DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Proton Pump Inhibitors Drug Quantity Management Policy – Per Rx

Prescription Proton Pump Inhibitor	Products Targeted	Manufacturer
Dexlansoprazole	Dexilant® delayed-release capsules, generic	Takeda
Esomeprazole	Nexium® delayed-release capsules, generic	AstraZeneca
	Nexium® delayed-release oral granules, generic	
	Esomeprazole strontium delayed-release capsules	Generic only
Lansoprazole	Prevacid® delayed-release capsules, generic	Takeda
	Prevacid® SoluTab® delayed-release orally disintegrating tablets, generic	
Omeprazole	Omeprazole delayed-release capsules	Generic only
	Prilosec® delayed-release oral granules	AstraZeneca
Omeprazole and sodium bicarbonate	Konvomep™ oral suspension	Azurity
	Zegerid® capsules, generic	Salix
	Zegerid® powder for oral suspension, generic	
Pantoprazole	Protonix® delayed-release tablets, generic	Wyeth
Rabeprazole	Aciphex® delayed-release tablets, generic	Eisai/Woodward
	Aciphex® Sprinkle™ delayed-release capsules, generic	Aytu Therapeutics

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Cigna National Formulary Coverage:

OVERVIEW

The FDA-approved indications for the proton pump inhibitors (PPIs) are in Table 1.

Table 1. FDA-Approved Indications for the Oral Prescription Proton Pump Inhibitors.[1-11]

Brand (generic)	Indications
Dexilant® (dexlansoprazole delayed-release capsules, generic)	• Erosive esophagitis (short-term treatment) • Erosive esophagitis, healed (maintenance) • Gastroesophageal reflux disease
Nexium® (esomeprazole magnesium delayed-release capsules and delayed-release granules for oral suspension [packets], generic)	• Erosive esophagitis (short-term treatment) • Erosive esophagitis, healed (maintenance) • Gastroesophageal reflux disease • *H. pylori* infection • NSAID-associated gastric ulcer, risk reduction • Pathological hypersecretory conditions (e.g., ZES)
Esomeprazole strontium (no trade name)	• Erosive esophagitis (short-term treatment) • Erosive esophagitis, healed (maintenance) • Gastroesophageal reflux disease • *H. pylori* infection • NSAID-associated gastric ulcer, risk reduction • Pathological hypersecretory conditions (e.g., ZES)

Table 1 (continued). FDA-Approved Indications for the Oral Prescription Proton Pump Inhibitors.[1-11]

Brand (generic)	Indications
Prevacid® (lansoprazole delayed-release capsules, generic) Prevacid SoluTab® (lansoprazole delayed-release ODT, generic)	• Duodenal ulcer, active (short-term treatment) • Duodenal ulcer, healed (maintenance) • Erosive esophagitis (short-term treatment) • Erosive esophagitis, healed (maintenance) • Gastric ulcer, active benign (short-term treatment) • Gastroesophageal reflux disease • *H. pylori* infection • NSAID-associated gastric ulcer, risk reduction • NSAID-associated gastric ulcer, treatment • Pathological hypersecretory conditions (e.g., ZES)
omeprazole delayed-release capsules (generic only) Prilosec® (omeprazole magnesium delayed-release oral suspension)	• Duodenal ulcer, active (short-term treatment) • Erosive esophagitis (short-term treatment) • Erosive esophagitis, healed (maintenance) • Gastric ulcer, active benign (short-term treatment) • Gastroesophageal reflux disease • *H. pylori* infection • Pathological hypersecretory conditions (e.g., ZES)
Konvomep™ (omeprazole and sodium bicarbonate for oral suspension)	• Benign gastric ulcer • Reduction of risk of upper GI bleeding in critically ill patients
Zegerid® (omeprazole and sodium bicarbonate capsules and powder for oral	• Duodenal ulcer, active (short-term treatment) • Erosive esophagitis (short-term treatment) • Erosive esophagitis, healed (maintenance) • Gastric ulcer, active benign (short-term treatment) • Gastroesophageal reflux disease

suspension, generic)	• Gastrointestinal bleeding in critically ill patients, risk reduction (suspension only)
Protonix® (pantoprazole sodium delayed-release tablets and oral suspension, generic)	• Erosive esophagitis (short-term treatment) • Erosive esophagitis, healed (maintenance) • Gastroesophageal reflux disease • Pathological hypersecretory conditions (e.g., ZES)
Aciphex® (rabeprazole sodium delayed-release tablets, generic) Aciphex® Sprinkle™ (rabeprazole sodium delayed-release capsules, generic)	• Duodenal ulcer, active (short-term treatment) • Erosive esophagitis (short-term treatment) • Erosive esophagitis, healed (maintenance) • Gastroesophageal reflux disease • *H. pylori* infection • Pathological hypersecretory conditions (e.g., ZES)

DR – Delayed-release; ZES – Zollinger-Ellison syndrome.

Dosing and Availability

Refer to Drug Quantity Limit table below for dosing and availability of the PPIs.

GUIDELINES

Gastroesophageal Reflux Disease (GERD) and Erosive/Reflux Esophagitis

The American College of Gastroenterology (ACG) guidelines on the treatment of GERD (2021) note that PPIs eliminate symptoms and heal esophagitis more frequently and more rapidly than the other agents (e.g., histamine$_2$ receptor antagonists [H_2RAs]).[12] All seven of the available (at time of publication) PPIs (omeprazole, lansoprazole, rabeprazole**,** pantoprazole, esomeprazole, omeprazole/sodium bicarbonate, and dexlansoprazole) 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 once daily (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 twice daily (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.[13]

The American Gastroenterological Association (AGA) published a clinical practice update on the management of GERD in 2022.[14] 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.

Laryngopharyngeal Reflux (LPR)
LPR is defined as the backflow of stomach contents (acid) into the throat.[15] Most LPR patients will require BID dosing of PPIs secondary to the need for consistent acid suppression (intragastric pH > 4) for 24 hours. A position statement from the American Academy of Otolaryngology Head and Neck Surgery (AAOHNS) recommends BID PPI dosing for a minimum of 6 months in most LPR patients. Prolonged tapering and/or chronic treatment (life-long) may be needed in some patients.

Helicobacter pylori
The ACG guidelines for the management of *H. pylori* infection were updated in 2017.[16] Despite FDA-approval of various dual drug regimens, the ACG recommends use of triple or quadruple drug regimens for the management of *H. pylori* since these regimens are more effective. PPIs are a component of all of the first-line recommended regimens. Of note, some PPIs are supplied in combination kits with other medications for the treatment of *H. pylori* infections. In the Omeclamox-Pak™ (omeprazole delayed-release capsules, clarithromycin tablets, amoxicillin capsules), it is noted that for patients with an ulcer present at initiation of therapy, an additional 18 days of omeprazole 20 mg QD is recommended following completion of the 10- to 14-day triple therapy regimen.[17]

Additional Information
The intent of the drug quantity management on lower strength PPIs is dose consolidation. The highest strength dosage form for each product does not have a quantity limit. For example, if a drug is available in a 20 mg and 40 mg strength, only the 20 mg strength has a quantity limit and criteria. Patients are encouraged to take one 40 mg unit instead of two 20 mg units. The highest strengths of the proton pump inhibitors do not have quantity limits since it is clinically appropriate in certain patients, such as for acute healing of ulcers and patients with a hypersecretory condition (e.g., Zollinger-Ellison syndrome, endocrine adenoma, systemic mastocytosis), to take a dose above the highest strength. Over-the-counter PPIs are managed by plan design and are not subject to quantity limits under this program.

POLICY STATEMENT
This Drug Quantity Management program has been developed to promote dose consolidation of proton pump inhibitors. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Brand (generic)	FDA-Approved Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Dexlansoprazole Products				

Dexilant® (dexlansoprazole delayed-release capsules, generic)	Patients ≥ 12 years of age • *Healing of EE*: 60 mg QD for up to 8 weeks. • *Maintenance of healed EE and relief of heartburn*: 30 mg QD for 4 to 6 months. • *Symptomatic non-erosive GERD*: 30 mg QD for 4 weeks. Note: If a dose larger than 30 mg per day is required, the patient should be referred to the 60 mg capsules.	30 mg delayed-release capsules	30 capsules	90 capsules
		60 mg delayed-release capsules	No quantity limit.	No quantity limit.
Esomeprazole Products				
Nexium® (esomeprazole magnesium delayed-release capsules and delayed-release granules for oral suspension [packets], generic)	Adults • *Healing of EE*: 20 mg to 40 mg QD for 4 to 8 weeks. • *Maintenance of healing of EE*: 20 mg QD (no studies beyond 6 months) • *Treatment of symptomatic GERD*: 20 mg QD (4 weeks + additional 4 weeks if symptoms do not resolve completely). • *Risk reduction of NSAID-associated gastric ulcer*: 20 mg to 40 mg QD (data does not extend beyond 6 months). • *H. pylori eradication to reduce the risk of duodenal ulcer recurrence (triple therapy)*: 40 mg QD in combination with other agents (for 10 days). Some studies used 20 mg BID in combination with other agents (for 7 to 10 days). • *Pathological hypersecretory conditions including Zollinger-Ellison syndrome*: doses up to 240 mg/day have been used as long as clinically indicated. Patient's 12 to 17 years of age • *Healing of EE (≥ 1 year)*: 20 mg to 40 mg QD for 4 to 8 weeks. • *Treatment of symptomatic GERD*: 20 mg QD for 4 weeks. Patient's 1 year to 11 years • *Healing of EE/EE due to acid-mediated GERD*: 10 mg QD (if < 20 kg) and 10 mg or 20 mg (if ≥ 20 kg) for 8 weeks. • *Treatment of symptomatic GERD*: 10 mg QD for 8 weeks. Patient's 1 month to < 1 year	20 mg delayed-release capsules	30 capsules	90 capsules
		40 mg delayed-release capsules	No quantity limit.	No quantity limit.
		2.5 mg delayed-release granules	30 packets	90 packets
		5 mg delayed-release granules	30 packets	90 packets
		10 mg delayed-release granules	30 packets	90 packets
		20 mg delayed-release granules	30 packets	90 packets
		40 mg delayed-release granules	No quantity limit.	No quantity limit

	• *Treatment of EE due to acid-mediated GERD*: 2.5 mg QD (if 3 to 5 kg), 5 mg QD (if > 5 kg to 7.5 kg), or 10 mg QD (if > 7.5 kg to 12 kg).			

Drug Quantity Limits (continued)

Brand (generic)	FDA-Approved Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Esomeprazole Products (continued)				
Esomeprazole strontium delayed-release capsules (no trade name)	Adults • *GERD*: 24.65 mg or 49.3 mg QD for 4 to 8 weeks. • *Risk Reduction of NSAID-associated gastric ulcer*: 24.65 mg or 49.3 mg QD for up to 6 months. • *H. pylori eradication*: 49.3 mg QD for 10 days, in combination with other agents • *Pathological hypersecretory conditions*: 49.3 mg BID. Note: 24.65 mg capsules are no longer available, so dosing at the 24.65 mg dose is not possible.	49.3 mg delayed-release capsules	No quantity limit.	No quantity limit
Lansoprazole Products				
Prevacid® (lansoprazole delayed-release capsules, generic) Prevacid SoluTab® (lansoprazole delayed-release ODT, generic)	Adults • *Duodenal ulcers*: 15 mg QD for 4 weeks as short-term treatment and ongoing for maintenance. • *Eradication of H. pylori to reduce the risk of duodenal ulcer recurrence*: 30 mg BID for 10 or 14 days as triple therapy in combination with other agents or 30 mg TID for 14 days as dual therapy in combination with another agent. • *Benign gastric ulcer*: 30 mg QD for 8 weeks. • *Risk reduction of NSAID-associated gastric ulcer*: 15 mg QD for up to 12 weeks. • *Healing of NSAID-associated gastric ulcer:* 30 mg QD for 8 weeks. • *Short-term treatment of symptomatic GERD*: 15 mg QD for up to 8 weeks. • *Short-term treatment of EE*: 30 mg QD for up to 8 weeks.	15 mg delayed-release capsules	30 tablets	90 tablets
		30 mg delayed-release capsules	No quantity limit.	No quantity limit.
		15 mg delayed-release ODT	30 tablets	90 tablets
		30 mg delayed-release ODT	No quantity limit.	No quantity limit.

	• *Maintenance healing of EE*: 15 mg QD. • *Pathological hypersecretory conditions including Zollinger-Ellison syndrome*: 60 mg QD. <u>Patient's 1 to 11 years of age</u> • *Symptomatic GERD and treatment of EE*: • *≤ 30 kg:* 15 mg QD for up to 12 weeks. • *> 30 kg:* 30 mg QD for up to 12 weeks. <u>Patient's 12 to 17 years of age</u> • *Non-erosive GERD*: 15 mg QD for up to 8 weeks. *EE associated with symptomatic GERD*: 30 mg QD for up to 8 weeks.			

Drug Quantity Limits (continued)

Brand (generic)	FDA-Approved Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Omeprazole Products				
omeprazole delayed-release capsules (generic only) Prilosec® (omeprazole magnesium delayed-release oral suspension)	<u>Adults</u> • *Duodenal ulcers*: 20 mg QD for 4 weeks; patients may require 4 more weeks. • *Eradication of H. pylori to reduce the risk of duodenal ulcer recurrence*: 20 mg BID for 10 days as triple therapy in combination with other agents or 40 mg QD for 14 days as dual therapy in combination with another agent. • *Active benign gastric ulcer*: 40 mg QD for 4 to 8 weeks. • *Symptomatic GERD*: 20 mg QD for up to 4 weeks. • *EE due to acid-mediated GERD*: 20 mg QD for 4 to 8 weeks. • *Maintenance healing of EE due to acid-mediated GERD*: 20 mg QD. • *Pathological hypersecretory conditions*: 60 mg QD as long as clinically indicated. <u>Patient's 1 to 16 years of age</u> • *Symptomatic GERD, treatment of EE due to acid-mediated GERD, and*	10 mg delayed-release capsules	30 capsules	90 capsules
		20 mg delayed-release capsules	30 capsules	90 capsules
		40 mg delayed-release capsules	No quantity limit	No quantity limit
		2.5 mg delayed-release oral suspension packets	60 packets	180 packets
		10 mg delayed-release oral suspension packets	30 packets	90 packets

	maintenance healing of EE due to acid-mediated GERD:: ○ *5 kg to < 10 kg:* 5 mg QD for 4 to 8 weeks (12 months for maintenance). ○ *10 kg to < 20 kg:* 10 mg QD for 4 to 8 weeks. ○ ≥ *10 kg*: 20 mg QD for 4 to 8 weeks. <u>Patient's 1 month to < 1 year of age</u> • *Treatment of EE due to acid-mediated GERD*: 2.5 mg QD (if 3 kg to < 5 kg), 10 mg QD (if 5 kg to < 10 kg), or 10 mg QD (if ≥ 10 kg) for up to 6 weeks.			
Omeprazole and Sodium Bicarbonate Products				
Konvomep™ (omeprazole and sodium bicarbonate for oral suspension)	<u>Adults</u> • *Benign gastric ulcer*: 40 mg QD for 4 to 8 weeks. • *Reduction of risk of upper GI bleeding in critically ill patients* 40 mg initially, followed by 40 mg 6 to 8 hours later, then 40 mg QD thereafter for a total of 14 days.	90 mL kit (2 mg omeprazole/84 mg Na bicarb per mL)	1 kit (90 mL)	1 kit (90 mL)
		150 mL kit (2 mg omeprazole/84 mg Na bicarb per mL)	1 kit (150 mL)	1 kit (150 mL)
		300 mL kit (2 mg omeprazole/84 mg Na bicarb per mL)	2 kits (600 mL)	2 kits (600 mL)

Drug Quantity Limits (continued)

Brand (generic)	FDA-Approved Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Omeprazole and Sodium Bicarbonate Products (continued)				
Zegerid® (omeprazole and sodium bicarbonate capsules and powder for oral suspension, generic)	<u>Adults</u> • *Active duodenal ulcer*: 20 mg QD for 4 weeks; some patients may require an additional 4 weeks. • *Active benign gastric ulcer*: 40 mg QD for 4 to 8 weeks. • *Symptomatic GERD*: 20 mg QD for up to 4 weeks. • *EE due to acid-mediated GERD*: 20 mg QD for 4 to 8 weeks. • *Maintenance healing of EE due to acid-mediated GERD*: 20 mg QD. • *Reduction of risk of upper GI bleeding in critically ill patients (40 mg oral suspension only):*	20 mg/1,100 mg capsules	30 capsules	90 capsules
		40 mg/1,100 mg capsules	No quantity limit.	No quantity limit
		20 mg/1,680 mg packets of powder for oral suspension	30 packets	90 packets
		40 mg/1,680 mg packets of powder for oral suspension	No quantity limit.	No quantity limit

	40 mg initially, followed by 40 mg 6 to 8 hours later and 40 mg QD thereafter for 14 days.			
Pantoprazole Products				
Protonix® (pantoprazole sodium delayed-release tablets and oral suspension, generic)	Adults • *EE associated with GERD*: 20 mg QD for up to 8 weeks. • *Maintenance healing of EE*: 40 mg QD. • *Pathological hypersecretory conditions*: 40 mg BID. Patients ≥ 5 years to 17 years of age • *EE associated with GERD*: ○ ≥ 15 kg to < 40 kg: 20 mg QD for up to 8 weeks. ○ ≥ 40 kg: 40 mg QD for up to 8 weeks.	20 mg delayed-release tablets	30 tablets	90 tablets
		40 mg delayed-release tablets	No quantity limit.	No quantity limit
		40 mg packets of delayed-release granules for oral suspension	No quantity limit.	No quantity limit
Rabeprazole Products				
Aciphex® (rabeprazole sodium delayed-release tablets, generic)	Adults • *Healing of erosive or ulcerative GERD*: 20 mg QD for 4 to 8 weeks. • *Maintenance healing of erosive or ulcerative GERD*: 20 mg QD (studied for 12 months). • *Symptomatic GERD*: 20 mg QD for 4 weeks. • *Healing of duodenal ulcers*: 20 mg QD after morning meal for up to 4 weeks. • *Eradication of H. pylori to reduce the risk of duodenal ulcer recurrence*: 20 mg BID for 7 days as triple therapy in combination with other agents. • *Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome*: 60 mg QD. Adolescents • *Symptomatic GERD in patients ≥ 12 years of age*: 20 mg QD for up to 8 weeks.	20 mg delayed-release tablets	No quantity limit	No quantity limit

Drug Quantity Limits (continued)

Brand (generic)	FDA-Approved Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Rabeprazole Products (continued)				
Aciphex® Sprinkle™ (rabeprazole sodium delayed-release	Patients 1 to 11 years of age • Weight < 15 kg: 5 mg QD for up to 12 weeks. If an inadequate response, may increase to 10 mg QD. • Weight ≥ 15 kg: 10 mg QD for up to 12 weeks.	5 mg delayed-release capsules	30 capsules	90 capsules
		10 mg delayed-release	30 capsules	90 capsules

capsules, generic)	Note: If a larger dose is required, the patient should be referred to the 20 mg tablet.	capsules (branded generic)		

Proton Pump Inhibitors Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Dexlansoprazole Products

Dexlansoprazole 30 mg delayed-release capsules (Dexilant, generic)

1. If according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.
Note: This exception provides for 30 mg twice daily dosing.

2. If the patient has laryngopharyngeal reflux, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Esomeprazole Products

Nexium 2.5 mg packets of delayed-release granules for oral suspension

1. If the patient is < 1 year of age and according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.
Note: This exception provides for 2.5 mg twice daily dosing.

Nexium 5 mg packets of delayed-release granules for oral suspension

1. If the patient is ≤ 11 years of age and according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.
Note: This exception provides for 5 mg twice daily dosing.

Esomeprazole magnesium 10 mg packets of delayed-release granules for oral suspension (Nexium, generic)

1. If the patient is ≤ 17 years of age and according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.
Note: This exception provides for 10 mg twice daily dosing.

Esomeprazole magnesium 20 mg packets of delayed-release granules for oral suspension (Nexium, generic)

1. If according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.
Note: This exception provides for 20 mg twice daily dosing.

2. If the patient has laryngopharyngeal reflux, approve 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.

Esomeprazole magnesium 20 mg delayed-release capsules (Nexium, generic)

1. If according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.
Note: This exception provides for 20 mg twice daily dosing.

2. If the patient has laryngopharyngeal reflux, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Lansoprazole Products

Lansoprazole 15 mg delayed-release capsules (Prevacid, generic)

1. If according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

2. If the patient has laryngopharyngeal reflux, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Lansoprazole 15 mg delayed-release orally-disintegrating tablets (Prevacid SoluTab, generic)

1. If according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.

2. If the patient has laryngopharyngeal reflux, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.

Omeprazole Products

Prilosec 2.5 mg delayed-release oral suspension packets

1. If the patient is ≤ 16 years of age and according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 120 packets per dispensing at retail or 360 packets per dispensing at home delivery.
Note: This exception provides for 2.5 mg or 5 mg twice daily dosing.

Prilosec 10 mg delayed-release oral suspension packets

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used AND would otherwise require two or more strengths to be used), approve the requested quantity per dispensing, not to exceed 90 packets at retail or 270 packets at home delivery.
Note: An example of this situation is a patient receiving 30 mg once daily (three packets per day), a quantity of 90 packets per dispensing at retail or 270 packets per dispensing at home delivery would be approved.

2. If the patient is ≤ 16 years of age and according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.
Note: This exception provides for 10 mg twice daily dosing.

3. If the patient has laryngopharyngeal reflux, approve 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.

Omeprazole 10 mg delayed-release capsules

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used AND would otherwise require two or more strengths to be used), approve the requested quantity per dispensing, not to exceed 90 capsules at retail or 270 capsules at home delivery.
   Note: For example, if a patient is receiving 30 mg once daily (three capsules per day), a quantity of 90 capsules per dispensing would be approved at retail or 270 capsules per dispensing at home delivery.
2. If the patient is ≤ 16 years of age and according to the prescriber, the patient's symptoms are not controlled by once daily dosing, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.
   Note: This exception provides for 10 mg twice daily dosing.
3. If the patient has laryngopharyngeal reflux, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Omeprazole 20 mg delayed-release capsules

1. If the patient has a hypersecretory condition, (e.g., Zollinger-Ellison syndrome, endocrine adenomas, or systemic mastocytosis), approve 90 capsules per dispensing at retail or 270 capsules per dispensing at home delivery.
   Note: If a larger dose is required, the patient should be referred to the 40 mg prescription omeprazole capsule.
2. If according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.
   Note: This exception provides for 20 mg twice daily dosing.
3. If the patient has laryngopharyngeal reflux, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.
4. If the patient has an ulcer caused by *H. pylori*, approve a one-time exception of 46 capsules at retail or home delivery.
5. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used AND would otherwise require two or more strengths to be used), approve the requested quantity per dispensing, not to exceed 90 tablets at retail or 270 tablets at home delivery.
   Note: An example of this would be if a patient is receiving 60 mg once daily (three tablets per day), a quantity exception for 90 capsules per dispensing would be approved at retail or 270 capsules per dispensing per dispensing at home delivery.

Omeprazole and Sodium Bicarbonate Products

Konvomep 2 mg/84 mg per mL Kits (90 mL, 150 mL, and 300 mL)

No exceptions.

Omeprazole and sodium bicarbonate 20 mg/1,100 mg capsules (Zegerid, generic)

1. If the patient has a hypersecretory condition (e.g., Zollinger-Ellison syndrome, endocrine adenomas, systemic mastocytosis), approve 90 capsules per dispensing at retail or 270 capsules per dispensing at home delivery).
   Note: If a larger dose of omeprazole and sodium bicarbonate (Zegerid, generic) is required, the patient should be referred to the 40 mg/1,100 mg capsules.
2. If according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.
   Note: This exception provide for 20 mg/1,100 mg twice daily dosing.
3. If the patient has laryngopharyngeal reflux, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Omeprazole and sodium bicarbonate 20 mg/1,680 mg oral suspension (Zegerid, generic)

1. If the patient has a hypersecretory condition (e.g., Zollinger-Ellison syndrome, endocrine adenomas, systemic mastocytosis), approve 90 packets per dispensing at retail or 270 packets per dispensing at home delivery.
   Note: If a larger dose of omeprazole and sodium bicarbonate (Zegerid, generic) is required, the patient should be referred to the 40 mg/1,680 mg packets.
2. If according to the prescriber the patient's symptoms are not controlled by once daily, approve 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.
   Note: This exception provides for 20 mg/1,680 mg twice daily dosing.
3. If the patient has laryngopharyngeal reflux, approve 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.

Pantoprazole Products

Pantoprazole 20 mg delayed-release tablets (Protonix, generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used AND would otherwise require two or more strengths to be used), approve the requested quantity per dispensing, not to exceed 90 tablets at retail or 270 tablets at home delivery.
   Note: An example of this would be if a patient is receiving 60 mg once daily (three tablets per day), a quantity exception for 90 tablets at retail or 270 tablets at home delivery would be approved.
2. If the patient is ≥ 5 years of age and according to the prescriber the patient's symptoms are not controlled with once daily dosing, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.
3. If the patient has laryngopharyngeal reflux, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Rabeprazole Products

Aciphex Sprinkle 5 mg delayed-release capsules

1. If the patient is ≤ 11 years of age and according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Rabeprazole 10 mg delayed release capsules (Aciphex Sprinkle, branded generic)

1. If the patient is ≤ 11 years of age and according to the prescriber the patient's symptoms are not controlled by once daily dosing, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.
2. If the patient is unable to swallow a 20 mg rabeprazole delayed-release tablet (Aciphex, generic), approve the requested quantity per dispensing, not to exceed 180 capsules at retail or 540 capsules at home delivery.

REFERENCES

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2. Aciphex® Sprinkle™ delayed-release capsules [prescribing information]. Englewood, CO: Aytu; November 2020.
3. Dexilant® delayed-release capsules [prescribing information]. Deerfield, IL: Takeda; March 2022.
4. Nexium® delayed-release capsules/delayed-release oral granules [prescribing information]. Wilmington, DE: AstraZeneca; March 2022.
5. Esomeprazole strontium delayed-release capsules [prescribing information]. Glasgow, KY: Amneal; March 2022.
6. Prevacid®/Prevacid® SoluTab™ delayed-release capsules/delayed-release orally disintegrating tablets [prescribing information]. Deerfield, IL: Takeda; March 2022.
7. Prilosec® delayed-release oral granules [prescribing information]. Wilmington, DE: AstraZeneca; March 2022.
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10. Protonix® delayed-release tablets/delayed-release oral suspension [prescribing information]. Philadelphia, PA: Wyeth; March 2022.
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17. Omeclamox-Pak™ [prescribing information]. Nashville, TN: Cumberland; March 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	05/27/2021
Annual Revision	Approval duration was changed from 3 years to 1 year. **Aciphex Sprinkle (rabeprazole sodium delayed-release capsules, generic)**: Branded generic to the 10 mg delayed-release capsules was added to the policy. Exception criteria were updated to approve a quantity of 60 units per dispensing if according to the prescriber, the patients symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the	07/06/2022

	prescriber" and required the symptoms to have not been controlled by 5 mg or 10 mg once daily dosing specifically. **Dexilant (dexlansoprazole delayed-release capsules, generic):** Branded generics to the 30 mg delayed-release capsules were added to the policy. Exception criteria for the 30 mg capsules were updated to approve a quantity of 60 units per dispensing if according to the prescriber, the patients symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the prescriber" and required the symptoms to have not been controlled by 60 mg once daily dosing specifically. **Esomeprazole strontium delayed-release capsules:** The quantity limit and exception criteria for the 25.65 mg delayed-release capsules were removed from the policy (product obsolete). **Nexium (esomeprazole magnesium delayed-release capsules, generic):** Exception criteria for the 20 mg capsules were updated to approve a quantity of 60 units per dispensing if according to the prescriber, the patients symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the prescriber" and required the symptoms to have not been controlled by 40 mg once daily dosing, specifically. **Nexium (esomeprazole magnesium delayed-release granules for oral suspension, generic to 10 mg, 20 mg, and 40 mg packets only):** Exception criteria for the 2.5 mg, 5 mg, 10 mg, and 20 mg packets were updated to approve a quantity of 60 units per dispensing if according to the prescriber, the patient's symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the prescriber" and required the symptoms to have not been controlled by 5 mg, 10 mg, 20 mg, or 40 mg once daily dosing, respectively. **Prevacid (lansoprazole delayed-release capsules, generic) and Prevacid SoluTab (lansoprazole delayed-release orally disintegrating tablets, generic):** Exception criteria for the 15 mg capsules were updated to approve a quantity of 60 units per dispensing if according to the prescriber, the patients symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the prescriber", and required the patient to be ≤ 11 years of age, weigh ≤ 30 kg, and the symptoms to have not been controlled by 15 mg or 30 mg once daily dosing, specifically. **Prilosec OTC (omeprazole delayed-release tablets):** Quantity limit and Exception criteria for the 20 mg tablets were removed.	

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Omeprazole delayed-release capsules (generic only):** A new quantity limit of 30 capsules per dispensing added to the policy for the prescription 20 mg omeprazole delayed-release capsules. Brand prescription Prilosec was removed from the policy (product obsolete). New exception criteria for the prescription 20 mg capsules were added for the following scenarios: a patient with a hypersecretory condition, a patient whose symptoms are not controlled by once daily dosing, according to the prescriber, a patient with laryngopharyngeal reflux, a patient with an ulcer caused by *H. pylori* and a patient who is taking	07/06/2022 (continued)

	a dose that does not correspond to a commercially-available dosage form. exception criteria for the prescription 10 mg capsules were updated to approve the requested quantity not to exceed 90 capsules per dispensing for a patient who is taking a dose that does not correspond to a commercially-available dosage form. Previously, this criteria approved a quantity to allow for a 30-day supply per dispensing. Also updated criteria for the 10 mg capsules to approve a quantity of 60 units per dispensing if according to the prescriber, the patients symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the prescriber" and required the symptoms to have not been controlled by 20 mg once daily dosing, specifically. **Prilosec (omeprazole magnesium delayed-release oral suspension):** Exception criteria for the 2.5 mg oral suspension packets were updated to approve a quantity of 120 units per dispensing if according to the prescriber, the patients symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the prescriber" and required the symptoms to have not been controlled by 10 mg once daily dosing specifically. Exception criteria for the 10 mg oral suspension packets were updated for a patient who is taking a dose that does not correspond to a commercially-available dosage form to approve the requested quantity per dispensing, not to exceed 90 packets. Previously, this criteria approved a quantity to allow for a 30-day supply per dispensing. Additionally, criteria were updated to approve a quantity of 60 units per dispensing if according to the prescriber, the patients symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the prescriber" and required the symptoms to have not been controlled by 20 mg once daily dosing specifically. Criteria providing an approval for 90 units per dispensing if the patient is ≤ 16 years of age with a hypersecretory condition were removed as this dose would be provided for by other exception criteria. Exception criteria were added to approve 60 units per dispensing for a patient with laryngopharyngeal reflux. **Protonix (pantoprazole sodium delayed-release tablets, generic):** For the 20 mg delayed-release tablets, the criteria providing an exception for patients who cannot swallow 40 mg tablets were removed. Exception criteria were updated for a patient who is taking a dose that does not correspond to a commercially-available dosage form to approve the requested quantity per dispensing, not to exceed 90 tablets. Previously, this criteria approved a quantity to allow for a 30-day supply per dispensing. Exception criteria were updated to approve a quantity of 60 units per dispensing if according to the prescriber, the patients symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the prescriber", and required the patient to weigh ≥ 15 kg and ≤ 40 kg, and the symptoms to have not been controlled by 20 mg once daily dosing, specifically. Exception criteria were added to approve 60 units per dispensing for a patient with laryngopharyngeal reflux. **Zegerid (omeprazole and sodium bicarbonate capsules, generic) and Zegerid (omeprazole and sodium bicarbonate for oral suspension, generic):** Exception criteria were updated to approve a quantity of 60 units per dispensing if according to the prescriber, the patients symptoms are not controlled by once daily dosing. Previously, criteria did not indicate "according to the	

	prescriber" and the symptoms to have not been controlled by 40 mg once daily dosing, specifically.	

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. **Konvomep (omeprazole and sodium bicarbonate 2 mg/84 mg per mL oral suspension; 90 mL kit)**: A new quantity limit of 1 kit (90 mL) per dispensing at retail and home delivery was added to the policy. No clinical exceptions apply. **Konvomep (omeprazole and sodium bicarbonate 2 mg/84 mg per mL oral suspension; 150 mL kit)**: A new quantity limit of 1 kit (150 mL) per dispensing at retail and home delivery was added to the policy. No clinical exceptions apply. **Konvomep (omeprazole and sodium bicarbonate 2 mg/84 mg per mL oral suspension; 300 mL kit)**: A new quantity limit of 2 kits (600 mL) per dispensing at retail and home delivery was added to the policy. No clinical exceptions apply.	03/22/2023