**New IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

**PURPOSE:**

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (department) will require prior authorization of prescriptions for Cinqair (reslizumab).
2. Issue handbook pages that include the requirements for prior authorization and the type of information needed to evaluate requests for prior authorization of prescriptions for Cinqair (reslizumab) for medical necessity.

**SCOPE:**

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

**BACKGROUND:**

The department’s Drug Utilization Review (DUR) Board meets semi-annually to review:

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**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
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 and Retrospective Drug Use Review programs.

DISCUSSION:

During the March 22, 2017 DUR Board meeting, the DUR Board recommended that the department require prior authorization of Cinqair (reslizumab) to ensure appropriate drug utilization. The DUR Board recommended guidelines to determine medical necessity of Cinqair (reslizumab) which were subject to public review and comment, and subsequently approved for implementation by the department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Cinqair (reslizumab) 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 Cinqair (reslizumab)) 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
Cinqair (reslizumab)
I. Requirements for Prior Authorization of Cinqair (reslizumab)

A. Prescriptions That Require Prior Authorization

All prescriptions for Cinqair (reslizumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

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

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package insert OR a medically-accepted indication

   AND

2. Is age-appropriate according to FDA-approved package labeling

   AND

3. Is prescribed a dose consistent with FDA-approved package labeling for the diagnosis

   AND

4. Is prescribed Cinqair by or in consultation with an allergist, pulmonologist, or immunologist

   AND

5. Will be administered Cinqair in accordance with FDA-approved package labeling

   AND

6. For the treatment of asthma:

   a. Has a diagnosis that is confirmed by:

      i. Medical history and physical exam findings that are consistent with asthma according to the most current National Heart, Lung, and Blood Institute (NHLBI) guidelines for the diagnosis and management of asthma
ii. Spirometry that demonstrates obstruction

AND

iii. Reversibility demonstrated by either an increase in FEV\textsubscript{1} of ≥ 12 percent from baseline or an increase of ≥ 10 percent of predicted FEV\textsubscript{1}
7. Will be evaluated, treated, and/or monitored for parasitic (helminth) infection before and/or during treatment with Cinqair as recommended in FDA-approved package labeling

OR

8. Does not meet the clinical review guidelines above, but in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

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

1. Is prescribed a dose consistent with FDA-approved package labeling for the diagnosis

AND

2. Is prescribed Cinqair by or in consultation with an allergist, pulmonologist, or immunologist

AND

3. Is being monitored and treated, if applicable, for parasitic (helminth) infection as recommended in the FDA-approved package labeling

AND

4. For the treatment of asthma, will continue to use Cinqair in addition to standard asthma controller medications as recommended by current national treatment guidelines

AND

5. Has shown measurable evidence of improvement in the severity of the condition being treated

OR

6. Does not meet the clinical review guidelines above, but in the professional judgement of the physician reviewer, the services
MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

are medically necessary to meet the medical needs of the recipient

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 Cinqair (reslizumab). 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 Cinqair (reslizumab) 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

References
