

ISSUE DATE January 18, 2019	EFFECTIVE DATE January 28, 2019	NUMBER *See below
SUBJECT Prior Authorization of Pulmonary Arterial Hypertension (PAH) Agents, Oral and Inhaled – Pharmacy Services	BY  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:
http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

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 Pulmonary Arterial Hypertension (PAH) Agents, Oral and Inhaled submitted for prior authorization.

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 delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to PAH Agents, Oral and Inhaled to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and

*01-19-07	09-19-07	27-19-07	33-19-07
02-19-06	11-19-06	30-19-06	
03-19-06	14-19-06	31-19-07	
08-19-09	24-19-06	32-19-06	

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>

recommends preferred or non-preferred status for new drugs in therapeutic classes already included on the Preferred Drug List (PDL), changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred, 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 27, 2018, meeting, the P&T Committee recommended revising the guidelines to determine medical necessity for the PAH Agents, Oral and Inhaled class of drugs that will avoid an interruption in therapy and ensure continuity of treatment with a non-preferred drug that a beneficiary was prescribed within the past 90 days. The proposed change to the medical necessity guidelines was subject to public review and comment and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of PAH Agents, Oral and Inhaled are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS 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 Pulmonary Arterial Hypertension (PAH) Agents, Oral and 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 that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

MEDICAL ASSISTANCE HANDBOOK
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I. Requirements for Prior Authorization of Pulmonary Arterial Hypertension (PAH) Agents, Oral and Inhaled

A. Prescriptions That Require Prior Authorization

Prescriptions for Pulmonary Arterial Hypertension (PAH) Agents, Oral and Inhaled that meet any of the following conditions must be prior authorized:

1. A non-preferred Pulmonary Arterial Hypertension (PAH) Agent, Oral and Inhaled. See the Preferred Drug List (PDL) for the list of preferred Pulmonary Arterial Hypertension (PAH) Agents, Oral and Inhaled at: <https://papdl.com/preferred-drug-list>.
2. A phosphodiesterase type 5 inhibitor (PDE5 inhibitor).
3. A Pulmonary Arterial Hypertension (PAH) Agent, Oral and Inhaled with a prescribed quantity that exceeds the quantity limit. The list of drugs subject to quantity limits, with accompanying quantity limits, is available at:
<http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

GRANDFATHER PROVISION – The Department of Human Services (DHS) will grandfather prescriptions for a non-preferred PAH Agent, Oral and Inhaled when the Point-Of-Sale On-Line Claims Adjudication System verifies that the beneficiary has a record of a paid claim for the same non-preferred PAH Agent, Oral and Inhaled within the past 90 days from the date of service of the new claim. If the beneficiary has a record of a paid claim for the same non-preferred PAH Agent, Oral and Inhaled, a prescription or a refill for the same non-preferred PAH Agent, Oral and Inhaled will be automatically approved.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a PAH Agent, Oral and Inhaled, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For a PDE5 inhibitor, whether the beneficiary has a diagnosis of PAH,

AND

2. If the beneficiary is less than 18 years of age:

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- a. The prescription is written by or in consultation with a pediatric pulmonologist, pediatric cardiologist, or heart and lung transplant surgeon.

AND

- b. If the request is for Revatio (sildenafil), the prescribed dose does not exceed the following:
 - i. 1 mg/kg/dose three (3) times daily (TID) (maximum 10 mg TID) for children ≤ 20 kg, **OR**
 - ii. 20 mg TID for all children above 20 kg.

AND

3. For a non-preferred PAH Agent, Oral and Inhaled, whether the beneficiary has a documented history of therapeutic failure, contraindication, or intolerance of the preferred PAH Agents, Oral and Inhaled and a diagnosis of PAH,

OR

4. Whether the beneficiary has a current history (within the past 90 days) of being prescribed the same non-preferred PAH Agent, Oral and Inhaled.

AND

5. If the prescription for a PAH Agent, Oral and Inhaled 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 above but, in the professional judgement 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. Automated Prior Authorization

Prior authorization of a prescription for Adcirca (tadalafil) or Revatio (sildenafil) at or below the quantity limits will be automatically approved when the Point-Of-Sale On-Line Claims Adjudication System verifies a record of paid claim(s) within 90 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met. NOTE: Automated Prior Authorization of

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Revatio (sildenafil) does not apply to prescriptions for children under 18 years of age.

D. 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 PAH Agent, Oral and 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.

E. References

1. Pulmonary Hypertension Association Consensus Statement; Revatio (sildenafil) for Pediatric Use: September 2012.
2. FDA Drug Safety Communication: FDA recommends against use of Revatio in children with pulmonary hypertension; September 21, 2012.
3. The European Medicines Agency Assessment report.
4. FDA Drug Safety Communication: FDA recommends against use of Revatio in children with pulmonary hypertension; August 30, 2012.
5. Abman SH. Pediatric Pulmonary Hypertension Network: Implications of the FDA warning against the use of sildenafil for the treatment of pediatric pulmonary hypertension: November 19, 2012.