



TENNCARE POLICY MANUAL

Policy No: BEN 06-001 (Rev 9)	
Subject: Erectile Dysfunction (ED) Medications	
Approval: <i>Renee Williams - Clark</i>	Date: 11-27-19

PURPOSE:

The purpose of this policy is to clarify TennCare's coverage of erectile dysfunction (ED) medications.

POLICY:

As permitted by federal statute,¹ the Division of TennCare does not cover any pharmaceuticals prescribed for the treatment of male impotence.² This exclusion extends to all forms of ED agents and devices, including—but not limited to—the following:

- Oral medications approved by the Food and Drug Administration (FDA),³ such as Viagra® (sildenafil citrate), Levitra® (vardenafil), Stendra® (avanafil), and Cialis® (tadalafil)
- Oral medications not approved by the FDA, such as Yocon® (yohimbine hydrochloride)
- Urethral pellets, such as Muse® (alprostadil), and implantable devices
- Intercavernous injections, such as Edex® and Caverject® (both alprostadil)
- Dietary supplements

Sildenafil citrate and tadalafil are used in certain pharmaceuticals designed to treat ED, as well as in pharmaceuticals prescribed for medical conditions known as pulmonary arterial hypertension (PAH) and benign prostatic hyperplasia (BPH). Prescriptions for pharmacy compounds containing sildenafil citrate will be approved only for the treatment of PAH, while compounds containing tadalafil will only be approved for the treatment of BPH and PAH, and only in those cases where the patient is unable to take a commercially available product (i.e., the patient is unable to swallow tablets, requires a medication

¹ 42 U.S.C. § 1396r-8(d)(2) lists several types of drugs that Medicaid programs may exclude from coverage, one of which is "[a]gents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration." 42 U.S.C. § 1396b(i)(21), furthermore, precludes the use of Federal Financial Participation (FFP) for ED drugs. State Medicaid Director Letter (SMDL) #05-006 provides additional guidance on these issues.

² See TennCare Rules 1200-13-13-.04(1)(c)2 and 1200-13-14-.04(1)(c)2, as well as TennCare Rules 1200-13-13-.10(3)(b)73 and 1200-13-14-.10(3)(b)73.

³ The FDA publishes materials about drug safety—including a list of approved medications—online at <http://www.fda.gov/Drugs/DrugSafety/default.htm>.

strength that is not commercially available, or has a documented allergy to an excipient). Such prescriptions, furthermore, must be filled using the bulk chemical powder forms of sildenafil citrate and tadalafil, if available, instead of commercially available products.

PROCEDURES:

Prescriptions for commercially available dosage forms of ED medications

- Medications prescribed for ED will be denied at the point of sale as non-covered products.
- Requests for medications that have FDA-approved indication(s) for PAH and/or BPH, in addition to ED, will require a prior authorization to ensure that the use is not for ED.
- If a physician requests authorization from the Pharmacy Benefits Manager's (PBM's) call center to treat PAH or BPH with an agent that has not been approved by the FDA for that purpose, a pharmacist at the call center will inform the physician that the medication in question is not classified as a "preferred agent" on TennCare's Preferred Drug List (PDL),⁴ and will recommend a medication approved by the FDA for that treatment as an alternative.

Prescriptions for pharmacy compounds containing ED medications

All prescriptions for pharmacy compounds used to treat PAH must have prior approval. Once prior approval is in place, additional elements of each prescription will be adjudicated as follows:

- Prescriptions for compounds filled with sildenafil citrate powder or tadalafil powder will be paid.
- Prescriptions for compounds filled with commercially available products will be rejected as requiring additional prior approval. A pharmacist with the PBM's call center will explain to the provider that TennCare prefers the use of sildenafil citrate powder or tadalafil powder, if available.

OFFICES OF PRIMARY RESPONSIBILITY:

Pharmacy Division
Office of the Chief Medical Officer

REFERENCES:

<https://www.gpo.gov/fdsys/pkg/USCODE-2015-title42/pdf/USCODE-2015-title42-chap7-subchapXIX-sec1396b.pdf>

42 U.S.C. § 1396b

<https://www.gpo.gov/fdsys/pkg/USCODE-2015-title42/pdf/USCODE-2015-title42-chap7-subchapXIX-sec1396r-8.pdf>

42 U.S.C. § 1396r-8

⁴ TennCare's PDL is located online at

https://tenncare.magellanhealth.com/static/docs/Preferred_Drug_List_and_Drug_Criteria/TennCare_PDL.pdf.

<https://www.cms.gov/smdl/downloads/SMD122905.pdf>

State Medicaid Director Letter (SMDL) #05-006

<https://publications.tnsosfiles.com/rules/1200/1200-13/1200-13-13.20190403.pdf>

TennCare Rule 1200-13-13-.04(1)(c)2

TennCare Rule 1200-13-13-.10(3)(b)72

<https://publications.tnsosfiles.com/rules/1200/1200-13/1200-13-14.20190403.pdf>

TennCare Rule 1200-13-14-.04(1)(c)2

TennCare Rule 1200-13-14-.10(3)(b)72

<http://www.fda.gov/Drugs/DrugSafety/default.htm>

FDA Webpage on Drug Safety

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111085.htm>

FDA Index to Drug-Specific Information

<http://www.accessdata.fda.gov/scripts/cder/daf/>

FDA Approved Drug Products

https://tenncare.magellanhealth.com/static/docs/Preferred_Drug_List_and_Drug_Criteria/TennCare_PDL.pdf

TennCare Preferred Drug List

Original: 01/26/06: KML

Revision 1: 04/15/08: KML

Reviewed / No changes: 03/12/09: KML

Revision 2 / No changes to policy language: 05/19/10: KML

Revision 3: 07/08/11: JTR

Revision 4: 07/30/12: JTR

Revision 5: 04/12/13: JTR

Revision 6: 12/12/13: JTR

Revision 7: 01/08/15: JTR

Revision 8: 02/28/17: LSH

Revision 9: 11/22/19: JHG