BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.21.176

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 11, 2021
Subject:	Rybrevant	**Page:**	1 of 5

Last Review Date: March 8, 2024

Rybrevant

Description

Rybrevant (amivantamab-vmjw)

Background
Rybrevant (amivantamab-vmjw) is a bispecific antibody that binds to the extracellular domains of epidermal growth factor receptor (EGFR) and MET. In studies, Rybrevant was able to disrupt EGFR and MET signaling functions through blocking ligand binding and, in exon 20 insertion mutation models, degradation of EGFR and MET. The presence of EGFR and MET on the surface of tumor cells also allows for targeting of these cells for destruction by immune effector cells, such as natural killer cells and macrophages, through antibody-dependent cellular cytotoxicity and trogocytosis mechanisms, respectively (1).

Regulatory Status
FDA-approved indication: Rybrevant is 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 (1).

Rybrevant has warnings regarding the following: infusion-related reactions, interstitial lung disease/pneumonitis, dermatologic adverse reactions, ocular toxicity, and embryo-fetal toxicity (1).

Rybrevant can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment and for 3 months after the final dose of Rybrevant (1).

Patients should be premedicated with antihistamines, antipyretics, and glucocorticoids as appropriate to reduce the risk of infusion-related reactions (1).

The safety and effectiveness of Rybrevant in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rybrevant may be considered **medically necessary** if the conditions indicated below are met.

Rybrevant may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
    a. EGFR exon 20 insertion mutation as detected by an FDA-approved test
    b. Disease has progressed on or after platinum-based chemotherapy

AND ALL of the following:

1. Patient will be premedicated with antihistamines, antipyretics, and glucocorticoids as appropriate

2. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Rybrevant and for 3 months after the final dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Patient will be premedicated with antihistamines, antipyretics, and glucocorticoids as appropriate
3. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Rybrevant and for 3 months after the final dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Body Weight	Quantity
Less than 80 kg	84 vials **OR**
80 kg or more	112 vials

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Body Weight	Quantity
Less than 80 kg	18 vials per 84 days **OR**
80 kg or more	24 vials per 84 days

Duration 12 months

Rationale

Summary

Rybrevant (amivantamab-vmjw) is a bispecific antibody that binds to the extracellular domains of epidermal growth factor receptor (EGFR) and MET. It is 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. Rybrevant has warnings regarding the following: infusion-related reactions, interstitial lung disease/pneumonitis, dermatologic adverse reactions, ocular toxicity, and embryo-fetal toxicity. The safety and effectiveness of Rybrevant in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Rybrevant while maintaining optimal therapeutic outcomes.

References

1. Rybrevant [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2022.
2. NCCN Drugs & Biologics Compendium® Amivantamab-vmjw 2024. National Comprehensive Cancer Network, Inc. Accessed on January 16, 2024.

Policy History

Date	Action
June 2021	Addition to PA
September 2021	Annual review and reference update
March 2022	Annual review and reference update
September 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.