

Pharmacy Policy Bulletin

Title: Erectile Dysfunction Agents

Policy #: Rx.01.29

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ Intent:

The intent of this policy is to communicate the medical necessity criteria for **sildenafil (Viagra®), vardenafil (Levitra®/Staxyn®), tadalafil (Cialis®), avanafil (Stendra®) and alprostadil (Muse®, Edex®, Caverject®, IFE-PG20)** as provided under the member's prescription drug benefit.

▶ Description:

Erectile dysfunction (ED) is a sexual disorder characterized by inability to obtain an erection of adequate duration and rigidity in the presence of sexual stimulation. During an erection, blood is supplied via the cavernosal artery, which receives input from the pudendal and cavernosal nerves. Dysfunction of the blood flow or neurologic input may contribute to the inability to acquire or sustain an erection. While the etiology of ED is variable, the disorder is largely contributed to an issue with the surrounding vasculature, preventing adequate blood supply to the penis.

Mechanism of Action

Cyclic guanosine monophosphate (cGMP) is a nucleotide which, when activated, causes vasodilation of the smooth muscle, including the supplying vasculature to the penis that is necessary for an erection. Phosphodiesterase-5 (PDE-5) acts to cease the vasodilatory actions caused by cGMP by resulting in its breakdown. Inhibition of PDE-5 results in persistence of cGMP action and associated sustainability of an erection. Of note, PDE-5 inhibitors have no effect in the absence of sexual stimulation. Importantly, PDE-5 inhibitors should not be used in individuals who are currently taking nitrates or guanylate cyclase stimulators due to risks related to hypotension.

Prostaglandin E1 (PGE1) contributes to an erection due to relaxation of the trabecular smooth muscle and dilation of cavernosal arteries.

Sildenafil (Viagra®), vardenafil (Levitra®/Staxyn®), tadalafil (Cialis®), and avanafil (Stendra®) are phosphodiesterase-5 (PDE-5) inhibitors indicated for the treatment of erectile dysfunction. Additionally, **tadalafil (Cialis®) 2.5mg and 5mg** are indicated for benign prostatic hyperplasia (BPH).

Alprostadil (Muse®, Edex®, Caverject®, IFE-PG20) are Prostaglandin E1 agonists indicated for the treatment of erectile dysfunction.

▸ **Policy:**

Cialis® (tadalafil), Viagra®, Levitra® (vardenafil), Staxyn® and Stendra® are approved when ALL of the following are met:

- A. Diagnosis of erectile dysfunction; and
- B. No concurrent use of nitrates; and
- C. Inadequate response or inability to tolerate sildenafil

Cialis® (tadalafil) for benign prostatic hypertrophy is approved when there is no concurrent use of nitrates.

Alprostadil (Muse®, Edex®, Caverject®, IFE-PG20) is approved when there is a diagnosis of erectile dysfunction.

Note: Edex®, Caverject®, IFE-PG20 and Muse do not require prior authorization for members 55 years of age and older when no nitrates are in the member's history.

▸ **Black Box Warning:**

None

▸ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▸ **References:**

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Caverject (alprostadil) [prescribing information]. New York, NY. Pfizer; December 2017. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a295fc1e-d82c-4f44-bc2d-a552bf594c98&type=display>. Accessed January 24, 2019.

Cialis (tadalafil) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; Feb 2018. Available from: <https://pi.lilly.com/us/cialis-pi.pdf>. Accessed January 24, 2019.

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Salonia A, Gallina A, Zanni G, et al. Acceptance of and discontinuation rate from erectile dysfunction oral treatment in patients following bilateral nerve-sparing radical prostatectomy. *European Urology*. 2008;53:564-70.

Staxyn (vardenafil) [prescribing information]. Research Triangle Park, NC. Glaxo Smith Kline. August 2017. Available from: <http://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Brands/STAXYN/> Accessed January 24, 2019.


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Viagra (sildenafil) [prescribing information]. New York, NY: Pfizer Labs; December 2017. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=0b0be196-0c62-461c-94f4-9a35339b4501&type=display>. Accessed January 24, 2019.

Zeitlin SI, Rajfer J. Hyperprolactinemia and erectile dysfunction. *Rev Urol*. 2000;2(1):39-42.

Cunningham MD, Rosen R. Overview of male sexual dysfunction. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com.proxy1.lib.tju.edu> (Accessed on January 24, 2019.)

▾ **Applicable Drugs:**

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Erectile Dysfunction Agents

Brand Name	Generic Name
Caverject®	alprostadil
Cialis®	tadalafil
Edex®	alprostadil
IFE-PG20	alprostadil
Levitra®	ildenafil
Muse®	alprostadil
Staxyn®	ildenafil
Viagra®	sildenafil
Stendra®	avanafil

➤ Cross References:

N/A

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.