Blue Cross Blue Shield Blue Care Network of Michigan

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RETIRED

Effective Date: 04/08/2021

Barhemsys® (amisulpride) for intravenous injection

FDA approval: February 26, 2020
HCPCS: J3490
Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. FDA approved indication
   c. FDA approved dosing
   d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. **FDA approved indication / Diagnosis**
   a. Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class
   b. Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis

**Please refer to most recent prescribing information.*

B. **Background Information**
   a. PONV is a common complication of surgery, occurring in approximately 30% of surgical patients and up to 80% of high-risk patients

b. It is associated with the use of anesthetic gases and opioid painkillers
c. It is particularly common following gynecological, abdominal, breast, eye, and ear operations, especially those lasting an hour or more
d. PONV has been ranked as the most undesirable of all surgical complications in some patient surveys, even worse than pain
e. It is estimated that approximately 65 million surgical procedures are conducted in the United States each year that are eligible for antiemetic use to prevent PONV
f. The total market in the US for high-risk prophylactic and rescue treatment comprises an estimated 34 million patients annually
g. The guidelines for management of postoperative nausea and vomiting recommend identifying those with risk factors for developing the condition
h. Risk factors for PONV include being female, younger, a non-smoker, history of PONV or motion sickness, general versus regional anesthesia, use of volatile anesthesia or nitrous oxide, postoperative opioids, duration of anesthesia, and the type of surgery being performed
i. If patients are medium to high risk for the development of PONV, prophylactic therapy should be given
j. If prophylactic therapy fails or was not given, an antiemetic from a class different from initial therapy should be administered
k. Guidelines recommend the following regimens to treat or for prophylaxis of PONV
    i. 5-HT3 receptor antagonist + dexamethasone
    ii. 5-HT3 receptor antagonist + droperidol
    iii. 5-HT3 receptor antagonist + dexamethasone + droperidol
    iv. Droperidol + dexamethasone
    v. Ondansetron + casopitant
l. Treatment guidelines have yet to be updated to include Barhemsys

C. **Efficacy**

**Please refer to most recent prescribing information.*

D. **Medication Safety Considerations**

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. **Dosing and administration**
a. Prevention of PONV, either alone or in combination with another antiemetic: 5 mg as a single intravenous dose infused over 1 to 2 minutes at the time of induction of anesthesia
b. Treatment of PONV: 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

**Please refer to most recent prescribing information.*

F. **How supplied**
a. 5 mg/2 mL single-dose vials

References:

1. Barhemsys [prescribing information]. Indianapolis, IN: Acacia Pharma Inc; February 2020.

2. Habib AS, Kranke P, Bergese SD, et al. Amisulpride for the rescue treatment of postoperative nausea or vomiting in patients failing prophylaxis: a randomized, placebo-controlled phase III trial. *Anesthesiology*. Feb 2019; 130(2): 203-212.
3. Kranke P, Bergese SD, Minkowitz, et al. Amisulpride prevents postoperative nausea and vomiting in patients at high risk: a randomized, double-blind, placebo-controlled trial. *Anesthesiology*. June 2018; 128(6): 1099-1106.
4. Gan TJ, Diemunsch P, Habib AS, et al. Consensus guidelines for the management of postoperative nausea and vomiting. *Anesth Analg*. Jan 2014; 118(1): 85-113.
5. Clinicaltrials.gov. Randomized, double-blind, placebo-controlled phase III study of APD421 (amisulpride for IV injection) as prophylaxis against post-operative nausea and vomiting (NCT01991860). Available at: https://clinicaltrials.gov/ct2/show/results/NCT01991860?term=NCT01991860&draw=2&rank=1. Accessed on March 2, 2020.
6. Clinicaltrials.gov. Randomized, double-blind, placebo-controlled phase III study of APD421 (amisulpride for IV injection) as combination prophylaxis against p6ost-operative nausea and vomiting in high-risk patients (NCT02337062). Available at: https://clinicaltrials.gov/ct2/show/NCT02337062?term=NCT02337062&draw=2&rank=1. Accessed on: March 2, 2020.
7. Candiotti KA, Kranke P, Bergese SD, et al. Randomized, double-blind, placebo-controlled study of intravenous amisulpride as treatment of established postoperative nausea and vomiting in patients who have had no prior prophylaxis. *Anesth Analg*. Jun 2019; 128(6): 1098 - 1105.
8. Clinicaltrials.gov. Randomized, double-blind, placebo-controlled study of APD421 (amisulpride for IV injection) as treatment of established post-operative nausea and vomiting in patients who have had prior prophylaxis (NCT02646566). Available at: https://clinicaltrials.gov/ct2/show/NCT02646566?term=NCT02646566&draw=2&rank=1. Accessed on March 2, 2020.

Policy History		
#	Date	Change Description
1.1	Effective Date: 04/08/2021	Retiring policy as drug is not managed with prior authorization
1.0	Effective Date: 4/16/2020	New full drug review

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*