

MEDICAL POLICY

SUBJECT: PELVIC FLOOR ELECTRICAL STIMULATION AS A TREATMENT FOR URINARY OR FECAL INCONTINENCE

EFFECTIVE DATE: 10/18/01
REVISED DATE: 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

POLICY NUMBER: 1.01.19
CATEGORY: Technology Assessment

ARCHIVED DATE: 09/20/12
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- *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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare 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.*

POLICY STATEMENT:

Based upon our criteria and assessment of peer-reviewed literature, there is no evidence that pelvic floor electrical stimulation demonstrates improvement in patient outcomes. Therefore, pelvic floor electrical stimulation (PFES) for the treatment of urinary or fecal incontinence is considered **not medically necessary**.

Refer to Corporate Medical Policy #1.01.01 regarding Electrical Stimulation - Transcutaneous Electrical Nerve (TENS), H-Wave and Interferential Stimulators.

Refer to Corporate Medical Policy #7.01.10 Sacral Nerve Stimulation for Pelvic Floor Dysfunction.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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 urinary incontinence is estimated to affect 10-12 million people in the United States, two thirds of who are female.

Pelvic floor electrical stimulation (PFES) has been advocated as a treatment of 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 also 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 thus, and 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. These 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 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 and 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

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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.

CODES: Number Description

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: 97014* Physical medicine and rehabilitation - application of a modality to one or more areas; electrical stimulation (unattended)
(*NMN for 625.6, 787.6, 788.30-788.38, N39.3, N39.41-N39.498, R15.0-R15.9, R32)

 97032* application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes (*NMN for 625.6, 787.6, 788.30-788.38, N39.3, N39.41-N39.498, R15.0-R15.9, R32)

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HCPCS: E0740 (NMN) Non-implanted pelvic floor electrical stimulator, complete system
 788.30-788.39 Urinary incontinence (code range)

ICD10: N39.3 Stress incontinence (female) (male)
 N39.41-N39.498 Other specified urinary incontinence (code range)
 R15.0-R15.9 Fecal incontinence (code range)
 R32 Unspecified urinary incontinence

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KEY WORDS:

Intravaginal electrical stimulation.

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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator. 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&>.