MASSACHUSETTS

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Pharmacy Medical Policy
Proton Pump Inhibitors

Table of Contents

Policy Number: 030

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply and can be found in Medical Policy #**621B**

Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☒ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**1/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☐ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary **Policy does NOT apply to**: • Medicare Advantage			

NOTE: As of 1/1/2019 Proton Pump Inhibitors are a Benefit Exclusion for any member which is 18 years or older unless an account has purchased a Rider.

Summary

This is a comprehensive policy covering prior authorization and quantity limit requirements for proton pump inhibitors (PPIs).

Policy

Length of Approval	12 months
Formulary Status	All requests must meet the Prior Authorization requirements and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Please refer to the chart below for the formulary status/requirements of the medications affected by this policy:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement	Additional Considerations
Omeprazole	Covered, QCD	Covered with no requirements	Limited Coverage - excluded from coverage under the pharmacy benefit for members 18 years of age and older
Pantoprazole	Covered, QCD		
Lansoprazole 30mg	Covered, QCD		
Lansoprazole ODT	Covered, QCD		
Rabeprazole	Covered, QCD		
First Omeprazole Suspension	Covered, QCD		
Esomeprazole	PA, NFNC	PA Required AND also meet Non-formulary exception criteria	Limited Coverage - excluded from coverage under the pharmacy benefit for members 18 years of age and older
Dexlansoprazole	PA, NFNC, QCD		
Aciphex ®	PA, NFNC, QCD		
Aciphex ® Sprinkle	PA, NFNC, QCD		
Dexilant ™	PA, NFNC, QCD		
Konvomep (omeprazole/sodium bicarbonate) 2-84mg/ml oral susp	PA, NFNC, QCD		
Nexium ® 40mg	PA, NFNC, QCD		
Nexium packets	PA, NFNC, QCD		
Omeprazole + Syrspend	PA, NFNC		
Omeprazole/sodium bicarbonate	PA, NFNC, QCD		
Omeprazole/Aspirin	PA, NFNC, QCD		
Prevacid ® 30mg	PA, NFNC, QCD		
Prevacid ® solutabs	PA, NFNC, QCD		
Prilosec ®	PA, NFNC, QCD		
Prilosec suspension	PA, NFNC, QCD		
Protonix ®	PA, NFNC, QCD		
Voquezna (vonoprazan)	PA, NFNC, QCD		
Yosprala	PA, NFNC, QCD		
Zegerid ® 40mg, Zegerid packets	PA, NFNC, QCD		

QCD - Quality Care Dosing (quantity limits policy #621B); PA – Prior Authorization, NFNC – Non-formulary, Non-Covered

NOTE: As of 1/1/2019 Proton Pump Inhibitors are a Benefit Exclusion for any member which is 18 years or older unless an account has purchased a Rider.

Non-Covered Over-the-counter products - Nexium® (esomeprazole) 20mg, Prilosec OTC®, Prevacid® (lansoprazole) 15mg, Omeppi 20mg, Zegerid 20mg capsules or omeprazole/sodium bicarbonate 20mg capsules are not covered because these medications are available without a prescription and therefore excluded from coverage under the pharmacy benefit.

Esomeprazole and Dexlansoprazole

Esomeprazole or **Dexlansoprazole** may be covered when the following criteria is met:

1. There has been previous treatment failure with or contraindication to **omeprazole** AND **pantoprazole** AND **lansoprazole 30mg** AND **rabeprazole 20mg**

Yosprala (aspirin and omeprazole) and Aspirin/Omeprazole

Yosprala (aspirin and omeprazole) or **Aspirin/Omeprazole** may be covered when **ALL** of the following criteria are met:

1. Documentation that the requested medication is being used for the secondary prevention of cardiovascular and cerebrovascular events; **AND**
2. There has been previous treatment failure with ALL of the following alternatives:
    a. Omeprazole plus OTC aspirin; **AND**
    b. Pantoprazole plus OTC aspirin; **AND**
    c. Lansoprazole plus OTC aspirin; **AND**
    d. Rabeprazole plus OTC aspirin

All other Proton Pump Inhibitors

Aciphex ®, Aciphex ® Sprinkle™, Dexilant ™, Konvomep (omeprazole/sodium bicarbonate) 2-84mg/ml oral susp, Nexium ® 40mg, Nexium packets, Omeprazole/sodium bicarbonate 40mg, Omeprazole/sodium bicarbonate 20mg, Omeprazole + Syrspend, , Prevacid 30mg ®, Prevacid ® solutabs, Prilosec ®, Prilosec suspension, Protonix ®, Zegerid ® 40mg, or Zegerid packets

may be covered when **ALL** of the following criteria is met:

1. There has been previous treatment failure with or contraindication to **omeprazole** AND **pantoprazole** AND **lansoprazole** AND **rabeprazole** AND **esomeprazole.**

Potassium-Competitive Acid Blocker (PCAB)

Voquezna (vonoprazan) may be covered when **ALL** of the following criteria are met:

1. Documentation that the requested medication is being used for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults; **AND**
2. There has been previous treatment failure with or contraindication to **omeprazole** AND **pantoprazole** AND **lansoprazole** AND **rabeprazole.**

Prior Use Criteria

The plan uses prescription claim records to support criteria for prior use within previous 130 days or the trial and failure of formulary alternatives when available. Additional documentation will be required from the provider when historic prescription claim data is either not available or the medication fill history fails to establish criteria for prior use or trial and failure of formulary alternatives. Documentation will also be required to support any clinical reasons preventing the trial and failure of formulary alternatives. Please see the section on documentation requirements for more information.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
1/2024	Updated to add Voquezna ® to the policy.
11/2023	Reformatted Policy.
10/2023	Reformatted Policy and updated IC section to align with 118E MGL § 51A

7/2023	Reformatted Policy.
4/2023	Updated to add Omeprazole + Syrspend ® and Konvomep™ to the Policy as non-preferred.
2/2023	Updated to add FIRST-OMEPRA SUS to policy at parity with Omeprazole.
4/2022	Updated to add Authorized Generic of Dexilant(dexlansoprazole) to the policy.
2/2020	Updated to include Aspirin/Omeprazole to the policy.
1/2019	Updated to add Exclusion note & remove Omeprazole/Syrspend Suspension.
6/2018	Updated to add Lansoprazole ODT.
9/2017	Updated to add Omeppi 40mg and to clarify criteria for Lansoprazole & Rabeprazole.
6/2017	Updated address for Pharmacy Operations.
01/2017	Updated Criteria for Branded PPIs.
10/2016	Updated to Include Yosprala criteria.
4/2016	Updated to remove First Products which were discontinued.
8/2015	Updated Request Form title.
3/2015	Updated to include two First Suspensions without PA.
10/2014	Updated to include No PA for Omeprazole and pantoprazole. Also to exclude Nexium 20mg because available OTC.
2/2014	Updated ExpressPAth language, added Esomeprazole, Omeprazole/Syrspend Suspension , Aciphex® Sprinkle™, and rabeprazole .
6/2012	Updated 6/12 to include coverage for pantoprazole as a Step 1 product.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
3/2011	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
1/2011	Updated to update pantoprazole criteria and to add coverage criteria for omperazole/sodium bicarbonate.
1/2011	Updated to reflect name change of Kapidex™ to Dexilant™ and to include coverage criteria for omeprazole/sodium bicarbonate: newly released generic of Zegerid®.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
3/2010	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
1/2010	Updated to remove step therapy language and to implement new prior authorization criteria. Lansoprazole and Prevacid® 15mg moved to benefit exclusion.
11/2009	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
3/2009	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy
8/2009	Updated to include Kapidex™ as a Step 3 medication for Standard formulary and Blue
1/2009	Updated for Medicare Advantage formulary.
9/2008	Updated to include generic pantoprazole on Step 2, movement of Prevacid® to Step 2,
1/2008	Updated approval criteria to require previous treatment or paid claim point of sale criteria
11/2007	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ
3/2007	Updated to include Step 3 criteria for Prevacid and consolidation of Omeprazole into Step
11/20/2005	New policy, effective 11/20/2005, describing covered and non-covered indications.

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. Prilosec® [package insert]. Wilmington, DE: AstraZeneca LP; July 2006.
2. Prevacid® [package insert]. Lake Forest, IL: TAP Pharmaceuticals Inc.; November 2003.
3. Protonix® [package insert]. Philadelphia, PA: Wyeth Laboratories; February 2004.
4. Aciphex® [package insert]. Teaneck, NJ: Eisai Inc., and Titusville, NJ: Janssen Pharmaceuticals Inc, August 2003.
5. Kapidex™ [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; August 2009.
6. Nexium® [package insert]. Wilmington, DE: AstraZeneca LP; March 2003.
7. Omeprazole delayed-release capsules [package insert]. Mequon, WI: Kremers Urban, Inc.; 2003.
8. Zegerid® [package insert]. San Diego, CA: Santarus.; December 2004
9. Aciphex® Srinkle™[package insert]. Wood Cliff Lake, NJ: Eisai Inc., and Titusville, NJ: Janssen Pharmaceuticals Inc, March 2013.
10. Voquezna® [package insert]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; November 2003.