

ISSUE DATE January 6, 2016	EFFECTIVE DATE January 20, 2016	NUMBER *See below
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SUBJECT Prior Authorization of Duloxetine Agents - Pharmacy Service	BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs
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IMPORTANT REMINDER: All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016**. New enrollment application including all revalidation requirements may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994
Please send in your application(s) as soon as possible.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for Duloxetine Agents (formerly Cymbalta), including the type of medical information needed to evaluate requests for medical necessity.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is re-issuing the pharmacy service handbook chapter formerly titled Cymbalta with the updated title Duloxetine Agents. This change is in response to the availability of new Duloxetine Agents in the market place.

*01-16-07	09-16-07	27-16-07	
02-16-07	11-16-07	30-16-07	
03-16-07	14-16-07	31-16-07	
08-16-07	24-16-07	32-16-07	33-16-07

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

PROCEDURE:

The procedures for prescribers to request prior authorization of Duloxetine Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapters related to Duloxetine Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Duloxetine Agents

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Duloxetine Agents (Formerly Cymbalta)

a. Prescriptions That Require Prior Authorization

All prescriptions for duloxetine agents, regardless of the quantity dispensed, must be prior authorized. See Quantity Limits for the list of drugs with quantity limits at:

http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a duloxetine agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For a diagnosis of diabetic peripheral neuropathic pain, whether the recipient has a documented history of therapeutic failure of Gabapentin (at least 1800mg/day)
2. For a diagnosis of depression, whether the recipient has a documented history of:
 - a. Therapeutic failure, contraindication or intolerance to the preferred Antidepressants, Other

AND

- b. Therapeutic failure of the selective serotonin reuptake inhibitors (SSRIs)

OR

- c. A current history (within the past 90 days) of being prescribed a duloxetine agent
3. For a diagnosis of fibromyalgia, whether the recipient has:
 - a. A documented history of widespread pain as defined by the American College of Rheumatology present for at least three (3) months.

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AND

A presence of 11 out of 18 paired, bilateral tender points as delineated by the American College of Rheumatology; see <http://www.nfra.net/Diagnost.htm> for a picture and description of the locations of tenderness

NOTE: Future revisions to the American College of Rheumatology criteria for the classification of Fibromyalgia will apply when determining medical necessity. See the American College of Rheumatology website at <http://www.rheumatology.org/practice/clinical/classification/fibromyalgia/fibro.asp>

AND

- b. Been evaluated and treated for other causes of pain consistent with a differential diagnosis to include but not limited to the following:
 - i. Polymyalgia rheumatica
 - ii. Myositis
 - iii. Hypothyroidism
 - iv. Neuropathies
 - v. Hypovitaminosis D
 - vi. Liver disease

AND

- c. A history of therapeutic failure of, or a documented contraindication to, the following first line therapies:
 - i. Non-pharmacologic therapies (Examples of non-pharmacologic therapies include, but are not limited to the following: heated pool treatment [with or without exercise], physiotherapy, cognitive-behavioral therapy, aerobic exercise, strength training, or relaxation, etc.),

AND

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- ii. At least 1 pharmacological treatment from the following therapeutic classes or medications: tricyclic antidepressants (TCAs), selective serotonin reuptake inhibitors (SSRIs), or gabapentin

- 4. For a diagnosis of chronic musculoskeletal pain, whether the recipient has documented history of therapeutic failure, contraindication or intolerance to the following:
 - a. A non-pharmacologic therapy such as but not limited to physiotherapy, therapeutic exercise, strength training

 - AND**

 - b. Counseling on the need for weight loss for recipients with a Body Mass Index greater than or equal to 25 and back pain or pain involving a weight bearing joint

 - AND**

 - c. Acetaminophen

 - AND**

 - d. NSAIDs

 - AND**

 - e. For patients with radiculopathy or spinal stenosis, the recipient failed medications supported in medical literature for use in neuropathic pain such as Gabapentin, TCA's, etc.

- 5. For a non-preferred duloxetine agent, whether the recipient has a documented history of therapeutic failure, contraindication, or intolerance to the preferred agents approved for the recipient's diagnosis

- 6. Whether the recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

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7. In addition, if a prescription for a duloxetine agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines that are set forth in the Quantity Limits Chapter.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

The Department will limit approvals of requests for prior authorization of a duloxetine agent as follows:

1. For a diagnosis of depression, up to 12 months
2. For a diagnosis of diabetic peripheral neuropathy:
 - a. Initial request, up to 6 months
 - b. Request for a renewal, up to 12 months.
3. For a diagnosis of fibromyalgia
 - a. Initial request, up to 6 months
 - b. Request for a renewal, up to 12 months
4. For a diagnosis of chronic musculoskeletal pain
 - a. Initial request, up to 3 months
 - b. Request for a renewal, up to 12 months

References:

1. Cymbalta [package insert]. Indianapolis, IN: [Eli Lilly and Company](#); June, 2008.
2. Diagnosis and treatment of low back pain: A joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Annals of Internal Medicine*. 2007 Oct 2;147 (7):478-91.
3. Institute of Health Economics Guideline for the evidence-informed primary care management of low back pain. *Toward Optimized Practice*; 2009 Mar 2.

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4. American Academy of Orthopedic Surgeons treatment of osteoarthritis of the knee (non-arthroplasty). Journal of the American Academy of Orthopedic Surgeons, 17(9); September 2009: 591-600
5. Kaunuan KC. Pharmacologic therapy of osteoarthritis, UpToDate.
6. Irenka [package insert]. Baltimore, MD: Lupin Pharma; June 2015.