

Medical Necessity Guidelines

IV PPIs in a home setting may be deemed medically necessary if:

- The patient has a medical condition where oral administration is contraindicated (e.g., dysphagia, severe vomiting, post-surgery).
- There is a documented failure or intolerance to oral PPIs therapy.
- The patient requires prolonged PPIs therapy beyond the usual duration of hospital stay, and their condition is stable enough for home-based care.
- The treatment is a continuation of therapy started in a hospital setting and is required to prevent readmission.
- Medical necessity should be supported by a physician's order and detailed documentation of the patient's condition and response to therapy.

FDA-approved dosing for intravenous proton pump inhibitors such as pantoprazole and esomeprazole is typically intended for hospital or acute care settings. The use of PPIs in a home setting via intravenous administration is not specifically detailed in FDA guidelines for home care; the approval is usually focused on inpatient or acute care settings. However, for clinical context, here are the FDA-approved IV doses for the most used PPIs (for acute care, not specifically for home care):

- pantoprazole (Protonix IV)
 - Indications: GERD with a history of erosive esophagitis, Zollinger-Ellison syndrome, and other hypersecretory conditions.
 - Usual Dose:
 - GERD with erosive esophagitis: 40 mg IV once daily for 7-10 days.
 - Zollinger-Ellison syndrome or other hypersecretory conditions: 80 mg IV every 12 hours, which may be increased to higher doses if clinically necessary.
 - Transition to Oral: pantoprazole IV should be transitioned to oral therapy as soon as possible.
- esomeprazole (Nexium IV)
 - Indications: GERD with erosive esophagitis, prevention of gastric ulcers in patients at risk, and Zollinger-Ellison syndrome.
 - Usual Dose:
 - GERD with erosive esophagitis: 20 mg or 40 mg IV once daily for up to 10 days.
 - Zollinger-Ellison syndrome: 80 mg IV every 12 hours, with the potential to increase based on the patient's clinical needs.

Limits or Restrictions

Restrictions and Contraindications:

- **Duration of Therapy:** IV PPI therapy is typically short-term, often transitioning to oral PPIs as soon as possible. Prolonged use may need regular reassessment of necessity.
- **Eligible Conditions:** Conditions requiring ongoing acid suppression (e.g., refractory GERD, Zollinger-Ellison syndrome) may qualify, but routine home use for conditions that can be managed with oral medication is not usually covered.
- **Monitoring Requirements:** Regular monitoring by healthcare providers is required, including assessment for complications from IV access (e.g., infections, thrombosis) and medication side effects.

Reference Information

- ACG Guidelines on GI bleeding and PPIs use, title: “ACG Clinical Guideline: Upper Gastrointestinal and Ulcer Bleeding” American College of Gastroenterology (ACG), Laine, Loren MD, FACP; Barkun, Alan N. MD, FACP; Saltzman, John R. MD, FACP; Martel, Myriam MSc; Leontiadis, Grigorios I. MD, PhD The American Journal of Gastroenterology 116(5):p 899-917, May 2021. Clinical Guideline, Key Reference: Guidance on IV PPI use for preventing rebleeding in upper GI ulcers, link: https://journals.lww.com/ajg/fulltext/2021/05000/acg_clinical_guideline_upper_gastrointestinal_and.14.aspx
- “The Role of Proton Pump Inhibitors in the Management of Upper Gastrointestinal Disorders” Gastroenterology and Hepatology journal, Muhammad Ali Khan 1, Colin W Howden. 2018 Mar;14(3):169–175, link : <https://pmc.ncbi.nlm.nih.gov/articles/PMC6004044/>
- FDA Prescribing Information: “Prescribing Information for Protonix (Pantoprazole) IV”, U.S. Food and Drug Administration (FDA), the latest updated label accessed was from 2024. Indications, Dosage and Administration, link: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/020988s070lbl.pdf
- FDA Prescribing Information: “Prescribing Information for Nexium (esomeprazole) IV”, U.S. Food and Drug Administration (FDA), the latest updated label accessed was from 2024. Indications, Dosage and Administration, link: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021689s038lbl.pdf

Policy History

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Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
INTERNAL POLICY	Proton Pump Inhibitors (PPIs) are medications used to reduce stomach acid production, often prescribed for conditions like GERD (gastroesophageal reflux disease), peptic ulcers, and Zollinger-Ellison syndrome.		12/20/2024