

# Geisinger Health Plan Policies and Procedure Manual

Policy: MP078

**Section: Medical Benefit Policy** 

**Subject: Sexual Dysfunction Therapies** 

Applicable line of business:

- Ipproduction and or adjustment of				
Commercial	X	Medicaid	X	
Medicare	Х	ACA	Х	
CHIP	Х			

I. Policy: Sexual Dysfunction Therapies

# II. Purpose/Objective:

To provide a policy of coverage regarding Sexual Dysfunction Therapies

### III. Responsibility:

- A. Medical Directors
- B. Medical Management

# IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary.

#### Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

#### Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

#### CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

#### Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

## V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

# **Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking
  into account both the functional capacity of the Member and those functional capacities that are appropriate for
  Members of the same age

## **DESCRIPTION:**

Sexual dysfunction describes any of a group of sexual disorders characterized by the inhibition of sexual desire or the physiological changes that characterize inhibition of sexual response. Impotency is a form of sexual dysfunction characterized by the inability to achieve and/or maintain penile erection sufficient to engage in sexual intercourse. Sexual dysfunction may be associated with complaints of decreased arousal, diminished vaginal lubrication, difficulty or inability to achieve orgasm, and discomfort with intercourse.

#### THERAPIES:

<u>Medications</u>: Medications for the treatment of erectile dysfunction are **excluded** and **NOT COVERED** for all lines of business unless specifically addressed in the applicable benefit document. For members with contracts that do not exclude these medications, coverage is subject to existence of a pharmacy benefit, and to the terms of the member's pharmacy benefit plan. Self-administered medications for the treatment of impotence are managed by the Geisinger Health Plan Pharmacy Department. Applicable co-payments and/or deductibles also apply per the member's pharmacy benefit plan.

# **External Devices:**

Coverage is subject to the terms, limitations and/or exclusions specific to the member's benefit document or applicable rider.

**Commercial group and non-group**: services, devices and equipment related to sexual dysfunction, male or female, are **excluded** and are **NOT COVERED** per the applicable benefit document section titled "Exclusions".

For members with contracts that do not exclude such devices, external penile vacuum constriction devices may be covered when prescribed by a Plan physician as an alternative to other therapies for the treatment of impotence.

# **Medicare Business Segment:**

External Vacuum Erection Devices (VED) (L7900) or Constriction Rings (L7902) (e.g., ErecAid) For dates of service on or after July 1, 2015, codes L7900 and L7902 are statutorily non-covered based on the Achieving a Better Life Experience (ABLE) Act of 2014 (see Social Security Act 1834(a)(1)(I)).

## Implantable Devices:

**Commercial group and non-group**: implantable devices related to sexual dysfunction, are **excluded** and are **NOT COVERED** per the applicable benefit document section titled "Exclusions".

For members with contracts that do not exclude implantable devices for the treatment of sexual dysfunction, coverage is subject to the terms, limitations and/or exclusions specific to the member's benefit document. When not specifically excluded, surgically implantable inflatable or non-inflatable penile prosthetic devices are considered medically necessary when:

Impotence is organic in nature; and

• The member has failed other treatment options, or other treatment options are contraindicated, including but not limited to injections or vacuum pump.

Surgical repair, removal and/or replacement may be necessary due to malfunction of the prosthesis or patient complications. Unless excluded by benefit contract, these services are considered medically necessary and are covered.

## **EXCLUSIONS:**

For group and non-group members, sexual dysfunction services, devices and equipment are excluded and are not covered per the applicable benefit document section titled "Exclusions" unless explicitly provided under the terms of a Rider and listed on the current face sheet.

<u>Clitoral stimulation devices</u> (e.g., Eros clitoral stimulation device). There is insufficient peer reviewed literature to support the efficacy of this treatment at this time. The device is considered **Unproven** and is **NOT COVERED**.

<u>Penile revascularization surgery</u> is considered **Unproven** and is **NOT COVERED.** There is insufficient evidence in the published, peer-reviewed medical literature to support the safety and efficacy of this procedure.

Extracorporeal shock wave therapy (ESWT) for treatment of erectile dysfunction is considered **Unproven** and is **NOT COVERED**. There is insufficient evidence in the published, peer-reviewed medical literature to support the safety and efficacy of this procedure.

Stem cell therapy) for treatment of erectile dysfunction is considered **Unproven** and is **NOT COVERED**. There is insufficient evidence in the published, peer-reviewed medical literature to support the safety and efficacy of this procedure.

Surgical and/or laser vaginal rejuvenation (eg, Mona Lisa procedure) for treatment of female sexual dysfunction is considered **Unproven** and is **NOT COVERED**. There is insufficient evidence in the published, peer-reviewed medical literature to support the safety and efficacy of this procedure.

Penile traction therapy (e.g., RestoreX) is considered to be unproven for the management of Peyronie's disease or other conditions. There is insufficient evidence in the published, peer-reviewed medical literature to support the safety and efficacy to support use of this device.

Surgically implanted penile prosthetic devices for the treatment of psychogenic erectile dysfunction is considered not medically necessary and is **NOT COVERED** 

# **Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

### **CODING ASSOCIATED WITH: Sexual Dysfunction Therapies**

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at <a href="https://www.cms.gov">www.cms.gov</a> or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- L7900 Vacuum erection system
- L7902 Tension ring, for vacuum erection device, any type, replacement only, each
- 54400 Insertion of penile prosthesis, non-inflatable (semi-rigid)
- 54401 Insertion of penile prosthesis, inflatable (self-contained)
- 54405 Insertion of inflatable (multi-component) penile prosthesis including placement of pump, cylinders and/or reservoir
- 54406 Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
- 54408 Repair of components of a multi-component inflatable penile prosthesis
- 54410 Removal and replacement of all components of a multi-component, inflatable penile prosthesis at the same operative session

through an infected field, at the same operative session, including irrigation and debridement of infected tissue

54415 Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis

54416 Removal of a non-inflatable (semi-rigid) or inflatable (self contained) penile prosthesis without replacement

54417 through an infected field

0864T Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy new code 2024

C1813 Prosthesis, penile, inflatable

C2622 Prosthesis, penile, non-inflatable

S4988 Penile contracture device, manual, greater than 3 lbs traction force

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

## **LINE OF BUSINESS:**

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

#### **REFERENCES:**

Billups KL. Berman L. Berman J. Metz ME. Glennon ME. Goldstein I. "A New Non-pharmacological Vacuum Therapy for Female Sexual Dysfunction", *Journal of Sex & Marital Therapy*. 27(5):435-41, 2001 Oct-Dec.

Phillips NA. "Female Sexual Dysfunction: Evaluation and Treatment", *American Family Physician*. 62(1):127-36, 141-2, 2000 Jul 1.

Josefson D. "FDA Approves Device for Female Sexual Dysfunction", BMJ. 320(7247):1427, 2000 May 27.

Goldstein I. Berman JR. "Vasculogenic Female Sexual Dysfunction: Vaginal Engorgement and Clitoral Erectile Insufficiency Syndromes", *International Journal of Impotence Research*. 10 Suppl 2:S84-90; discussion S98-101, 1998 May.

Burchardt M. Burchardt T. Baer L. Kiss AJ. Pawar RV. Shabsigh A. de la Taille A. Hayek OR. Shabsigh R. "Hypertension is Associated with Severe Erectile Dysfunction", *Journal of Urology*. 164(4):1188-91, 2000 Oct.

Lue TF. "Erectile Dysfunction". New England Journal of Medicine. 342(24):1802-13, 2000 Jun 15.

Romeo JH. Seftel AD. Madhun ZT. Aron DC. "Sexual Function in Men with Diabetes Type 2: Association with Glycemic Control", *Journal of Urology*. 163(3):788-91, 2000 Mar.

Morgentaler A. "Male Impotence". Lancet. 354(9191):1713-8, 1999 Nov 13.

Sexual Dysfunction in Men. Merck Manual. Section 14, Ch115. <a href="http://www.merck.com/pubs/mm\_geriatrics/sec14/ch115.htm">http://www.merck.com/pubs/mm\_geriatrics/sec14/ch115.htm</a>

Montague DK., "Nonpharmacologic Treatment of Erectile Dysfunction", Reviews in Urology.4: Suppl. 3, S9-S16.

Mangir N, Turkeri L. Stem cell therapies in post-prostatectomy erectile dysfunction: A critical review. Can J Urol. 2017;24(1):8609-8619.

Fojecki GL, Tiessen S, Osther PJ. Effect of low-energy linear shockwave therapy on erectile dysfunction -- A double-blinded, sham-controlled, randomized clinical trial. J Sex Med. 2017;14(1):106-112

Man L, Li G. Low-intensity extracorporeal shock wave therapy for erectile dysfunction: A systematic review and metaanalysis. Urology. 2017 Sep 26

Wong C, Louie DR, Beach C. A systematic review of pelvic floor muscle training for erectile dysfunction after prostatectomy and recommendations to guide further research. J Sex Med. 2020 Feb 3

Noridian DME Jurisdiction A. L34824/ A52712 Vacuum Erection Devices (VED)

Joseph J, Ziegelmann MJ, Alom M, et al. Outcomes of RestoreX penile traction therapy in men with Peyronie's disease: Results from open label and follow-up phases. J Sex Med. 2020;17(12):2462-2471.

Zganjar A, Toussi A, Ziegelmann M, et al. Efficacy of RestoreX after prostatectomy: Open-label phase of a randomized controlled trial. BJU Int. 2023;132(2):217-226.

Zganjar A, Toussi A, Ziegelmann M, et al. Efficacy of RestoreX after prostatectomy: Open-label phase of a randomized controlled trial. BJU Int. 2023;132(2):217-226.

Zhu Y, Jiang T, Yao C, et al. Effects of stem cell-derived exosome therapy on erectile dysfunction: A systematic review and meta-analysis of preclinical studies. Sex Med. 2023 Mar 1;11(2):qfac019.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 08/02

**Revised:** 10/02 (correction of GOLD exclusion for penile implant); 10/03 (Remove D.O.C.language from penile prosthesis section); 3/04 (contract exclusions added); 3/05 (clarify HMO exclusion language); 3/07(Clarify exclusion language); 3/08(subcert language); 3/10 (subcert language), 7/16 (Gender Language); 2/19 (add exclusions); 2/22 (Update Medicare VED exclusion) 2/25 (update Unproven language, add exclusion)

Reviewed: 3/06, 3/09, 3/11, 3/12, 3/13, 3/14, 3/15, 2/16; 2/17, 2/18, 2/20, 2/21, 2/23, 2/24

CMS UM Oversight Committee Approval: 12/23, 5/24, 4/25

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.