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5.50.028

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	April 3, 2020
Subject:	Barhemsys	**Page:**	1 of 4

Last Review Date: March 8, 2024

Barhemsys

Description

Barhemsys (amisulpride)

Background
Barhemsys (amisulpride) is a selective dopamine-2 (D_2) and dopamine-3 (D_3) receptor antagonist indicated for prevention and/or treatment of postoperative nausea and vomiting. D_2 receptors are located in the chemoreceptor trigger zone (CTZ) and respond to the dopamine released from the nerve endings. Antagonism of D2 receptors in the CTZ relays inhibitory stimuli to the vomiting center. Antagonism of D3 receptors in the area postrema also inhibits emesis (1).

Regulatory Status
FDA-approved indications: Barhemsys is indicated in adults for: (1)

- Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic or a different class.
- Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.

Barhemsys has a warning regarding QT prolongation. As Barhemsys can cause dose- and concentration-dependent prolongation of the QT interval, it should be avoided in patients with congenital long QT syndrome and in patients taking droperidol. Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders, electrolyte abnormalities, congestive heart failure, and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval (1).

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

Related policies
5HT3 Antagonists, Cannabinoids, NK-1 antagonists

Policy

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

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

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

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** the following:

1. Post-operative nausea and/or vomiting (PONV)
    a. Operation was within the last month
2. Prevention of post-operative nausea and/or vomiting (PONV)
    a. Operation will be within the next month

AND the following:

1. Prescriber agrees to monitor electrocardiogram (ECG) for QTc prolongation, as clinically indicated

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 4 vials per 30 days

Duration 1 month

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Barhemsys (amisulpride) is a selective dopamine-2 (D_2) and dopamine-3 (D_3) receptor antagonist used for prevention and/or treatment of postoperative nausea and vomiting. Barhemsys has a warning regarding QT prolongation. The safety and effectiveness of Barhemsys in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Barhemsys [package insert]. Indianapolis, IN: Acacia Pharma Inc.; September 2022.

Policy History

Date	Action
April 2020	Addition to PA
June 2020	Annual review
June 2021	Annual editorial review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.50.028
June 2023	Annual review
March 2024	Annual review

Keywords

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