


<b>ISSUE DATE</b>  November 9, 2022	<b>EFFECTIVE DATE</b>  January 9, 2023	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Glucocorticoids, Inhaled – Pharmacy Services		<b>BY</b>   Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

**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 Glucocorticoids, Inhaled 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 Glucocorticoids, Inhaled will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Glucocorticoids, Inhaled to the appropriate managed care organization.

**BACKGROUND:**

The Department of Human Services’ (Department) Pharmacy and Therapeutics (P&T)

*01-22-60	09-22-59	27-22-47	33-22-57
02-22-44	11-22-44	30-22-50	
03-22-43	14-22-44	31-22-63	
08-22-68	24-22-52	32-22-44	

<p><b>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</b></p> <p>The appropriate toll-free number for your provider type.</p> <p>Visit the Office of Medical Assistance Programs website at <a href="https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx">https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx</a>.</p>
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Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included in the Preferred Drug List (PDL).
- Changes in the status of drugs and products on the PDL from preferred to non-preferred and non-preferred to preferred.
- New quantity limits.
- Therapeutic classes of drugs and products to be added to or deleted from the PDL.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

**DISCUSSION:**

During the September 13, 2022, meeting, the P&T Committee recommended a revision to the medical necessity guidelines for Glucocorticoids, Inhaled related to the quantity limits for a formoterol-containing Glucocorticoid, Inhaled to address consensus treatment guideline-supported uses such as Single Maintenance and Reliever Therapy (SMART).

The revisions to the guidelines to determine medical necessity of prescriptions for Glucocorticoids, Inhaled submitted for prior authorization, as recommended by the P&T Committee, 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 Glucocorticoids, Inhaled 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 Glucocorticoids, Inhaled) 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>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II  
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Glucocorticoids, Inhaled**

**A. Prescriptions That Require Prior Authorization**

Prescriptions for Glucocorticoids, Inhaled that meet any of the following conditions must be prior authorized:

1. A non-preferred Glucocorticoid, Inhaled. See the Preferred Drug List (PDL) for the list of preferred Glucocorticoids, Inhaled at: <https://papdl.com/preferred-drug-list>.
2. A Glucocorticoid, Inhaled 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 Glucocorticoid, Inhaled when there is a record of a recent paid claim for another agent that contains an inhaled glucocorticoid in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
4. An inhaled long-acting anticholinergic when there is a record of a recent paid claim for another inhaled long-acting anticholinergic in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).
5. An inhaled long-acting beta agonist when there is a record of a recent paid claim for another agent that contains an inhaled long-acting beta agonist in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

**B. Review of Documentation for Medical Necessity**

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

1. For a non-preferred single-ingredient Glucocorticoid, Inhaled (i.e., a product that contains only one active ingredient), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred single-ingredient Glucocorticoids, Inhaled; **AND**
2. For a non-preferred Glucocorticoid, Inhaled combination agent (i.e., a product that contains more than one active ingredient), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Glucocorticoid, Inhaled combination agents; **AND**
3. For therapeutic duplication, **one** of the following:
  - a. For an inhaled glucocorticoid, is being titrated to or tapered from another inhaled glucocorticoid,

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- b. For an inhaled long-acting anticholinergic, is being titrated to or tapered from another inhaled long-acting anticholinergic,
- c. For an inhaled long-acting beta agonist, is being titrated to or tapered from another inhaled long-acting beta agonist,
- d. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

**AND**

- 4. If a prescription for a Glucocorticoid, Inhaled is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account **one** of the following:
  - a. The guidelines set forth in the Quantity Limits Chapter
  - b. For a formoterol-containing Glucocorticoid, Inhaled for the treatment of asthma, **both** of the following:
    - i. The beneficiary is using the requested medication as part of a therapy that is supported by consensus treatment guidelines [e.g., Single Maintenance and Reliever Therapy (SMART)]
    - ii. The prescribed dose is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

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 Glucocorticoid, Inhaled. 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.

**D. References**

- 1. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, Blake KV, Brooks EG, Bryant-Stephens T, DiMango E, Dixon AE, Elward KS, Hartert T, Krishnan JA, Lemanske

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- RF Jr, Ouellette DR, Pace WD, Schatz M, Skolnik NS, Stout JW, Teach SJ, Umscheid CA, Walsh CG. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. *J Allergy Clin Immunol.* 2020 Dec;146(6):1217-1270. doi: 10.1016/j.jaci.2020.10.003. Erratum in: *J Allergy Clin Immunol.* 2021 Apr;147(4):1528-1530. PMID: 33280709; PMCID: PMC7924476.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention: 2022 update. <https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf>. (Accessed July 25, 2022).