RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	amisulpride
Policy Number:	RxA.644
Drug(s) Applied:	Barhemsys®
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

BARHEMSYS is a dopamine-2 antagonist indicated in adults for prevention of postoperative nausea and vomiting either alone or in combination with an antiemetic of a different class or as a treatment of PONV in patients who have received antiemetics prophylaxis with an agent of a different class or have not received prophylaxis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
amisulpride (Barhemsys®)	Prevention of postoperative nausea and vomiting (PONV) either alone or in combination with an antiemetic of a different class	5 mg as a single intravenous dose infused over 1 to 2 minutes at the time of induction of anesthesia	10 mg/dose IV
	Treatment of PONV in patients who have received antiemetics prophylaxis with an agent of a different class or have not received prophylaxis	10 mg as a single intravenous dose infused over 1 to 2 minutes in the event of nausea and/or vomiting after a surgical procedure	10 mg/dose IV

Dosage Forms

Injection: 5 mg/2 mL (2.5 mg/mL) in a single-dose vial.

Clinical Policy

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

I. Initial Approval Criteria

A. Post-operative nausea and/or vomiting (PONV) (must meet all):

1. Indicated for one of the following (a or b);

a)Treatment of PONV with operation date being within the last 30 days

b)Prevention of PONV with operation date within 30 days

2. Age ≥ 18 years;
3. Prescribers agrees to monitor electrocardiogram (ECG) for QTc prolongation as clinically indicated;
4. Patient does not have congenital long QT syndrome and is not taking droperidol;
5. Dose does not exceed 10 mg IV.

Approval Duration
Commercial: 1 month
Medicaid: 1 month

II. Continued Therapy Approval

A. Post-operative nausea and/or vomiting (PONV):

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

Approval Duration
Commercial: Not applicable
Medicaid: Not applicable

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
PONV: Post-operative nausea and/or vomiting
ECG: electrocardiogram

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
dexamethasone	Treatment of PONV: 2 to 4 mg IV once Prophylaxis of PONV: 4 to 5 mg IV at anesthesia induction	N/A
droperidol	Treatment of PONV: 0.625 to 1.25 mg IV at the end of surgery Prophylaxis of PONV: initially, no more than 2.5 mg IM/IV. Additional doses of up to 1.25 mg IM/IV may be given	2.5 mg IM/IV
scopolamine patch	Apply 1 patch to hairless area of the skin behind the ear the evening before scheduled surgery. Remove the patch 24 hours following surgery.	1 patch every 3 days
Promethazine (Phenergan®)	12.5 to 25 mg PO, PR, IM or IV every 4 to 6 hours PRN	50 mg/dose; 100 mg/day

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

APPENDIX D: General Information

- Not Applicable

References

1. Product Information: BARHEMSYS; amisulpride. Acacia Pharma Inc, Ltd (per FDA), Indianapolis, IN, 2020 Feb. Accessed August 20, 2020
2. Cau X, et al. An Update on the Management of Postoperative Nausea and Vomiting J Anesth. 2017; 31(4):617-626. doi: 10.1007/s00540-017-2363-x.
3. Micromedex®® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 20, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established		09/14/2020