



PDE-5 Inhibitors

Vardenafil (Levitra[®], Staxyn[®]) Sildenafil (Viagra[®]) Tadalafil (Cialis[®])

Prior Authorization Criteria for the TRICARE Pharmacy Program

Prior authorization for PDE-5 inhibitors is NOT required for male patients 40 years of age or older being treated for erectile dysfunction with Levitra. Prior authorization IS required for male patients less than 40 years of age being treated for erectile dysfunction, for ALL new erectile dysfunction patients being treated with Cialis, Staxyn or Viagra, and for ALL patients being treated for primary pulmonary hypertension, Raynaud's phenomenon, benign prostatic hyperplasia, and post-prostatectomy uses.

PDE-5 (phosphodiesterase-5) inhibitors are indicated for the treatment of erectile dysfunction and pulmonary arterial hypertension (also known as primary pulmonary hypertension [PPH]). PDE-5 inhibitors indicated for erectile dysfunction include sildenafil (Viagra), tadalafil (Cialis), vardenafil (Levitra), and vardenafil orally dissolving tablet (Staxyn). Two PDE-5 inhibitors are specifically indicated for the treatment of PPH: sildenafil (under the brand name of Revatio), and tadalafil (under the brand name Adcirca). If you want to use Revatio or Adcirca, see the criteria and forms available for these agents on the [TRICARE Pharmacy Prior Authorization page](#).

The following criteria were established by the DoD Pharmacy & Therapeutics (P&T) Committee for vardenafil (Levitra), vardenafil ODT (Staxyn), sildenafil (Viagra) or tadalafil (Cialis) obtained through the TRICARE Mail Order Pharmacy (MOP) or retail network pharmacies. The prior authorization form for these PDE-5 inhibitors is available on the [TRICARE Pharmacy Prior Authorization page](#). This prior authorization does not have an expiration date.

Coverage IS provided for:

- PDE-5 inhibitors for male patients 18 to 39 years of age with an approved prior authorization for:
 - Organic erectile dysfunction (e.g., diabetes-related, vascular-related); or
 - Mixed organic/psychogenic erectile dysfunction; or
 - Drug-induced erectile dysfunction where the causative drug cannot be altered or discontinued.
- PDE-5 inhibitors for male patients with erectile dysfunction, 40 years of age and older.
 - Vardenafil (Levitra) – no prior authorization form required
 - Vardenafil ODT (Staxyn), Sildenafil (Viagra) or tadalafil (Cialis) – step therapy PA applies (See criteria below).
- Sildenafil (Revatio or Viagra) or tadalafil (Cialis or Adcirca) for any patient with primary pulmonary hypertension. Sildenafil (Viagra) vardenafil (Levitra) or tadalafil (Cialis) for any patient

with Raynaud's phenomenon or preservation and/or restoration of erectile function post-prostatectomy.

- Tadalafil 5 mg (Cialis 5mg) for patients with benign prostatic hyperplasia (BPH) meeting prior authorization criteria listed below.

Prior Authorization Criteria for Cialis (tadalafil), Staxyn (vardenafil ODT), and Viagra (sildenafil) used for Erectile Dysfunction

1. Patient received a trial of Levitra (vardenafil) for erectile dysfunction and had an inadequate response.
2. Patient received a trial of Levitra (vardenafil) for erectile dysfunction, but was unable to tolerate it due to adverse effects.
3. Treatment with Levitra (vardenafil) is contraindicated (e.g., due to hypersensitivity).

Prior Authorization Criteria for Cialis (tadalafil) used for Benign Prostatic Hyperplasia (BPH)

TRICARE will NOT cover Cialis for patients with benign prostatic hyperplasia UNLESS the patient meets the following criteria:

1. The patient has tried tamsulosin or alfuzosin and had an inadequate response.
2. The patient has tried tamsulosin or alfuzosin and was unable to tolerate it due to adverse effects.
3. Treatment with tamsulosin or alfuzosin is contraindicated (e.g., hypersensitivity).

- Approved Prior Authorizations will be effective for 1 year.

Coverage IS NOT provided for:

- Female sexual dysfunction, or
- Erectile dysfunction in males under 18 years of age, or
- Psychogenic erectile dysfunction

Quantity Limits

• Treatment of Erectile Dysfunction – The PDE-5 inhibitors are limited to a maximum of 18 tablets per 90 days from the MOP or 6 tablets per 30 days from retail network pharmacies. This quantity limit applies collectively to all three medications. This means that no more than 18 tablets per 90-day supply of any combination of these medications will be dispensed in the TRICARE Mail Order Pharmacy and no more than 6 tablets per 30-day supply of any combination of these medications will be dispensed by retail network pharmacies. (Note: Staxyn (vardenafil ODT) is available in packages of four (4) tablets each. The Mail Order Pharmacy cannot break packaging and must dispense this product in multiples of 4.)

• Treatment of Pulmonary Arterial Hypertension, Raynaud's phenomenon, post-prostatectomy preservation/restoration of erectile function, Benign Prostatic Hyperplasia (BPH) - Usual rules apply (90-day supply in the MOP or 30-day supply at retail network pharmacies, based on the directions for use on the prescription).

- Use of Multiple Pharmacy Points of Service – The amount of medication obtained by a patient from all Military Health System pharmacy points of service will be taken into account in the application of this quantity limit.

(Criteria approved July 2004 by the DoD Pharmacy & Therapeutics Committee, revised July 2009; December 2009)

Medical necessity forms are available on the TRICARE Pharmacy website at www.tricare.osd.mil/pharmacy/medical-nonformulary.cfm.

Criteria approved through the Uniform Formulary decision-making process.

www.tricare.mil is the official Web site of the
TRICARE Management Activity,
a component of the [Military Health System](#)
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