



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1026-8
Program	Notification – Oxford, ASO (Also applies to HealthyNY) and Indiana ⁺
Medication/Therapeutic Class	Erectile dysfunction agents Caverject (alprostadil), Cialis (tadalafil), Edex (alprostadil), Levitra (vardenafil HCl), Muse (alprostadil), Staxyn (vardenafil HCl), Stendra (avanafil), Viagra* (sildenafil citrate)
P&T Approval Date	1/2008, 5/2010, 3/2011, 7/2011, 1/2012, 2/2013, 4/2014, 2/2015, 2/2016, 5/2016, 2/2017, 6/2017, 6/2018
Effective Date	9/1/2018; Oxford only: 9/1/2018

1. Background:

This program is designed for clients who would like to cover erectile dysfunction agents for organic causes of erectile dysfunction.

⁺For Indiana groups in which erectile dysfunction medications are excluded unless medically necessary

2. Coverage Criteria:

A. Authorization

1. **Viagra*, Levitra or Staxyn** will be approved based on **all** of the following criteria:

- a. Patient has an organic cause of erectile dysfunction [ie: diabetes mellitus, hypertension, atherosclerosis, drug induced**, hypercholesterolemia, renal insufficiency, neurological disease (stroke, seizure disorder, demyelinating disease, spinal cord injury, tumor), endocrine disorder including hypogonadism, vascular or neurologic disease affecting the genitalia, or history of male genital surgery (including prostatectomy, trauma, or irradiation)]

-AND-

- b. Patient is not receiving nitrate therapy

-AND-

- c. Patient is not concurrently receiving an alternative phosphodiesterase-5 enzyme inhibitor (e.g. Cialis, Levitra, Staxyn, Stendra, or Viagra).

2. **Stendra** will be approved based on **all** of the following criteria:

- a. Patient has an organic cause of erectile dysfunction [ie: diabetes mellitus, hypertension, atherosclerosis, drug induced**, hypercholesterolemia, renal

insufficiency, neurological disease (stroke, seizure disorder, demyelinating disease, spinal cord injury, tumor), endocrine disorder including hypogonadism, vascular or neurologic disease affecting the genitalia, or history of male genital surgery (including prostatectomy, trauma, or irradiation)]

-AND-

- b. Patient is not receiving nitrate therapy

-AND-

- c. Patient is not concurrently receiving an alternative phosphodiesterase-5 enzyme inhibitor (e.g. Cialis, Levitra, Staxyn, Stendra, or Viagra).

-AND-

- d. History of failure, contraindication or intolerance to **two** of the following (document date tried and reason for failure):

- (1) Cialis
- (2) Levitra
- (3) sildenafil (generic Viagra)

3. **Muse, Caverject or Edex** will be approved based on the following criterion:

- a. Patient has an organic cause of erectile dysfunction [ie: diabetes mellitus, hypertension, atherosclerosis, drug induced**, hypercholesterolemia, renal insufficiency, neurological disease (stroke, seizure disorder, demyelinating disease, spinal cord injury, tumor), endocrine disorder including hypogonadism, vascular or neurologic disease affecting the genitalia, or history of male genital surgery (including prostatectomy, trauma, or irradiation)]

4. **Cialis** will be approved based on **one** of the following criteria:

- a. **All** of the following:

- (1) Patient has an organic cause of erectile dysfunction [ie: diabetes mellitus, hypertension, atherosclerosis, drug induced**, hypercholesterolemia, renal insufficiency, neurological disease (stroke, seizure disorder, demyelinating disease, spinal cord injury, tumor), endocrine disorder including hypogonadism, vascular or neurologic disease affecting the genitalia, or history of male genital surgery (including prostatectomy, trauma, or irradiation)]

-AND-

- (2) Patient is not receiving nitrate therapy

-AND-

- (3) Patient is not concurrently receiving an alternative phosphodiesterase-5 enzyme inhibitor (e.g. Levitra, Staxyn, Stendra, or Viagra).

-OR-

b. **All** of the following:

- (1) Patient has requested a dose for 2.5 or 5 mg
- (2) Patient has a diagnosis of benign prostatic hyperplasia
- (3) Patient has tried an alpha-adrenergic blocker such as Uroxatrol (alfuzosin), Cardura (doxazosin), Flomax (tamsulosin), Hytrin (terazosin) for the treatment of signs and symptoms of benign prostatic hyperplasia

-AND-

(1) **One** of the following

- i. Patient has experienced treatment failure of an alpha-adrenergic blocker after a trial of at least 4 weeks
- ii. Patient experiences intolerable adverse effects to one of the alternative agents

Authorization will be issued for 12 months.

Brand Viagra is typically excluded from coverage.

**Examples (not all-inclusive): spironolactone, thiazide diuretics (e.g. chlorthalidone, chlorothiazide, hydrochlorothiazide), methyl dopa, clonidine, guanfacine, reserpine, beta-blockers (e.g. propranolol, metoprolol), digoxin, tricyclic antidepressants (e.g. amitriptyline, doxepin, imipramine, nortriptyline, protriptyline), selective serotonin reuptake inhibitors (e.g. citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), duloxetine, venlafaxine, cimetidine, phenytoin, carbamazepine, phenobarbital, primidone, lithium carbonate, chlorpromazine, thioridazine, fluphenazine, trifluoperazine, finasteride, dutasteride, chronic use opioids, estrogens, anti-androgens (e.g. bicalutamide, flutamide, nilutamide), luteinizing hormone releasing hormone agonists (leuprolide, histrelin, goserelin, triptorelin)

3. **Other Clinical Programs:**

Supply limits also apply

4. **References:**

1. Viagra prescribing information. New York, NY: Pfizer Inc.; August 2017.
2. Cialis prescribing information. Indianapolis, IN: Eli Lilly and Company; February 2018.
3. Levitra prescribing information. Wayne, NJ: Bayer HealthCare Pharmaceuticals; August 2017.
4. Staxyn prescribing information. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2017.
5. Caverject prescribing information. New York, NY: Pfizer Inc.; December 2017.
6. Edex [prescribing information]. Lake Forest, IL: Actient Pharmaceutical, LLC; March 2015.
7. Muse prescribing information. Somerset, NJ: Meda Pharmaceuticals, Inc.; August 2014.



8. Stendra prescribing information. Mountain View, CA: Vivus, Inc.; September 2017.
9. Drugs That May Cause Male Sexual Dysfunction. Pharmacist’s Letter. Detail Document #220907. September 2006.
10. Drug-Induced Sexual Dysfunction. Drugdex® Consults. Micromedex® Healthcare Series. Last Modified: July 1, 2014.
11. Montague DK, Jarow JP, Broderick GA, et al. Erectile Dysfunction. The Management of Erectile Dysfunction: An Update. American Urological Association. 2005 (Reviewed and validity confirmed, 2011.)
12. American Urological Association. Guideline on the Management of Benign Prostatic Hyperplasia (BPH). 2010.

Program	Notification – Oxford and ASO
Change Control	
Date	Change
2/2013	Administrative changes.
4/2014	Added criterion that patient requesting Cialis, Viagra, Levitra, Staxyn or Stendra not concurrently be receiving another medication in this class.
2/2016	Clarified trial durations for alpha-adrenergic blocking agents. Updated references.
5/2016	Removed gender and age requirements.
2/2017	Revised formatting for Cialis. Updated requirements for Stendra to include trial of two of the following: Cialis, Levitra, Viagra.
6/2017	Updated criteria to apply to Indiana groups which only cover erectile dysfunction medications if medically necessary.
6/2018	Noted Brand Viagra is typically excluded from coverage. Updated references.