

Geisinger Health Plan Policies and Procedure Manual

Policy: MP244

Section: Medical Benefit Policy

Subject: Pelvic Floor Stimulation

Applicable Lines of Business

Commercial	Х	СНІР	X
Medicare	Х	ACA	X
Medicaid	Х		

I. Policy: Pelvic Floor Stimulation

II. Purpose/Objective:

To provide a policy of coverage regarding Pelvic Floor Stimulation

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.

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:

Pelvic Floor Stimulation (PFS) involves the electrical stimulation of the pelvic floor muscles using either a probe wired to a device for controlling the electrical stimulation or, more recently, extracorporeal pulsed magnetic innervation. It is believed that pelvic floor stimulation will improve urethral closure by activating pelvic floor musculature. In addition, PFS is also hypothesized to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinervation.

ALL Durable Medical Equipment provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are <u>NOT SEPARATELY REIMBURSABLE</u>. Pelvic floor stimulator must be obtained through a participating Durable Medical Equipment Vendor(s).

INDICATIONS: <u>Requires Prior Medical Director or Designee Authorization</u>. Consideration for coverage is limited to the Medicare and Medicaid Business Segment, in compliance with CMS mandates.

Electrical Stimulation of the pelvic floor muscles with a non-implantable stimulator may be considered *medically necessary* for the treatment of urinary incontinence in members when ALL of the following criteria are met:

- 1. Member is diagnosed with stress, urge or mixed incontinence; and
- 2. Member must be cognitively competent
- 3. Member has tried and failed a documented trial of pelvic muscle exercise (PME) training with no clinically significant improvement in urinary continence after completing 4 weeks of exercises.

NOTE: Stimulation of the sacral nerve as a treatment of incontinence is discussed in MP 91 - Sacral Nerve Stimulation

EXCLUSIONS:

The Plan does not cover pelvic floor stimulation for the treatment of incontinence unless required by state or federal mandate. Outcomes evidence from multiple randomized, controlled trials have not found that electrical pelvic floor stimulation used to treat urinary incontinence in women consistently improved net health outcome compared with placebo or other conservative treatments, nor did it support the efficacy of this treatment in members with post-prostatectomy incontinence. It is considered **experimental, investigational or unproven** and therefore, **NOT COVERED.**

The Plan does **NOT** provide coverage for the use of the Omnistim[™] FX² Gold portable system because it is considered **experimental**, **investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment when compared to established tests or technologies.

The Plan does **NOT** provide coverage for the use of magnetic stimulators of the pudendal nerve considered **experimental**, **investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment when compared to established tests or technologies.

The Plan does **NOT** provide coverage for the use of pelvic floor stimulation for the treatment of refractory chronic urinary retention unless required by state or federal mandate because it is considered **experimental**, **investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment when compared to established tests or technologies.

<u>Note:</u> 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.**

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.

CODING ASSOCIATED WITH: Pelvic Floor Stimulation

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.

- **53899** Unlisted procedure, urinary system
- 97014 Application of a modality to one or more areas; electrical stimulation (unattended)
- **97032** Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes
- E0740 Incontinence treatment system; pelvic floor stimulator, monitor, sensor and/or trainer
- **G0283** Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

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

LINE OF BUSINESS:

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

REFERENCES:

National Institute for Health and Clinical Excellence (NICE). Clinical Guideline 40. Urinary incontinence: the management of urinary incontinence in women, October 2006. Available at: <u>www.nice.org.uk</u>

Shamliyan TA, Kane RL, Wyman J et al. Systematic review: randomized, controlled trials of nonsurgical treatments for urinary incontinence in women. Ann Intern Med 2008; 148(6):459-73.

McClurg D, Ashe RG, Lowe-Strong AS. Neuromuscular electrical stimulation and the treatment of lower urinary tract dysfunction in multiple sclerosis--a double blind, placebo controlled, randomized clinical trial. Neurourol Urodyn 2008; 27(3):231-7.

NIH state-of-the-science conference statement on prevention of fecal and urinary incontinence in adults. NIH Consens State Sci Statements 2007; 24(1):1-37.

Suzuki T, Yasuda K, Yamanishi T, et al. Randomized, double-blind, sham-controlled evaluation of the effect of functional continuous magnetic stimulation in patients with urgency incontinence. *Neurourol Urod;* 2007;26(6):767-72.

Hayes, Inc. Medical Technology Directory. Extracoporeal Magnetic Stimulation for Urinary Incontinence. Lansdale, PA: Hayes, Inc. July 17, 2003.

Voorham-van der Zalm PJ, Pelger RC, Stiggelbout AM, et al. Effects of magnetic stimulation in the treatment of pelvic floor dysfunction. BJU Int. 2006;97(5):1035-1038.

Hunter KF, Moore KN, Glazener CMA. Conservative management for postprostatectomy urinary incontinence. Cochrane Database of Systematic Reviews 2007, Issue 2.

California Technology Assessment Forum (CTAF). Electrical Stimulation for the Treatment of Urinary Incontinence in Women. October 20, 2004. Accessed August 19, 2010. Available at URL address: http://ctaf.org/content/general/detail/540

Goode P, Burgio K, Lovcher J, Roth D, Umlauf M, Richter H. et al., Varner R, Lloyd L. Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. JAMA. 2003 Jul;290(3):395-7.

Wang, A.C., Wang, Y.Y., et al. Single-blind, randomized trial of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in the management of overactive bladder. Urology (2004) 63(1):61-6.

Demurturk F Akbayrak T, et al. Interferential current versus biofeedback results in urinary stress incontinence. Swiss Med Weekly2008 May 31;138(21-22):317-21.

Kajbafzadeh AM, Sharifi-Rad L, Baradaran N at al. Effect of pelvic floor interferential electrostimulation on urodynamic parameters and incontinency of children with myelomeningocele and detrusor overactivity. *Urology.* 2009 Aug;74(2):324-9. Epub 2009 May 24

Mariotti G, Sciarra A, Gentilucci A at al. Early recovery of urinary continence after radical prostatectomy using early pelvic floor electrical stimulation and biofeedback associated treatment. *J Urol.* 2009 Apr;181(4):1788-93. Epub 2009 Feb 23

Gilling PJ, Wilson LC, Westenberg AM at al. A double-blind randomized controlled trial of electromagnetic stimulation of the pelvic floor vs sham therapy in the treatment of women with stress urinary incontinence. *BJU Int.* 2009 May;103(10):1386-90. Epub 2009 Jan 14

CMS: National Coverage Determinations (NCDs). Non-Implantable Pelvic Floor Electrical Stimulator (230.8) Available at: <u>http://www.cms.hhs.gov</u>. Accessed May 2009.

Hayes, Inc. Medical Technology Directory. Extracoporeal Magnetic Stimulation for Urinary Incontinence. Lansdale, PA: Hayes, Inc. July 17, 2003.

American College of Obstetricians and Gynecologists (ACOG). *Urinary Incontinence*. ACOG Technical Bulletin No. 213. Washington, DC: American College of Obstetricians and Gynecologists; October 1995. Available at: <u>http://www.acog.org</u>.

U.S. Food and Drug Administration (FDA). 510(k) summary for Neotonus PNS Magnetic Stimulator System. Sep 14, 2000. Accessed August 20, 2010. Available at URL address: <u>http://www.fda.gov/cdrh/pdf/K002889.pdf</u>

U.S. Food and Drug Administration (FDA). 510(k) summary for NeoControl[®] Pelvic Floor System. Jun 21, 2000. Accessed August 20, 2010. Available at URL address: <u>http://www.fda.gov/cdrh/pdf/k001903.pdf</u>

U.S. Food and Drug Administration (FDA). Controlling urinary incontinence. Sept-Oct 2005. Accessed August 20, 2010. Available at URL address: <u>http://www.fda.gov/fdac/features/2005/505_incontinence.html#devices</u>

U.S. Food and Drug Administration (FDA). 510(k) summary. Magstim Company Ltd – Magstim Rapid² and Magstim Super Rapid². Dec 21, 2005. Accessed August 20, 2010. Available at URL address: <u>http://www.fda.gov/cdrh/pdf/k001903.pdf</u>

Imamura M, Abrams P, Bain C et al. Systematic review and economic modeling of the effectiveness and costeffectiveness of non-surgical treatments for women with stress urinary incontinence. Health Technology Assessment 2010; Volume 14, No. 40.

Shamliyan T, Wyman J, Kane R. Agency for Healthcare Research and Qualtiy (AHRQ): Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness. 2012.

Rickey LM. Chronic urinary retention in women. Uptodate. Last reviewed Nov. 14, 2017.

Stoffel JT, Peterson AC, Sandhu JS, et al. AUA White Paper on Nonneurogenic Chronic Urinary Retention: Consensus Definition, Treatment Algorithm, and Outcome End Points. J Urol 2017; 198:153.

Sciarra A, Viscuso P, Arditi P, et al. A biofeedback-guided programme or pelvic floor muscle electric stimulation can improve early recovery of urinary continence after radical prostatectomy: A meta-analysis and systematic review. Int J Clin Pract.2021;75(10):e14208.

Firinci S, Yildiz N, Alkan H, Aybek Z. Which combination is most effective in women with idiopathic overactive bladder, including bladder training, biofeedback, and electrical stimulation? A prospective randomized controlled trial. Neurourology and urodynamics.2020;39(8):2498-50

Stania M, Niemiec B, Kamieniarz A, et al. Intravaginal electrical stimulation as a monotherapy for female stress urinary incontinence: A systematic review and metaanalysis. Complement Ther Clin Pract. 2022;49:101624

Leonardo K, Seno DH, Mirza H, et al. Biofeedback-assisted pelvic floor muscle training and pelvic electrical stimulation in women with overactive bladder: A systematic review and meta-analysis of randomized controlled trials. Neurourology and urodynamics.2022;41(6):1258-69

Ignacio Antonio F, Bo K, Pena CC, et al. Intravaginal electrical stimulation increases voluntarily pelvic floor muscle contractions in women who are unable to voluntarily contract their pelvic floor muscles: a randomised trial. J Physiother. 2022;68(1):37-42.

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

Revised: 4/15 (added exclusion), 7/16 (Gender Language), 9/17 (member language), 9/18 (add exclusion)

Reviewed: 10/11, 10/12, 10/13, 10/14, 9/19, 9/20, 9/21, 9/22, 9/23

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.