

***Title: Erectile Dysfunction Agents including, but not limited to:
sildenafil (Viagra), tadalafil (Cialis), vardenafil (Levitra), alprostadil
(Caverject, Edex, Muse)***

Origination: 05/20/98	Revised: 11/11/11	Annual Review: 12/15/11
------------------------------	--------------------------	--------------------------------

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Sildenafil, tadalafil and vardenafil are selective inhibitors of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). This inhibition leads to increased levels of cGMP, which enhances the effects of Nitric Oxide (NO) and results in smooth muscle relaxation and inflow of blood in the corpus cavernosum.
- Sildenafil and vardenafil are indicated **only** for the treatment of erectile dysfunction (ED). Tadalafil is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia.
- Alprostadil (Prostaglandin E₁ (PGE₁)) pharmacological activities include vasodilation and inhibition of platelet aggregation. Alprostadil induces erection by relaxation of trabecular smooth muscle and dilation of cavernosal arteries.

***Title: Erectile Dysfunction Agents including, but not limited to:
sildenafil (Viagra), tadalafil (Cialis), vardenafil (Levitra), alprostadil
(Caverject, Edex, Muse)***

Background Information, continued:

Eligibility Criteria

- Member must be eligible for benefit coverage within the specified date(s) of service.
- Member should be male and 18 years of age or older.
- Sexual dysfunction medications are covered **only** for the treatment of erectile dysfunction due to organic etiology identified through appropriate clinical findings and diagnostic tests: *Physiological and neurogenic conditions are defined as erectile dysfunction attributed to, but not limited to diabetes, spinal cord injury, radical prostatectomy, and radical cystoprostatectomy.*
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Contraindications/Exclusions

- Sildenafil, tadalafil and vardenafil were shown to potentiate the hypotensive effects of nitrates; therefore, they are **contraindicated in Members who are currently using organic nitrates** in any form (i.e., Nitro stat SL, Imdur), either regularly or intermittently.
- The use of sildenafil, tadalafil or vardenafil in combination with alpha-adrenergic blocking agents (e.g. doxazosin or terazosin) can lower blood pressure significantly and should be used with caution.
- Female Member, or Male Member less than 18 years of age.
- General precautions include cardiovascular status (Member with cardiovascular disease for whom sexual activity is inadvisable), anatomical deformations of the penis (e.g., angulation, cavernosal fibrosis or Peyronie's disease), concomitant use with other PDE5 inhibitors (including, but not limited to, Levitra, Cialis, Revatio), and conditions predisposing to priapism (e.g., sickle cell anemia, multiple myeloma, or leukemia).
- The safety and efficacy of combinations of Viagra, Cialis, Levitra or Staxyn with other treatments for erectile dysfunction have not been studied and, therefore, are not covered.
- Hypersensitivity to alprostadil or other prostaglandins (for Caverject, Edex, or Muse requests).
- Members with penile implants.

***Title: Erectile Dysfunction Agents including, but not limited to:
sildenafil (Viagra), tadalafil (Cialis), vardenafil (Levitra), alprostadil
(Caverject, Edex, Muse)***

Procedure:

Request for Initial Therapy

- 1.0 The management of erectile dysfunction begins with the identification of comorbidities and psychosexual dysfunctions, therefore a complete History and Physical (H&P) will be required. Comorbidities should be appropriately treated prior to initiating treatment with an ED agent.
- 2.0 Approval for an erectile dysfunction (ED) agent will require medical documentation from the requesting independent practitioner indicating the medical condition causing impotence related to the following physiological and neurogenic conditions including, but not limited to:
 - 2.1 Diabetes Mellitus;
 - 2.2 Spinal cord injury;
 - 2.3 Radical prostatectomy;
 - 2.4 Radical cystoprostatectomy.
- 3.0 If the **Commercial** Member meets the criteria, the ED agent may be approved for twelve (12) months with the following maximum quantity:
 - 3.1 Viagra – 8 tablets per 30 days;
 - 3.2 Cialis 2.5 or 5mg–30 tablets per 30 days; Cialis 10 or 20 mg -6 tablets per 30 days
 - 3.3 Levitra or Staxyn – 8 tablets per 30 days;
 - 3.4 Caverject, Edex, or Muse – 8 units (all strengths) per 30 days;
 - 3.5 If the prescribing independent practitioner wants the Member to have a refill prior to the end of 30 days, the independent practitioner is required to submit the refill request.

Request for continuation of therapy beyond initial authorization period

- 1.0 Approval for an ED agent will require medical documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying:
 - 1.1 Member shows favorable response; **AND**
 - 1.2 Member demonstrates lack of intolerable or serious adverse effects;
 - 1.3 Request may be approved for up to one (1) year of therapy if the above criteria are met.

***Title: Erectile Dysfunction Agents including, but not limited to:
sildenafil (Viagra), tadalafil (Cialis), vardenafil (Levitra), alprostadil
(Caverject, Edex, Muse)***

References:

1. AACE Male Sexual Dysfunction Task Force. American Association of Clinical Endocrinologists Medical Guidelines For Clinical Practice For the Evaluation and Treatment of Male Sexual Dysfunction: A Couple's Problem – 2003 Update. *Endocro Pract.* 2003;9(1):77-95.
2. American Urological Association. The Management of Erectile Dysfunction: An Update. 2006. Accessed 04/14/08.
3. *Caverject Impulse* (alprostadil) Full Prescribing Information. Pharmacia Corporation. Kalamazoo, MI. 2007.
4. *Cialis* (tadalafil) Full Prescribing Information. Eli Lilly and Company. Indianapolis, IN. 2008.
5. *Edex* (alprostadil) Full Prescribing Information. Schwarz Pharma. Milwaukee, WI. Jan, 2006.
6. *Levitra* (vardenafil LHCL) Full Prescribing Information. Bayer Pharmaceuticals Corporation. West Haven, CT. 2007.
7. *Muse* (alprostadil) Full Prescribing Information. Vivus, Inc. Mountain View, CA. Aug, 2003.
8. *Viagra* (sildenafil citrate) Full Prescribing Information. Pfizer, Inc. New York, NY. 2008.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.