

ISSUE DATE June 13, 2016	EFFECTIVE DATE June 13, 2016	NUMBER *See below
SUBJECT Prior Authorization of Nucala (mepolizumab) - Pharmacy Service		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISe to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Providers who enrolled on or before SEPTEMBER 25, 2011 must complete the revalidation process as soon as possible. DHS must complete the revalidation for all providers enrolled on or before September 25, 2011 by September 25, 2016.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers that the Department will require prior authorization of prescriptions for Nucala (mepolizumab)
2. Issue handbook pages that include the type of information needed to evaluate requests for prior authorization of prescriptions for Nucala (mepolizumab) 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.

*01-16-16	09-16-15	27-16-14	
02-16-14	11-16-14	30-16-14	
03-16-14	14-16-14	31-16-17	
08-16-15	24-16-15	32-16-13	33-16-14

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</p>

BACKGROUND:

The Department of Human Services (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

DISCUSSION:

During the March 23, 2016 meeting, the DUR Board recommended that the Department require a clinical prior authorization of Nucala (mepolizumab), and proposed guidelines to determine medical necessity and limits on dose and duration of therapy to ensure appropriate patient selection and drug utilization. The requirement for prior authorization, guidelines to determine medical necessity, and limits on dose and duration of therapy, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization, clinical review guidelines to determine the medical necessity of Nucala (mepolizumab), and limits on dose and duration of therapy are included in the attached updated provider handbook pages.

PROCEDURE:

The procedures for prescribers to request prior authorization of Nucala (mepolizumab) 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 chapter related to Nucala (mepolizumab)) 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
Nucala (mepolizumab)

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Nucala (mepolizumab)

A. Prescriptions That Require Prior Authorization

All prescriptions for Nucala (mepolizumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Nucala (mepolizumab), the determination of whether the requested prescription is medically necessary will take into account whether:

1. The recipient is 12 years of age or older

AND

2. Nucala (mepolizumab) is being prescribed by, or in consultation with, a pulmonologist, allergist or immunologist

AND

3. The dose of Nucala (mepolizumab) is consistent with Food and Drug Administration (FDA) approved package labeling for the diagnosis

AND

4. The recipient has a diagnosis of asthma confirmed by all of the following:

- a. Medical history and physical exam findings that are consistent with asthma according to the most current National Heart, Lung, and Blood Institute (NHLBI) or Global Initiative for Asthma (GINA) guidelines on the diagnosis and management of asthma

AND

- b. Spirometry that demonstrates obstruction

AND

- c. Reversibility demonstrated either by an increase in FEV1 of ≥ 12 percent from baseline or by an increase ≥ 10 percent of predicted FEV1

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AND

5. The recipient has asthma with an eosinophilic phenotype with absolute blood eosinophil count $\geq 150/\mu\text{L}$

AND

6. The recipient's asthma is graded as severe, despite maximal therapeutic doses of, intolerance, or contraindication to asthma controller medications, confirmed by one or more of the following:
 - a. Asthma symptoms such as coughing, wheezing, and dyspnea that occur throughout the day
 - b. Use of a rescue inhaler such as a short acting beta2-agonist several times per day
 - c. Two or more exacerbations per year requiring oral systemic corticosteroids
 - d. Nighttime awakenings often occurring seven times a week
 - e. $\text{FEV}_1 < 60\%$
 - f. FEV_1/FVC reduced $> 5\%$

AND

7. The recipient does not have current parasitic (helminth) infection

AND

8. If 50 years or older, the recipient:
 - a. Received the varicella-zoster vaccine at least 4 weeks prior to initiation of therapy

OR

- b. Has a contraindication to the varicella-zoster vaccine

OR

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9. 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.

FOR RENEWALS OF PRESCRIPTIONS FOR NUCALA (mepolizumab):
Requests for prior authorization of renewals of prescriptions for Nucala (mepolizumab) that were previously approved will take into account whether the recipient:

1. Has shown measurable evidence of improvement in the severity of the asthma condition

AND

2. Does not have current parasitic (helminth) infection

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 Nucala (mepolizumab). 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.

E. Dose and Duration of Therapy

Requests for prior authorization of Nucala (mepolizumab) will be approved as follows:

1. The initial prescription will be approved for a period of up to 6 months.
2. Renewals of prescriptions that were previously approved will be approved for a period of up to 12 months.

F. References

1. National Heart, Lung, and Blood Institute National Asthma Education and Prevention Program Expert Panel Report 3:

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Guidelines for the Diagnosis and Management of Asthma, Full Report 2007

2. Nucala prescribing information. April 2015
3. Treatment of severe asthma in adolescents and adults. Up To Date. Accessed January 14, 2016