EXPRESS SCRIPTS®

PRIOR AUTHORIZATION POLICY

POLICY: Erectile Dysfunction – Stendra™ (avanafil tablets – Mist Pharmaceuticals, LLC)

TAC APPROVAL DATE: 08/22/2018

OVERVIEW

Stendra is a phosphodiesterase type 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction (ED).[1] Stendra and the other PDE5 inhibitors have the same mechanism of action in ED; they enhance the effect of nitric oxide by inhibiting PDE5, which degrades cyclic guanosine monophosphate (cGMP). cGMP is responsible for producing smooth muscle relaxation in the corpus cavernosum of the penis, which results in increased blood flow and erection. Sexual stimulation is required for all PDE5 inhibitors to be effective since it initiates the local release of nitric oxide. Though all PDE5 inhibitors have the same mechanism of action, they still differ with regards to some pharmacokinetic parameters. For example, compared with the other agents, Stendra has a faster onset of action and can be taken as early as ~15 minutes before sexual activity.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Stendra. All approvals are provided for the duration noted below.

Automation: When available, the ICD-9/ICD-10 codes for impotence of organic origin (ICD-9: 607.84) or male erectile dysfunction (ICD-10: N52.*) will be used for automation to allow approval of the requested medication. This automation is gender-selective and is not applicable for women; PDE5 inhibitor approval for use in women is always determined by prior authorization criteria.

Note: PDE5 inhibitors should not be administered, either regularly or intermittently, with concomitant nitrate therapy. Patients will be informed of the consequences should they initiate nitrate therapy while taking a PDE5 inhibitor.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Stendra is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Erectile Dysfunction (ED)**. Approve for 1 year.

   Stendra is indicated for the treatment of ED.[1]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Stendra has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Benign Prostatic Hyperplasia (BPH).** There are no data available with the use of Stendra for BPH.

2. **Prophylaxis of Erectile Dysfunction (ED) after Radical Prostatectomy.** The efficacy of Stendra for the treatment of ED after nerve-sparing radical prostatectomy has been demonstrated in a Phase III study.[2] There are no data available for the prophylactic use (early penile rehabilitation) of Stendra in this patient population.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

References

1. Stendra™ tablets [prescribing information]. Cranford, NJ: Mist Pharmaceuticals, LLC; August 2018.
2. Mulhall JP, Burnett AL, Wang R, et al. A Phase 3, placebo controlled study of the safety and efficacy of avanafil for the treatment of erectile dysfunction after nerve sparing radical prostatectomy. *J Urol.* 2013;189:2229-2236.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
DEU revision	Changed automation section to include reference to ICD-10 code. The specific ICD-9 code was removed for diabetes and only the indication is listed.	10/12/2015
Annual revision	No criteria changes	11/11/2015
Selected revision	Approval duration changed back to 1 year for all indications.	12/02/2015
Selected revision	Removed automation which used ICD-9/ICD-10 codes (when available) for diabetes or claims history for diabetes medications (oral or insulin) as surrogate marker for ED. The new automation will use ICD-9 and/or ICD-10 codes for male erectile dysfunction when available. This new automation will be in effect 4/1/2016.	03/16/2016
Early annual revision	Deleted "Men with" from Erectile Dysfunction indication; also deleted Raynaud's phenomenon, pulmonary arterial hypertension, women, women with antidepressant-associated sexual dysfunction, female sexual arousal disorder, premature ejaculation, penile rehabilitation for erectile dysfunction of nonsurgical etiology indications from Conditions Not Recommended for Approval.	08/03/2016
Annual revision	No criteria changes	08/09/2017
Annual revision	No criteria changes	08/22/2018

TAC – Therapeutic Assessment Committee; NA – Not applicable; DEU – Drug Evaluation Unit; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.