



## Drug Quantity Management – Per Rx Proton Pump Inhibitors (PPI) Dispensing Limit

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### Product Identifier(s)

33552, 35553, 35682, 35683, 35684, 35685, 37673

### 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.

## National Formulary Medical Necessity

### Drugs Affected

- rabeprazole sodium delayed-release capsules (Aciphex® Sprinkle™)
- dexlansoprazole delayed-release capsules (Dexilant™)
- esomeprazole delayed-release capsules and oral suspension (Nexium® [capsules, 20 mg oral suspension packets])
- esomeprazole strontium capsules
- lansoprazole delayed-release capsules, delayed-release orally disintegrating tablets, (Prevacid®, Prevacid® SoluTab™)
- omeprazole oral capsules and suspension packets (Prilosec® – [suspension packets, OTC tablets], generics [capsules only])
- pantoprazole delayed-release tablets (Protonix®)
- omeprazole/sodium bicarbonate capsules and powder for oral suspension (Zegerid®)

The intent of drug quantity management on lower strength proton pump inhibitors (PPIs) is dose consolidation. For example, if a drug is available in 20 mg and 40 mg, only the 20 mg strength has a limit and criteria. Participants are encouraged to take one 40 mg unit instead of two 20 mg units. Under the per Rx program, the highest strengths of PPIs do not have quantity limits since it is clinically appropriate for situations such as a

hyper secretory condition (e.g., Zollinger-Ellison syndrome, endocrine adenomas, systemic mastocytosis) and acute healing of ulcers, to take doses above the highest strength. Over-the-counter PPIs are managed by plan design (for example, not covered) and are not subject to quantity limits under this program.

#### Criteria

#### **Cigna covers quantities as medically necessary when the following criteria are met:**

All approvals are provided for 3 years in duration unless otherwise noted below.

#### **Aciphex 5mg and 10 mg Sprinkle**

Maximum quantity per RX = 30 capsules

Aciphex is available as 20 mg delayed-release tablets and 5 mg and 10 mg delayed-release capsules. For the treatment of gastroesophageal reflux disease (GERD) in pediatric individuals aged 1 to 11 years the recommended dose is 5 mg once daily for children weighing < 15 kg and may increase to 10 mg per day if inadequate response to 5 mg daily. For children weighing ≥ 15 kg, the recommended dose is 10 mg once daily. Hence, 30 capsules should supply enough drug for a one month (30 day) supply in individuals receiving 5 mg or 10 mg once daily. If a larger dose is required, refer participant to the 20 mg tablet.

#### **Aciphex 5 mg Sprinkle**

1. Pediatric individual, aged less than or equal to 11 years of age whose symptoms cannot be controlled with 5 mg or 10 mg once daily, a quantity of 60 capsules per dispensing is recommended.

#### **Aciphex 10 mg Sprinkle**

1. Pediatric individual, aged less than or equal to 11 years of age whose symptoms cannot be controlled with 10 mg once daily, a quantity of 60 capsules per dispensing is recommended.
2. Individual is unable to swallow a 20 mg tablet. Authorize two 10 mg Sprinkle capsules to equal the total daily dose required of the 20 mg tablet sufficient for a 30 day supply per dispensing.

#### **Dexilant 30mg capsules**

Maximum quantity per RX = 30 capsules

Dexilant is available as 30 mg and 60 mg capsules. The manufacturer recommended dosing guidelines for the approved indications are 30 mg or 60 mg once daily. For the treatment of symptomatic non-erosive gastroesophageal reflux disease (GERD) and maintenance of healed erosive esophagitis in individuals 12 years of age and older, the recommended dose is 30 mg once daily. For healing of all grades of erosive esophagitis, the recommended dose is 60 mg once daily. A maximum daily dose of Dexilant 30 mg should be considered for individuals with moderate hepatic impairment (Child-Pugh Class B). The safety and effectiveness of Dexilant in pediatric individuals (less than 12 years of age) have not been established. Hence, 30 capsules should supply enough drug for a one month (30 day) supply if the dosage is 30 mg once daily.

1. Individual whose symptoms were not controlled by 60 mg once daily, a quantity override may be issued for a maximum of 60 capsules per dispensing for twice daily dosing.
2. Individuals with laryngopharyngeal reflux: a quantity override may be issued for a maximum of 60 capsules per dispensing.

#### **Nexium 2.5 mg, 5 mg, and 10 mg oral suspension (packets)**

Maximum quantity per RX = 30 packets

Nexium is available in 20 mg and 40 mg capsules and 2.5 mg, 5 mg, 10 mg, 20 mg, and 40 mg packets for oral suspension. The manufacturer recommended dosing guidelines for the approved indications are 2.5 mg, 5 mg, 10 mg, 20 mg or 40 mg once daily. Therefore, a quantity of 30 should provide enough drug for a one month (30 day) supply if the dosage is 2.5 mg once daily, 5 mg once daily or 10 mg once daily.

#### **Nexium 2.5 mg packets**

1. Pediatric individuals less than 1 year of age, whose symptoms are not controlled by 5 mg once daily, a quantity override may be issued for a maximum of 60 packets per dispensing to facilitate twice daily dosing.
2. No other quantity overrides are recommended.

**Nexium 5 mg packets**

1. Pediatric individuals less than 11 years of age, whose symptoms are not controlled by 10 mg once daily, a quantity override may be issued for a maximum of 60 packets per dispensing to facilitate twice daily dosing.
2. No other quantity overrides are recommended.

**Nexium 10 mg packets**

1. Pediatric individuals less than or equal to 17 years of age, whose symptoms are not controlled by 20 mg once daily, a quantity override may be issued for a maximum of 60 packets per dispensing to facilitate twice daily dosing.
2. No other quantity overrides are recommended.

**Nexium 20 mg capsules (generic)****Nexium 20 mg oral suspension (packets)**

Maximum quantity per RX = 30 capsules/packets

Nexium is available in 20 mg and 40 mg capsules and 2.5 mg, 5 mg, 10 mg, 20 mg, and 40 mg packets for oral suspension. The manufacturer recommended dosing guidelines for the approved indications are 20 mg or 40 mg once or twice daily. Therefore, a quantity of 30 capsules/packets should provide enough drug for a one month (30 day) supply if the dosage is 20 mg once daily. Nexium 40 mg once daily for 10 days is indicated in combination with clarithromycin and amoxicillin for eradication of *H. pylori* infections. Some studies indicate that Nexium 20 mg twice daily for 7 days or 10 days in combination with clarithromycin and amoxicillin is effective in eradicating *H. pylori* infections.

**Nexium 20 mg capsules (generic)****Nexium 20 mg oral suspension (packets)**

1. Individual whose symptoms were not controlled by 40 mg once daily, a quantity override may be issued for a maximum of 60 capsules/packets per dispensing for twice daily dosing.
2. Individuals with laryngopharyngeal reflux: a quantity override may be issued for a maximum of 60 capsules/packets per dispensing.
3. No other quantity overrides are recommended.

**Esomeprazole strontium 24.65 mg capsules  
(equivalent to esomeprazole 20 mg)**

Maximum quantity per RX = 30 capsules

Esomeprazole strontium is available in 24.65 mg and 49.3 mg capsules. The manufacturer recommended dosing guidelines for the approved indications are 24.65 mg or 49.3 mg once daily or 49.3 mg twice daily for pathological hypersecretory conditions such as Zollinger-Ellison Syndrome. Therefore, a quantity of 30 capsules should provide enough drug for a one month (30 day) supply if the dosage is 24.65 mg once daily. Esomeprazole 49.3 mg once daily for 10 days is indicated in combination with clarithromycin and amoxicillin for eradication of *H. pylori* infections.

**Esomeprazole strontium 24.65 mg capsules (equivalent to esomeprazole 20 mg)**

1. Individual whose symptoms were not controlled by 49.3 mg once daily, a quantity override may be issued for a maximum of 60 capsules per dispensing for twice daily dosing.
2. Individuals with laryngopharyngeal reflux: a quantity override may be issued for a maximum of 60 capsules per dispensing.
3. No other quantity overrides are recommended.

**Prevacid 15 mg capsule (generic), Prevacid 15 mg SoluTab** Maximum quantity per RX = 30 capsules/tablets

Prevacid delayed-release capsules and Prevacid delayed-release orally disintegrating tablets are available in two strengths, 15 and 30 mg. For most approved indications the dosage is 15 or 30 mg once daily. For children aged 1-11 years with symptomatic gastroesophageal reflux disease (GERD) or erosive esophagitis, the recommended dose for those weighing ≤ 30 kg is 15 mg once daily (for up to 12 weeks). Hence, 30 capsules/tablets should supply enough drug for a one month (30 day) supply in individuals receiving 15 mg once daily. If a larger dose is required, refer participant to the 30 mg strength.

**Prevacid 15 mg capsules (generic), Prevacid 15 mg SoluTab**

1. Individuals with laryngopharyngeal reflux: a quantity override may be issued for a maximum of 60 capsules/tablets per dispensing.
2. Pediatric individual, aged less than or equal to 11 years of age, weighing  $\leq 30$  kg whose symptoms cannot be controlled with 15 mg once daily, a quantity of 60 capsules/tablets per dispensing is recommended.
3. Individual whose symptoms cannot be controlled with 30 mg once daily, a quantity override may be issued for a maximum of 60 capsules/tablets per dispensing.

**Prilosec 2.5 mg oral suspension packets**

Maximum quantity per RX = 60 packets

**Prilosec 10 mg oral suspension packets**

Maximum quantity per RX = 30 packets

Prilosec is available as 20 mg (OTC) tablets and 2.5 mg and 10 mg oral suspension packets. Generic omeprazole is available in 10 mg, 20 mg and 40 mg capsules. For the treatment of gastroesophageal reflux disease (GERD) and maintenance healing of erosive esophagitis in pediatric individuals aged 1 to 16 years the recommended dose is 5 mg once daily for children weighing 5 to  $< 10$  kg, 10 mg once daily for children weighing 10 to  $< 20$  kg and 20 mg once daily for children weighing  $\geq 20$  kg. Two of the 2.5 mg packets would be required for a 5 mg dose and one 10 mg packet would be required for a 10 mg dose. Individuals requiring doses  $> 5$  mg should use the 10 mg packets. Hence, 60 of the 2.5 mg packets should supply enough drug for a one month (30 day) supply and 30 of the 10 mg packets should supply enough drug for a one month (30 day) supply.

**Prilosec 2.5 mg oral suspension packets**

1. Pediatric individuals, less than or equal to 16 years of age, whose symptoms were not controlled by 10 mg once daily, a quantity override may be issued for a maximum of 120 packets per dispensing.
2. Other indications. Quantity override is not recommended.

**Prilosec 10 mg oral suspension packets**

1. Exceptions can be made when an individual 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]. For example, if an individual is receiving 30 mg once daily, a quantity override for 3 packets per day would be required (total of 90 of the 10 mg packets). Approve a quantity to allow for a 30 day supply per dispensing.
2. Pediatric individuals, less than or equal to 16 years of age, with a hyper secretory condition (e.g., Zollinger-Ellison syndrome, endocrine adenomas, systemic mastocytosis). A quantity override may be issued for a maximum of 90 packets per dispensing. If a larger dose of Prilosec or omeprazole is required, the individual should be referred to the 20 mg Prilosec capsule.
3. Pediatric individuals, less than or equal to 16 years of age, whose symptoms were not controlled by 20mg once daily, a quantity override may be issued for a maximum of 60 packets per dispensing.

**Omeprazole 10 mg (generic)**

Maximum quantity per RX = 30 capsules

Prilosec is available as 20 mg tablets (OTC), and 2.5 mg and 10 mg oral suspension packets. Generic omeprazole is available in 10 mg, 20 mg and 40 mg capsules. For the treatment of gastroesophageal reflux disease (GERD) and maintenance of healing of erosive esophagitis in pediatric individuals aged 1 to 16 years the recommended dose is 5 mg once daily for children weighing 5 to  $< 10$  kg, 10 mg once daily for children weighing 10 to  $< 20$  kg and 20 mg once daily for children weighing  $\geq 20$  kg. Indications for adults require doses of 20 mg once daily or more. Therefore, most dosage regimens will utilize the 20 mg strength, unless a dose of 10 mg once daily or a dose that cannot be achieved by utilizing 20 mg or 40 mg (e.g., 30 mg, 50 mg, etc.) is required. Hence, 30 capsules should supply enough drug for a one month (30 day) supply.

**Omeprazole 10 mg (generic)**

1. Exceptions can be made when an individual 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]. For example, if an individual is receiving 30 mg once daily, a quantity override for 3 packets per day would be required (total of 90 of the 10 mg packets). Approve a quantity to allow for a 30 day supply per dispensing.

2. Pediatric individuals, less than or equal to 16 years of age, whose symptoms were not controlled by 20 mg once daily, a quantity override may be issued for a maximum of 60 capsules per dispensing.
3. Pediatric individuals, less than or equal to 16 years of age, with a hyper secretory condition (e.g., Zollinger-Ellison syndrome, endocrine adenomas, systemic mastocytosis). A quantity override may be issued for a maximum of 90 capsules per dispensing. If a larger dose of Prilosec or omeprazole is required, the individual should be referred to the 20 mg Prilosec capsule.

#### **Prilosec 20 mg, OTC [brand name only]**

Maximum quantity per RX = 30 tablets

***There is no quantity limit on generic omeprazole 20 mg.*** Prilosec is available as 20 mg tablets (OTC) and 2.5 mg and 10 mg oral suspension packets. The manufacturer recommended dosing guidelines for most approved indications are 20 mg or 40 mg once daily. Hence, 30 capsules should provide enough drug for a one month (30 day) supply for most approved indications. Recent reports have stated that acid secretion may be decreased more with twice daily dosing of proton pump inhibitors, compared with once daily dosing. Therefore, exceptions are available for individuals who have tried 40 mg once daily and symptoms are not controlled. A maximum of 90 capsules may be given for hyper secretory conditions, such as Zollinger-Ellison Syndrome for which the manufacturer's recommended starting dose is 60 mg/day. Prilosec is indicated in combination with clarithromycin for eradication of *H. pylori* infections. Manufacturer recommended dosing for this indication (dual therapy) is Prilosec 40 mg once daily plus clarithromycin 500 mg three times daily for 14 days, followed by 20 mg once daily for 14 days if an ulcer was present when therapy was initiated. Small studies have shown that using twice daily dosing may be helpful for this condition. Therefore, a one-time override for a quantity of 44 capsules may be given to allow for twice daily dosing during the first 14 days of the recommended regimen. The manufacturer also has a triple therapy regimen for eradication of *H. pylori* which includes Prilosec 20 mg, clarithromycin 500 mg plus amoxicillin 1000 mg each given twice daily for 10 days. If an ulcer is present at the initiation of therapy, an additional 18 days of Prilosec 20 mg once daily is recommended. If additional capsules are needed (i.e., a larger dose of Prilosec), refer the participant to the 40 mg Prilosec capsule.

#### **Prilosec 20 mg, OTC [brand name only]**

1. Individual with a hyper secretory condition (e.g., Zollinger-Ellison syndrome, endocrine adenomas, systemic mastocytosis). A quantity override may be issued for a maximum of 90 tablets per dispensing. If a larger dose is required, the individual should be referred to the 40 mg omeprazole capsule.
2. Individual whose symptoms were not controlled by 40 mg of omeprazole once daily, a quantity override may be issued for a maximum of 60 tablets per dispensing.
3. Individuals with laryngopharyngeal reflux: a quantity override may be issued for a maximum of 60 tablets per dispensing.
4. Individual with ulcer caused by *H. Pylori*. A onetime quantity override of 44 tablets may be issued.
5. Exceptions can be made when an individual 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]. For example, if an individual is receiving 60 mg once daily, a quantity override for three 20 mg tablets per day would be required (total of 90 of the 20 mg tablets). Approve a quantity to allow for a 30 day supply per dispensing.
6. Other indications. Quantity override not recommended.

#### **Protonix 20 mg, generics**

Maximum quantity per RX = 30 tablets

Protonix is available in two strengths, 20 mg and 40 mg tablets and in a 40 mg suspension pack. In adults, for the indications of treatment of erosive esophagitis associated with gastroesophageal reflux disease (GERD) and maintenance of healing of erosive esophagitis, the recommended dose is 40 mg once daily. For these indications, refer the individual to the 40 mg tablet strength. In adults, for the treatment of pathological hyper secretory conditions, the recommended starting dose is 40 mg twice daily and doses up to 240 mg daily have been administered. For children 5 years of age and older, with erosive esophagitis associated with GERD, the recommended dose is 20 mg once daily for those weighing  $\geq 15$  kg to  $< 40$  kg and 40 mg once daily for those weighing  $\geq 40$  kg. The product labeling specifically states that if individuals are unable to swallow a 40 mg tablet, two 20 mg tablets may be taken. Most indications for adults require doses of 40 mg once daily or more. Therefore most dosage regimens will utilize the 40 mg strength, unless a dose of 20 mg once daily or a dose that

cannot be achieved utilizing the highest commercially available strength (e.g., 60 mg) is required. Hence, 30 tablets should supply enough drug for a 30 day supply for individuals receiving 20 mg daily.

#### **Protonix 20 mg, generics**

1. Individual is unable to swallow a 40 mg tablet. Authorize two 20 mg tablets to equal the total daily dose required of the 40 mg tablet for a 30 day supply per dispensing.
2. Exceptions can be made when an individual 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]. For example, if an individual is receiving 60 mg once daily, a quantity override for three 20 mg tablets per day would be required (total of 90 of the 20 mg tablets). Approve a quantity to allow for a 30 day supply per dispensing.
3. Pediatric individual, 5 years and older, weighing  $\geq 15$  kg and  $< 40$  kg, whose symptoms cannot be controlled with 20 mg once daily, a quantity of 60 tablets per dispensing is recommended.

#### **Zegerid 20 mg (generics)**

Maximum quantity per RX = 30 packets or capsules

Zegerid is available in 20 mg and 40 mg unit dose suspension packets and as 20 mg and 40 mg capsules. Both the 20 mg and 40 mg packets contain the same amount of sodium bicarbonate (1680 mg), accordingly, two packets of 20 mg are not equivalent to one packet of 40 mg. Both the 20 mg and 40 mg capsules contain the same amount of sodium bicarbonate (1100 mg), accordingly, two of the 20 mg capsules are not equivalent to one capsule of 40 mg. For the short-term treatment of active duodenal ulcer, treatment of gastroesophageal reflux disease (GERD), treatment of erosive esophagitis, and maintenance of healing of erosive esophagitis the recommended dose is 20 mg once daily. For the treatment of gastric ulcers the recommended dose is 40 mg once daily. In the reduction of risk of upper gastrointestinal bleeding in critically ill individuals, the recommended dose is 40 mg of the oral suspension (packets) once daily after two 40 mg doses initially. Hence, 30 unit dose packets or capsules should provide enough drug for a one month (30 day) supply for the approved indications.

#### **Zegerid 20 mg (generics)**

1. Individual with Zollinger-Ellison syndrome or other hyper secretory condition, a quantity override may be issued for a maximum of 90 packets or capsules per dispensing. If a larger dose of Zegerid is required, the individual should be referred to the 40 mg strength packet or capsule.
2. Individual whose symptoms were not controlled by Zegerid 40 mg once daily, a quantity override may be issued for a maximum of 60 packets or capsules per dispensing.
3. Individuals with laryngopharyngeal reflux, a quantity override may be issued for a maximum of 60 packets or capsules per dispensing.

## **Conditions Not Covered**

Any other exception is considered not medically necessary.

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## Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Reviewed by Clinical Specialists. No criteria changes	05/29/2020

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