GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

RYBREVANT® *(amivantamab-vmjw)* injection, for IV use
RYBREVANT FASPRO® *(amivantamab and hyaluronidase-lpuj)* subQ

PA Criteria	Criteria Details
Description	RYBREVANT is a bispecific EGF receptor-directed and MET receptor-directed antibody. RYBREVANT FASPRO is a combination of amivantamab, a bispecific EGF receptor-directed and MET receptor-directed antibody, and hyaluronidase, an endoglycosidase.
Covered Uses (FDA approved indication)	RYBREVANT and RYBREVANT FASPRO are indicated: • in combination with lazertinib for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test. • in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor. • in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test. • as a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.
Dosing and Administration	See table below

Indication	Treatment Regimen	Source for Testing
First-Line Treatment of NSCLC with EGFR Exon 19 Deletions or Exon 21 L858R Substitution Mutations	RYBREVANT or RYBREVANT FASPRO in combination with lazertinib	• Tumor or plasma specimens. • Testing may be performed at any time from initial diagnosis. • Testing does NOT need to be repeated once EGFR mutation status has been established.
Previously treated has been established. locally advanced or metastatic NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations (progressive disease on an EGFR tyrosine kinase inhibitor)	RYBREVANT or RYBREVANT FASPRO in combination with carboplatin and pemetrexed	
First-Line Treatment of NSCLC with EGFR Exon 20 Insertion Mutations	RYBREVANT or RYBREVANT FASPRO in combination with carboplatin and pemetrexed	
Previously Treated NSCLC with EGFR Exon 20 Insertion Mutations	RYBREVANT or RYBREVANT FASPRO as single agent	

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Indication	Dosing Regimen	
RYBREVANT	Combo with Lazertinib or as Single Agent	< 80 kg: 1050 mg IV weekly for first five weeks • **Week one:** Split infusion into two days (Days one & two) • **Weeks two-five:** Infuse weekly on Day one • **Week six:** NO DOSE • **Week seven onwards:** Maintenance dose (one dose every two weeks) ≥ 80 kg: 1400 mg IV weekly for first five weeks • **Week one:** Split infusion into 2 days (Days one & two) • **Weeks two-five:** Infuse weekly on Day one • **Week six:** NO DOSE • **Week seven onwards:** Maintenance dose (one dose every two weeks) Continue until disease progression or unacceptable toxicity. Use BASELINE actual body weight; dose adjustment is not required for subsequent body weight changes.
	Combo with Carboplatin and Pemetrexed	< 80 kg: 1400 mg IV weekly for first four weeks • **Week one:** Split infusion into two days (Days one & two) • **Weeks two-four:** Infusion weekly on Day one • **Weeks five and six:** NO DOSE • **Week seven onwards:** 1750 mg IV every three weeks ≥ 80 kg: 1750 IV weekly for first four doses • **Week one:** Split infusion into two days (Days one & two) • **Weeks two-four:** Infusion weekly on Day one • **Weeks five and six:** NO DOSE • **Week seven onwards:** 2100 mg IV every three weeks Continue until disease progression or unacceptable toxicity. Use BASELINE actual body weight; dose adjustment is not required for subsequent body weight changes.

Indication	Dosing Regimen	
RYBREVANT FASPRO	Administer each injection of RYBREVANT FASPRO subcutaneously in the abdomen over approximately five minutes. RYBREVANT FASPRO must be administered by a health care professional. **CANNOT BE SELF ADMINISTERED**. RYBREVANT FASPRO has different recommended dosage and administration than IV RYBREVANT products. **Do NOT substitute RYBREVANT FASPRO for or with IV RYBREVANT products.** Adult patients currently receiving **intravenous** RYBREVANT at an every two-week dosing regimen may switch to subcutaneous RYBREVANT FASPRO at an every two-week dosing regimen or at an every four-week dosing regimen at their next scheduled dose on or after Week five. Adult patients currently receiving **intravenous** RYBREVANT at an every three-week dosing regimen may switch to subcutaneous RYBREVANT FASPRO at an every three-week dosing regimen at their next scheduled dose on or after Week four. Adult patients currently receiving RYBREVANT **FASPRO** at an every two-week dosing regimen may switch to an every four-week dosing regimen at their next scheduled dose on or after Week five.	
	Combo with Lazertinib or as Single Agent	< 80 kg: • **Weeks one-four:** 1600 mg amivantamab & 20,000 units hyaluronidase subQ weekly • **Week five onwards:** 3520 mg amivantamab & 44,000 units hyaluronidase subQ every 4 weeks ≥ 80 kg: • **Weeks one-four:** 2240 mg amivantamab & 28,000 units hyaluronidase subQ weekly • **Week five onwards:** 4640 mg amivantamab & 58,000 units hyaluronidase subQ every four weeks Continue until disease progression or unacceptable toxicity. Use BASELINE actual body weight; dose adjustment is not required for subsequent body weight changes.

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	Combo with Carboplatin and Pemetrexed	< 80 kg: • **Week one:** 1600 mg amivantamab & 20,000 units hyaluronidase subQ weekly (injection on Day one) • **Weeks two-three:** 2400 mg amivantamab & 30,000 units hyaluronidase subQ weekly (injection on Day one) • **Week four onwards:** 2400 mg amivantamab/30,000 units hyaluronidase subQ every three weeks ≥ 80 kg: • **Week one:** 2240 mg amivantamab & 28,000 units hyaluronidase subQ weekly (injection on Day one) • **Weeks two-three:** 3360 mg amivantamab & 42,000 units hyaluronidase subQ weekly (injection on Day one) • **Week four onwards:** 3360 mg amivantamab/42,000 units hyaluronidase subQ every three weeks Continue until disease progression or unacceptable toxicity. Use BASELINE actual body weight; dose adjustment is not required for subsequent body weight changes.

Billing and Coding Information

	10-digit NDC	11-digit NDC
RYBREVANT	57894-501-01	57894-0501-01
RYBREVANT FASPRO	1600 mg/20,000 u: 57894-510-01 2240 mg/28,000 u: 57894-514-01 2400 mg/30,000 u: 57894-515-01 3520 mg/44,000 u: 57894-522-01	1600 mg/20,000 u: 57894-0510-01 2240 mg/28,000 u: 57894-0514-01 2400 mg/30,000 u: 57894-0515-01 3520 mg/44,000 u: 57894-0522-01

	HCPCS Code	Description
RYBREVANT	J9061	Injection, amivantamab-vmjw, 2 mg
RYBREVANT FASPRO	J9999 C9399	Not otherwise classified, antineoplastic drugs Unclassified drugs or biologicals

CPT Procedural Codes	Description
96401	Chemotherapy antineoplastic injection SQ/IM
96413	Chemotherapy administration, IV infusion, up to one hour
96415	Chemotherapy administration, IV infusion, each additional hour

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Product Availability	RYBREVANT • *Single-dose vial:* 350 mg/7 mL (50 mg/mL) RYBREVANT FASPRO • *Single-dose vial* » 1600 mg/20,000 units per 10 mL » 2240 mg/28,000 units per 14 mL » 2400 mg/30,000 units per 15 mL » 3520 mg/44,000 units per 22 mL
Contraindications	RYBREVANT: None. RYBREVANT FASPRO: Known hypersensitivity to hyaluronidase or to any of its excipients.
Recommended Medical Monitoring	RYBREVANT and RYBREVANT FASPRO have been associated with: • Hypersensitivity and Administration-Related Reactions (ARR) • Interstitial Lung Disease (ILD)/Pneumonitis • Venous Thromboembolic (VTE) Events with Concomitant Use with Lazertinib • Dermatologic Adverse Reactions • Ocular Toxicity • Embryo-Fetal Toxicity Verify pregnancy status of females of reproductive potential prior to initiating RYBREVANT or RYBREVANT FASPRO. Advise pregnant women and females of reproductive potential of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment and for **three months** after the last dose of RYBREVANT or RYBREVANT FASPRO.
Approval Criteria	A. Physician administered IV infusion (RYBREVANT) or subcutaneous injection (RYBREVANT FASPRO); in-office or HOPD i. Cannot be self-administered B. Non-Small Cell Lung Cancer **(must meet all)**: 1. Diagnosis of recurrent, advanced, or metastatic NSCLC; 2. Prescribed by or in consultation with an oncologist; 3. Age ≥ 18 years; 4. One of the following (a, b, c, or d): a. Disease is positive for EGFR exon 20 insertion mutations, and Rybrevant/Rybrevant Faspro is prescribed for one of the following uses (i or ii): i. As first line therapy in combination with carboplatin and pemetrexed; OR ii. As a single agent for disease that has progressed on or after platinum-based therapy b. Rybrevant/Rybrevant Faspro is prescribed as subsequent therapy after progression on an EGFR tyrosine kinase inhibitor (e.g., erlotinib, Gilotrif®, Lazcluze™, Tagrisso®) AND both of the following (i and ii): i. Disease is positive for EGFR exon 19 deletions or exon 21 L858R substitution mutations; AND ii. Prescribed in combination with carboplatin and pemetrexed;

	c. Rybrevant/Rybrevant Faspro is prescribed in combination with Lazcluze for disease that is positive for EGFR exon 19 deletion(s) or exon 21 L858R substitution mutation(s) AND one of the following (i, ii, or iii): i. Prescribed as first-line therapy; OR ii. Prescribed for continuation of therapy following disease progression on the combination of Rybrevant/Rybrevant Faspro and Lazcluze for asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited progression; OR iii. Prescribed as subsequent therapy following disease progression after administration of one of the following (1 or 2): 1. Tagrisso for symptomatic systemic disease with multiple lesions; OR 2. Tagrisso/(carboplatin or cisplatin)/pemetrexed; d. Member has brain metastases, and both of the following (i and ii): i. Disease is positive for EGFR exon 19 deletion(s) or exon 21 L858R substitution mutation(s); AND ii. Rybrevant/Rybrevant Faspro is prescribed in combination with one of the following (1 or 2): 1. Carboplatin and pemetrexed; OR 2. Lazcluze; 5. Request meets one of the following (a or b): a. Dose does not exceed maximum recommended dose (see *Dosing and Administration*); OR b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence); **prescribed regimen must be FDA-approved or recommended by NCCN.**
Age Restriction	None.
Coverage Duration	**Initial/Reauthorization:** up to 12 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
Other Criteria (LCD, NCD, etc.)	Must follow LCD L37205 – Chemotherapy Drugs and their Adjuncts.
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	4/22/26	4/22/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	5/14/26	Pharmacy & Therapeutics (P&T) Committee	5/14/26