Drug and Biologic Coverage Policy

Effective Date **1/1/2021**
Next Review Date… **1/1/2022**
Coverage Policy Number **IP0010**

Famotidine

Table of Contents

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for famotidine (Pepcid).

Coverage Policy Statement

Famotidine (Pepcid) is medically necessary when the following are met:

1. Criteria associated with FDA Indications
2. Criteria associated with Other Uses with Supportive Evidence
3. Specific Additional Criteria [*when part of Cigna managed drug list or plan requirements*]
4. Preferred Product Requirement Criteria [*when part of Cigna managed drug list or plan requirements*]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

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Approval duration is 12 months unless otherwise stated.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

Documentation: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts

Refer to each criteria section below.

FDA Indication Criteria

NONE

Other Uses with Supportive Evidence Criteria

NONE

Specific Additional Criteria

NONE

Preferred Product Requirement Criteria

Coverage varies across plans. Refer to the customer's benefit plan document for coverage details. Where coverage requires the use of preferred products, the following criteria apply:

Approve for an individual when there is documentation of ONE of the following:

- The individual has had inadequate efficacy OR contraindication according to FDA label OR significant intolerance to ALL of covered alternatives according to the table below **OR**

- The individual is not a candidate for ALL covered alternatives according to the table below due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation

Employer Group Non-Covered Products and Preferred Covered Alternatives by Drug List:

Non-Covered Product	Standard / Performance	Value / Advantage	Cigna Total Savings	Legacy
Pepcid (famotidine)	Meets Multi-Source Brand Name Drugs Policy criteria* AND ONE of the following: cimetidine (tablet or solution), nizatidine (capsule or solution), or ranitidine (tablet, capsule, or syrup)			

**Documentation that individual has tried the bioequivalent generic product AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction*

Conditions Not Covered

Any other exception is considered not medically necessary

Background

Famotidine is approved for the treatment of GERD and esophagitis due to GERD and the treatment of active duodenal or gastric ulcers. Note, that although a labeled indication, proton pump inhibitors are considered the standard of care for treatment of peptic ulcer disease (PUD) rather than H2-receptor antagonists (for example, famotidine).[1] Off label uses include the following: chronic spontaneous urticaria (alternative agent), infusion reaction/premedication, mastocytosis, stress ulcer prophylaxis in select critically ill patients.[2]

Gastroesophageal Reflux Disease (GERD) and Erosive/Reflux Esophagitis

The ACG guidelines on the treatment of GERD, published in 2013, note that PPIs eliminate symptoms and heal esophagitis more frequently and more rapidly than the other agents (e.g., H_2RAs).[3] While H_2RAs are a viable option for GERD patients, especially those with mild disease, they are typically inferior, even at higher doses or with more frequent administration, to the PPIs. The guidelines note that all seven of the available (at time of publication) PPIs (omeprazole, lansoprazole, rabeprazole**,** pantoprazole, esomeprazole, omeprazole/sodium bicarbonate, and Dexilant) have been demonstrated to control GERD symptoms and to heal esophagitis when used at prescription strengths. The ACG guidelines also note that chronic PPI therapy is effective and appropriate for maintenance therapy of GERD in patients who continue to have symptoms after an 8-week course of PPI therapy and in patients with complications including erosive esophagitis and Barrett's esophagus. For optimal use, the ACG guidelines note that when giving PPIs QD, it is best to administer 30 to 60 minutes prior to meals and prior to the morning meal for most patients (with the exception of omeprazole-sodium bicarbonate [administer at bedtime for nighttime acid] and dexlansoprazole [administer at any time of the day]). For patients with partial response to QD therapy, tailored therapy with adjustment of dose timing and/or BID dosing should be considered in patients with night-time symptoms, variable schedules, and/or sleep disturbance. BID dosing has also been shown to improve nighttime acid control.[4] For severe and complicated (erosive) GERD, PPIs are the primary therapy.[5] Healing rates for the PPIs (rabeprazole, omeprazole, lansoprazole, and pantoprazole) appear to be similar for the healing of erosive esophagitis. The ACG guidelines also state that patients with non-erosive reflux disease (NERD) and otherwise non-complicated GERD can be successfully managed with on-demand or intermittent PPI therapy.

The American Gastroenterological Association (AGA) published a medical position statement on the management of GERD in 2008.[5] The AGA position statement is similar to the ACG guidelines, and indicates that PPIs are more effective than H_2RAs. In addition, BID PPI therapy for patients with esophageal syndrome with an inadequate response to QD PPI therapy may improve outcomes.

Pediatrics

In March 2018, NASPGHAN published updated clinical practice guidelines on pediatric GERD jointly with the ESPGHAN.[7] With regard to pharmacologic therapies, the guidelines focus on reducing acid suppression whenever possible with short empiric trials lasting four to six weeks for GERD symptoms. PPI therapy or H2RAs can be used for treatment of typical symptoms (i.e., heartburn, retrosternal or epigastric pain) in children with GERD. The guidelines further discuss that acid suppression should only be prescribed when there is a clear diagnosis of GERD and regular assessment of the ongoing need of the acid suppression is necessary. In 2013, the American Academy of Pediatrics (AAP) released a guideline on the management of GERD in children stating that PPIs are superior to H_2RAs. Concern about overprescribing of acid suppressants was noted, and use in preterm infants may be a risk factor for community-acquired pneumonia, gastroenteritis, candidemia, and necrotizing enterocolitis.[8]

References

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5. Ramakrishnan A, Katz PO. Pharmacologic management of gastroesophageal reflux disease. *Curr Gastroenterol Rep.* 2002;4(3):218-224.
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8. Lightdale JR, Gremse DE, and section on gastroenterology, hepatology, and nutrition. Gastroesophageal reflux disease: management guidance for the pediatrician. *Pediatrics*. 2013;131(5):e1684-1695.