UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2119-8
Program	Prior Authorization/Medical Necessity - Erectile Dysfunction
Medication	Stendra® (avanafil)
P&T Approval Date	2/2017, 3/2018, 3/2019, 4/2020, 6/2021, 6/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Stendra (avanafil) is a phosphodiesterase 5 inhibitor (PDE5) indicated for the treatment of erectile dysfunction.

This prior authorization program is intended to encourage the use of lower cost alternatives. This program requires a member to try two alternative erectile dysfunction medications before providing coverage for Stendra.

2. Coverage Criteria[a]:

A. Stendra will be approved based on **ALL** of the following criteria:

1. Patient has an organic cause of erectile dysfunction [i.e.: diabetes mellitus, hypertension, atherosclerosis, drug induced*, hypercholesterolemia, renal insufficiency, neurological disease (e.g. 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. History of failure, contraindication, or intolerance to **two** of the following (document drug, date tried and reason for failure):

   a. tadalafil (generic Cialis)
   b. vardenafil (generic Levitra)
   c. sildenafil (generic Viagra)

-AND-

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

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Examples (not all-inclusive): spironolactone, thiazide diuretics (e.g. chlorthalidone, chlorothiazide, hydrochlorothiazide), methyldopa, 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 of opioids, estrogens, anti-androgens (e.g. bicalutamide, flutamide, nilutamide), luteinizing hormone releasing hormone agonists (leuprolide, histrelin, goserelin, triptorelin)

3. Additional Clinical Rules:

- 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.

4. References:

1. Stendra [package insert]. Freehold, NJ: Metuchen Pharmaceuticals, LLC; November 2022.
2. Drugs That May Cause Male Sexual Dysfunction. Pharmacist's Letter. Detail Document #220907. September 2006.
3. Burnett AL, Nehra A, Breau RH, et al. Erectile Dysfunction: AUA Guideline. American Urological Association. 2018.

Program	Prior Authorization/Medical Necessity – Stendra
Change Control	
Date	Change
2/2017	New program.
3/2018	Annual review. Clarified existing criteria with no change to intent and updated references.
3/2019	Changed the required step agents from brand Cialis to generic tadalafil and brand Levitra to generic vardenafil. Updated references.
4/2020	Updated references.
6/2021	Annual review. Updated references.
6/2022	Annual review. Updated references.
7/2023	Annual review. Updated references.
7/2024	Annual review. Updated references.