I. Requirements for Prior Authorization of Pulmonary Arterial Hypertension 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 prescription for a non-preferred PAH Agent, Oral and Inhaled regardless of the quantity prescribed. See the Preferred Drug List (PDL) for the list of preferred PAH Agents, Oral and Inhaled at: www.providersynergies.com/services/documents/PAM_PDL.pdf

2. A prescription for all phosphodiesterase type 5 inhibitors (PDE5 inhibitor)

3. A prescription for a preferred PAH Agent, Oral and Inhaled with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm

GRANDFATHER PROVISION – The Department will grandfather prescriptions for Tyvaso (treprostinil) when the PROMISe Point-Of-Sale On-Line Claims Adjudication System verifies that the recipient has a record of a paid claim for Tyvaso (treprostinil) within the past 90 days from the date of service of the new claim. If the recipient has a record of a paid claim for Tyvaso (treprostinil), a prescription or a refill for Tyvaso (treprostinil) 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 all of the following:

1. For a PDE5 inhibitor, whether the recipient has a diagnosis of Pulmonary Arterial Hypertension (PAH)

AND

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

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 TID (max 10 mg TID) for children ≤ 20 kg
ii. 20 mg TID for all children above 20 kg

OR

3. For a non-preferred PAH Agent, Oral and Inhaled whether the recipient 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. The recipient 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.

In addition, if a prescription for a PAH Agent, Oral and Inhaled is in 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.

C. Automated Prior Authorization Approvals

Prior authorization of a prescription for Adcirca (tadalafil) or Revatio (sildenafil) at or below the quantity limits will be automatically approved when the PROMISe 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 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. 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

The Department will limit initial authorization of PAH Agents, Oral and Inhaled to a six (6) month period. The Department will consider subsequent requests for prior authorization of up to 12 months. Prescriptions may be refilled as long as the refills do not exceed a six (6) month or five (5) refill supply, whichever comes first, from the time of the original filling of the prescription. See 55 Pa Code § 1121.53(c). Thus, if a recipient receives either a six (6) month or five (5) refill supply, whichever comes first, a new prescription, using the same prior authorization number will be required.

F. 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. Pulmonary Hypertension Association Consensus Statement; Revatio (sildenafil) for Pediatric Use: September 2012
5. FDA Drug Safety Communication: FDA recommends against use of Revatio in children with pulmonary hypertension; August 30, 2012
6. 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