# Clinical Policy: Amisulpride (Barhemsys)

Reference Number: PA.CP.PMN.236
Effective Date: 08/2022
Last Review Date: 07/2023

Coding Implications
Revision Log

**Description**
Amisulpride (Barhemsys®) is a dopamine-2 ($D_2$) 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. Member is scheduled to undergo surgery;
3. 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 does, 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);
4. 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 approval**)

**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

## 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.LTSS.PHAR.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 for all relevant lines of business and may require prior authorization.*

| Pharmacologic Class Combination | 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*

*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/2022/209510s005lbl.pdf. Accessed April 20, 2023.
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 |
|---|---|
| J3490 | Unclassified drugs |
| C9399 | Unclassified drugs or biologicals |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 07/2022 | |
| 3Q 2023 annual review: no significant changes; references reviewed and updated. | 07/2023 | |