sildenafil (Revatio®); tadalafil (Adcirca®, Alyq®, Cialis®) EOCCO POLICY

Policy Type: NF Policy Pharmacy Coverage Policy: EOCCO020

Description
Sildenafil (Revatio), and tadalafil (Adcirca) are phosphodiesterase type 5 (PDE5) inhibitors.

Length of Authorization
- Initial: Length of benefit
- Renewal: Not applicable

Quantity limits

Product Name	Indication	Dosage Form	Quantity Limit
sildenafil (Revatio)	Raynaud's phenomena Pulmonary arterial hypertension	20 mg tablets	90 tablets/30 days
		10 mg/mL suspension	224 mL/30 days (2 bottles)
tadalafil (Cialis)	Benign prostatic hyperplasia	2.5 mg tablets	30 tablets/30 days
		5 mg tablets	
	Pulmonary arterial hypertension	20 mg tablets	60 tablets/30 days
tadalafil (Adcirca)	Pulmonary arterial hypertension	20 mg tablets	60 tablets/30 days
tadalafil (Alyq)	Pulmonary arterial hypertension	20 mg tablets	60 tablets/30 days
tadalafil (Tadliq)	Pulmonary arterial hypertension	20 mg/5 mL suspension	300 mL/30 days (2 bottles)

Initial Evaluation

I. Medication contained in this policy may be considered medically necessary when the following criteria below are met:
   A. A diagnosis of one of the following:
      1. **Pulmonary arterial hypertension (PAH)**; **AND**
         i. The medication is prescribed by or in consultation with a specialist (e.g., pulmonologist, cardiologist); **AND**
         ii. The patient is classified as having World Health Organization (WHO) Functional Class II-IV symptoms; **AND**
         iii. The request is for generic sildenafil tablets or generic tadalafil tablets; **OR**

a. The request is for Revatio tablets or Adcirca and both generic sildenafil and generic tadalafil are found to be ineffective, not tolerated, or contraindicated; **OR**
b. The request is for generic sildenafil oral suspension 10 mg/mL, and the member is unable to swallow oral tablets; **OR**
    i. The request is for Revatio oral suspension 10 mg/mL, and the generic has been ineffective, not tolerated, or contraindicated; **OR**
    ii. The request is for Tadliq oral suspension 20 mg/5mL; **AND**
        1. Generic sildenafil oral suspension 10 mg/mL has been ineffective, not tolerated, or contraindicated; **OR**

2. **Benign prostatic hyperplasia (BPH); AND**
    i. At least one alpha-1 blocker AND one 5-alpha-reductase inhibitor medication have been ineffective, not tolerated, or both are contraindicated
        a. Examples of 5-alpha reductase inhibitors: dutasteride, finasteride
        b. Examples of alpha-1 blockers: alfuzosin, doxazosin, silodosin, tamsulosin, terazosin; **AND**
    ii. Generic tadalafil 2.5 or 5 mg tablets are requested (please note, no other medications addressed in this policy are covered for BPH); **OR**
3. **Raynaud's disease/phenomena; AND**
    i. Generic sildenafil 20mg has been prescribed at a maximum quantity of 90 tablets per 30-day supply (please note, no other medications in this policy are covered for Raynaud's); **AND**
    ii. Treatment with a dihydropyridine calcium channel blocker (e.g., nifedipine, amlodipine, isradipine, felodipine) or diltiazem has been ineffective, not tolerated, or is contraindicated; **OR**
        a. Generic sildenafil 20mg tablets will be used in combination with a calcium channel blocker or diltiazem as additional treatment.

II. Medications listed in this policy are considered <u>not medically necessary</u> when criteria above are not met and/or when used for:
    A. Erectile dysfunction.

III. Medications listed in this policy are considered <u>investigational</u> when used for all other conditions, including but <u>not limited to</u>:
    A. Traumatic brain injury
    B. Hypertension, not of the pulmonary atrial type
    C. Heart failure and/or other cardiovascular or central nervous system conditions, disorders, or diseases
    D. Oncologic conditions

E. Encephalopathy
F. Cirrhosis

Renewal Evaluation

I. Renewal criteria; Not applicable, approval allowed for length of benefit.

Supporting Evidence

I. Pulmonary arterial hypertension: Pulmonary hypertension (PH) specific therapy is directed at the PH itself rather than the underlying cause of PH. Patients with persistent PH with World Health Organization (WHO) functional class II, III, or IV despite treatment of the underlying cause of PH should be evaluated for PH specific therapy. Group I patients should be observed and treated for the contributing factors. As of 2019, preferential treatments for group II-III patients include tadalafil plus other agents, and group IV should be treated with IV agents or double or triple combination therapy regimen that may or may not include tadalafil or sildenafil. Therapy is individualized to the patient and there are several suitable agents outside of sildenafil or tadalafil.
II. Benign prostatic hyperplasia (BPH): common treatment for BPH include alpha-1 adrenergic antagonists, 5-alpha-reductase inhibitors, anticholinergic agents, and phosphodiesterase-5 (PED-5) inhibitors. As of 2019, it was recommended that those with mild disease should be considered for an alpha-1 adrenergic antagonist. This is due to 5-alpha-reductase inhibitors requiring long-term treatment for efficacy (six to twelve months of treatment required prior to symptom improvement); however, it shall be noted that some patients will experience hypotension with alpha-1-adrenergic antagonists. Alternative options beyond these two classes include anticholinergic agents and PDE-5 inhibitors.
III. Raynaud phenomenon (RP): An exaggerated vascular response to cold temperature or emotional stress. This is manifested clinically by sharply demarcated color changes of the skin. Attacks occur commonly in the hands but may also occur in the toes, and attacks may cause symptoms such as numbness, clumsiness of the hand, aches, pains, or a feeling of pins and needles. Initial management of RP includes avoidance of triggers and vasoconstricting medications (e.g., nasal decongestants, amphetamines, ephedra, stimulants, triptans, ergotamines), as well as smoking cessation.
IV. Initial pharmacologic management of RP is recommended with calcium channel blockers of the dihydropyridine type. Amlodipine is preferred, but other such as nifedipine may be used. Other agents, such as PED-5 medications (e.g., sildenafil, tadalafil, vardenafil) may be considered with calcium channel blockers are contraindicated or not tolerated.

Investigational or Not Medically Necessary Uses

I. Erectile dysfunction treatment is deemed medically necessary by the plan and is excluded from coverage.

II. All of the aforementioned indications, conditions, diseases listed in the experimental/investigational section and treated with medications in this policy are being evaluated in clinical trials. Safety and efficacy have not yet been determined.

References

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9. Zidek W, Spiecker C, Knaup G, Steindl L, Breuer HW. Comparison of the efficacy and safety of nifedipine coat-core versus amlodipine in the treatment of patients with mild-to-moderate essential hypertension. Hypertension Study Group. Clin Ther. 1995;17(4):686-700.
10. Roustit M, Blaise S, Allanore Y, Carpentier PH, Caglayan E, Cracowski JL. Phosphodiesterase-5 inhibitors for the treatment of secondary Raynaud's phenomenon: systematic review and meta-analysis of randomised trials. Ann Rheum Dis. 2013;72(10):1696-9.

Policy Implementation/Update:

Action and Summary of Changes	Date
Added tadliq suspension into policy criteria with a step through generic sildenafil suspension	11/2022
Added new product tadalafil (Tadliq) 20 mg/5 ml oral suspension	09/2022
Creation of policy from prior authorization criteria. Opened up criteria to allow for generic sildenafil and tadalafil for BPH and PAH due to generic availability.	05/2019
Updated PAH questions to remove contraindication questions, assess function classification of staging and trial and failure of generic sildenafil. Aligned with commercial PAH criteria. Added clinical note of Raynaud phenomena.	03/2018