



Proton Pump Inhibitors (PPIs) Quantity Limit Program Summary

This program is implemented for MN Medicaid only.

POLICY REVIEW CYCLE

Effective Date
1/1/2024

Date of Origin
8/1/2017

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Aciphex® Sprinkle™, Rabeprazole Sprinkle (rabeprazole) Capsule	Treatment of GERD in pediatric patients 1 to 11 years of age for up to 12 weeks		2
Aciphex® (rabeprazole) Tablet*	<ul style="list-style-type: none"> • Healing of erosive or ulcerative gastroesophageal reflux disease (GERD) in adults • Maintenance of healing of erosive or ulcerative GERD in adults • Treatment of symptomatic GERD in adults and adolescents 12 years of age and older • Healing of duodenal ulcers in adults • <i>Helicobacter pylori</i> eradication to reduce the risk of duodenal ulcer recurrence in adults • Treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome in adults 	* generic available	1
Dexilant® (dexlansoprazole)* Capsule	<ul style="list-style-type: none"> • Healing of erosive esophagitis in patients 12 years of age and older • Maintenance of healed erosive esophagitis and relief of heartburn in patients 12 years of age and older • Treatment of symptomatic non-erosive GERD in patients 12 years of age and older 	* generic available	3
Esomeprazole Strontium Capsule	<ul style="list-style-type: none"> • Treatment of gastroesophageal reflux disease (GERD) in adults • Risk reduction of NSAID-associated gastric ulcer in adults • H. pylori eradication to reduce the risk of duodenal ulcer recurrence in adults • Pathological hypersecretory conditions, including Zollinger-Ellison syndrome in adults 		4
Konvomep™ (omeprazole/sodium bicarbonate) Oral suspension	<ul style="list-style-type: none"> • Treatment of active benign gastric ulcer • Reduction of risk of upper gastrointestinal (GI) bleeding in critically ill patients 		16

Agent(s)	FDA Indication(s)	Notes	Ref#
Nexium® (esomeprazole magnesium) Capsule* Suspension packet	<ul style="list-style-type: none"> Treatment of GERD Risk reduction of NSAID-associated gastric ulcer <i>H. pylori</i> eradication to reduce the risk of duodenal ulcer recurrence Pathological hypersecretory conditions, including Zollinger-Ellison syndrome 	* generic available	5
Prevacid®, Prevacid® SoluTab™ (lansoprazole) * Capsule Orally disintegrating tablet (ODT)	<ul style="list-style-type: none"> Short-term treatment of active duodenal ulcer in adults <i>H. pylori</i> eradication to reduce the risk of duodenal ulcer recurrence in adults Maintenance of healed duodenal ulcers in adults Short-term treatment of active benign gastric ulcer in adults Healing of non-steroidal anti-inflammatory drug (NSAID)-associated gastric ulcer Risk reduction of NSAID-associated gastric ulcer in adults Treatment of symptomatic GERD Treatment of erosive esophagitis Maintenance of healing of erosive esophagitis in adults Pathological hypersecretory conditions including Zollinger-Ellison syndrome in adults 	* generic available	6
Prilosec® (omeprazole) Capsule* Suspension packet	<ul style="list-style-type: none"> Treatment of active duodenal ulcer in adults Eradication of <i>Helicobacter pylori</i> to reduce the risk of duodenal ulcer recurrence in adults Treatment of active benign gastric ulcer in adults Treatment of symptomatic GERD in patients 1 year of age and older Treatment of erosive esophagitis due to acid-mediated GERD in patients 1 month of age and older Maintenance of healing of erosive esophagitis due to acid-mediated GERD in patients 1 year of age and older Pathological hypersecretory conditions in adults 	* generic available	7
Protonix® (pantoprazole) Tablet* Suspension packet	<ul style="list-style-type: none"> Short-term treatment of erosive esophagitis associated with GERD in patients 5 years of age and older Maintenance of healing of erosive esophagitis and reduction in relapse rates of daytime and nighttime heartburn symptoms in adult patients with GERD Pathological hypersecretory conditions including Zollinger-Ellison syndrome in adults 	* generic available	8
Zegerid® (omeprazole/sodium bicarbonate) Capsule* Suspension packet	<ul style="list-style-type: none"> Short-term treatment of active duodenal ulcer in adults Short-term treatment of active benign gastric ulcer in adults Treatment of heartburn and other symptoms associated with GERD in adults Treatment of erosive esophagitis due to acid-mediated GERD which has been diagnosed by endoscopy in adults Maintenance of healing of erosive esophagitis due to acid-mediated GERD in adults Reduction of risk of upper GI bleeding in critically ill adult patients (oral suspension only) 	* generic available	9

CLINICAL RATIONALE

<p>Overview</p>	<p>Current guidelines recognize the proton pump inhibitors (PPIs) as first-line therapy for the management of dyspepsia, gastroesophageal reflux disease (GERD), peptic ulcer disease (PUD), eradication of <i>Helicobacter pylori</i> (<i>H. pylori</i>), and Zollinger Ellison syndrome (ZES).(10-15,17)</p> <p>In studies comparing PPIs to one another, while some differences have been reported, the magnitude of differences (safety/efficacy) has been small and of uncertain clinical importance. The degree to which any differences would justify the selection of one vs. another PPI, particularly when considering cost-effectiveness, is unclear. Data suggests the similar efficacy of PPIs that has been observed in controlled clinical trials may not necessarily translate into equivalent effectiveness when these drugs are substituted for one another. Differences in dosage formulations and drug interactions may occasionally influence choice of PPI in individual cases.(10-13)</p>
<p>Safety(1-9, 16)</p>	<p>Aciphex is contraindicated in the following:</p> <ul style="list-style-type: none"> • Patients with known hypersensitivity to rabeprazole, substituted benzimidazoles, or to any component of the formulation • Patients receiving rilpivirine-containing products <p>Dexilant is contraindicated in the following:</p> <ul style="list-style-type: none"> • Patients with known hypersensitivity to any component of the formulation • Patients receiving rilpivirine-containing products <p>Esomeprazole Strontium is contraindicated in the following:</p> <ul style="list-style-type: none"> • Patients with known hypersensitivity to proton pump inhibitors (PPIs) (angioedema and anaphylaxis have occurred) <p>Konvomep is contraindicated in the following:</p> <ul style="list-style-type: none"> • Known hypersensitivity to any components of the formulation • Patients receiving rilpivirine-containing products <p>Nexium is contraindicated in the following:</p> <ul style="list-style-type: none"> • Patients with known hypersensitivity to substituted benzimidazoles or any component of the formulation • Patients receiving rilpivirine-containing products <p>Prevacid is contraindicated in the following:</p> <ul style="list-style-type: none"> • Patients with known severe hypersensitivity to any component of the formulation • Patients receiving rilpivirine-containing products <p>Prilosec is contraindicated in the following:</p> <ul style="list-style-type: none"> • Patients with known hypersensitivity to substituted benzimidazoles or any component of the formulation • Patients receiving rilpivirine-containing products <p>Protonix is contraindicated in the following:</p>

	<ul style="list-style-type: none"> • Patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation • Patients receiving rilpivirine-containing products <p>Zegerid is contraindicated in the following:</p> <ul style="list-style-type: none"> • Patients with known hypersensitivity to substituted benzimidazoles or to any components of the formulation • Patients receiving rilpivirine-containing products
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REFERENCES

Number	Reference
1	Aciphex prescribing information. Woodward Pharm Services LLC. March 2022.
2	Aciphex Sprinkle prescribing information. Aytu Therapeutics, LLC. December 2020.
3	Dexilant prescribing information. Takeda Pharmaceuticals America, Inc. March 2022.
4	Esomeprazole strontium prescribing information. Amneal Pharmaceuticals LLC. January 2021.
5	Nexium prescribing information. AstraZeneca Pharmaceuticals LP. March 2022.
6	Prevacid prescribing information. Takeda Pharmaceuticals America, Inc. Prevacid 2022.
7	Prilosec delayed-release suspension prescribing information. Covis Pharma. March 2022.
8	Protonix prescribing information. Wyeth Pharmaceuticals LLC. November 2020.
9	Zegerid prescribing information. Santarus Inc. March 2022.
10	Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. <i>The American Journal of Gastroenterology</i> . 2022;117(1):27-56.
11	Drugs for GERD and peptic ulcer disease. <i>Medical Letter Treatment Guidelines</i> . 2022;64(1647):49-56.
12	Laine L, Barkun A, Saltzman J, et al. ACG Clinical Guideline: Upper Gastrointestinal and Ulcer Bleeding <i>The American Journal of Gastroenterology</i> 116(5):p 899-917, May 2021.
13	Shaheen N, Falk G, Iyer P, et al. ACG Clinical Guideline: Diagnosis and Management of Barrett's Esophagus. <i>American Journal of Gastroenterology</i> 111(1):p 30-50, January 2016.
14	The Zollinger-Ellison syndrome: dangers and consequences of interrupting antisecretory treatment. <i>Clinical Gastroenterology and Hepatology</i> . 2012 Feb;10(2):199-202.
15	Zollinger-Ellison syndrome: classical considerations and current controversies. <i>The Oncologist</i> . 2014 Jan;19(1):44-50.
16	Konvomep prescribing information. Azurity Pharmaceuticals, Inc. December 2022.
17	Chey W, Leontiadis G, Howden CW & Moss, S. F. Correction: ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. <i>The American Journal of Gastroenterology</i> , 113(7), 1102, 2018 https://doi.org/10.1038/s41395-018-0132-6

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	esomeprazole strontium cap delayed release	49.3 MG	30	Capsules	30	DAYS			
	Omeprazole Cap Delayed Release 10 MG	10 MG	30	Capsules	30	DAYS			
	Omeprazole Cap Delayed Release 20 MG	20 ; 20 MG	30	Capsules	30	DAYS			
	Omeprazole Cap Delayed Release 40 MG	40 MG	30	Capsules	30	DAYS			
Aciphex	rabeprazole sodium ec tab	20 MG	30	Tablets	30	DAYS			
Aciphex sprinkle	rabeprazole sodium capsule sprinkle dr	10 MG ; 5 MG	30	Capsules	30	DAYS			
Cvs esomeprazole magnesium ; Eq esomeprazole magnesium ; Gnp esomeprazole magnesium ; Goodsense esomeprazole ma ; Hm esomeprazole magnesium ; Kls esomeprazole magnesium ; Nexium ; Nexium 24hr ; Nexium 24hr clear minis ; Qc esomeprazole magnesium ; Ra esomeprazole magnesium ; Sm esomeprazole magnesium	esomeprazole magnesium cap delayed release	20 MG ; 40 MG	30	Capsules	30	DAYS			
Cvs lansoprazole ; Eq lansoprazole ; Eql lansoprazole ; Ft acid reducer ; Gnp lansoprazole ; Goodsense lansoprazole ; Hm lansoprazole ; Kls lansoprazole ; Prevacid ; Prevacid 24hr ; Qc lansoprazole ; Sm lansoprazole	lansoprazole cap delayed release	15 MG ; 30 MG	30	Capsules	30	DAYS			
Cvs lansoprazole ; Goodsense lansoprazole ; Prevacid solutab	lansoprazole tab delayed release orally disintegrating	15 MG ; 30 MG	30	Tablets	30	DAYS			
Cvs omeprazole/sodium bic ; Goodsense omeprazole/sodi ; Zegerid	omeprazole-sodium bicarbonate cap	20-1100 MG ; 40-1100 MG	30	Capsules	30	DAYS			
Dexilant	dexlansoprazole cap delayed release	30 MG ; 60 MG	30	Capsules	30	DAYS			
Konvomep	omeprazole-sodium bicarbonate for oral susp	2-84 MG/ML	600	mLs	30	DAYS			
Nexium	esomeprazole magnesium for delayed release susp pack ; esomeprazole magnesium for	10 MG ; 2.5 MG ; 20 MG ; 40 MG ; 5 MG	30	Packets	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	delayed release susp packet								
Prilosec	Omeprazole Magnesium For Delayed Release Susp Packet 10 MG	10 MG	30	Packets	30	DAYS			
Prilosec	Omeprazole Magnesium For Delayed Release Susp Packet 2.5 MG	2.5 MG	60	Packets	30	DAYS			
Protonix	pantoprazole sodium ec tab	20 MG ; 40 MG	30	Tablets	30	DAYS			
Protonix	pantoprazole sodium for delayed release susp packet	40 MG	30	Packets	30	DAYS			
Zegerid	omeprazole-sodium bicarbonate powd pack for susp	20-1680 MG ; 40-1680 MG	30	Packets	30	DAYS			

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	esomeprazole strontium cap delayed release	49.3 MG	Medicaid
	Omeprazole Cap Delayed Release 10 MG	10 MG	Medicaid
	Omeprazole Cap Delayed Release 20 MG	20 ; 20 MG	Medicaid
	Omeprazole Cap Delayed Release 40 MG	40 MG	Medicaid
Aciphex	rabeprazole sodium ec tab	20 MG	Medicaid
Aciphex sprinkle	rabeprazole sodium capsule sprinkle dr	10 MG ; 5 MG	Medicaid
Cvs esomeprazole magnesium ; Eq esomeprazole magnesium ; Gnp esomeprazole magnesium ; Goodsense esomeprazole ma ; Hm esomeprazole magnesium ; Kls esomeprazole magnesium ; Nexium ; Nexium 24hr ; Nexium 24hr clear minis ; Qc esomeprazole magnesium ; Ra esomeprazole magnesium ; Sm esomeprazole magnesium	esomeprazole magnesium cap delayed release	20 MG ; 40 MG	Medicaid
Cvs lansoprazole ; Eq lansoprazole ; Eq1 lansoprazole ; Ft acid reducer ; Gnp lansoprazole ; Goodsense lansoprazole ; Hm lansoprazole ; Kls lansoprazole ; Prevacid ; Prevacid 24hr ; Qc lansoprazole ; Sm lansoprazole	lansoprazole cap delayed release	15 MG ; 30 MG	Medicaid
Cvs lansoprazole ; Goodsense lansoprazole ; Prevacid solutab	lansoprazole tab delayed release orally disintegrating	15 MG ; 30 MG	Medicaid
Cvs omeprazole/sodium bic ; Goodsense omeprazole/sodi ; Zegerid	omeprazole-sodium bicarbonate cap	20-1100 MG ; 40-1100 MG	Medicaid
Dexilant	dexlansoprazole cap delayed release	30 MG ; 60 MG	Medicaid
Konvomep	omeprazole-sodium bicarbonate for oral susp	2-84 MG/ML	Medicaid
Nexium	esomeprazole magnesium for delayed release susp pack ; esomeprazole magnesium for delayed release susp packet	10 MG ; 2.5 MG ; 20 MG ; 40 MG ; 5 MG	Medicaid
Prilosec	Omeprazole Magnesium For Delayed Release Susp Packet 10 MG	10 MG	Medicaid
Prilosec	Omeprazole Magnesium For Delayed Release Susp Packet 2.5 MG	2.5 MG	Medicaid

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Protonix	pantoprazole sodium ec tab	20 MG ; 40 MG	Medicaid
Protonix	pantoprazole sodium for delayed release susp packet	40 MG	Medicaid
Zegerid	omeprazole-sodium bicarbonate powd pack for susp	20-1680 MG ; 40-1680 MG	Medicaid

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. Information has been provided to support therapy with a higher dose for the requested indication OR 2. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR 3. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication AND 2. Information has been provided to support therapy with a higher dose for the requested indication <p>Length of Approval: up to 12 months</p> <ul style="list-style-type: none"> • Hypersecretory disease (i.e., Zollinger-Ellison Syndrome), Barrett's esophagitis, or esophageal stricture - approve 12 months • Conventional therapy failure (failure of standard labeled dosing with the requested agent) - approve 12 months • H pylori treatment - approve once