MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence**
Policy Number	**1.01.19**
Category	**Technology Assessment**
Original Effective Date	**10/18/01**
Committee Approval Date	**10/18/01, 07/18/02, 05/21/03, 06/17/04, 06/16/05, 06/15/06, 05/17/07, 05/14/08, 09/18/08, 09/17/09, 09/16/10, 09/15/11**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line*

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, pelvic floor electrical stimulation (PFES) does not improve patient outcomes and, therefore, is considered **not medically necessary**.

Refer to Corporate Medical Policy #1.01.01 Transcutaneous and Percutaneous Electrical Nerve Stimulation as a Treatment for Pain and Other Conditions

Refer to Corporate Medical Policy #7.01.10 Sacral Nerve Stimulation

DESCRIPTION

Urinary incontinence is defined by the International Continence Society (ICS) as "a condition in which involuntary loss of urine is a social or hygienic problem." The National Institute of Health (NIH) statistics indicate that urinary incontinence is estimated to affect 10-12 million people in the United States, two-thirds of whom are female.

Pelvic floor electrical stimulation (PFES) has been advocated as a treatment for urinary stress incontinence, urge incontinence, and incontinence due to detrusor instability. PFES is also being investigated as a treatment modality for patients with fecal incontinence due to pelvic floor dysfunction and has been proposed as a non-invasive alternative to surgical intervention for patients with damage to the anal sphincter.

PFES is the application of electrical current to the pudendal nerve. This electrical stimulation causes reflex contraction of the pelvic floor musculature (detrusor/bladder muscle and levator ani muscle). PFES is applied to the body using skin electrodes around the anus or by vaginal or rectal sensors (probes). PFES may be used alone or in conjunction with biofeedback or pelvic floor muscle exercises. The goal of PFES is to regain volitional control of the pelvic floor muscles through their passive activation. The patient should progress to regaining voluntary control of muscle contraction without stimulation, increasing the strength of pelvic floor muscles, thereby eliminating urinary leakage.

RATIONALE

While case series have reported promising outcomes of pelvic floor electrical stimulation, the evidence from these case series tends to overestimate the treatment effect. The studies do not account for placebo effects or for dropouts. Many of the studies investigating electrical stimulation as a treatment of urinary or fecal incontinence combined biofeedback and/or pelvic floor muscle exercises with electrical stimulation as the intervention, which makes it difficult to determine the independent effect of electrical stimulation alone. Published studies of randomized, controlled clinical trials investigating this treatment modality have reported inconsistent and/or inconclusive results. The evidence is insufficient to determine the effectiveness of pelvic floor electrical stimulation on urinary incontinence or fecal incontinence. Most of the published studies have not measured the effect of these devices on pelvic muscle strength, which is a measurement of the effectiveness of pelvic floor stimulation. There is insufficient evidence from clinical trials to determine whether electrical stimulation is more effective than pelvic floor muscle exercises or even sham electrical stimulation.

The American Urological Association does not have specific guidelines for the use of electrical stimulation for urinary incontinence. In the amended 2023 version it states that "Laser and magnetic/electrical stimulation therapy are emerging therapies for the treatment of SUI. However, evidence to date is inconsistent and of poor quality. The Panel acknowledges that these therapies exist and may offer some benefit in index SUI patients seeking non-surgical treatment. However, given the limitations in rigorous evidence-based data supporting their use and FDA advisory warning against the use of energy-based devices for "vaginal rejuvenation," patients should be extensively counseled on the immaturity of the data."

The National Institute of Health and Care Excellence (NICE) guideline (NG)123 Urinary incontinence and pelvic organ prolapse in women: management was updated June 24, 2019, and continues its guidelines from 2006 that state, electrical stimulation should not be used routinely in the treatment of overactive bladder or in combination with pelvic floor muscle training. Another guideline state that electrical stimulation and/or biofeedback should be considered for women who cannot actively contract pelvic floor muscles to aid motivation and adherence to therapy. NG120 Pelvic floor dysfunction: prevention and non-surgical management published on December 9, 2021 states for women who are unable to perform an effective pelvic floor muscle contraction, consider supplementing pelvic floor muscle training with biofeedback techniques, electrical stimulation or vaginal cones.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
97014*	Application of a modality to one (1) or more areas; electrical stimulation (unattended) (***NMN** for N39.3, N39.41-N39.498, R15.0-R15.9, R32)
97032*	Application of a modality to one (1) or more areas; electrical stimulation (manual), each 15 minutes (***NMN** for N39.3, N39.41-N39.498, R15.0-R15.9, R32)

HCPCS Codes

Code	Description
E0740 **(NMN)**	Non-implanted pelvic floor electrical stimulator, complete system

Code	Description
E0715 **(NMN)**	Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises *(effective 10/01/24)*
G0283*	Electrical stimulation (unattended), to one (1) or more areas for indication(s) other than wound care, as part of a therapy plan of care (***NMN** for N39.3, N39.41-N39.498, R15.0-R15.9, R32)

ICD10 Codes

Code	Description
N39.3 **(NMN)**	Stress incontinence (female) (male)
N39.41-N39.498 **(NMN)**	Other specified urinary incontinence (code range)
R15.0-R15.9 **(NMN)**	Fecal incontinence (code range)
R32 **(NMN)**	Unspecified urinary incontinence

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*Key Article

KEY WORDS

Intravaginal electrical stimulation

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator (230.8). Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=231&ncdver=2&bc=AgAAgAAAAAAA& accessed 03/27/24.