pennsylvania
DEPARTMENT OF HUMAN SERVICES

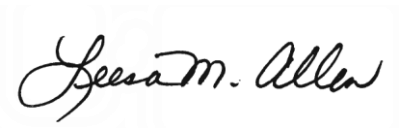
MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
March 14, 2016	March 14, 2016	*See below

SUBJECT

Prior Authorization of Anticonvulsants, Oral; Duloxetine Agents; and Neuropathic Pain Agents - Pharmacy Service

BY



Leesa M. Allen, Deputy Secretary
Office of Medical Assistance Programs

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:

1. Issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for Anticonvulsants, Oral, including the type of medical information needed to evaluate requests for medical necessity.
2. Issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for Neuropathic Pain Agents, including the type of medical information needed to evaluate requests for medical necessity.
3. Obsolete MA Bulletin 01-16-07 et al, titled Prior Authorization of Duloxetine Agents - Pharmacy Service.

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.

*01-16-09	09-16-11	27-16-09	
02-16-09	11-16-09	30-16-09	
03-16-09	14-16-09	31-16-11	
08-16-09	24-16-10	32-16-09	33-16-09

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

BACKGROUND/DISCUSSION:

Both Lyrica and duloxetine are designated as preferred on the Department's preferred drug list (PDL) and represent clinical alternative medications to opioids for the treatment of pain.

The Department of Human Services' (Department) no longer requires prior authorization of Lyrica and is removing all references to Lyrica in the handbook chapters related to Anticonvulsants, Oral and Neuropathic Pain Agents.

The Department also no longer requires prior authorization of duloxetine and is obsoleting the handbook chapter related to Duloxetine Agents. Requirements for prior authorization and medical necessity guidelines, when applicable, are addressed in the chapters related to Antidepressants, Other and Neuropathic Pain Agents. There are no other changes to the requirements for prior authorization or the guidelines to determine medical necessity of prescriptions for Duloxetine Agents.

PROCEDURE:

The procedures for prescribers to request prior authorization of Anticonvulsants, Oral; Antidepressants, Other; and Neuropathic Pain 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 Anticonvulsants, Oral; Antidepressants, Other; and Neuropathic Pain 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.

OBSOLETE BULLETIN:

This MA Bulletin obsoletes MA Bulletin 01-16-07 et al, titled Prior Authorization of Duloxetine Agents - Pharmacy Service, issued January 6, 2016, effective January 20, 2016, and the attached Prior Authorization of Pharmaceutical Services Handbook pages for Duloxetine Agents.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Anticonvulsants, Oral
Neuropathic Pain Agents

I. Requirements for Prior Authorization of Oral Anticonvulsants

A. Prescriptions That Require Prior Authorization

Prescriptions for Oral Anticonvulsants that meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Oral Anticonvulsant regardless of the quantity prescribed. See the most recent version of the PDL which includes the list of preferred Oral Anticonvulsants at: http://www.providersynergies.com/services/documents/PAM_PDL.pdf

2. A prescription for either a preferred or non-preferred Oral Anticonvulsant with a prescribed quantity that exceeds the quantity limit. See Quantity Limits/Daily Dose Limits which lists drugs with quantity limits at: http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf

GRANDFATHER PROVISION: The Department will grandfather prescriptions for non-preferred Oral Anticonvulsants for those recipients currently being prescribed the same non-preferred Oral Anticonvulsant if the PROMISe Point-Of-Sale On-Line Claims Adjudication System verifies the record of payment by the Department for a prescription for the same non-preferred Oral Anticonvulsant within 90 days from the date of service of the new claim. If the recipient has a record of a prescription for the same non-preferred Oral Anticonvulsant, a prescription or a refill for the non-preferred Oral Anticonvulsant will be automatically approved.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a preferred or non-preferred Oral Anticonvulsant, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For all non-preferred Oral Anticonvulsants, whether the recipient has a history of therapeutic failure of at least four (4) preferred Oral Anticonvulsants; therapeutic failure of at least four (4) preferred Oral Anticonvulsants must include the generic

equivalent when the generic equivalent is designated as preferred.

2. In addition, if a prescription for either a preferred or non-preferred Oral Anticonvulsant is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

3. For either a preferred or non-preferred Oral Anticonvulsant that does not meet the clinical review guidelines listed above, the request 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.

C. Automated Prior Authorization Approvals

Prior authorization of a prescription for a non-preferred Oral Anticonvulsant at or below the quantity limits will be automatically approved when the PROMISe Point-Of-Sale On-Line Claims Adjudication System verifies a record of paid claim(s) within 90 days prior to the date of service of the new request.

D . 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 for a prescription for a preferred or non-preferred Oral Anticonvulsant. 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.

References:

1. Lyrica[package insert]. New York, NY: Pfizer Inc; June 2007. http://www.pfizer.com http://www.nfra.net/Diagnost.htm
2. Kaniecki R, Lucas S. Treatment of primary headache: preventive treatment of migraine. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache foundation; 2004. p. 40-52 (Includes US Headache Consortium Guidelines for Migraine Prophylaxis)

3. American Academy of Neurology. Practice parameter: Practice parameter: Evidence-based Guidelines for Migraine Headache (An Evidence-based Review) Report of the Quality Standards Subcommittee of the American Academy of Neurology, Neurology 2000;55;754-762.

I. Requirements for Prior Authorization of Neuropathic Pain Agents (Formerly Myalgia and Neuropathy Agents)

A. Prescriptions That Require Prior Authorization

Prescriptions for Neuropathic Pain Agents that meet any of the following conditions must be prior authorized:

1. All prescriptions for non-preferred Neuropathic Pain Agents, regardless of the quantity prescribed. See the most recent Preferred Drug List (PDL) for the list of preferred and non-preferred Neuropathic Pain Agents at: http://www.providersynergies.com/services/documents/PAM_PDL.pdf

2. A prescription for a Neuropathic Pain Agent with a prescribed quantity that exceeds the quantity limit. 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 Neuropathic Pain Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For Gralise (gabapentin extended release) whether the recipient:

   a. Has a diagnosis of postherpetic neuralgia (PHN)

   AND

   b. Has a documented history of therapeutic failure, contraindication or intolerance to tricyclic antidepressants and regular release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day)

   AND

c. Does not have a creatinine clearance less than 30 mL/min

OR

2. For Lidoderm (lidocaine topical patch) whether the recipient:

a. Has a diagnosis of postherpetic neuralgia (PHN)

AND

b. Has a documented history of therapeutic failure, contraindication or intolerance to tricyclic antidepressants and gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day)

3. For Horizant (gabapentin enacarbil), whether the recipient is being prescribed a dose of the requested medication that is appropriate for his/her renal function according to package labeling **AND**:

a. Has a diagnosis of postherpetic neuralgia (PHN)

AND

b. Has a documented history of therapeutic failure, intolerance, or contraindication to tricyclic antidepressants and therapeutic failure or intolerance to regular release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day)

OR

c. Has a diagnosis of moderate-to-severe primary Restless Leg Syndrome (RLS)

AND

d. Has a documented history of therapeutic failure or intolerance to regular release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day) and therapeutic failure, contraindication or intolerance to pramipexole or ropinirole

4. For all other non-preferred Neuropathic Pain Agents, whether the recipient has a documented history of therapeutic failure,

contraindication or intolerance to the preferred Neuropathic Pain Agents with the same indication

OR

5. For requests for prior authorization of a non-preferred Neuropathic Pain Agent, 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.

6. In addition, if a prescription for either a preferred or non-preferred Neuropathic Pain 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.

7. For requests for renewals of prior authorization of a non-preferred Neuropathic Pain Agent**,** whether the MA recipient has a documented clinical response showing symptom improvement or stabilization

C. Clinical Review Process

All requests for prior authorization of a Neuropathic Pain Agent will be automatically forwarded to a physician reviewer for a medical necessity determination.

The physician reviewer will prior authorize the prescription when:

1. The guidelines in Section B. are met, **OR**
2. In the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

References:

1. Mease, P. J. "Further strategies for treating fibromyalgia: the role of serotonin and norepinephrine reuptake inhibitors." Am J Med 122.12 (2009): S44-55. PubMed.gov. U.S. National Library of Medicine.
2. Savella. [package insert]. Pierre Fabre Medicament and Cypress Bioscience, Inc. 2009.
3. Cymbalta. [package insert]. Eli Lilly and Company. Indianapolis, IN. 2010.
4. Lyrica [package insert]. Pfizer. New York, NY. 2009.
5. National Guideline Clearinghouse. Fibromyalgia Treatment Guideline. 2009.

6. Wolfe F, Smythe HA, Yunus MB, et al. "The American College Of Rheumatology 1990 Cirteria For The Classification Of Fibromyalgia." Arthritis and Rheumatism 33.2 (1990): 160-72.
7. National Guideline Clearinghouse. Guideline For The Management Of Fibromyalgia Syndrome Pain In Adults And Children. 2009.
8. Goldenberg, DL et.al. Differential Diagnosis of Fibromyalgia. UpToDate. Accessed October 28, 2011
9. Bajwa ZH et.al. Postherpetic Neuralgia, UpToDate. Accessed October 28, 2011
10. Horizant prescribing information. GlaxoSmithKline. 2012
11. R. M. Dubinsky et al. Practice Parameter: Treatment of postherpetic neuralgia : An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2004;63;959
12. UpToDate, Postherpetic neuralgia. Accessed October 18, 2012
13. UpToDate, Restless leg syndrome. Accessed October 18, 2012.