PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

Generic	Brand	HICL	GCN	Exception/Other
SILDENAFIL	REVATIO		24758 28273 33186	
TADALAFIL	ADCIRCA, ALYQ		26587	

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ADCIRCA/ALYQ (TADALAFIL)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I) and meet **ALL** of the following criteria?
   - The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) > 3 Wood units
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - The patient is **NOT** concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
   - The patient is **NOT** concurrently taking guanylate cyclase stimulators (e.g. Adempas)

   If yes, **approve Adcirca/Alyq (Tadalafil) 20mg tablet for 12 months by GPID (26587) with a quantity limit of #2 tablets per day.**
   APPROVAL TEXT: Renewal requires that the patient has shown improvement from baseline in the 6-minute walk distance test **OR** that the patient has a stable 6-minute walk distance test with a stable or improved WHO functional class.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

INITIAL CRITERIA (CONTINUED)

REVATIO (SILDENAFIL) TABLETS OR INJECTION

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I) and meet **ALL** of the following criteria?
   - The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) > 3 Wood units
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - The patient is **NOT** concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
   - The patient is **NOT** concurrently taking guanylate cyclase stimulators (e.g. Adempas)

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**
   - **Sildenafil (Revatio, GPID 24758) 20mg tablets: #3 tablets per day.**
   - **Sildenafil (Revatio, GPID 28273) 10mg/12.5mL vial: 37.5mL (#3 vials) per day.**

   APPROVAL TEXT: Renewal requires that the patient has shown improvement from baseline in the 6-minute walk distance test **OR** that the patient has a stable 6-minute walk distance test with a stable or improved WHO functional class.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

INITIAL CRITERIA (CONTINUED)

REVATIO (SILDENAFIL) ORAL SUSPENSION

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I) and meet **ALL** of the following criteria?
   - The patient is unable to swallow pills and has tried crushed sildenafil tablets
   - The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) > 3 Wood units
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - The patient is **NOT** concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
   - The patient is **NOT** concurrently taking guanylate cyclase stimulators (e.g. Adempas)

   If yes, **approve Revatio (Sildenafil) oral suspension for 12 months by GPID (33186) with a quantity limit of #224mL (2 bottles) per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has shown improvement from baseline in the 6-minute walk distance test **OR** that the patient has a stable 6-minute walk distance test with a stable or improved WHO functional class.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline for **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio, Adcirca/Alyq)** requires a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO Group I). The following criteria must also be met:

- The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
- Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
  - Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
  - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
  - Pulmonary vascular resistance (PVR) greater than 3 Wood units
- The patient has NYHA-WHO Functional Class II to IV symptoms
- The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
- The patient is NOT concurrently taking guanylate cyclase stimulators (e.g. Adempas)
- In addition to the above requirements, the following criteria apply to the specific agents listed.
  - **Request for REVATIO (Sildenafil) ORAL SUSPENSION** requires that the patient is unable to swallow pills and has tried crushed sildenafil tablets

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I)?

   If yes, continue to #2
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown improvement from baseline in the 6-minute walk distance test?

   If yes**, approve for 12 months by GPID for the requested drug with the following quantity limits:**
   - **Tadalafil (Adcirca/Alyq GPID 26587): #2 tablets per day.**
   - **Sildenafil (Revatio GPID 24758) 20mg tablets: #3 tablets per day.**
   - **Sildenafil (Revatio GPID 28273) 10mg/12.5mL vial: #37.5mL (#3 vials) per day.**
   - **Sildenafil (Revatio GPID 33186) 10mg/mL suspension: #224mL (2 bottles) per 30 days.**

   If no, continue to #3.

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

RENEWAL CRITERIA (CONTINUED)

3. Has the patient remained stable from baseline in the 6-minute walk distance test with a stable or improved WHO functional class?

   If yes**, approve for 12 months by GPID for the requested drug with the following quantity limits:**
   - **Tadalafil (Adcirca/Alyq GPID 26587): #2 tablets per day**
   - **Sildenafil (Revatio GPID 24758) 20mg tablets: #3 tablets per day.**
   - **Sildenafil (Revatio GPID 28273) 10mg/12.5mL vial: #37.5mL (#3 vials) per day.**
   - **Sildenafil (Revatio GPID 33186) 10mg/mL suspension: #224mL (2 bottles) per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio, Adcirca/Alyq)** requires a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1. In addition, **ONE** of the following criteria must be met for renewal:
   - The patient has shown improvement from baseline in the 6-minute walk distance test
   - The patient has a stable 6-minute walk distance test with a stable or improved WHO functional class

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcirca/Alyq and Revatio.

REFERENCES

- Revatio [Prescribing Information] New York, NY: Pfizer Inc.; February 2018.
- Adcirca [Prescribing Information] Indianapolis, IN: Eli Lilly and Company; August 2017.
- Alyq [Prescribing Information] North Wales, PA: Teva Pharmaceuticals USA, Inc., January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 01/08
Client Approval: 11/19
P&T Approval: 10/19