Barhemsys (amisulpride) injection 2.5 mg/mL

Billing Guide

J-code for billing: J0184
effective January 1, 2024

Granted 3-year transitional pass-through payment status
effective October 1, 2023

Reimbursement for Barhemsys

- Effective October 1, 2023, Barhemsys has been granted a 3-year transitional pass-through payment status by the Centers for Medicare & Medicaid Services (CMS). Pass through status provides additional payment for Barhemsys (ASP + 6%) for ASCs and HOPDs when billed to Medicare for a period of three years.[1]
- Commercial payers may have varied payment methodologies for Barhemsys. Please contact the patient's insurer to understand how Barhemsys is reimbursed.

Note: reimbursement is subject to CMS updates.

Coding for Barhemsys

Healthcare Common Procedure Coding System (HCPCS) Level II Codes[2]

HCPCS Level II national codes are used to identify and report drugs on claims. The CMS has established a unique, product-specific billing code for Barhemsys, effective January 1, 2024.

HCPCS Code	Description
J0184	Injection, amisulpride, 1 mg

National Drug Code (NDC)[3]

Some payers may also require the inclusion of the National Drug Code (NDC) on the medical claim.

10-Digit NDC	11-Digit NDC	Package Description
71390-125-20	71390-0125-20	Bundle of 10 single-dose vials, each containing 5 mg/2 mL of intravenous solution
71390-125-21	71390-0125-21	One single-dose vial containing 5 mg/2 mL of intravenous solution
71390-125-50	71390-0125-50	Bundle of 10 single-dose vials, each containing 10 mg/4 mL of intravenous solution
71390-125-51	71390-0125-51	One single-dose vial containing 10 mg/4 mL of intravenous solution

Note: NDCs are displayed in a 10-digit format on the FDA-approved product labeling. Proper billing for most payers or electronic data interchange systems requires that the NDC be submitted in the 11-digit numeric format.
Note: individual vial ordering is not available.

Billable Units

The billable unit for J0184 is 1 mg. Use the HCPCS modifier **JZ** to indicate that the full single-dose vial was administered.

Indication	Recommended Dose	Billable Units
PONV Prevention	One Barhemsys 5 mg vial (1 x 5 mg/2 mL)	5
PONV Rescue Treatment	One Barhemsys 10 mg vial (1 x 10 mg/4 mL) or two Barhemsys 5 mg vials (2 x 5 mg/2 mL)	10

Indications

Barhemsys is a selective dopamine-2 (D_2) and dopamine-3 (D_3) receptor 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 antiemetic prophylaxis with an agent of a different class or have not received prophylaxis

Select Important Safety Information

Contraindication

Barhemsys is contraindicated in patients with known hypersensitivity to amisulpride.

Please see full Important Safety Information on next page and full Prescribing Information.

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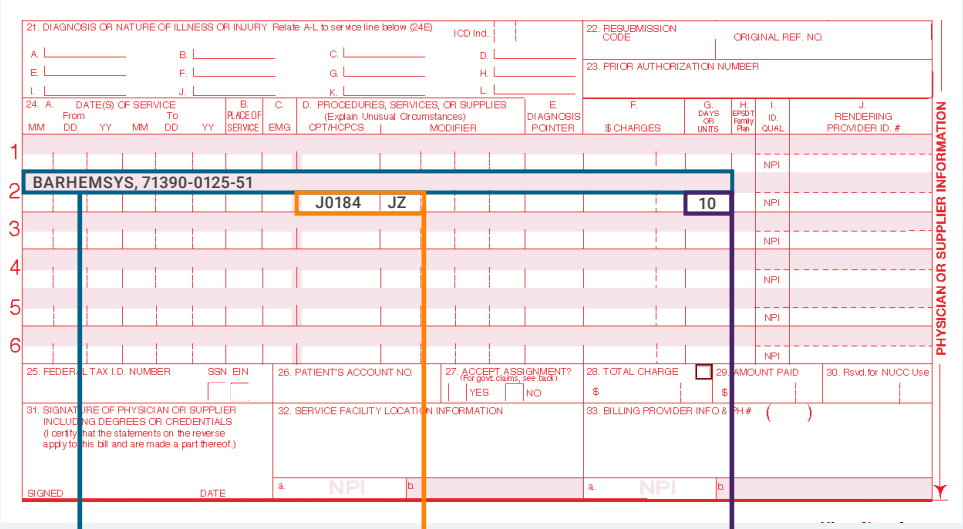
SAMPLE CLAIM FORM CMS-1500[4]



Field 24 (Shaded Area)
Include the required information (eg, product name and NDC). **Confirm NDC requirements with payer or Eagle Pharmaceuticals as they may vary.**

Field 24D
Specify the HCPCS code. For dates of service on or after January 1, 2024, use **J0184**.

- To indicate that the full single-dose vial was administered, use the HCPCS modifier **JZ**.

Field 24G
Specify the number of units administered. The **billable unit for J0184** is **1 mg**.

- For the **treatment of PONV**, the **10 mg** single dose in each Barhemsys 4 mL vial or two Barhemsys 2 mL vials corresponds to **10 billable units**.
- For the **prevention of PONV**, the **5 mg** single dose in each Barhemsys 2 mL vial corresponds to **5 billable units**.

Information in this guide was obtained from third-party sources and is made available for illustrative purposes only; it is non-exhaustive, subject to change, and does not constitute coding or legal advice regarding the selection of codes to describe a particular service. Healthcare professionals are responsible for determining which code(s), charge(s), or modifier(s), if any, are appropriate to reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity, supported by adequate documentation. Eagle Pharmaceuticals, Inc. makes no guarantee of coverage or payment for items or services. Payment and coverage vary by payer. Questions about coding, coverage, and payment may be directed to the applicable third-party payer, reimbursement specialist, and/or legal counsel.

Questions?

For reimbursement questions, please contact: Barhemsys.reimbursement@eagleus.com

Please see full Important Safety Information on next page and full Prescribing Information.

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Important Safety Information

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QT Prolongation

Barhemsys causes dose- and concentration-dependent prolongation of the QT interval. The recommended dosage is 5 mg or 10 mg as a single intravenous (IV) dose infused over 1 to 2 minutes.

Avoid Barhemsys in patients with congenital long QT syndrome and in patients taking droperidol.

Electrocardiogram (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.

Adverse Reactions

Common adverse reactions reported in ≥ 2% of adult patients who received Barhemsys 5 mg (N=748) and at a higher rate than placebo (N=741) in clinical trials for the prevention of PONV were: chills (4% vs. 3%), hypokalemia (4% vs. 2%), procedural hypotension (3% vs. 2%), and abdominal distention (2% vs. 1%).

Serum prolactin concentrations were measured in one prophylaxis study where 5% (9/176) of Barhemsys-treated patients had increased blood prolactin reported as an adverse reaction compared with 1% (1/166) of placebo-treated patients.

The most common adverse reaction, reported in ≥ 2% of adult patients who received Barhemsys 10 mg (N=418) and at a higher rate than placebo (N=416), in clinical trials for the treatment of PONV was infusion site pain (6% vs. 4%).

Use in Specific Populations

Pregnancy

Available data with amisulpride use in pregnant women are insufficient to establish a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

Lactation

Amisulpride is present in human milk. There are no reports of adverse effects on the breastfed child and no information on the effects of amisulpride on milk production.

Barhemsys may result in an increase in serum prolactin levels, which may lead to a reversible increase in maternal milk production. In a clinical trial, serum prolactin concentrations in females (n=112) increased from a mean of 10 ng/mL at baseline to 32 ng/mL after Barhemsys treatment and from 10 ng/mL to 19 ng/mL in males (n=61). No clinical consequences due to elevated prolactin levels were reported.

To minimize exposure to a breastfed infant, lactating women may consider interrupting breastfeeding and pumping and discarding breast milk for 48 hours after receiving a dose of Barhemsys.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Drug Interactions

- Barhemsys causes dose- and concentration-dependent QT prolongation. To avoid potential additive effects, avoid use of Barhemsys in patients taking droperidol.
- ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval (e.g., ondansetron).
- Reciprocal antagonism of effects occurs between dopamine agonists (e.g., levodopa) and Barhemsys. Avoid using levodopa with Barhemsys.

To report SUSPECTED ADVERSE REACTIONS, contact Acacia Pharma at 1-877-357-9237 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full **Prescribing Information**.

BAR HCP ISI 09/2022

ASC=ambulatory surgical center. ASP=average sales price. HOPD=hospital outpatient department. IV=intravenous. NDC=National Drug Code. PACU=postanesthesia care unit. PONV=postoperative nausea and vomiting. WAC=wholesale acquisition cost.

References

1. Centers for Medicare & Medicaid Services. Addendum B Updates. CMS website. Released October 2023. Accessed November 30, 2023. https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-b-updates/october-2023-0. **2.** Centers for Medicare & Medicaid Services. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations. Third Quarter, 2023 HCPCS Coding Cycle. CMS website. Updated November 16, 2023. Accessed December 15, 2023. https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-3-2023-drugs-and-biologicals-updated-11/16/2023.pdf **3.** Barhemsys [package insert]. Indianapolis, IN: Acacia Pharma Inc; 2022. **4.** Centers for Medicare & Medicaid Services. CMS 1500 form. CMS website. Revised Feburary 1, 2012. Accessed December 15, 2023. https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms1500.pdf

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