



TENNCARE POLICY MANUAL

Policy No:	BEN 06-001 (Rev 3)	
Subject:	Erectile Dysfunction (ED) Medications	
Approval:	<i>Nicole C. Woods</i>	Date: 7/8/11

PURPOSE:

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

POLICY:

As permitted by federal statute¹, the Bureau of TennCare does not cover any drug prescribed for the treatment of male impotence.² This exclusion extends to all forms of ED agents, including the following:

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

Viagra® is occasionally prescribed to treat a medical condition known as pulmonary arterial hypertension (PAH). Any TennCare enrollees previously prescribed and currently taking Viagra® for PAH may continue to have their prescriptions covered. New prescriptions for Viagra®—whether for PAH or for any other condition—will be denied. Instead, TennCare will recommend that the prescribing physician substitute the drug Revatio®, which contains the same active ingredient as Viagra®, to treat patients with PAH.

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)72 and 1200-13-14-.10(3)(b)72.

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

Prescriptions for pharmacy compounds containing sildenafil, the active ingredient in Viagra® and Revatio®, will be approved only for the treatment of PAH. Such prescriptions, furthermore, must be filled using sildenafil citrate bulk chemical powder instead of Revatio® or Viagra® tablets, unless the prescribing physician provides a clinical reason that the powder cannot be used. Viagra® tablets will then be used to fill prescriptions for pharmacy compounds, unless the prescribing physician provides a clinical reason that Revatio® tablets must be used.

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.
- Viagra® prescribed for PAH will be denied at the point of sale as a non-covered product, unless the recipient's use of the drug began prior to the availability of Revatio®. If a physician requests authorization from the Pharmacy Benefits Manager's (PBM's) call center to treat PAH with Viagra®, a pharmacist at the call center will inform the physician that Viagra® is not on TennCare's Preferred Drug List (PDL)⁴ and will recommend Revatio® as an alternative.
- Viagra® prescribed for PAH will be approved at the point of sale only for patients who have historically been authorized to take the drug and who have consistently done so. (New PAH patients, by contrast, will not have a previous fill for Viagra®, and the prescription will be denied.)

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 powder will be paid.
- Prescriptions for compounds filled with Viagra® tablets 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 powder.
- Prescriptions for compounds filled with Revatio® tablets 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 powder (with Viagra® tablets as the preferred alternative if there is a clinical reason that the powder cannot be used).

OFFICES OF PRIMARY RESPONSIBILITY:

Pharmacy Division
Office of the Medical Director

⁴ TennCare's PDL (located online at <https://tnm.rxportal.sxc.com/rxclaim/TNM/PDLtable.htm>) has four preferred agents for the treatment of PAH: Adcirca, Revatio, Tracleer, and Ventavis. Of these, however, only Revatio contains the same active ingredient as Viagra.

REFERENCES:

[http://frwebgate.access.gpo.gov/cgi-bin/usc.cgi?ACTION=RETRIEVE&FILE=\\$\\$xa\\$\\$busc42.pt1.wais&start=20590431&SIZE=269188&TYPE=PDF](http://frwebgate.access.gpo.gov/cgi-bin/usc.cgi?ACTION=RETRIEVE&FILE=$$xa$$busc42.pt1.wais&start=20590431&SIZE=269188&TYPE=PDF)
42 U.S.C. § 1396b

[http://frwebgate.access.gpo.gov/cgi-bin/usc.cgi?ACTION=RETRIEVE&FILE=\\$\\$xa\\$\\$busc42.pt1.wais&start=21664514&SIZE=108733&TYPE=PDF](http://frwebgate.access.gpo.gov/cgi-bin/usc.cgi?ACTION=RETRIEVE&FILE=$$xa$$busc42.pt1.wais&start=21664514&SIZE=108733&TYPE=PDF)
42 U.S.C. § 1396r-8

<https://www.cms.gov/smdl/downloads/SMD122905.pdf>
State Medicaid Director Letter (SMDL) #05-006

<http://www.tn.gov/sos/rules/1200/1200-13/1200-13.htm>
TennCare Rule 1200-13-13-.04(1)(c)2
TennCare Rule 1200-13-13-.10(3)(b)72
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/drugsatfda/index.cfm>
FDA Approved Drug Products

<https://tnm.rxportal.sxc.com/rxclaim/TNM/PDLtable.htm>
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