Clinical Policy: Amisulpride (Barhemsys)

Reference Number: ERX.NPA.146
Effective Date: 09.01.20
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

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

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 generic formulary agent for PONV 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);
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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
PONV Therapies per 2014 Society for Ambulatory Anesthesia (SAMBA) Guidelines		
5-HT_3 receptor antagonist (e.g., ondansetron [*preferred*], granisetron, palonosetron)	Varies	Varies
Glucocorticoid (e.g., dexamethasone, methylprednisolone)	Varies	Varies
Transdermal scopolamine	Apply 1 patch to the skin behind the ear the evening before scheduled surgery. Remove 24 hours after surgery.	1 patch/dose
Butyrophenone (e.g., droperidol, haloperidol)	Varies	Varies
Neurokinin 1 receptor antagonist (e.g., aprepitant, rolapitant)	Varies	Varies
Antihistamine (e.g., dimenhydrinate)	Varies	Varies

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.

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 2020. Available at: www.barhemsys.com. Accessed March 19, 2021.
2. Gan TJ, Diemunsch P, Habib AS, et al. Society for Ambulatory Anesthesia: Consensus guidelines for the management of postoperative nausea and vomiting. Anesth Analg. 2014; 118(1): 85-113.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.19.20	08.20
3Q 2021 annual review: revised initial approval duration from 3 days to 1 month to allow for sufficient time to obtain medication; references reviewed and updated.	03.19.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.