



MASSACHUSETTS

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Pharmacy Medical Policy Pregabalin (Lyrica[®] and Lyrica[®] CR)

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Policy Number: 057

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	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Step Therapy <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Administrative	Reviewing Department Policy Effective Date	Pharmacy Operations: Tel: 1-800-366-7778 Fax: 1-800-583-6289 11/1/2023
Pharmacy (Rx) or Medical (MED) benefit coverage	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> MED	To request for coverage: Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.	
Policy applies to Commercial Members: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Medicare Advantage 		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	

Summary

This is a comprehensive policy covering prior authorization and quantity limit requirements for pregabalin products.

Pregabalin is the (S)-enantiomer of a racemic mixture. Lyrica (pregabalin) is indicated for:

- Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
- Postherpetic neuralgia (PHN)
- Adjunctive therapy for certain adult and pediatric patients with partial onset seizures,
- Fibromyalgia
- neuropathic pain associated with spinal cord injury

Formulary status/requirements of medications affected by this policy are as follows:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
Preferred		
pregabalin capsules/oral solution	Covered	Covered with no requirements
Formulary Non-Preferred		
pregabalin CR	Covered, PA, QCD	PA required Requires prior use of a preferred pregabalin formulation OR history of prior use within the previous 130 days.
Non-Covered, Non-Preferred		
Lyrica [®] capsules/oral solution (pregabalin)	NFNC	PA required
Lyrica [®] CR (pregabalin ER)	NFNC, QCD	Requires prior use of gabapentin and pregabalin OR history of prior use within the previous 130 days.

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

Policy

Length of Approval	12 months
Formulary Status	All requests must meet the Prior Authorizations requirement 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.

Pregabalin CR

Pregabalin CR may be covered when ONE of the following criteria is met:

1. A diagnosis of fibromyalgia; **OR**
2. A diagnosis of neuropathic pain associated with diabetic peripheral neuropathy; **OR**
3. A diagnosis of postherpetic neuralgia; **OR**
4. A diagnosis of partial onset seizures; **OR**
5. A diagnosis of neuropathic pain associated with spinal cord injury; **OR**
6. Evidence of a paid claim or previous treatment with pregabalin within the previous 130 days.

Lyrica[®]

Lyrica[®] (pregabalin) may be covered when ALL of the following criteria is met:

1. Diagnosis of neuropathic pain associated with diabetic peripheral neuropathy OR postherpetic neuralgia OR partial-onset seizures (in patients 1 month of age and older) OR fibromyalgia OR neuropathic pain associated with spinal cord injury; **AND**
2. Evidence of a paid claim or previous treatment of both gabapentin AND pregabalin/pregabalin CR.

Lyrica® CR

Lyrica® CR (pregabalin ER) may be covered when ALL of the following criteria sets is met:

1. A diagnosis of neuropathic pain associated with diabetic peripheral neuropathy OR postherpetic neuralgia; **AND**
2. Evidence of a paid claim or previous treatment of both gabapentin AND pregabalin/pregabalin CR

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
11/2023	Reformatted Policy.
10/2023	Reformatted Policy and updated IC to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
4/2022	Removed pregabalin from PA and clarified coding the nonformulary criteria for Lyrica to be in line with Lyrica CR.
7/2021	Updated to add pregabalin CR to the policy.
10/2019	Updated to include pregabalin into the policy
3/2018	Updated to add Lyrica® CR to the policy.
6/2017	Updated address for Pharmacy Operations.
5/2017	Updated to include new Lyrica® criteria.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
1/2014	Updated ExpressPath language and remove Blue Value
9/2012	Updated 9/2012 to include coverage for Lyrica® oral solution.
11/2011- 4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
9/2009	Policy updated 9/2009 to remove Medicare Part D criteria from Medical Policy.
9/1/2008	New policy describing covered and non-covered indications. Effective 9/1/2008.

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. Lyrica® [package insert]. Vega Baja, PR: Pfizer Pharmaceuticals; 2007.
2. U.S. Food and Drug Administration (June 21, 2007). "FDA Approves First Drug for Treating Fibromyalgia". Press Release. Retrieved on 2008-5-27. Available at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01656.html>
3. Lyrica® CR [package insert]. New York, NY: Parke-Davis; Oct 2017.