Clinical Policy: Amisulpride (Barhemsys)

Reference Number: CP.PMN.236
Effective Date: 09.01.20
Last Review Date: 08.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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 ≥ 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 does, unless clinically significant adverse effects are experienced or all are contraindicated (see *Appendix B);**
   ***For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
   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 (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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 antagonists	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 vials 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 21, 2025.
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. DOI: 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	P&T Approval Date
3Q 2021 annual review: revised initial approval duration from 3 days to 1 month to allow for sufficient time to obtain medication; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	03.19.21	08.21
3Q 2022 annual review: revised initial approval criteria for PONV prophylaxis to require failure of one multimodal combination therapy; updated appendix B to include examples of combination agents recommended by Anesthesia & Analgesia guideline; reference reviewed and updated.	04.07.22	08.22
Updated Appendix B to only include FDA approved drugs. Template changes applied to other diagnoses/indications.	09.08.22	
3Q 2023 annual review: no significant changes; references reviewed and updated.	04.20.23	08.23
Added HCPCS code [J0184]	10.27.23	
3Q 2024 annual review: added age requirement per prescribing information; revised approval duration from one time “approval” to “dose”; references reviewed and updated.	05.06.24	08.24
3Q 2025 annual review: no significant changes; references reviewed and updated. Added step therapy bypass for IL HIM per IL HB 5395.	06.26.25	08.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional

organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.