

## Policies Repository



**Policy Title** Erectile Dysfunction Agents

**Policy Number** FS.CLIN.24

*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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.*

**Policy** Sildenafil (Viagra®), vardenafil (Levitra®), tadalafil (Cialis®), and alprostadil (Muse®, Edex®, Caverject®) are indicated for the treatment of erectile dysfunction. Erectile dysfunction can be caused by any of the following:

- Neurogenic factors
- Spinal cord injury
- Vasculogenic factors
- Vascular disease
- Diabetes
- Psychogenic factors
- Psychological factors
- Mixed etiology
- Combination, defined as any of the three above-listed causes

Currently, two types of drugs are available to treat erectile dysfunction: alprostadil agents and selective inhibitors of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5).

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

**Policy Description**

**Sildenafil (Viagra®), vardenafil (Levitra®), 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®), 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®), and tadalafil (Cialis®) have no effect in the absence of sexual stimulation. Sildenafil (Viagra®), vardenafil (Levitra®), 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 Guideline Inclusion

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

Group	Quantity Limit
Camden County	4

Exception:

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

#### **FOR INDIVIDUALS 55 YEARS OF AGE AND OLDER:**

**Sildenafil (Viagra®), vardenafil (Levitra®), 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®), 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)

---

## Policy Guideline Exclusion

### **FOR INDIVIDUALS 55 YEARS OF AGE AND OLDER:**

**Sildenafil (Viagra®), vardenafil (Levitra®), and tadalafil (Cialis®)** are denied when **ANY** of the following exclusion criteria are present:

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

**Alprostadil (Muse®, Edex®, Caverject®)** is denied when the following exclusion criterion is present:

- No documentation of erectile dysfunction

### **FOR INDIVIDUALS YOUNGER THAN 55 YEARS OF AGE:**

**Sildenafil (Viagra®), vardenafil (Levitra®), and tadalafil (Cialis®)** are denied when **ANY** of the following inclusion criteria are met:

- No documentation of erectile dysfunction and **one** of the following:
  - No documentation of a concomitant condition (such as diabetes, prostate cancer, pelvic surgery, radiation [eg, colon cancer], spinal cord injury, neurological disease)
  - No documentation of a normal testosterone level
  - No 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
  - No 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)
- Documentation or history of nitrate use within the past six months

**Alprostadil (Muse®, Edex®, Caverject®)** is denied when the following exclusion criteria are present:

- No documentation of erectile dysfunction and **one** of the following:
  - No documentation of a concomitant condition (such as diabetes, prostate cancer, pelvic surgery, radiation [eg, colon cancer], spinal cord injury, neurological disease)
  - No documentation of a normal testosterone level
  - No 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
  - No 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)

<b>Nitrates</b>	
<b>Brand Name</b>	<b>Generic Name</b>
Amyl Nitrite Aspirols	amyl nitrite
Amyl Nitrite Vaporole	amyl nitrite
Deponit	nitroglycerin
Dilatrate-SR	isosorbide dinitrate
Imdur	isosorbide mononitrate
ISDN	isosorbide dinitrate
ISMO	isosorbide mononitrate
Isochron	isosorbide dinitrate
Isordil	isosorbide dinitrate
Isordil Tembids	isosorbide dinitrate
Isordil Titrados	isosorbide dinitrate
Isotrate-ER	isosorbide mononitrate
Mintran	nitroglycerin
Monoket	isosorbide mononitrate
Nitrek	nitroglycerin
Nitro-Bid	nitroglycerin
Nitrocine	nitroglycerin
Nitrocot	nitroglycerin
Nitrodisc	nitroglycerin
Nitro-Dur	nitroglycerin
Nitrogard	nitroglycerin
Nitroglyn	nitroglycerin

Nitrol	nitroglycerin
Nitrolingual	nitroglycerin
Nitrong	nitroglycerin
Nitro-Par	nitroglycerin
Nitroquick	nitroglycerin
Nitrostat	nitroglycerin
NitroTab	nitroglycerin
Nitro-Time	nitroglycerin
Sorbitrate	isosorbide dinitrate
Transderm-Nitro	nitroglycerin
Tridil	nitroglycerin

### Policy List of Applicable Drugs

Erectile Dysfunction Agents	
Brand Name	Generic Name
Caverject	alprostadil
Cialis	tadalafil
Edex	alprostadil
Levitra	vardeafil
Muse	alprostadil
Viagra	sildenafil

### Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

### Policy References

Mulhall J, Land S, Parker M, et al. The use of erectogenic pharmacotherapy regimen following radical prostatectomy improves recovery of spontaneous erectile function. *J Sex Med.* 2005 Jul; 2(4): 532-10; discussion 540-2.

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.

Rambhatla A, Kovanecz I, Ferrini M, et al. Rationale for phosphodiesterase 5 inhibitor use post-radical prostatectomy: experimental and clinical review. *International Journal of Impotence Research.* 2008; 20: 30-34.

Beers MH, Porter RS, Jones TV, Kaplan JL, Berkwits M, eds. *Merck Manual of Diagnosis and Therapy.* 18th ed. 2006. Available at: <http://www.statref.com> [via subscription only]. Accessed March 19, 2010.

Erectile Dysfunction Guideline Update Panel; American Urological Association Education and Research, Inc. The management of erectile dysfunction: an update. [National Guideline Clearinghouse Web site]. Available at: <http://www.guideline.gov>. Accessed March 19, 2010.

Facts & Comparisons. Caverject®. [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed March 19, 2010.

Facts & Comparisons. Cialis®. [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed March 19, 2010.

Facts & Comparisons. Edex®. [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed March 19, 2010.

Facts & Comparisons. Levitra®. [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed March 19, 2010.

Facts & Comparisons. Muse®. [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed March 19, 2010.

Facts & Comparisons. Viagra®. [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed March 19, 2010.

Medicine Net. Sildenafil (Viagra®). [MedicineNet.com Web site]. 10/19/07. Available at: <http://www.focusonmenshealth.com/script/main/art.asp?articlekey=6173&rd=1>. Accessed March 19, 2010.

Mulligan T, Siddiqi W. Changes in male sexuality. In: Cassel CK, Leipzig RM, Cohen HJ, et al, eds. *Geriatric Medicine: An Evidence-Based Approach*. 4th ed. New York, NY: Springer -Verlag; 2003. Available at: <http://www.online.statref.com> [via subscription only]. Accessed March 19, 2010.

Tadalafil (Cialis®) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; 2008; Rev 4/09. Available at: <http://pi.lilly.com/us/cialis-pi.pdf>. Accessed March 19, 2010.

Turek PJ. Male infertility. In: Tanagho EA, McAninch JW, eds. *Smith's General Urology*. 16th ed. New York, NY: McGraw-Hill; ;2004. Available at: <http://www.online.statref.com>. Accessed March 19, 2010.

Vardenafil (Levitra®) [prescribing information]. West Haven, CT: Bayer Pharmaceuticals Corporation; 2007. Available at: <http://www.univgraph.com/bayer/inserts/levitraip.pdf>. Accessed March 19, 2010.

Viagra [prescribing information]. New York, NY: Pfizer Labs; 2007. Available at: [http://www.pfizer.com/files/products/uspi\\_v Viagra.pdf](http://www.pfizer.com/files/products/uspi_v Viagra.pdf). Accessed March 19, 2010.

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

---

## Policy Link to Related Policies

---

Printed

05/07/2010 15:55:01

---

The Policy Bulletins on this web site were developed to assist AmeriHealth and its subsidiaries ("AmeriHealth") in administering the provisions of the respective benefit programs, and do not constitute a contract. If you are an AmeriHealth member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. AmeriHealth 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 AmeriHealth. If you have a specific medical condition, please consult with your doctor. AmeriHealth reserves the right at any time to change or update its Policy Bulletins. ©2008 AmeriHealth, Inc. All Rights Reserved. Current Procedural Terminology ©2008 American Medical Association. All Rights Reserved.