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: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Leukotriene Modifiers submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Leukotriene Modifiers will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Leukotriene Modifiers to the appropriate MCO.

BACKGROUND/DISCUSSION:

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*01-22-32  09-22-31  27-22-21  33-22-30
02-22-20  11-22-21  30-22-25
03-22-20  14-22-20  31-22-32
08-22-38  24-22-26  32-22-20
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The Department of Human Services (Department) is updating the medical necessity guidelines for Leukotriene Modifiers by revising the language in the guidelines for clarity and consistency. There are no other changes to the medical necessity guidelines.

The revisions to the guidelines to determine medical necessity of prescriptions for Leukotriene Modifiers 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 Leukotriene Modifiers 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 Leukotriene Modifiers) 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 and products that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

**RESOURCES:**

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
[https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx)

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
[https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx)
I. Requirements for Prior Authorization of Leukotriene Modifiers

A. Prescriptions That Require Prior Authorization

Prescriptions for Leukotriene Modifiers that meet any of the following conditions must be prior authorized:

1. A non-preferred Leukotriene Modifier. See the Preferred Drug List (PDL) for the list of preferred Leukotriene Modifiers at: https://papdl.com/preferred-drug-list.

2. A Leukotriene Modifier with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A Leukotriene Modifier when there is a record of a recent paid claim for another Leukotriene Modifier in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

EXEMPTION FROM PRIOR AUTHORIZATION: Montelukast pediatric granules are exempt from prior authorization when prescribed for a child under 2 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Leukotriene Modifier, the determination of whether the prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Leukotriene Modifier, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Leukotriene Modifiers; AND

2. For therapeutic duplication, one of the following:
   a. Is being transitioned to or from another Leukotriene Modifier with the intent of discontinuing one of the medications
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

   AND

3. If a prescription for a Leukotriene Modifier 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 set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

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 a prescription for a Leukotriene Modifier. 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 beneficiary.