VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Erectile Dysfunction – Sildenafil (Viagra) Prior Authorization Policy
- Viagra® (sildenafil tablets – Pfizer, generic)

REVIEW DATE: 10/13/2021

OVERVIEW

Sildenafil (Viagra, generic) are indicated for the treatment of **erectile dysfunction**.[1]

Sildenafil has been studied for other indications.

- **Benign Prostatic Hyperplasia.** The European Association of Urology guidelines (2021) note that phosphodiesterase type 5 inhibitors can be used in men with moderate-to-severe lower urinary tract symptoms with or without erectile dysfunction.[13] The guidelines add that based on the results from a meta-analysis[12], younger men with lower body mass index and more severe lower urinary tract symptoms benefit the most from phosphodiesterase type 5 inhibitors.
- **High-Altitude Pulmonary Edema.** Published guidelines for the prevention of high-altitude pulmonary edema recommend nifedipine as the preferred pharmacologic treatment option .[12] Other pharmacologic therapies include salmeterol, tadalafil, sildenafil, dexamethasone, or acetazolamide.
- **Prophylaxis after Radical Prostatectomy.** Viagra given on a daily basis has been used to improve the return of normal spontaneous erectile function, improve tissue oxygenation, and prevent penile fibrosis after nerve-sparing radical prostatectomy.[10,11] It is better to initiate a penile rehabilitation program as soon as possible after surgery in order to limit and prevent postoperative local hypoxygenation and fibrosis.
- **Pulmonary Arterial Hypertension**. Sildenafil tablets (Revatio®) are approved for pulmonary arterial hypertension.[2] Sildenafil (Viagra, generics) are available in 25 mg, 50 mg, and 100 mg tablets, and Revatio is available as 20 mg tablets. Viagra has been used for this diagnosis.[3,4] Doses of Viagra that were used in these reports ranged from 25 mg twice daily to 100 mg five times daily. Patients will have usually been started on Revatio 20 mg three times daily.
- **Raynaud Phenomenon**. Studies show Viagra has been effective in patients with Raynaud phenomenon (usually with scleroderma) who have digital ischemia, gangrene, or ulcers.[5-7] Capillary blood flow velocity increased in patients after therapy with Viagra.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of sildenafil (Viagra, generics). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with sildenafil (Viagra, generics) as well as the monitoring required for adverse events and long-term efficacy, some approvals require sildenafil (Viagra, generics) to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: When available, the ICD-10 codes for male erectile dysfunction (ICD-10: N52.*) will be used for automation to allow approval of the requested medication. This automation is gender-selective and is not applicable for women; approval for use in women is always determined by prior authorization criteria.

Note: Phosphodiesterase type 5 inhibitors should not be administered, either regularly or intermittently, with concomitant nitrate therapy. Patients will be informed of the consequences should they initiate nitrate therapy while taking a phosphodiesterase type 5 inhibitor.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of sildenafil (Viagra, generic) are recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Erectile Dysfunction**. Approve for 1 year.

Other Uses with Supportive Evidence

1. **Benign Prostatic Hyperplasia**. Approve for 1 year if the patient meets one of the following criteria (A or B):
   Note: For men with erectile dysfunction and benign prostatic hyperplasia, use criterion 1 above.
   A) Patient has tried an α_1-blocker; OR
   Note: Examples of α_1-blockers include doxazosin, terazosin, tamsulosin, alfuzosin.
   B) Patient has tried a 5α-reductase inhibitor.
   Note: Examples of a 5α-reductase inhibitor includes finasteride, dutasteride.

2. **High-Altitude Pulmonary Edema (HAPE), Treatment or Prevention.** Approve for 1 year in patients who meet the following criteria (A and B):
   A) Patient has HAPE or a history of HAPE; AND
   B) Patient has tried one other pharmacologic therapy for the treatment or prevention of HAPE.
   Note: Examples of other pharmacologic therapy for the treatment of HAPE are nifedipine, Serevent (salmeterol inhalation powder), dexamethasone, acetazolamide, Cialis (tadalafil tablets).

3. **Prophylaxis After Radical Prostatectomy (Early Penile Rehabilitation).** Approve for 1 year in patients who meet the following criteria (A and B):
   A) Patient had radical prostatectomy within the previous 12 months; AND
   B) The medication is prescribed by or in consultation with an urologist.

4. **Pulmonary Arterial Hypertension**. Approve for 1 year.

5. **Raynaud's Phenomenon**. Approve for 1 year if the patient meets one of the following criteria (A or B):
   A) Patient has tried at least two of the following therapies for Raynaud disease: calcium channel blockers, α-adrenergic blockers, nitroglycerin, losartan, fluoxetine, or angiotensin converting enzyme (ACE) inhibitors; OR
   Note: Examples of calcium channel blockers include amlodipine, felodipine, nifedipine. Examples of α-adrenergic blockers include prazosin, doxazosin. Examples of ACE inhibitors include lisinopril, benazepril, captopril, enalapril.
   B) Patient has tried one vasodilator.
   Note: Examples of vasodilators include: Flolan (epoprostenol for injection), Edex (alprostadil for injection), Tracleer (bosentan tablets).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of sildenafil (Viagra, generic) is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Viagra tablets [prescribing information]. New York, NY: Pfizer; December 2017.
2. Revatio® tablets [prescribing information]. New York, NY: Pfizer; February 2020.
3. Garg N, Sharma MK, Sinha N. Role of oral sildenafil in severe pulmonary arterial hypertension: Clinical efficacy and dose response relationship. *Int J Cardiol.* 2007;120:306-313.
4. Galié N, Ghofrani HA, Torbicki A, et al; Sildenafil Use in Pulmonary Arterial Hypertension (SUPER) Study Group. Sildenafil citrate therapy for pulmonary arterial hypertension. *N Engl J Med.* 2005;353:2148-2157.
5. Levien TL. Phosphodiesterase inhibitors in Raynaud's phenomenon. *Ann Pharmacother.* 2006;40:1388-1393.
6. Gore, J, Silver R. Oral sildenafil for the treatment of Raynaud's phenomenon and digital ulcers secondary to systemic sclerosis. *Ann Rheum Dis.* 2005;64:1387.
7. Fries R, Shariat K, von Wilmowsky H, et al. Sildenafil in the treatment of Raynaud's phenomenon resistant to vasodilatory therapy. *Circulation.* 2005;112:2980-2985.
8. Gacci M, Corona G, Salvi M, et al. A systematic review and meta-analysis on the use of phosphodiesterase 5 inhibitors alone or in combination with α-blockers for lower urinary tract symptoms due to benign prostatic hyperplasia. *Eur. Urol.* 2012;61:994-1003.
9. Gravas S, Cornu JN, Gacci C, et al. Management of non-neurogenic male lower urinary tract symptoms (LUTS). © European Association of Urology 2021. Available at: http://uroweb.org/guideline/treatment-of-non-neurogenic-male-luts/ Accessed on September 8, 2021.
10. Bannowsky A, Schulze H, van der Horst C, et al. Recovery of erectile function after nerve-sparing radical prostatectomy: improvement with nightly low-dose sildenafil. *BJU Int.* 2008;101:1279-1283.
11. Bratu O, Oprea I, Marcu D, et al. Erectile dysfunction post-radical prostatectomy- a challenge for both patient and physician. *J Med Life.* 2017;10(1):13-18.
12. Luks AM, Auerbach PS, Freer L, et al. Wilderness Medical Society Consensus Guidelines for the Prevention and Treatment of Acute Altitude Illness: 2019 Update. Available at: https://www.wemjournal.org/article/S1080-6032(19)30090-0/fulltext. Accessed on October 7, 2021.