

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 and 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:

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

The use of sildenafil (Viagra®), vardenafil (Levitra/Staxyn), tadalafil (Cialis®), and alprostadil (Muse®, Edex®, Caverject®) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

Description:

Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) 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®), vardenafil (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®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) have no effect in the absence of sexual stimulation. Sildenafil (Viagra®), vardenafil (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:

Erectile dysfunction agents are generally limited to a cumulative total of eight injections, tablets, or pellets per 30 days.

Exception: Cialis 2.5mg and Cialis 5mg are FDA-approved for once-daily dosing and are therefore limited to 30 units per 30 days.

ERECTILE DYSFUNCTION

FOR INDIVIDUALS 55 YEARS OF AGE AND OLDER:

Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) are approved when **BOTH** of the following inclusion criteria are met:

- Documentation of erectile dysfunction
- No documentation or history of nitrate use within the past six months

Alprostadil (Muse®, Edex®, Caverject®) is approved when the following inclusion criterion is met:

Documentation of erectile dysfunction

FOR INDIVIDUALS YOUNGER THAN 55 YEARS OF AGE:

Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) are approved when **ALL** of the following inclusion criteria are met:

- Documentation of erectile dysfunction and **one** of the following:
 - Documentation of a concomitant condition (such as diabetes, prostate cancer, pelvic surgery, radiation [eg, colon cancer], spinal cord injury, neurological disease)
 - Documentation of a normal testosterone level
 - Documentation of a low testosterone level and a low or normal prolactin level, with a trial and failure of/contraindication/intolerance/allergy to a testosterone-containing product
 - Documentation of a low testosterone level and a high prolactin level, with evidence of appropriate work up and treatment plan (treatment plan must be provided to the Company with this request)
- No documentation or history of nitrate use within the past six months

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

- Documentation of erectile dysfunction and **one** of the following:
 - Documentation of a concomitant condition (such as diabetes, prostate cancer, pelvic surgery, radiation [eg, colon cancer], spinal cord injury, neurological disease)
 - Documentation of a normal testosterone level
 - Documentation of a low testosterone level and a low or normal prolactin level, with a trial and failure of/contraindication/intolerance/allergy to a testosterone-containing product
 - Documentation of a low testosterone level and a high prolactin level, with evidence of appropriate work up and treatment plan (treatment plan must be provided to the Company with this request)

BENIGN PROSTATIC HYPERPLASIA (CIALIS 2.5 AND 5MG ONLY)

Tadalafil (Cialis) is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of BPH

Documentation of a trial and failure/contraindication/intolerance/allergy to an alpha blocker

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.

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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	varденаfil
Muse	alprostadil
Staxyn	varденаfil
Viagra	sildenafil

Cross References:

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