MEDICATION POLICY

Generic Name: PDE-5 Inhibitors

Therapeutic Class or Brand Name: PDE-5 Inhibitors

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Sildenafil (generic).

Non-Preferred: Adcirca® (tadalafil), Revatio® (sildenafil).

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 12/13/17

GPI Code: 4014306010, 4014308000

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

I. Documented diagnosis of Pulmonary Arterial Hypertension (PAH), WHO Group I (see Appendix).
II. Patient is under the care or referral of a cardiologist or pulmonologist.
III. Minimum age requirement: 18 years old.
IV. Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to the preferred product.

Exclusion Criteria:

- Concomitant use of organic nitrates in any form, either regularly or intermittently.
- Concomitant use of a guanylate cyclase (GC) stimulator [i.e. Adempas® (riociguat)].

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Adcirca®: 60 tablets per 30 days.
- Sildenafil (generic), Revatio®: 90 tablets per 30 days OR up to two 112mL bottles of suspension (10mg/mL) per 30 days.

Approval Length:

- **Authorization:** 1 year.

- **Re-Authorization:** An updated letter of medical necessity or progress notes confirming the current medical necessity criteria are met and showing the medication is effective.

Appendix:

Revised WHO Classification of Pulmonary Hypertension – Group 1:

- Idiopathic (IPAH).
- Familial (FPAH).
- Associated with (APAH):*
  - Connective tissue disorder (e.g. rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), scleroderma, systemic sclerosis (formerly known as CREST syndrome)).
  - Congenital systemic-to-pulmonary shunts (e.g. congenital heart disease (CHD), including atrial or ventricular septal defect, patent ductus arteriosus (PDA), patent foramen ovale (PFO), truncus arteriosus, Eisenmenger syndrome, tetralogy of Fallot, transposition of the great vessels).
  - Portal hypertension.
  - HIV infection.
  - Drugs and toxins (e.g. anorexic agents, cocaine, methamphetamine, L-tryptophan).
  - Other (thyroid disorders, glycogen storage disease, Gaucher's disease, hereditary hemorrhagic telangiectasia, hemoglobinopathies (e.g. sickle cell anemia, thalassemia), chronic myeloproliferative disorders, splenectomy).
- Associated with significant venous or capillary involvement:
  - Pulmonary veno-occlusive disease (PVOD).
  - Pulmonary capillary hemangiomatosis (PCH).
- Persistent pulmonary hypertension of the newborn.

* Diagnoses, include, but are not limited to these common diagnoses.

References:

1. http://journal.publications.chestnet.org/article.aspx?articleid=1881654.
2. http://www.bcbsnc.com/assets/services/public/pdfs/formulary/pah_pde_5_inhibitors_um_criteria.pdf.
3. http://blue.regence.com/trgmedpol/drugs/dru117.pdf.
4. http://blue.regence.com/trgmedpol/drugs/dru184.pdf.
5. Medi-Span.
6. http://pi.lilly.com/us/adcirca-pi.pdf.
7. http://labeling.pfizer.com/ShowLabeling.aspx?id=645.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
12/13/2017	1. Policy reviewed: no changes made.
10/6/2016	1. Policy reviewed: no changes made.
4/23/2015	1. **Changed** "Adcirca® (tadalafil) and Revatio® (sildenafil)" **to** "Preferred: Sildenafil (generic); Non-Preferred: Adcirca® (tadalafil), Revatio® (sildenafil)" **under Applicable Drugs**. 2. **Removed** "Patient is not on any concurrent nitrate therapy in any form" **under Prior Authorization Criteria** (in order to decrease duplication – this is already listed under Exclusion Criteria). 3. **Added** "Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to the preferred product" **under Prior Authorization Criteria**. 4. **Changed** "Do not use Adcirca® or Revatio® in patients taking organic nitrates in any form, either regularly or intermittently. Consistent with their known effects on the nitric oxide/cGMP pathway, these drugs have been shown to potentiate the hypotensive effects of nitrates" **to** "Concomitant use of organic nitrates in any form, either regularly or intermittently, because of the greater risk of hypotension; Concomitant use of a guanylate cyclase (GC) stimulator [i.e. Adempas® (riociguat)]" **under Exclusion Criteria**. 5. **Changed** "Adcirca® and Revatio® are only to be used in combination with other PAH therapies when treatment with one PAH agent failed to adequately control the patient's symptoms" **to** "N/A" **under Other Criteria**. 6. **Changed** "Revatio®: 90 tablets per 30 days OR up to two 112mL bottles of suspension (10mg/mL) per 30 days" **to** "Sildenafil (generic), Revatio®: 90 tablets per 30 days OR up to two 112mL bottles of suspension (10mg/mL) per 30 days" **under Quantity/Days Supply Restrictions**. 7. **Added** "http://journal.publications.chestnet.org/article.aspx?articleid=1881654" **and** "http://blue.regence.com/trgmedpol/drugs/dru184.pdf" **under References**.
1/28/2014	1. **Adapted policy to new format.** 2. **Added GPI Codes**. 3. **Added** "Minimum age requirement: 18 years old" **to Prior Authorization Criteria**. 4. **Changed Quantity/Days Supply Restriction for Revatio® from** "OR up to two - 125mL bottles of suspension (10mg/mL) per 30 days" **to** "OR up to two 112mL bottles of suspension (10mg/mL) per 30 days". 5. **Updated references** to include Medi-Span and package inserts.