Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/24**
(See policy history boxes for previous effective dates)

Title: Magnetic Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

Description/Background

Incontinence, especially urinary, is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 44% have reported issues with urinary incontinence and 17% issues with fecal incontinence.[1]

Treatment

Nonsurgical treatment options for incontinence may include pharmacologic therapy, pelvic floor muscle exercises, bowel or bladder training exercises, electrical stimulation, magnetic stimulation and neuromodulation.

Pelvic Floor Stimulation

Pelvic floor stimulation (PFS) has been investigated as a method of modifying bladder and urinary sphincter behavior to decrease or eliminate urge, stress and mixed forms of urinary incontinence. Magnetic PFS involves the stimulation of pelvic floor muscles using extracorporeal pulsed magnetic innervation. It is thought that pelvic floor stimulation of the pudendal nerve will improve urethral closure by activating the pelvic floor musculature. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. Extracorporeal Magnetic Innervation (ExMI) involves pulsed magnetic stimulation of the sacral nerves and/or pudendal nerves, with the goal of rehabilitating the pelvic floor musculature to reduce urinary incontinence. Typically, the patient sits fully clothed in a treatment chair while the electromagnetic field is generated from a magnetic stimulator located beneath the pelvic floor and controlled by an external power unit.

Variation in the amplitude and frequency of the electromagnetic pulse is used to mimic and stimulate the different physiologic mechanisms of the voiding response, depending on the etiology of the incontinence, i.e., either detrusor instability, stress incontinence or a mixed pattern.

Magnetic pelvic floor stimulation does not require an internal electrode. Magnetic PFS, also referred to as electromagnetic stimulation (EMS), may be administered in the physician's office. Patients may sit fully clothed on a specialized chair. This chair contains a device that generates a magnetic field that induces contraction of the pelvic floor, levator ani complex, vaginal vault, as well as the internal and external sphincter muscles. The magnetic field is applied in a "pulsed" fashion resulting in intermittent contraction followed by relaxation of the pelvic muscles to build strength, endurance, and continence over the course of therapy. The NeoControl® Pelvic Floor Therapy System is a type of electromagnetic PFS device.

No controlled studies were found in the published literature demonstrating that pelvic floor stimulation can improve the frequency of incontinence and improve quality of life. Pelvic floor stimulation does not meet any of the following technology evaluation criteria:

- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
- The technology must improve the net health outcome.
- The technology must be as beneficial as any established alternatives.
- The improvement must be attainable outside the investigational settings.

Regulatory Status:

In June 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus, Inc) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for treating urinary incontinence in women. This device was formerly known as the Neotonus Model 1000 Magnetic Stimulator, and it provides noninvasive electromagnetic stimulation of pelvic floor musculature. The magnetic system is embedded in a chair seat; patients sit on the chair fully clothed and receive the treatment. The magnetic fields are controlled by a separate power unit.

Medical Policy Statement

Magnetic stimulation of pelvic floor muscles (also known as electromagnetic stimulation or EMS) for the treatment of urinary incontinence is experimental/investigational. While this service may be safe, current medical literature does not support the clinical efficacy of this procedure.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

53899

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

MAGNETIC PELVIC FLOOR STIMULATION FOR URINARY INCONTINENCE

Clinical Context and Therapy Purpose

The purpose of magnetic pelvic floor stimulation (PFS) in individuals who have urinary incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Populations

The relevant populations of interest are patients with urinary incontinence. Types of urinary incontinence include stress incontinence, urgency incontinence, and mixed (both stress and urgency). Urinary incontinence in women is common, with some estimates citing a 50% incidence. Factors that increase a woman's risk include older age, obesity, parity, vaginal delivery, and family history. Urinary incontinence is less common in men, with estimates ranging from 11% to 34% in men greater than 65 years. Factors that increase a man's risk

include older age, prostate disease, urinary tract infection history, impaired activities of daily living, neurologic disease, constipation, diabetes, and sleep apnea.

Interventions
The therapy being considered is magnetic PFS for urinary incontinence. The mechanism of action of a magnetic PFS procedure is similar to the electrical procedure, though using magnetic pulses to activate the pelvic floor musculature. The magnetic pulses are delivered without a probe, with patients sitting fully clothed in a specialized chair with an embedded magnet. Magnetic PFS is administered in a physician's office or a physical therapy facility. Patients may also be trained on the use of a rental PFS system to continue treatments at home.

Comparators
The following therapies are currently being used to make decisions about urinary incontinence: electrical PFS and behavioral therapies (e.g., monitoring fluid intake, pelvic floor muscle training, diet), and medications.

Outcomes
The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in QOL and cure rates. Treatment is for approximately eight weeks, and follow-up is generally up to six months.

Women

Systematic Reviews
A systematic review of RCTs on magnetic stimulation for treatment of urinary incontinence was published in 2015 by Lim et al.[1] Reviewers identified 8 blinded sham-controlled trials (total N=484). Treatment protocols (e.g., frequency, duration of electrical stimulation) varied among trials. The primary outcome was cure rate; only 1 trial reported this outcome, so data were not pooled. A meta-analysis of 3 studies reporting improvement in the continence rate found significantly greater improvement in the treatment group than in the sham group (RR=2.29; 95% CI, 1.60 to 3.29). Due to the variability across trials in types of incontinence treated and/or outcome reporting, data were also not pooled for other outcomes. Reviewers noted that the evidence was limited by low-quality trials with short-term follow-up.

Randomized Controlled Trials
In 2014, Yamanishi et al in Japan published an industry-sponsored evaluation of magnetic stimulation provided to women with urinary urgency using an armchair-type stimulator.[2] The device was produced by a Japanese company and does not appear to have Food and Drug Administration approval. Patients received active (n=101) or sham (n=50) stimulation, 2 times a week for 6 weeks. The level of stimulation was tailored to each patient’s maximum tolerable intensity; sham stimulation was set at a lower level than active treatment. Because noises differed between the 2 procedures, patients were isolated from the sounds to maintain blinding. Study personnel were not blinded. A total of 143 (95%) of 151 patients were included in the efficacy analysis. The primary end point was the change in the number of urinary incontinence episodes per week, as reported in a patient diary. The decrease in the weekly number (standard deviation) of incontinence episodes was 13 (11) in the active treatment group compared with 9 (13) in the sham group; the difference between groups was statistically significant (p=.038). Patients in the active stimulation group had significantly better results on

some secondary outcomes (e.g., number of urgency episodes per 24 hours), but not others (e.g., number of voids per 24 hours).

A 2009 sham-controlled randomized trial evaluating magnetic stimulation using the NeoControl chair did not find evidence that stimulation improved outcomes. In this trial, published by Gilling et al in New Zealand, sham treatment involved inserting a thin aluminum plate in the chair to prevent penetration of the magnetic field.[3] The trial included 70 women, 35 in each group, with stress or mixed urinary incontinence. Both groups received 3 treatment sessions per week for 6 weeks. There was no significant difference between the active and sham treatment groups for the primary outcome measure, change from baseline in the 20-minute pad test result to 8 weeks after the start of treatment (2 weeks after finishing treatment). At 8 weeks, the mean change in the 20-minute pad test was 20.1 mL in the treatment group and 7.5 mL in the control group. The groups also did not differ significantly in the 20-minute pad weight or quality of life measure at the 6-month follow-up. Data from 29 (83%) women in the active treatment group and 26 (74%) women in the sham group were available at 6 months; all participants appear to be included in the 8-week outcomes analysis.

Men With Post Prostatectomy Urinary Incontinence

Randomized Controlled Trial

One RCT was identified on magnetic stimulation for treating post prostatectomy urinary incontinence. The study was published in 2004 by Yokoyama et al and reported findings from a 3-arm randomized trial from Japan.[4] A total of 36 men (12 in each group) were randomized to receive extracorporeal magnetic stimulation (NeoControl chair), functional electrical stimulation, or pelvic floor exercises. The primary outcome was pad weight testing for up to 6 months after the 1-month treatment period. At 1 month after catheter removal, pad weight was significantly lower in the electrical stimulation group than the control group; at 2 months, pad weight was significantly lower in the magnetic stimulation group compared with the control group; and, beginning at 3 months, there were no significant differences in pad weight. There were no significant differences between groups in quality-of-life measures at any follow-up point. The trial lacked a sham magnetic stimulation group; also lacking was a placebo effect, which might at least partially explain the short-term reduction in pad weight in the magnetic stimulation treatment group.

SUMMARY OF EVIDENCE

For individuals who have urinary incontinence who receive magnetic PFS, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A systematic review of RCTs on magnetic PFS for urinary incontinence in women concluded that the evidence was insufficient due to the following factors: low number of trials with short-term follow-up, methodologic limitations, as well as heterogeneity in terms of patient populations, interventions, and outcomes reporting. Only 1 RCT evaluated magnetic stimulation for treating men with Post-prostatectomy urinary incontinence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association

In 2019, the American Urological Association (AUA) published guidelines on the diagnosis and management of overactive bladder.[6] Magnetic PFS was not mentioned as recommended first, second, or third-line treatment options.

Joint guidelines issued in 2019 by the AUA and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) on management of post-prostatectomy urinary incontinence did not specifically magnetic PFS as treatment options. Pelvic floor muscle training/exercise is recommended as first-line treatment for post-prostatectomy incontinence.[8]

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence (NICE) issued guidance on the management of urinary incontinence in women.[7] The NICE stated that electrical stimulation, alone or as an adjunct to pelvic floor muscle training, should not be routinely used to treat women with overactive bladder. The NICE guidance further stated: "electrical stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy." Magnetic PFS is not mentioned.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04644614	Effectiveness of magnetic stimulation in patients with urinary incontinence after radical prostatectomy, a prospective randomized sham controlled clinical study	40	Apr 2023
Unpublished			
NCT01924728[a]	A Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Investigate the Effects of Transpelvic Magnetic Stimulation (Using QRS®-1010 PelviCenter) in Patients with Stress Urinary Incontinence	120	Feb 2016 (completed)

NCT03969368	Randomized Trial of rPMS Pelvic Floor Stimulation Device Compared With Pelvic Floor Exercises for Treatment of Urinary Incontinence	60	Jun 2022

NCT: national clinical trial
[a] Denotes industry-sponsored or cosponsored trial.

Government Regulations

National: NCD for Non-implantable pelvic floor electrical stimulator (230.8). Effective 6/19/2006.[6]

Non-implantable pelvic floor electrical stimulators provide neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator.

The methods of pelvic floor electrical stimulation vary in location, stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration (duty cycle), treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings. In general, the stimulus frequency and other parameters are chosen based on the patient's clinical diagnosis.

Indications and Limitations of Coverage

Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.

A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

There is no mention of magnetic pelvic floor stimulation in the coverage guidelines.

Local:

There is no LCD on this topic. Defer to the NCD above.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Sacral Nerve Stimulation for Urinary Dysfunction
- Periurethral Injections for the Treatment of Urinary Incontinence
- Biofeedback

References

1. Lim R, Lee SW, Tan PY, et al. Efficacy of electromagnetic therapy for urinary incontinence: A systematic review. Neurourol Urodyn. Nov 2015;34(8):713-722. PMID 25251335
2. Yamanishi, T., et al. Comparative study of the effects of magnetic versus electrical stimulation on inhibition of detrusor over activity. *Urology*. Volume 56, Number 5, 2000, pp.777-781.
3. Gilling, P. J., et 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. Volume 103, Number 10, May 2009, Epub January 14, 2009, pp. 386-390.
4. Yokoyama T, Nishiguchi J, Watanabe T et al. Comparative study of effects of extracorporeal magnetic innervation versus electrical stimulation for urinary incontinence after radical prostatectomy. Urology 2004; 63(2):264-7.
5. Lucas MG, Bosch RJ, Burkhard FC, et al. EAU guidelines on assessment and nonsurgical management of urinary incontinence. Eur Urol. Dec 2012;62(6):1130-1142. PMID 22985745
6. Lightner DJ, Gomelsky A, Souter L, et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. J Urol. Sep 2019; 202(3): 558-563. PMID 31039103
7. National Institute for Health and Care Excellence (NICE) Guideline. Urinary Incontinence and Pelvic Organ Prolapse in Women: Management. NICE Guideline. 2019. Accessed November 3, 2022. https://www.nice.org.uk/guidance/ng123.
8. Sandhu JS, Breyer B, Comiter C, et al. Incontinence after Prostate Treatment: AUA/SUFU Guideline. J Urol. Aug 2019; 202(2): 369-378. PMID 31059663
9. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator (230.8).

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 25, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/20/04	7/20/04	7/21/04	Joint medical policy established
9/1/06	7/10/06	7/06/06	Routine maintenance; policy retired
11/1/07	8/21/07	10/20/07	Magnetic Pelvic Floor Stimulation piece made into a separate policy.
11/1/09	8/18/09	8/18/09	Routine maintenance; 0029T deleted, replaced by NOC 53899
9/1/12	6/12/12	6/19/12	Routine maintenance. References added; policy reformatted on new template.
1/1/14	10/17/13	10/25/13	Routine maintenance. No change in policy status.
3/1/16	12/10/15	12/10/15	Routine maintenance, references updated. No change in policy status.
3/1/17	12/13/16	12/13/16	Routine maintenance, updated rationale, references and Medicare sections.
3/1/18	12/12/17	12/12/17	Routine policy maintenance, rearranged references and eliminated some references. No change in policy status.
1/1/19	12/11/18		Rationale reorganized. No new references. No change in policy status.
3/1/20	12/17/19		Routine policy maintenance. No change in policy status.
3/1/21	12/15/20		Updated practiced guidelines, no change in policy status.
3/1/22	12/14/21		Routine policy maintenance. No change in policy status.
3/1/23	12/20/22		Routine policy maintenance. No change in policy status. (ky)
3/1/24	12/19/23		Routine policy maintenance. No change in policy status. Vendor: N/A. (ky)

Next Review Date: 4th Qtr. 2024

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 5/8/01	Revised: N/A
BCBSM: 4/30/00	Revised: 2/1/01

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MAGNETIC PELVIC FLOOR STIMULATION AS A TREATMENT OF URINARY INCONTINENCE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.