

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, gender or quantity restrictions. 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 use of **sildenafil (Viagra®)**, **vardeafil (Levitra/Staxyn)**, **tadalafil (Cialis®)**, **avanafil (Stendra)** and **alprostadil (Muse®, Edex®, Caverject®)** requires prior authorization (i.e. clinical pharmacist and/or Medical Director review).

▶ Description:

Sildenafil (Viagra®), **vardeafil (Levitra/Staxyn)**, **tadalafil (Cialis®)**, **avanafil (Stendra)** and **alprostadil (Muse®, Edex®, Caverject®)** are indicated for the treatment of erectile dysfunction. Additionally, **tadalafil (Cialis)** 2.5mg and 5mg are indicated for benign prostatic hyperplasia (BPH).

Sildenafil (Viagra®), **vardeafil (Levitra/Staxyn)**, **tadalafil (Cialis®)**, and **avanafil (Stendra)** inhibit an enzyme called phosphodiesterase-5 (PDE-5), which destroys cGMP. Cyclic guanosine monophosphate (cGMP) is a nucleotide that affects the amount of blood that is delivered to and removed from the penis. The longer cGMP persists, the longer the penis is engorged and able to maintain an erection. Thus, **sildenafil (Viagra®)**, **vardeafil (Levitra/Staxyn)**, and **tadalafil (Cialis®)** prevent the destruction of cGMP and allow it to accumulate and persist longer in vascular smooth muscle cells. **Sildenafil (Viagra®)**, **vardeafil (Levitra/Staxyn)**, and **tadalafil (Cialis®)** have no effect in the absence of sexual stimulation. **Sildenafil (Viagra®)**, **vardeafil (Levitra/Staxyn)**, and **tadalafil (Cialis®)** should not be used in individuals who are currently taking nitrates due to risks related to hypotension.

Alprostadil (Muse®, Edex®, Caverject®) creates an erection by relaxing the smooth muscle tissue and dilating the major artery, thereby enhancing blood flow to the penis. These drugs are indicated for the treatment of all types of impotence.

▶ Policy:

Cialis®, **Viagra®**, **Levitra®**, **Staxyn®** and **Stendra®** are approved when ALL of the following inclusion criteria are met:

1. Diagnosis of erectile dysfunction; and
 2. No concurrent use of nitrates; and
 3. Any one of the following:
 - a. Member is 55 years of age or older
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- b. Diagnosis of a concomitant condition (such as diabetes, prostate cancer, pelvic surgery/radiation [e.g., colon cancer], spinal cord injury, neurological disease)
 - c. Normal testosterone level
 - d. Low testosterone level and a low or normal prolactin level, with an inadequate response or inability to tolerate a testosterone replacement product
 - e. Low testosterone level and a high prolactin level, with evidence of appropriate work up and treatment plan (treatment plan must be provided with this request); and
4. Inadequate response or inability to tolerate tadalafil (Cialis[®]) [applies to Sildenafil (Viagra[®]), Vardenafil (Levitra[®]/Staxyn[®]) and avanafil (Stendra[®])]

Cialis[®] for benign prostatic hypertrophy is approved when there is documentation of BOTH of the following inclusion criteria are met:

1. No concurrent use of nitrates; and
2. Inadequate response or inability to tolerate an alpha blocker

Alprostadil (Muse[®], Edex[®], Caverject[®]) is approved when BOTH of the following inclusion criteria are met:

1. Diagnosis of erectile dysfunction; and
2. ONE of the following:
 - a. Member is 55 years of age or older
 - b. Concomitant condition (such as diabetes, prostate cancer, pelvic surgery/radiation [e.g., colon cancer], spinal cord injury, neurological disease)
 - c. Normal testosterone level
 - d. Low testosterone level and a low or normal prolactin level, with inadequate response or inability to tolerate a testosterone-replacement product

▸ **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 pharmacy 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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Turek PJ. Male infertility. In: Tanagho EA, McAninch JW, eds. Smith's General Urology. 16th ed. New York, NY: McGraw-Hill; 2004. Vardenafil (Levitra®) [prescribing information]. West Haven, CT: Bayer Pharmaceuticals Corporation; May 2010. Available at: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Brands/LEVITRA/pdf/Levitra_PI.PDF Revised 04/2014, Accessed June 5, 2015.

Viagra [prescribing information]. New York, NY: Pfizer Labs; January 2010. Available at: http://www.pfizer.com/files/products/uspi_viagra.pdf. Revised 03/2015. Accessed June 5, 2015.

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

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
Levitra	vardenafil
Muse	alprostadil
Staxyn	vardenafil
Viagra	sildenafil
Stendra	avanafil

Cross References:

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