

Medical Policy:

Barhemsys® (amisulpride)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.320	April 2, 2024	November 11, 2020

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Barhemsys (amisulpride) is a selective dopamine-2 (D 2) and dopamine-3 (D 3) receptor antagonist. D 2 receptors are located in the chemoreceptor trigger zone (CTZ) and respond to the dopamine released from the nerve endings. Activation of CTZ relays stimuli to the vomiting center which is involved in emesis. Studies in multiple species indicate that D 3 receptors in the area postrema also play a role in emesis.

Amisulpride has no appreciable affinity for any other receptor types apart from low affinities for 5-HT 2B and 5-HT 7 receptors.

Length of Authorization

Coverage will be provided for 1 month.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 5 mg as a single dose for prevention of postoperative nausea and vomiting (PONV)

- 10 mg as a single dose for treatment of PONV

Guideline

I. INITIAL APPROVAL CRITERIA

Barhemsys may be considered medically necessary if all of the below conditions are met **AND** use is consistent with the medical necessity criteria that follows:

1. Prevention of PONV

- A. Patient is 18 years of age or older; **AND**
- B. Patient has a scheduled surgery within the next 30 days.

2. Treatment of PONV

- A. Patient is 18 years of age and older; **AND**
- B. Patient has had a surgery within the last 30 days

Limitations/Exclusions

Barhemsys is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

II. RENEWAL CRITERIA

N/A

Dosage/Administration

Indication	Dose
Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class.	The recommended dose of <i>Barhemsys</i> for prevention of PONV is 5 mg as a single intravenous dose infused over 1 to 2 minutes at the time of induction of anesthesia.
Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.	The recommended dose of <i>Barhemsys</i> for treatment of PONV is 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.

Applicable Procedure Codes

Code	Description
J0184	Injection, amisulpride, 1 mg

Applicable NDCs

Code	Description
71390-0125-xx	<i>Barhemsys</i> (amisulpride) injection, 5mg in 2ml
71390-0125-xx	<i>Barhemsys</i> (amisulpride) injection, 10mg in 4ml

ICD-10 Diagnoses

Code	Description
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.12	Projectile vomiting
R11.2	Nausea with vomiting, unspecified
T41.0X5A	Adverse effect of inhaled anesthetics, initial encounter
T41.1X5A	Adverse effect of intravenous anesthetics, initial encounter
T41.205A	Adverse effect of unspecified general anesthetics, initial encounter
T41.295A	Adverse effect of other general anesthetics, initial encounter
T41.45XA	Adverse effect of unspecified anesthetic, initial encounter
T88.59XA	Other complications of anesthesia, initial encounter

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/2/2024	Annual Review: Removed Code C9153 and C9399, added J0184, updated NDCs
EmblemHealth & ConnectiCare	9/11/2023	Removed JCode3490 - Unclassified drugs. Added C9153 Injection, amisulpride, 1 mg.
EmblemHealth & ConnectiCare	7/27/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	3/30/2022	Updated Procedure Code to Q2055 and put on new template
EmblemHealth & ConnectiCare	11/11/2020	New Policy

References

1. Barhemsys [package insert]. Indianapolis, IN: Acacia Pharma Inc.; February 2020.