Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Frequently Revision:
H2 Antagonist - Intravenous Administration in Home Settings	**MP-ME-FP-06-25**	☒ **MMM MA** ☒ **MMM MultiHealth**	**08/22/2025**	**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 patients with gastric conditions when the oral route is not viable.

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- Ranitidine was withdrawn from the market by the FDA in 2020 due to the presence of (NDMA) N-nitroso dimethylamine (carcinogenic chemical compound); this policy only considers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 of the medicines listed in this policy that does not correspond to the expressly established indications must be evaluated in accordance with the Medical Policies in force and/or the pre-authorization criteria defined by the Pharmacy Department.

Background Information:

Intravenous famotidine is a histamine H_2 receptor antagonist used to reduce gastric acid secretion in patients who present with active gastric or duodenal ulcers, gastroesophageal reflux disease (GERD), erosive esophagitis, Zollinger-Ellison syndrome, or other hypersecretory conditions. This intravenous formulation is given to patients who cannot take medications by mouth and is used for a short period of time until you can transition to oral treatment. In the home care setting, IV famotidine may be administered under specialized medical supervision by intermittent infusion or slow injection. This allows the continuity of treatment to be maintained in clinically stable patients, avoiding unnecessary hospitalizations. promoting a better quality of life [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 rare heartburn or indigestion. H2RA are sometimes part of a multi-drug regimen for Helicobacter pylori eradication [2].

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 CNS adverse 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 Policy Manual:

The Centers for Medicare & Medicaid Services (CMS) allows coverage for the IV home service as broken down in Chapter 7: Home Health Services Therapies and indicates that the service have medically necessary, clinically appropriate, and included in a plan of care supervised by a qualified provider. According to the Medicare Benefit Policy Manual, Chapter 7, intravenous, intramuscular, subcutaneous, hypodermoclysis, or home parenteral nutrition medication administration services require the involvement of qualified clinical personnel, such as a registered nurse, for safe and effective administration or teaching [5-6].

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Medical Necessity Guidelines:

The indication for H2 Antagonist should be supported by documented short-term medical necessity, and its administration should be conducted according to standardized protocols for preparation, surveillance, and transition to oral therapy [2,5-6]. It is considered medically necessary when it meets the following:

A. Conditions Patient Must Meet to Qualify for Coverage of Home Health Services [5]:
- Being homebound **and;**
- Under the care of a physician or licensed professional **and;**
- Receive services under an established plan of care and periodically reviewed by a physician or licensed professional **and;**
- Needing skilled nursing care intermittently **and;**

B. Documented diagnosis of an indicated condition requiring an H2 antagonist [6] **and;**

C. Medical reason that prevents the medication from being taken by mouth [6] **and;**

D. Presentation of the Medication as directed and recommended by the National Home Infusion Association:

Medication (generic-brand)	Indication and usege	Dosage and Admisnitration	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 Medical Necessity:

Home administration of H2 antagonist intravenous **will not be considered medically necessary** in the following circumstances:

1. Availability of functional oral route: When the patient can tolerate and absorb medications orally safely and effectively.
2. Conditions not related to gastric hypersecretion or without a validated diagnosis.
3. Request based solely on patient preference or logistical convenience, with no clinical judgment justifying home IV administration.

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Limits or Restrictions:

1. This service requires going through the evaluation and determination process.
2. Overuse of histamine-2 receptor antagonists (HRAs) can predispose people to iron deficiency anemia [2].
3. The frequency and duration of administration 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 [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	ERGE's 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
99211	Brief outpatient consultation (minimal)
99212	Limited Outpatient Consultation
99213	Outpatient consultation of moderate complexity
99214	Outpatient consultation of medium-high complexity

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.

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/2025/219935s000lbl.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.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
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	**08/22/2025**