pennsylvania
DEPARTMENT OF HUMAN SERVICES

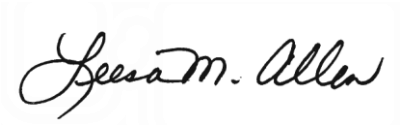
MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
January 6, 2016	January 20, 2016	*See below

SUBJECT

Prior Authorization of COPD 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. Inform providers that the Department of Human Services (Department) will require prior authorization of tiotropium when prescribed for a diagnosis of asthma.
2. Issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for COPD Agents, 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:

The Department's Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to new drugs in therapeutic classes already included in the Preferred Drug List (PDL), changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred,

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

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

new quantity limits, and classes of drugs to be added to or deleted from the PDL. The P&T Committee also recommends new guidelines or modifications to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

DISCUSSION:

During the November 3, 2015 meeting, the P&T Committee recommended that the Department require a clinical prior authorization of tiotropium when prescribed for a diagnosis of asthma. At the recommendation of the Committee, the guidelines to determine medical necessity of tiotropium when prescribed for a diagnosis of asthma were reviewed and agreed to by an independent medical specialist. The guidelines were then subject to public review and comment, and subsequently approved for implementation by the Department. The revised clinical review guidelines to determine the medical necessity of COPD Agents are included in the attached updated provider handbook pages.

PROCEDURE:

The procedures for prescribers to request prior authorization of COPD 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 COPD 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
COPD Agents

I. Requirements for Prior Authorization of Chronic Obstructive Pulmonary Disease (COPD) Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for COPD Agents that meet any of the following conditions must be prior authorized.

1. A prescription for a non-preferred COPD Agent. See the most recent version of the PDL which includes the list of preferred COPD Agents at: www.providersynergies.com/services/documents/PAM_PDL.pdf

2. A prescription for either a preferred or non-preferred COPD Agent when there is a record of a recent paid claim for another drug in the same therapeutic class of drugs in PROMISe, the Department's Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

3. A prescription for tiotropium for a diagnosis of asthma

4. A prescription for a preferred or non-preferred COPD 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 non-preferred COPD Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For Daliresp (roflumilast), whether the recipient:

   a. Has a diagnosis of severe COPD as documented by medical history, physical exam findings, and lung function testing (Forced Expiratory Volume (FEV1) < 50% of predicted) that are consistent with severe COPD according to the most current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines on the diagnosis and management of COPD

AND

b. Has a diagnosis of chronic bronchitis as documented by cough and sputum production for at least 3 months in each of 2 consecutive years

AND

c. Had other causes of their chronic airflow limitations excluded

AND

d. Continues to experience more than 2 exacerbations of COPD per year requiring Emergency Department visits, hospitalization, or oral steroid use despite maximum therapeutic doses of, intolerance, or contraindication to regular scheduled use of a:

    i. Long-acting inhaled beta 2 agonist

    AND

    ii. Preferred long-acting inhaled anticholinergic

    AND

    iii. Inhaled corticosteroid

AND

e. Does not have moderate to severe liver impairment (Child-Pugh B or more severe)

AND

f. Will not be taking strong cytochrome P450 enzyme inducers such as but not limited to rifampin, phenobarbital, carbamazepine, and phenytoin

AND

g. Does not have suicidal ideations

AND

h. Was evaluated, treated, and determined to be a candidate for treatment with Daliresp by a psychiatrist if the recipient has a history of prior suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance use disorders, anxiety disorders, borderline personality disorder and antisocial personality disorder

OR

i. For all others, had a mental health evaluation performed by the prescriber and determined to be a candidate for treatment with Daliresp

In evaluating a request for a renewal of prior authorization of a prescription for Daliresp, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

a. Has documented improvement in the forced expiratory volume (FEV_1) and FEV_1/forced vital capacity (FVC) ratio, and a decrease in the frequency of COPD exacerbations

AND

b. Will not be taking strong cytochrome P450 enzyme inducers such as but not limited to rifampin, phenobarbital, carbamazepine, and phenytoin

AND

c. Does not have suicidal ideations

AND

d. Was reevaluated and treated for new onset or worsening symptoms of anxiety and depression and determined to continue to be a candidate for treatment with Daliresp

2. For all other non-preferred COPD Agents , whether the recipient has a documented history of therapeutic failure, intolerance or contraindication of the preferred COPD Agents

3. For therapeutic duplication, whether:

a. The recipient is being titrated to, or tapered from, a drug in the same class

OR

b. Supporting peer-reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested

4. For tiotropium when prescribed for a diagnosis of asthma, whether the recipient:

a. Is 12 years of age or older

AND

b. Is currently receiving optimally tolerated doses of all of the following:

i. Inhaled glucocorticoids
ii. Long acting beta agonists

OR

c. Has a contraindication or intolerance to optimally titrated doses of all of the following:

i. Inhaled glucocorticoids
ii. Long acting beta agonists

5. 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.

In addition, if a prescription for either a preferred or non-preferred COPD Agent 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.

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 for a prescription for a COPD Agent. 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

Requests for prior authorization of Daliresp will be approved for up to 12 months.

E. References:

1. Daliresp package insert. Forest Pharmaceuticals, Inc. St. Louis, MO, 2010.
2. 2010 Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the diagnosis, management and prevention of Chronic Obstructive Pulmonary Disease.
3. American Psychiatric Association Practice Guideline for the Assessment and Treatment of Patients with Suicidal Behaviors, November 2003
4. Busse WW et.al. National Heart Lung and Blood Institute Guidelines for the Diagnosis and Management of Asthma (EPR-3).
5. Peters, S. et.al. Treatment of moderate persistent asthma in adolescents and adults. Up To Date. Accessed October 9, 2015.
6. Wenzel, S. Treatment of severe asthma in adolescents and adults. Accessed October 9, 2015.

7. Martin, R.J. Alternative and experimental agents for the treatment of asthma. Up To Date. Accessed October 9, 2015.