Clinical Policy: Amisulpride (Barhemsys)
Reference Number: CP.PMN.236
Effective Date: 09.01.20
Last Review Date: 08.20
Line of Business: Commercial, HIM, Medicaid

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.

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. 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: One time approval (3 days)

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      **Approval duration: Duration of request or 12 months (whichever is less); or**
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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.PHAR.21 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.*

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>PONV Therapies per 2014 Society for Ambulatory Anesthesia (SAMBA) Guidelines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-HT\textsubscript{3} receptor antagonist (e.g., ondansetron [preferred], granisetron, palonosetron)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>Glucocorticoid (e.g., dexamethasone, methylprednisolone)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>Transdermal scopolamine</td>
<td>Apply 1 patch to the skin behind the ear the evening before scheduled surgery. Remove 24 hours after surgery.</td>
<td>1 patch/dose</td>
</tr>
<tr>
<td>Butyrophenone (e.g., droperidol, haloperidol)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
</tbody>
</table>
CLINICAL POLICY
Amisulpride

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Neurokinin 1 receptor antagonist (e.g., aprepitant, rolapitant)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>Antihistamine (e.g., dimenhydrinate)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>Perphenazine</td>
<td>2.5 mg to 5 mg IV or IM</td>
<td>5 mg/dose</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of PONV</td>
<td>5 mg as a single IV dose infused over 1 to 2 minutes at the time of induction of anesthesia</td>
<td>5 mg/dose</td>
</tr>
<tr>
<td>Treatment of PONV</td>
<td>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</td>
<td>10 mg/dose</td>
</tr>
</tbody>
</table>

VI. Product Availability
Single-dose vial for injection: 5 mg/2 mL (2.5 mg/mL)

VII. References

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.

<table>
<thead>
<tr>
<th>HCPSC Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>TBD</td>
<td>TBD</td>
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</table>
**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.

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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.

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