

Biomarker testing for patients with advanced/ metastatic NSq NSCLC

A comprehensive look includes testing for
c-Met protein overexpression with MET IHC¹

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 [$\geq 50\%$ 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).

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.

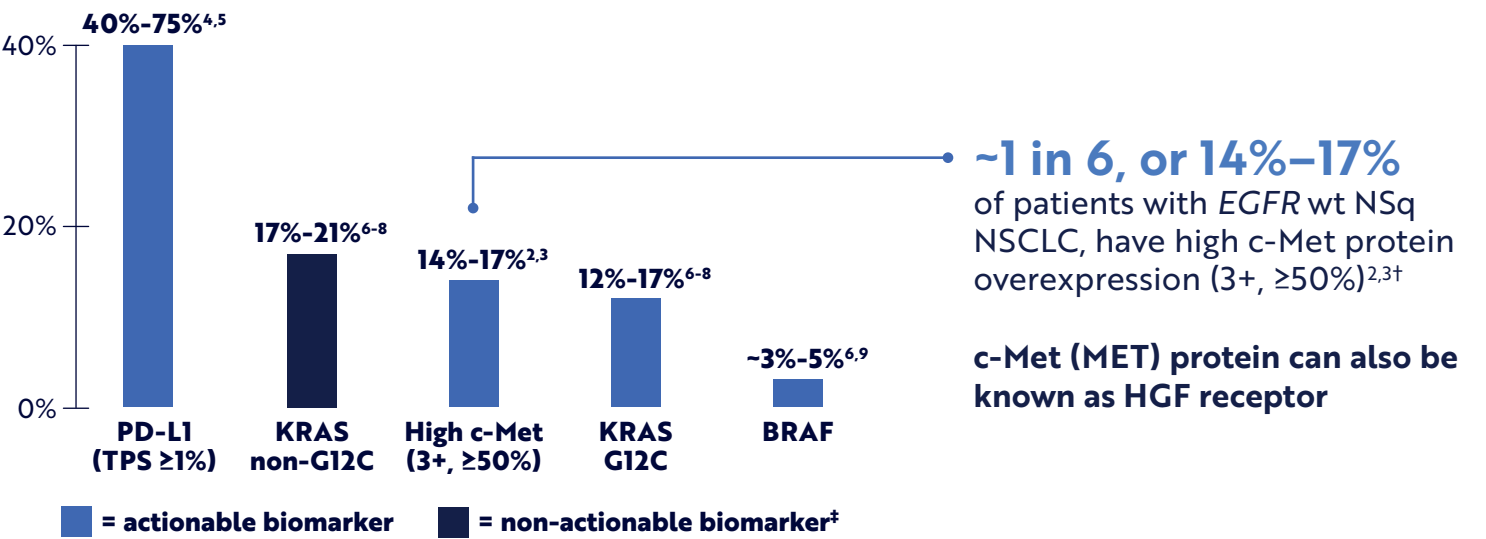
Monitor patients for signs and symptoms of new or worsening peripheral neuropathy such as hypoesthesia, hyperesthesia, paresthesia, a burning sensation, neuropathic pain, or muscle weakness. Withhold, reduce the dose, or permanently discontinue EMRELIS based on severity.

Please see full Important Safety Information throughout.

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

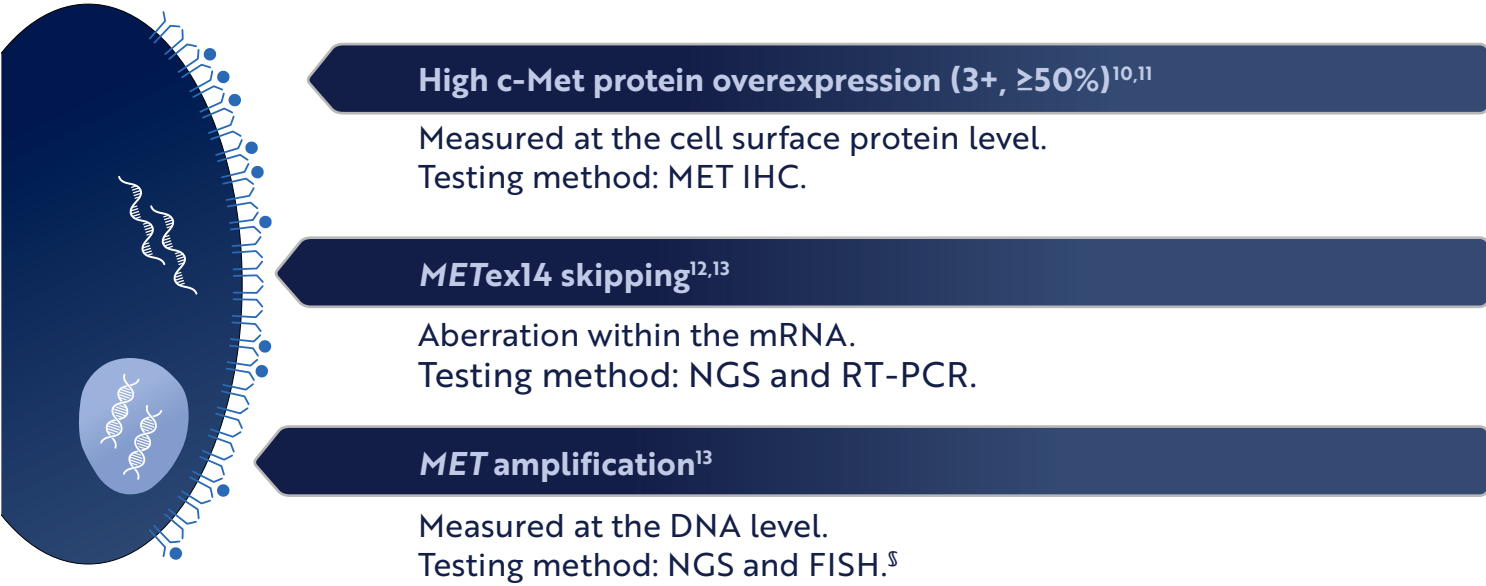
High c-Met protein overexpression (3+, ≥50%) is one of the top 3 most prevalent actionable biomarkers in EGFR wt NSq NSCLC¹⁻⁸

Prevalence of select biomarkers within EGFR wt* NSq NSCLC patients



Biomarker prevalence is based on data from various sources and patient populations, and does not indicate clinical importance, impact, safety, or efficacy of associated therapies. Some patients may have more than one NSCLC biomarker. Some biomarkers are more established than others.

High c-Met protein overexpression (3+, ≥50%) is distinct from other MET biomarkers (MET gene amplification and METex14 skipping mutation)



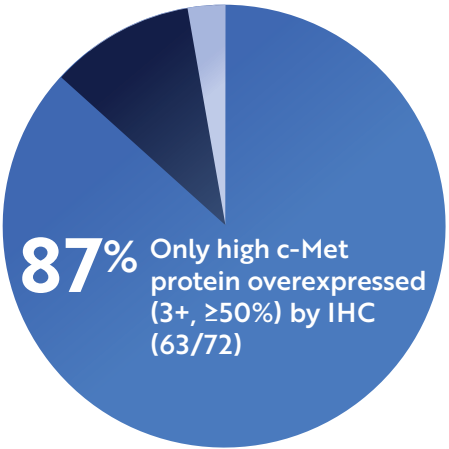
*KRAS mutations (KRAS G12C and KRAS non-G12C), and BRAF mutations are generally considered mutually exclusive from actionable EGFR mutations with rare co-occurrence often associated to resistance to TKIs.^{7,14,15}
[†]≥50% of tumor cells with strong (3+) c-Met (MET) staining.
[‡]Non-actionable biomarker defined as not having an associated FDA-approved indication.
[§]MET gene amplification is a non-actionable biomarker and may be evaluated at different molecular thresholds with different testing methods.
DNA=deoxyribonucleic acid; EGFR=epidermal growth factor receptor; FISH=fluorescent *in situ* hybridization; HGFR=hepatocyte growth factor receptor; IHC=immunohistochemistry; mRNA=messenger ribonucleic acid; NGS=next-generation sequencing; NSCLC=non-small cell lung cancer; NSq=non-squamous; RT-PCR=reverse transcription polymerase chain reaction; PDL=programmed death ligand 1; wt=wild-type.

Different MET aberrations

Patients with high c-Met protein overexpression (3+, ≥50%) can only be detected with MET IHC^{3,16}

High c-Met protein overexpressed (3+, ≥50%) EGFR wt NSq NSCLC patients (N=72) within a US-based, real-world, retrospective, multicenter study³

Total N=72	
High c-Met protein overexpressed with METex14skip (3+, ≥50%)	10% (7/72)
High c-Met protein overexpressed (3+, ≥50%) with MET amplification	3% (2/72)



More than 87% (63 out of 72) of EGFR wt, NSq NSCLC patients with high c-Met protein overexpression (3+, ≥50%) by IHC didn't have overlap with METex14 skipping or MET gene amplification in a US-based, real-world, retrospective, multicenter study.

Based on a single, retrospective, real-world, multicenter study in the US by CARIS Life Sciences, including 417 EGFR wt patients. 72 patients showed high c-Met protein overexpression (3+, ≥50%); among these, 63 patients did not have a concurrent MET gene alteration (MET gene amplification or METex14 skipping) as identified by whole exome sequencing. 2 patients had concurrent MET gene amplification, and 7 patients had concurrent METex14 skipping mutations.

Of 19 patients identified with either MET gene amplification or METex14 skipping mutations, 10 did not show high c-Met protein overexpression (3+, ≥50%).

IMPORTANT SAFETY INFORMATION (cont.)

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

Do you c-Met?

Test your appropriate patients for c-Met protein overexpression with IHC today.*

Scan the code or visit www.emrelishcp.com to get started



IMPORTANT SAFETY INFORMATION (cont.)

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

Embryo-Fetal Toxicity (cont.)

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 ($\geq 20\%$) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

The most common Grade 3 or 4 laboratory abnormalities ($\geq 2\%$) 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.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V5.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed April 27, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. 2. 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;42(25):3000-3011. doi:10.1200/JCO.24.00720 3. Data on file, ABVRR181961. AbbVie Inc. 4. Brahmer JR, Lee JS, Ciuleanu TE, et al. Five-year survival outcomes with nivolumab plus ipilimumab versus chemotherapy as first-line treatment for metastatic non-small-cell lung cancer in CheckMate 227. *J Clin Oncol*. 2023;41(6):1200-1212. doi:10.1200/JCO.22.01503 5. Saw SP, Takano A, Zhou S, et al. EGFR mutation status affects intra-tumoural heterogeneity of PD-L1 expression but not agreement between assays in resectable non-small cell lung cancer. *Lung Cancer*. 2025;202:108463. doi:10.1016/j.lungcan.2025.108463 6. Thai AA, Solomon BJ, Sequist LV, Gainor JF, Heist RS. Lung cancer. *Lancet*. 2021;398(10299):535-554. doi:10.1016/S0140-6736(21)00312-3 7. Finn SP, Addeo A, Dafni U, et al. Prognostic impact of KRAS G12C mutation in patients with NSCLC: results from the European Thoracic Oncology Platform Lungscape Project. *J Thorac Oncol*. 2021;16(6):990-1002. doi:10.1016/j.jtho.2021.02.016 8. Biernacka A, Tsongalis PD, Peterson JD, et al. The potential utility of re-mining results of somatic mutation testing: KRAS status in lung adenocarcinoma. *Cancer Genet*. 2016;209(5):195-198. doi:10.1016/j.cancergen.2016.03.001 9. Paik PK, Arcila ME, Fara M, et al. Clinical characteristics of patients with lung adenocarcinomas harboring BRAF mutations. *J Clin Oncol*. 2011;29(15):2046-2051. doi:10.1200/JCO.2010.33.1280 10. Organ SL, Tsao MS. An overview of the c-MET signaling pathway. *Ther Adv Med Oncol*. 2011;3(1 Suppl):S7-S19. doi:10.1177/1758834011422556 11. Roche Diagnostics. VENTANA MET (SP44) Rx Dx Assay Method Sheet. Roche; 2025. 12. Drilon A, Cappuzzo F, Ou SI, Camidge DR. Targeting MET in lung cancer: will expectations finally be MET? *J Thorac Oncol*. 2017;12(1):15-26. doi:10.1016/j.jtho.2016.10.014 13. Liang H, Wang M. MET oncogene in non-small cell lung cancer: mechanism of MET dysregulation and agents targeting the HGF/c-Met axis. *Oncotargets Ther*. 2020;13:2491-2510. 14. Zeng R, Luo L, Sun X, et al. EGFR/BRAF/MEK co-inhibition for EGFR-mutated lung adenocarcinoma patients with an acquired BRAFV600E mutation: a case report and review of literature. *Cancer Drug Resist*. 2021;4(4):1019-1027. doi:10.20517/cdr.2021.98 15. Serna-Blasco R, Sánchez-Herrero E, Sanz-Moreno S, et al. KRAS p.G12C mutation occurs in 1% of EGFR-mutated advanced non-small-cell lung cancer patients progressing on a first-line treatment with a tyrosine kinase inhibitor. *ESMO Open*. 2021;6(5):100279. doi:10.1016/j.esmoop.2021.100279 16. EMRELIS [package insert]. North Chicago, IL: AbbVie Inc.; 2025.

*In addition to testing, physicians should evaluate their patient's profile for informed treatment decisions.

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

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