

CLINICAL POLICY

Amisulpride



Clinical Policy: Amisulpride (Barhemsys)

Reference Number: PA.CP.PMN.236

Effective Date: 08/2022

Last Review Date: 07/2024

Description

Amisulpride (Barhemsys®) is a dopamine-2 (D₂) antagonist.

FDA Approved Indication(s)

Barhemsys is indicated in adults for:

- Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of 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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Barhemsys is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Postoperative Nausea and Vomiting (must meet all):

1. Prescribed for the prevention or treatment of PONV;
2. Age \geq 18 years;
3. Member is scheduled to undergo surgery;
4. Member meets one of the following (a or b):
 - a. For prevention: failure of one multimodal regimen consisting of two or more formulary agents for PONV, each from different therapeutic classes (e.g. 5HT₃ receptor antagonist + oral corticosteroid, neurokinin 1 receptor antagonist + 5HT₃ receptor antagonist, neurokinin 1 receptor antagonist + oral corticosteroid), at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
 - b. For treatment: Member did not receive a preoperative D₂ antagonist (e.g., metoclopramide);
5. Request meets one of the following (a or b):
 - a. For prevention: Dose does not exceed 5 mg once;
 - b. For treatment: Dose does not exceed 10 mg once.

Approval duration: 1 month (one time dose)

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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II. Continued Therapy

A. Postoperative Nausea and Vomiting

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA PHARM.01) applies;

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

PONV: postoperative nausea and vomiting

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Pharmacologic Combination	Class	Examples of pharmacologic combination therapy
PONV		
5-HT ₃ receptor antagonist + oral corticosteroid		Ondansetron (preferred) + dexamethasone, palonosetron + dexamethasone, granisetron + dexamethasone
5-HT ₃ receptor antagonist + neurokinin 1 receptor antagonist		Ondansetron + aprepitant, palonosetron + aprepitant
Neurokinin 1 receptor antagonist + oral corticosteroid		Aprepitant + dexamethasone
5-HT ₃ receptor antagonist + droperidol		Ondansetron + droperidol, granisetron + droperidol, palonosetron + droperidol
Other 5-HT ₃ receptor antagonist		Ondansetron + haloperidol, dexamethasone + haloperidol + ondansetron
Other antidopaminergic combinations		Dexamethasone + haloperidol, metoclopramide + dimenhydrinate, haloperidol + midazolam

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

**Off-label*

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Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to amisulpride
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prevention of PONV	5 mg as a single IV dose infused over 1 to 2 minutes at the time of induction of anesthesia	5 mg/dose
Treatment of PONV	10 mg as a single IV dose infused over 1 to 2 minutes in the event of nausea and/or vomiting after a surgical procedure	10 mg/dose

VI. Product Availability

Single-dose vial for injection: 5 mg/2 mL, 10 mg/4 mL

VII. References

1. Barhemsys Prescribing Information. Indianapolis, IN: Acacia Pharma Inc.; September 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209510s0051bl.pdf. Accessed May 6, 2024.
2. Gan TJ, Diemunsch P, Belani KG, Bergese S, et al. Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting, *Anesthesia & Analgesia*: 2020; 131 (2): 411-448. <https://doi.org/10.1213/ane.0000000000004833>

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0184	Injection, amisulpride, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	07/2022
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023
3Q 2024 annual review: added age requirement per prescribing information; revised approval duration from one time “approval” to “dose”; added HCPCS code [J0184]; references reviewed and updated.	07/2024