

Proton Pump Inhibitors Coverage in Out-Patient Setting

Adjudication Guideline

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Approved by:

Daman

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1. Abstract

1.1 For Members

Proton pump inhibitors reduce the amount of acid made by your stomach. They are commonly used to treat acid reflux and ulcers of the stomach and part of the gut called the duodenum.

There are several different proton pump inhibitors which all act in a similar way. These include Omeprazole, Lansoprazole, Pantoprazole, Esomeprazole, Rabeprazole and Dex-lansoprazole.

Most people who take a proton pump inhibitor do not develop any side-effects. Proton pump inhibitor is taken 30 minutes before food.

1.2 For Medical Professionals

Proton pump inhibitor remain the leading evidence-based therapy for acid-related diseases, including GERD, Peptic Ulcer, dyspepsia, NSAID-induced ulcer, H. pylori infection, and Zollinger Ellison syndrome.

The strong evidence supporting proton pump inhibitor efficacy, and a favorable safety profile has led to the overuse of proton pump inhibitors in many treatment arenas. Despite of 25 years of extensive literature addressing proton pump inhibitor therapy in upper GI disorders, inappropriate use remains consistently high in hospitals and primary care.

Inappropriate proton pump inhibitor use in the absence of documented evidence, is likely due to the perception among healthcare provider about proton pump inhibitor safety, which makes them forget to assess the harms and benefits of (especially long-term) therapy. Several studies have shown that proton pump inhibitor use is not properly documented and reviewed, which often results in their long-term or even indefinite continuation.

Eventually proton pump inhibitor inappropriate use has raised two main concerns; proton pump inhibitor misuse and drug expenditure, which has risen dramatically in recent years.



2. Scope

This adjudication Guideline addresses the medical indications, quantity, and eligible Speciality for Proton Pump Inhibitor (Oral Dosage forms) in out-patient setting for all Daman health insurance plans.

Proton pump inhibitor is covered for the treatment of the following Known Conditions:

- Gastroesophageal Reflux Disease (GERD)
- Extra digestive-GERD
- Non-erosive Reflux disease (NERD)
- Barret Esophagus.
- Eosinophilic esophagitis
- H-pylori eradication
- Gastric and Peptic ulcer disease
- Duodenal Ulcer Disease
- History of ulcer complications (such as bleeding or perforation)
- Zollinger Ellison syndrome
- New onset dyspepsia in patients younger than 45 years
- Functional dyspepsia
- NSAID gastropathy prevention of gastro-duodenal lesions and events)
 Gastro Duodenal lesion
- Long-term use of anti-platelets therapy
 Hypertension gastropathy
- Chronic pancreatitis.
- Other long-term drug therapy.

Proton pump inhibitor Dose and Administration:

- Proton Pump Inhibitor are taken 30 minutes before breaking fast or taken at bedtime.
- Proton Pump Inhibitor are available in solid dosage form for oral administration.
- Esomeprazole and lansoprazole are also available in sachet form.

Proton pump inhibitor standard and double dose table

| PPI | Full dose Or Standard Dose | Low Dose (on demand dose) | Double dose |
|------------------|-------------------------------|---------------------------|-------------------|
| Esomeprazole | 40 mg once a day | 20 mg once a day | 40 mg twice a day |
| Lansoprazole | 30 mg once a day | 15 mg once a day | 30 mg twice a day |
| Omeprazole | 40 mg once a day | 20 mg once a day | 40 mg twice a day |
| Pantoprazole | 40 mg once a day | 20 mg once a day | 40 mg twice a day |
| Rabeprazole | 20 mg once a day | 10 mg once a day | 20 mg twice a day |
| Dex-lansoprazole | 60 mg once a day | 30 mg once a day | NA |

Note: It should be noted that a double dose is only recommended when the usual dose is ineffective. The trend of double dosing will be closely monitored across providers to guarantee pharmacological efficacy and patient safety.



3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Diagnosis-based PPI Dose and Duration:

| Diagnosis | PPI Dose | Duration |
|--|--|-----------------------|
| Eosinophilic Esophagitis | Standard or Double Dose | 8-12 weeks |
| Erosive esophagitis-GERD, Extra esophagitis-GERD | Standard or double dose | 8-12 weeks |
| Non-erosive gastroesophageal reflux disease-NERD | Standard dose | 4-8 weeks |
| Long-term Management of both GERD and NERD | Standard or half-dose PPI maintenance (continuous, intermittent, or on-demand, depending on the clinical characteristics of the patient) | Long term |
| Barrett's Esophagus | Individually tailored PPI therapy | Long Term |
| Zollinger-Ellison Syndrome | High dose (eventually twice daily) | Long term |
| H. pylori Eradication | Double dose, twice daily, (in combination with antimicrobials) | 10-14 days |
| Gastric / Peptic Ulcer Disease | Standard or double dose | 8 -12 weeks |
| Duodenal Ulcer Disease | Standard dose | 4-8 weeks |
| History of ulcer complications (such as bleeding or perforation) | Standard dose | Long term |
| Functional Dyspepsia | Standard or half dose | 4 weeks |
| Un-investigated Dyspepsia | Standard or half-dose | 4 weeks |
| NSAID-gastropathy- Prevention of Gastro-Duodenal lesions and events | Standard or half-dose PPI therapy, starting from the very first dose of NSAID in patients at GI risk | With NSAID therapy |
| Gastro-duodenal Lesions | Standard dose PPI therapy for 8 weeks | 8 weeks |
| Hypertensive Gastropathy Prevention or/and treatment of Oesophageal ulcers after sclerotherapy or variceal band ligation | No need for acid suppression. Standard dose (longer treatment should be avoided considering the risk of spontaneous bacterial peritonitis) | 10 days |
| Anti-Platelet Therapy | Standard dose PPI therapy, starting from the very first dose of the antiplatelet agent in patients at GI risk | Long-term |
| Chronic Pancreatitis | Standard PPI therapy only in patients with steatorrhea. | Long-term |
| Other long-term drug therapy | Standard or half-dose | Long-term |



3.2 Requirements for Coverage

- 1. Proton pump inhibitor use is covered in known medical indications supported by best practice guidelines.
- 2. Proton pump inhibitor dose and duration of treatment is covered as per best practice guidelines.
- 3. Patient cannot take two PPI's in the same time period

3.3 Non-Coverage

- Proton pump inhibitor is not covered for visitor plan.
- Proton pump inhibitor is not covered for condition other than approved and validated by best practice guideline.
- Proton pump inhibitor dose and duration of treatment beyond the scope of best medical practice guidelines will not be covered.
- Dispersible tablets/ sachets should be prescribed for only patients with difficulty in swallowing due to esophageal Strictures or any other conditions, under 13 years of age.
- Conditions warrant 40mg would not be eligible for 20mg BD.
- Dexlansoprazole is not recommended by FDA label for Pathological hypersecretory conditions nor H.Pylori treatment
- Proton pump inhibitor will not be covered if concomitantly used with drug has known drug interaction and contra-indicated.
- Patients who require maintenance treatment should be given the lowest effective dose
- In line with best practice guideline, Proton pump inhibitor is not covered in acute gastritis.
- Proton pump inhibitor prescription in GERD, Barrett's Esophagus, Eosinophilic Esophagitis, Zollinger-Ellison Syndrome, Peptic ulcer, will not be consider for payment if prescribed by clinician Specialty other than in clinical table.

Eligible Clinician Specialties:

Proton pump inhibitor prescriptions for GERD, Barrett's Esophagus, Eosinophilic Esophagitis, Zollinger-Ellison Syndrome, and Peptic Ulcer are restricted to the Clinician specialties listed in below Table.

| Eligible Clinician Specialty |
|------------------------------|
| Gastroenterologist |
| Internal Medicine |
| Emergency medicine |
| Otolaryngology |
| Family Medicine |
| Hepatologist |
| General Surgery |
| Oncologists |
| Pediatrics |



3.4 Payment and Coding Rules

Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

| Code | Code Description |
|----------|---|
| MNEC-003 | Service is not clinically indicated based on good clinical practice |
| MNEC-004 | Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities |
| CODE-010 | Activity/diagnosis inconsistent with clinician specialty |
| CODE-013 | Invalid principal diagnosis (for example E-codes) |
| MNEC-005 | Inappropriate package size requested for the specified duration |

5. Appendices

5.1 References

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5.2 Revision History

| Date | Version No. | Change(s) |
|------------|-------------|--|
| 14/03/2023 | V1.0 | Creation of Adjudication Guideline-External Instruction Template. |
| 28/04/2023 | V2.0 | Added: note on dose table |
| 08/05/2023 | V3.0 | Update : Clinician eligibility update |
| 25/12/2024 | V4.0 | PPI's Dose and treatment duration added based on each diagnosis Dose/Denial Codes / requirements updated |

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