



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2020 P 1026-10
Program	Notification – Oxford, ASO (Also applies to HealthyNY) and Indiana <sup>†</sup>
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, 4/2019, 4/2020
Effective Date	7/1/2020; Oxford only: 7/1/2020

**1. Background:**

This program is designed for clients cover erectile dysfunction agents for organic causes of erectile dysfunction.

<sup>†</sup>For Indiana groups in which erectile dysfunction medications are excluded unless medically necessary

**2. Coverage Criteria:**

**A. Authorization**

1. **Sildenafil (generic Viagra) or vardenafil (generic Levitra)** will be approved based on **both** 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 concurrently receiving an alternative phosphodiesterase-5 enzyme inhibitor (e.g. Cialis, Staxyn, or Stendra).

2. **Levitra\*** 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 concurrently receiving an alternative phosphodiesterase-5 enzyme inhibitor (e.g. Cialis, Staxyn, Stendra, or Viagra).

**-AND-**

- c. History of trial/failure, contraindication or intolerance to vardenafil (generic Levitra)

3. **Viagra\*** 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 concurrently receiving an alternative phosphodiesterase-5 enzyme inhibitor (e.g. Cialis, Levitra, Staxyn, or Stendra).

**-AND-**

- c. History of trial/failure, contraindication or intolerance to sildenafil (generic Viagra)

4. **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 concurrently receiving an alternative phosphodiesterase-5 enzyme inhibitor (e.g. Cialis, Levitra, Staxyn, or Viagra).

**-AND-**

- c. History of failure, contraindication or intolerance to **two** of the following (document date tried and reason for failure):
- (1) tadalafil (generic Cialis)
  - (2) vardenafil (generic Levitra)
  - (3) sildenafil (generic Viagra)
5. **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)]
6. **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 concurrently receiving an alternative phosphodiesterase-5 enzyme inhibitor (e.g. Levitra, Staxyn, Stendra, or Viagra).
- AND-**
- (3) History of trial/failure, contraindication or intolerance to tadalafil (generic Cialis)
- 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) History of failure following a trial for at least 4 weeks, contraindication or intolerance to an alpha-adrenergic blocking medication [e.g., Cardura, Flomax, Hytrin , Rapaflo or Uroxatrol]
  - (4) History of trial/failure, contraindication or intolerance to tadalafil (generic Cialis)

7. **Tadalafil (generic 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 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) History of failure following a trial for at least 4 weeks, contraindication or intolerance to an alpha-adrenergic blocking medication [e.g., Cardura, Flomax, Hytrin , Rapaflo or Uroxatrol]

8. **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 concurrently receiving an alternative phosphodiesterase-5 enzyme inhibitor (e.g. Cialis, Levitra, Stendra, or Viagra).

**-AND-**

- c. History of trial/failure, contraindication or intolerance to vardenafil (generic Levitra)

**Authorization will be issued for 12 months.**

\*\*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:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place  
Cialis (brand only), Levitra (brand only), Staxyn and Viagra (brand only) are typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specific to determine coverage status.

### **4. References:**

1. Viagra prescribing information. New York, NY. Pfizer Inc. December 2017.
2. Cialis prescribing information. Indianapolis, IN. Eli Lilly and Company. February 2018.
3. Levitra prescribing information. Whippany, NJ. Bayer HealthCare Pharmaceuticals. November 2018.
4. Staxyn prescribing information. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. August 2017.
5. Caverject prescribing information. New York, NY. Pfizer Inc. December 2017.
6. Edex prescribing information. Malvern, PA. Endo Pharmaceuticals Inc. July 2018.
7. Muse prescribing information. Somerset, NJ. Meda Pharmaceuticals, Inc. June 2017.
8. Stendra prescribing information. Cranford, NJ. Mist Pharmaceuticals, LLC. August 2018.
9. Drug-Induced Sexual Dysfunction. Drugdex<sup>®</sup> Consults. Micromedex<sup>®</sup> Healthcare Series. Last Modified: May 11, 2016.
10. American Urological Association. Guideline on the Management of Benign Prostatic Hyperplasia (BPH). 2010, confirmed 2014.
11. Effects of Tadalafil on Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia in Men With or Without Erectile Dysfunction. Broderick, GA, et al. Urology. 2010;75; 1452-59.



Program	Notification – Oxford and ASO
<b>Change Control</b>	
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.
4/2019	Added step through corresponding generic for brand Cialis and brand Levitra. References updated.
4/2020	Updated references. Updated that Cialis (brand), Levitra (brand), Staxyn and Viagra (brand) are typically excluded from coverage. Added tried/failed criteria for Staxyn to criteria.