Clinical Policy Title:	amivantamab-vmjw
Policy Number:	RxA.690
Drug(s) Applied:	Rybrevant™
Original Policy Date:	08/16/2021
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All line of business

Background

Amivantamab-vmjw (Rybrevant™) is a bispecific EGF receptor-directed and MET receptor-directed antibody indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
amivantamab-vmjw (Rybrevant™)	Non-Small Cell Lung Cancer (NSCLC)	Rybrevant™ is administered weekly for 4 weeks, with the initial dose as a split infusion in Week 1 on Day 1 and Day 2, then administer every 2 weeks starting at Week 5. Recommended dose of Rybrevant™ based on baseline body weight: • Less than 80 kg: 1050 mg (3 vials) • Greater than or equal to 80 kg: 1400 mg (4 vials)	Weight < 80 kg: 1,050 mg intravenously. Weight ≥ 80 kg or more: 1,400 mg intravenously.

Dosage Forms

- Injection: 350 mg/7 mL (50 mg/mL) solution in a single-dose vial.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Disease is positive for sensitizing EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy;
4. Subsequent therapy as a single agent for EGFR exon 20 insertion mutation positive recurrent, advanced, or metastatic disease in patients with ECOG performance status 0-2;
5. The member is 18 years of age or older;
6. Member doesn't have untreated brain metastases and history of ILD requiring treatment with prolonged steroids or other immunosuppressive agents within the last 2 years;
7. Maximum Dose does not exceed (a or b):
   a. Weight < 80 kg: 1050 mg;
   b. Weight ≥ 80 kg: 1400 mg.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Non-Small Cell Lung Cancer (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Rybrevant™ for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Maximum Dose does not exceed (a or b):
   a. Weight < 80 kg: 1050 mg;
   b. Weight ≥ 80 kg: 1400 mg.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
NSCLC: Non-Small Cell Lung Cancer
ILD: Interstitial Lung Disease
ECOG: Eastern Cooperative Oncology Group
EGFR: epidermal growth factor receptor
EGF: Epidermal growth factor
MET: mesenchymal epithelial transition
FDA: Food and Drug Administration
IRR: Infusion-related reactions

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Interrupt infusion at the first sign of IRR; Reduce infusion rate or permanently discontinue Rybrevant™ based on IRR severity.
- Monitor for new or worsening symptoms indicative of ILD; Immediately withhold Rybrevant™ in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.
- May cause rash including acneiform dermatitis and toxic epidermal necrolysis; Withhold, reduce the dose or permanently discontinue Rybrevant™ based on severity.
- Promptly refer patients with worsening eye symptoms to an ophthalmologist; Withhold, reduce the dose or permanently discontinue Rybrevant™ based on severity.
- ECOG Performance Status:

GRADE	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Deceased

References

1. Rybrevant™ Prescribing Information. Horsham, PA: Janssen Biotech Inc; July 2021. Available at: https://janssenlabels.com/package-insert/product-monograph/prescribing-information/RYBREVANT-pi.pdf. Accessed August 16, 2021.
2. Rybrevant™, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed August 16, 2021.
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: https://www.clinicalkey.com/pharmacology/login . Accessed August 16, 2021.
4. Rybrevant™, IPD Analytics New Drug Review_Rybrevant™_06 2021.pdf. Accessed with subscription at: https://www.ipdanalytics.com/. Accessed August 16, 2021.
5. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 5.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf . Accessed August 16, 2021.

6. ECOG performance status. ECOG-ACRIN. Available at: https://ecog-acrin.org/resources/ecog-performance-status. Accessed August 16, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established.	08/16/2021	09/14/2021