Clinical Policy Title:	amisulpride
Policy Number:	RxA.644
Drug(s) Applied:	Barhemsys®
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Amisulpride (Barhemsys®) is a dopamine-2 (D2) antagonist 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 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	5 mg/dose intravenous
	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 intravenous

Dosage Forms

- Injection: 5 mg/2 mL (2.5 mg/mL) or 10 mg/4 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Post-operative nausea and 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. Prescribed by or in consultation with a specialist;
4. Prescribers agrees to monitor electrocardiogram (ECG) for QTc prolongation as clinically indicated;
5. Patient does not have congenital long QT syndrome and is not taking droperidol;
6. 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
Commercial: 1 month
Medicaid: 1 month

II. Continued Therapy Approval

A. Post-operative nausea and 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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
dexamethasone	Treatment of PONV: 2 to 4 mg intravenous once Prophylaxis of PONV: 4 to 5 mg intravenous at anesthesia induction	N/A
droperidol	Treatment of PONV: 0.625 to 1.25 mg intravenous at the end of surgery Prophylaxis of PONV: initially, no more than 2.5 mg intramuscular/intravenous Additional doses of up to 1.25 mg intramuscular/intravenous may be given	2.5 mg intramuscular/intravenous
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 orally, rectally, intramuscular or intravenous every 4 to 6 hours as needed	50 mg/dose; 100 mg/day

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to amisulpride.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- QT Prolongation: Occurs in a dose- and concentration-dependent manner. Avoid use in patients with congenital long QT syndrome and in patients taking droperidol. ECG monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders; electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia); congestive heart failure; and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval.

References

1. Barhemsys® Prescribing Information. Indianapolis, IN: Acacia Pharma Inc. May 2021 . Available at: https://bynder.acaciapharma.com/m/5d7c2cd0d58865f7/original/Barhemsys-Prescribing-Information.pdf. Accessed July 05, 2021.
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. Available at: https://pubmed.ncbi.nlm.nih.gov/28455599/. Accessed July 05, 2021.
3. Barhemsysr. Micromedex Solutions. Truven Health Analtics Inc. Greenwood Village, CO. Available at http://www.micromedexsolutions.com. Accessed July 05, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	09/14/2020	09/14/2020
Policy was reviewed: 1. Background was updated to include generic drug name “amisulpride”. 2. Dosing Information maximum dose for indication “Prevention of postoperative nausea and vomiting (PONV) either alone or in combination with an antiemetic of a different class” was updated from “10mg/dose” to “5mg/dose”. 3. Dosage Forms was updated to include “…or 10 mg/4 mL (2.5 mg/mL)…”. 4. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy.	07/05/2021	09/14/2021

5. Initial Approval Criteria I.A was updated from “Post-operative nausea and/or vomiting (PONV)” to “Post-operative nausea and vomiting (PONV)”. 6. Initial Approval Criteria I.A.3 was updated to include prescriber criteria “Prescribed by or in consultation with a specialist;”. 7. Initial Approval Criteria I.A.6 was updated to include “Request meets one of the following (a or b)…”. 8. Initial Approval Criteria I.A.6.a was updated to include “For prevention: Dose does not exceed 5 mg once;”. 9. Initial Approval Criteria I.A.6.b was updated to include “For treatment: Dose does not exceed 10 mg once;”. 10. Continued Therapy Approval Criteria II.A was updated from “Post-operative nausea and/or vomiting (PONV)” to “Post-operative nausea and vomiting (PONV)”. 11. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 12. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 13. Appendix D was updated to include “QT Prolongation: Occurs in a dose- and concentration-dependent manner…”. 14. References were reviewed and updated.		