbbVie of that or any other provision. By utilizing this co-pay assistance program, you hereby accept and agree to abide by these terms and conditions. Any individual or entity who enrolls or assists in the enrollment of a patient in the co-pay assistance program represents that the patient meets the eligibility criteria and other requirements described herein. Further, you agree that you currently meet the eligibility criteria and other requirements described herein every time you use the co-pay assistance program. **To learn about AbbVie's privacy practices and your privacy choices, visit https://abbv.ie/corpprivacy.**

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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.

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, or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf

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