

Utilization Management and Clinical Medical Policy

Policy Name: H2 Antagonist - Intravenous Administration in Home Settings	Policy Number: MP-ME-FP-06-25	Scope: ☒ MMM MA ☒ MMM MultiHealth	Origination Date: 08/22/2025 Last Review Date: 08/20/2026	Effective Date: 08/20/2026 Frequently Revision: Annual
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Service Category:

- ☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures

- ☒ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☐ Other: _____

Service Description:

This policy applies to intravenous home administration of H2 receptor antagonists in the home setting for clinically stable patients with documented gastric acid-related conditions when oral administration is temporarily not feasible, safe, or clinically appropriate.

This Internal Coverage Criteria (ICC) policy establishes the Plan's clinical coverage criteria for intravenous famotidine administration in the home setting pursuant to 42 CFR §422.101(b)(6), when applicable Medicare coverage requirements do not establish fully defined clinical criteria for the requested service. The criteria are informed by current FDA-approved prescribing information, applicable Medicare coverage requirements, and evidence-based clinical standards. Coverage determinations remain subject to applicable Medicare benefit requirements and the "reasonable and necessary" standard under §1862(a)(1)(A) of the Social Security Act.

Receptor H2 Antagonist included under this policy are:

- Famotidine (Pepcid®)

Special Note:

- Ranitidine was withdrawn from the market by the FDA in 2020 due to the presence of (NDMA) N-nitroso dimethylamine (carcinogenic chemical compound); this policy only considers authorized molecules in current use [\[1\]](#).
- Nizatidine IV is not approved by the FDA for intravenous formulation in the U.S [\[2\]](#).

General note:

Any use outside the indications or criteria established in this policy must be evaluated in accordance with applicable Medicare coverage requirements, current Medical Policies, Pharmacy Department criteria, and member-specific benefit requirements, as applicable.

Background Information:

Intravenous famotidine is a histamine H2 receptor antagonist used to reduce gastric acid secretion in patients with active gastric or duodenal ulcers, gastroesophageal reflux disease (GERD), erosive esophagitis, Zollinger-Ellison syndrome, or other pathological hypersecretory conditions. The

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intravenous formulation is generally used for short-term treatment when oral administration is not feasible or clinically appropriate, with transition to oral therapy as soon as medically appropriate. In the home setting, intravenous famotidine may be administered when the patient is clinically stable, the medication can be safely furnished in the home, and appropriate clinical monitoring and professional supervision can be provided [2].

H2 receptor blockers, or histamine-2 receptor antagonists (H2RAs), are gastric acid suppressant agents that are frequently used to treat various gastric conditions. The U.S. Food and Drug Administration (FDA) has approved short-term administration of H2RA for patients with uncomplicated gastroesophageal reflux disease (GERD), gastric or duodenal ulcers, gastric hypersecretion, and mild to moderate heartburn or indigestion. H2RA are sometimes part of a multi-drug regimen for Helicobacter pylori eradication [2-4].

The recommended dosage for famotidine injection, USP in adult patients is 20 mg intravenously q 12 h. The doses and regimen for parenteral administration in patients with GERD have not been established [3].

This form of famotidine is given intravenously and is used to treat these conditions for a short time, when it cannot be taken by mouth. As soon as possible, your doctor should switch the injection to the oral medication [4].

FDA label: Geriatric specific population:

Of the 1,442 patients treated with oral famotidine in clinical studies, approximately 10% were 65 and older. In these studies, no overall differences in safety or effectiveness were observed between elderly and younger patients. In elderly patients, there are no clinically significant age-related changes in the pharmacokinetics of famotidine. In post marketing experience, CNS adverse reactions have been reported in elderly patients with and without renal impairment receiving famotidine. Monitor elderly patients for adverse CNS reactions. Famotidine is known to be substantially excreted by the kidney, and the risk of adverse reactions to Famotidine Injection may be greater in elderly patients, particularly those with impaired renal function [4].

Medicare Benefit Framework

Medicare coverage of medication administration in the home depends on the applicable Medicare benefit and the circumstances under which the service is furnished.

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Medicare Benefit Policy Manual, Pub. 100-02, Chapter 7 establishes the Medicare Home Health Services coverage framework. When intravenous medication administration is furnished as a skilled nursing service under the Medicare Home Health benefit, the beneficiary must meet applicable Home Health eligibility and coverage requirements, including being confined to the home, being under the care of a physician or allowed practitioner, receiving services under an established and periodically reviewed plan of care, and requiring qualified skilled services.

CMS recognizes that medication administration services may constitute skilled nursing services when the service is reasonable and necessary for treatment of the beneficiary's illness or injury and requires the skills of qualified clinical personnel for safe and effective administration.

For purposes of this policy, intravenous famotidine administration in the home setting is evaluated based on medical necessity, appropriateness of the intravenous route, the patient's clinical condition, ability to safely furnish the service in the home, applicable plan-of-care requirements, and the need for appropriate clinical monitoring and professional involvement.

Home Health eligibility requirements apply when the requested service is furnished under the Medicare Home Health benefit and should not independently be interpreted as universal clinical medical necessity requirements for every intravenous administration of famotidine in the home setting.

This policy establishes Internal Coverage Criteria (ICC) for clinical medical necessity and does not independently establish Medicare benefit eligibility, reimbursement, coding, or the applicable payment pathway. Applicable Medicare benefit, provider, coding, billing, and claims-processing requirements must be separately satisfied.

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Medical Necessity Guidelines:

Short-term intravenous administration of an H2 receptor antagonist in the home setting should be supported by documented medical necessity and clinical appropriateness. Intravenous famotidine administration in the home setting may be considered medically necessary when **ALL** the following clinical criteria are met:

A. Clinical Medical Necessity Criteria:

Intravenous famotidine administration in the home setting may be considered medically necessary when ALL the following criteria are met:

- The medication is prescribed by a physician or other qualified healthcare professional; **and**
- The patient has a documented diagnosis or clinical condition requiring treatment with intravenous famotidine; **and**
- There is a documented clinical reason why the oral route is not feasible, safe, effective, or clinically appropriate; **and**
- The patient is clinically stable, and the medication can be safely administered in the home setting with the level of clinical monitoring and professional supervision required for the prescribed therapy; **and**
- The medication, dose, route, frequency, and duration are consistent with applicable FDA labeling and/or accepted standards of medical practice, as clinically appropriate.

B. Medicare Home Health Benefit Requirements:

When the requested service is furnished under the Medicare Home Health benefit, the beneficiary must also meet applicable Medicare Home Health eligibility and coverage requirements, including, as applicable:

- The beneficiary is confined to the home (homebound); **and**
- The beneficiary is under the care of a physician or allowed practitioner; **and**
- Services are furnished under an established and periodically reviewed plan of care; **and**
- The beneficiary requires qualifying skilled services.

These requirements apply specifically when the requested service is furnished under the Medicare Home Health benefit and are separate from the clinical medical necessity criteria established in Section A.

C. Drug-Specific Clinical Information:

Intravenous famotidine administration should follow applicable FDA-approved prescribing information and accepted standards of medical practice. The following table summarizes applicable indications and

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dosage and administration information. Follow FDA labeling and accepted standards of medical practice such the National Home Infusion Association:

Medication (generic-brand)	Indication and usege	Dosage and Admisnitation	Source:
Famotidine - Pepcid®	- Active Duodenal Ulcer - Active Gastric Ulcer - Symptomatic Nonerosive GERD - Erosive Esophagitis Diagnosed by Endoscopy - Reduction of the Risk of Duodenal Ulcer Recurrence	20 mg every 12 hours*	FDA Label [4]
	Pathological Hypersecretory Conditions	Starting dosage is 20 mg every 12 hours; titrate the dosage to individual patient needs. *	FDA Label [4]

*Administer as an intravenous injection over at least 2 minutes or an intravenous infusion over 15 minutes to 30 minutes. [4]

Not Medically Necessary:

Home administration of intravenous famotidine will not be considered medically necessary in the following circumstances:

- 1. Functional oral route:** The patient can safely and effectively tolerate and absorb appropriate oral therapy.
- 2. Absence of an appropriate clinical indication:** There is no documented gastric acid-related condition supporting the medical necessity of intravenous famotidine therapy.
- 3. Preference or convenience:** The request is based solely on patient preference or logistical convenience without clinical justification for intravenous administration in the home setting.

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Limits or Restrictions:

1. This service requires going through the evaluation and determination process according to applicable medical necessity criteria and benefit requirements
2. Overuse of histamine-2 receptor antagonists (HRAs) can predispose people to iron deficiency anemia [2].
3. The frequency and duration of the drug must be within accepted standards of medical practice, or there must be a valid explanation about the extenuating circumstances that justify the need for additional injections/administration [5].
4. **Table of contraindication and warnings:**

Medication (generic-brand)	Contraindication	Warnings	Source
Famotidine - Pepcid®	Hypersensitivity to any component of this product. Cross-sensitivity has been observed in this class of compounds. Therefore, famotidine should not be administered to patients with a history of hypersensitivity to other H.2-receptor antagonists [3].	- Central Nervous System (CNS) Adverse Reactions: Reported in elderly patients and patients with moderate and severe renal impairment; monitor elderly patients for CNS adverse reactions. - Concurrent GI Malignancy: Absence of GI symptoms does not preclude the presence of gastric malignancy; evaluate prior to initiating therapy.	FDA Label [3-4]

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Codes Information:

ICD-10 Diagnostic Codes:

Codes	Description
K21.00	GERD with esophagitis, no bleeding
K21.01	GERD with esophagitis, with bleeding
K21.9	Gastro-esophageal reflux disease without esophagitis
K25.0 / K26.9	Gastric and duodenal ulcer diagnosis
Z51.89	Medical care for other reasons

HCPCS Codes:

Codes	Description
J1308	Famotidine IV Injection, 0.25 mg

CPT Codes:

Codes	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
96368	Concurrent infusion (for multiple substances)
96374	Therapeutic, prophylactic or diagnostic injection; IV push, single or initial substance/drug

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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Reference Information:

1. FDA. Ranitidine: FDA Statement. [Internet]. 2020. Disponible en: <https://www.fda.gov>
2. Nugent CC, Falkson SR, Terrell JM. H2 blockers. In: StatPearls. Treasure Island (FL): StatPearls Publishing; 2025.
3. FDA label for famotidine [Internet]. Ndclist.com. [cited 2025 Jul 18]. Available from: <https://ndclist.com/ndc/63323-739/label>
4. FAMOTIDINE injection for intravenous use: HIGHLIGHTS OF PRESCRIBING INFORMATION [Internet]. [cited 2025 Jul 28]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219935s0001bl.pdf
5. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual, Pub. 100-02, Chapter 7 – Home Health Services; section 30 Conditions Patient Must Meet to Qualify for Coverage of Home Health Services (Rev. 10438, Issued 11-06-20; Effective 03-01-20; Implementation 01-11-21). Baltimore: CMS.
6. Centers for Medicare & Medicaid Services. *Medicare Benefit Policy Manual, Pub. 100-02, Chapter 7 – Home Health Services; section 40.1.2.4 Administration of Medications (Rev. 1, 10-01-03)*. Baltimore: CMS.
7. Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15 - Covered Medical and Other Health Services, Section 320 - Home Infusion Therapy Services. Baltimore, MD: CMS.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Policy reviewed for continued clinical and regulatory applicability. Medicare benefit framework was clarified to distinguish clinical medical necessity criteria from applicable Medicare Home Health eligibility and coverage requirements. Medical necessity criteria were reorganized and refined to consolidate existing requirements related to the clinical indication and inability to use the oral route and to incorporate clinical stability, safe administration in the home setting, required monitoring and professional supervision, consistency with applicable FDA labeling and accepted standards of medical practice, and transition to oral therapy when clinically appropriate. Medicare Home Health eligibility and coverage requirements were retained as applicable when the requested service is furnished under the Medicare Home Health benefit. Drug-specific clinical information for intravenous famotidine was maintained and aligned with applicable FDA prescribing information. Minor terminology, coding, reference, and formatting updates were completed. No substantive change was made to the overall coverage intent of the policy.	Not required	8/20/2026
Superseded	This policy MP-ME-FP-06-25 supersedes version MP-ME-FP-02-24, which is archived for reference and/or auditing purposes. This action responds to the need to align the criteria with regulatory agencies and FDA guidelines, strengthening their structure and ensuring consistency with current clinical standards.	Not required	8/22/2025