

Proton Pump Inhibitors

Created: 3/22/2006

Reviewed: 5/13/2019, 12/2021

Includes:

Aciphex®	<i>Rabeprazole</i>
Dexilant®	<i>Dexlansoprazole</i>
Kapidex®	<i>Dexlansoprazole</i>
Nexium® and Nexium 24HR®	<i>Esomeprazole</i>
Prevacid® and Prevacid 24HR®	<i>Lansoprazole</i>
Prilosec® and Prilosec OTC®	<i>Omeprazole capsules</i>
Protonix®	<i>Pantoprazole tablets</i>

*Highlighted agent is available on Advanced Health formulary without a prior authorization.

GUIDELINE FOR USE:

Generic omeprazole capsules and pantoprazole tablets are available on the Advanced Health formulary with no prior authorization required. Non-formulary proton pump inhibitors will be considered for coverage under the following drug use criteria.

Initial Request:

1. Is the medication being used to treat a condition funded for coverage by Oregon Health Plan?
 - a. If yes, continue to 2
 - b. If no, deny as below the line.
2. Has the patient had an adequate trial of all formulary proton pump inhibitors, or does the patient have a documented allergy or contraindication to formulary agents? *Adequate trial is defined as consistent prescription fill history for at least 8 weeks. All formulary and least costly alternative agents must be trialed before consideration of more costly non-formulary agents.*
 - a. If yes, continue to 3
 - b. If no, deny as non-formulary with message to please trial formulary alternatives.
3. Is the medication being prescribed for an indication and dose supported by the FDA approved package insert?
 - a. If yes, go to 4
 - b. If no, deny as not meeting criteria. Off-label use of medications is not a covered benefit on Oregon Health Plan.

Approved by Advanced Health Pharmacy and Therapeutics Committee 5/13/19, 1/7/21

4. Does the patient meet guideline note 144, Proton Pump Inhibitor Therapy for Gastroesophageal Reflux Disease (GERD) of the Health Evidence Review Commission Prioritized List of Health Services?
 - a. If yes and request is for short term treatment of GERD without Barrett's, approve for up to 8 weeks. Dosing must be consistent with the FDA approved package insert.
 - b. If yes and request is for long term proton pump inhibitor therapy for Barrett's esophagus, approve for 12 fills or one year of therapy. Dosing must be consistent with the FDA approved package insert.
 - c. If no, deny as not meeting criteria with message that request does not meet Guideline Note 144 of the HERC Prioritized List. Long term coverage of PPI therapy for GERD is not a covered benefit on OHP.

Renewal Request:

1. Is the request for a continuation of therapy for a previously approved non-formulary proton pump inhibitor?
 - a. If yes, go to 2
 - b. If no, see above for initial prior authorization criteria.
2. Is there documented improvement in patient's condition and patient continues to meet guideline note 144 of the Prioritized List?
 - a. If yes, approve for 12 fills or one year of therapy
 - b. If no, deny as not meeting criteria with message requesting documentation of patient's response to therapy and/or that request does not meet guideline note 144 of the Prioritized List.

Rationale:

To ensure use of formulary, least costly proton pump inhibitors for conditions intended for coverage by the Health Evidence Review Commission Prioritized List of Health Services. To ensure utilization consistent with Guideline Note 144, Proton Pump Inhibitor Therapy for Gastroesophageal Reflux Disease. To ensure prescribing consistent with the FDA approved package insert.

FDA Approved Indications:

<u>Drug Name</u>	<u>Indications: Dosing</u>
<u>Rabeprazole</u>	<ul style="list-style-type: none"> • Healing of erosive or ulcerative GERD: 20mg once daily for 4 to 8 weeks • Maintenance of Healing of erosive or ulcerative GERD: 20mg once daily <i>*studied for 12 months</i>

	<ul style="list-style-type: none"> • Treatment of symptomatic GERD in adults: 20mg once daily for 4 weeks • Healing of Duodenal Ulcers: 20mg once daily after morning meal for up to 4 weeks • H. Pylori eradication to reduce the risk of duodenal ulcer recurrence: 20mg twice daily with morning and evening meals for 7 days. Taken with Amoxicillin 1000mg and Clarithromycin 500mg. • Treatment of pathological hypersecretory conditions including Zollinger-Ellison Syndrome: Starting dose 60mg once daily then adjust to patient need • In adolescent patients 12 years of age and older: short term tx of symptomatic GERD: 20mg once daily for up to 8 weeks • In pediatric patients 1 to 11 years of age: tx of GERD: <15 kg- 5mg once daily with option to increase to 10mg once daily. ≥15kg- 10mg once daily for up to 12 weeks
<u>Dexlansoprazole</u>	<ul style="list-style-type: none"> • Healing of all grades of erosive esophagitis (EE): 60mg once daily for up to 8 weeks • Maintenance of healed EE: 30mg once daily for up to 6 months • Symptomatic non-erosive GERD: 30mg once daily for 4 weeks.
Esomeprazole	<ul style="list-style-type: none"> • Healing of erosive esophagitis (EE): Adults- 20mg to 40mg once daily for 4 to 8 weeks; 12-17 years- 20mg to 40mg once daily for 4 to 8 weeks; 1 month to 11 years- weight-based dosing and duration • Maintenance of Healing of EE: Adults- 20mg once daily for up to 6 months • Treatment of symptomatic GERD: Adults- 20mg once daily for 4 to 8 weeks; 12-17 years- 20mg to 40mg once daily for 4 weeks; 1 to 11 years-10mg once daily for up to 8 weeks • Risk Reduction of NSAID-Associated Gastric Ulcer: 20mg or 40mg once daily for up to 6 months • H. Pylori Eradication (triple therapy): 40mg once daily for 10 days in combination with Amoxicillin 1000mg twice daily for 10 days and Clarithromycin 500mg twice daily for 10 days • Pathological hypersecretory conditions: 40mg twice daily
Lansoprazole	<p>Adult</p> <ul style="list-style-type: none"> • Duodenal Ulcer: Short-term Treatment- 15mg once daily for 4 weeks. Maintenance of Healed- 15mg once daily • H. Pylori Eradication: Triple therapy- 30mg twice daily for 10-14 days in combination with amoxicillin 1 gram and clarithromycin 500mg; Dual therapy; 30mg three times daily for 14 days in combination with amoxicillin 1 gram

	<ul style="list-style-type: none"> • Benign Gastric Ulcer: 30mg once daily for up to 8 weeks • NSAID Induced Gastric Ulcer: Healing-30mg once daily for up to 8 weeks. Risk Reduction- 15mg once daily up to 12 weeks • GERD: Short term treatment of symptomatic GERD- 15mg once daily up to 8 weeks. Short term treatment of EE- 30mg once daily up to 8 weeks • <u>Pediatric (1-11 years of age):</u> Short term treatment of symptomatic GERD and Short Term treatment of EE- ≤30 kg- 15mg once daily up to 12 weeks. >30kg- 30mg once daily up to 12 weeks. • <u>Pediatric (12-17 years of age):</u> Short term treatment of symptomatic GERD: Nonerosive GERD-15mg once daily up to 8 weeks. EE-30mg once daily up to 8 weeks • Maintenance of Healing EE: 15mg once daily • Pathological Hypersecretory Conditions: 60mg once daily
Omeprazole	<ul style="list-style-type: none"> • Treatment of active duodenal ulcer: 20mg once daily for 4 weeks. Some patients may require an additional 4 weeks. • H. Pylori Eradication: Triple therapy- 20mg twice daily for 10 days in combination with amoxicillin 1 gram and clarithromycin 500mg; Dual therapy; 40mg once daily for 14 days in combination with clarithromycin 500mg • Gastric Ulcer: 40mg once daily for 4 to 8 weeks • GERD: 20mg once daily for 4 to 8 weeks • Maintenance of healing EE: 20mg once daily • Pathological Secretory Conditions: 60mg once daily. Varies by individual patient. • Pediatric Patients (1 to 16 years of age): GERD, Maintenance of healing EE- Weight Based- 5<10 kg- 5mg once daily, 10<20kg-10mg once daily, ≥20kg-20mg once daily
Pantoprazole	<ul style="list-style-type: none"> • Short term treatment of EE associated with GERD: Adults- 40mg once daily up to 8 weeks, Children 5 years and younger: ≥15kg to < 40kg- 20mg once daily for up to 8 weeks; ≥40 kg- 40mg once daily for up to 8 weeks • Maintenance of Healing EE: 40mg once daily • Pathological Hypersecretory Conditions including Zollinger- Ellison Syndrome- 40mg twice daily

Mechanism of Action and Dosing:

Proton Pump Inhibitor. Suppresses gastric basal and stimulated acid secretion by inhibiting the parietal cell H⁺/K⁺ ATP pump.

Contraindications:

Hypersensitivity to any component of the formulation.

References:

1. The Prioritized List of Health Services. Extracted from the October 1, 2021 Prioritized List. Guideline Note 144, Proton Pump Inhibitor Therapy for Gastroesophageal Reflux Disease (GERD).
2. Aciphex Prescribing Information. Revised 6/2018.
3. Dexilant Prescribing Information. Revised 6/2018.
4. Nexium Prescribing Information. Revised 10/2020.
5. Prevacid Prescribing Information. Revised 10/2017.
6. Prilosec Prescribing Information. Revised 9/2012.
7. Protonix Prescribing Information. Revised 11/2020.