GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

EMRELIS™ *(telisotuzumab vedotin-tllv)* injection, for IV use

PA Criteria	Criteria Details
Description	EMRELIS is a c-Met-directed antibody and microtubule inhibitor conjugate.
Covered Uses (FDA approved 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 (defined as present in ≥ 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).*
Dosing and Administration	**Indication:** Non-squamous NSCLC **Dosing Regimen:** 1.9 mg/kg IV infusion every two weeks. Continue until disease progression or unacceptable toxicity. Infuse over **30 minutes**. **Maximum Dose:** 190 mg* (*for patients ≥ 100 kg)
Billing and Coding Information	**10-digit NDC:** **20 mg:** 0074-1044-01; **100 mg:** 0074-1055-01 **11-digit NDC:** **20 mg:** 00074-1044-01; **100 mg:** 00074-1055-01 **HCPCS Code:** J9326 — **Description:** Injection, telisotuzumab vedotin-tllv, 1 mg **CPT Procedural Codes:** Unclassified Drug — **Description:** Chemotherapy IV infusion, up to one hour
Product Availability	*Single dose vial:* 20 mg and 100 mg as a lyophilized powder.
Contraindications	None.

Recommended Medical Monitoring	EMRELIS™ has been associated with: a. Peripheral Neuropathy b. Interstitial Lung Disease (ILD) and Pneumonitis c. Ocular Surface Disorders d. Infusion-Related Reactions (IRR) e. Embryo-Fetal Toxicity Patients should be monitored for any of these reactions. EMRELIS dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions. EMRELIS can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating EMRELIS treatment. Female patients of reproductive potential should be advised to use effective contraception during treatment with EMRELIS and for two months after the last dose. **Drug-Drug Interactions:** MMAE is a small molecular component of EMRELIS; it is a strong substrate for cytochrome P450 3A. • Concomitant use with strong CYP3A inhibitors may increase unconjugated MMAE AUC, possibly increasing EMRELIS adverse reactions. • Monitor patients closely if coadministered with strong 3A inhibitors *(see Appendix)*. **Moderate-to-Severe Hepatic Impairment:** AVOID USE of EMRELIS in patients with moderate to severe hepatic impairment (total bilirubin > 1.5X ULN and any AST). • Patients with moderate to severe hepatic impairment are likely to have increased exposure to MMAE, which may increase EMRELIS adverse reactions.
Approval Criteria **Breast Cancer**	a. Physician administered IV infusion; in-office or HOPD i. Cannot be self-administered b. Non-squamous Non-small Cell Lung Cancer **(must meet all)**: i. Diagnosis of non-squamous NSCLC ii. Disease is recurrent, locally advanced or metastatic iii. Disease has all of the following characteristics: 1. Non-squamous 2. High c-Met protein overexpression, defined as presence in ≥ 50% of tumor cells 3. Strong (3+) immunohistochemistry staining (IHC 3+) 4. EGFR Wild-type iv. Prescribed by or in consultation with an oncologist v. Age ≥ 18 years vi. Patient received prior systemic therapy for NSCLC (see Appendix) vii. Request is for single agent therapy viii. Request meets one of the following: 1. Dose does not exceed 1.9 mg/kg (MAX 190 mg) every two weeks 2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)

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Age Restriction	Adults ≥ 18 years old.
Coverage Duration	Initial: six months. Reauthorization: 12 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
Misc Info, Appendix Etc.	**Examples of Systemic Therapies for Advanced or Metastatic NSCLC** a. Bevacizumab + Carboplatin + Paclitaxel b. Bevacizumab + Carboplatin + Pemetrexed c. Imjudo + Imfinfzi + Carboplatin + albumin-bound Paclitaxel d. Imjudo + Imfinfzi + Carboplatin + Pemetrexed e. Imjudo + Imfinfzi + Cisplatin + Pemetrexed f. Keytruda + Carboplatin + Pemetrexed g. Keytruda + Cisplatin + Pemetrexed h. Libtayo + Carboplatin + Pemetrexed i. Libtayo + Cisplatin + Pemetrexed j. Opdivo + Yervoy k. Opdivo + Yervoy + Pemetrexed + Carboplatin l. Opdivo + Yervoy + Pemetrexed + Cisplatin m. Tecentriq + Carboplatin + albumin-bound Paclitaxel n. Tecentriq + Carboplatin + Paclitaxel + Bevacizumab **Examples of Strong CYP3A Inhibitors** a. Adagrasib b. Atazanavir c. Ceritinib d. Clarithromycin e. Cobicistat and cobicistat-containing coformulations f. Darunavir g. Diltiazem h. Erythromycin i. Grapefruit juice j. Idelalisib k. Indinavir l. Itraconazole m. Ketoconazole n. Lonafarnib o. Lopinavir p. Mifepristone (chronically used) q. Nefazodone r. Nelfinavir s. Nirmatrelvir-ritonavir t. Ombitasvir-paritaprevir-ritonavir u. Ombitasvir-paritaprevir-ritonavir plus dasabuvir v. Posaconazole w. Ritonavir and ritonavir-containing coformulations x. Saquinavir y. Tucatinib z. Verapamil aa. Voriconazole

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	9/16/2025	9/16/2025	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	11/13/2025	Pharmacy & Therapeutics (P&T) Committee	11/13/2025