MEDICAL POLICY

SUBJECT: EXTRACORPOREAL MAGNETIC INNERVATION (ExMI)

POLICY NUMBER: 8.01.08
CATEGORY: Technology Assessment

EFFECTIVE DATE: 10/18/01
REVISED DATE: 05/16/02, 03/20/03, 01/15/04, 11/18/04,
12/15/05, 12/21/06, 12/20/07, 12/18/08
ARCHIVED DATE: 12/17/09
EDITED DATE: 12/16/10, 12/15/11, 12/20/12, 12/19/13,
12/18/14, 01/19/16
PAGE: 1 OF: 3

• If the member’s subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:
Based upon our criteria and assessment of peer-reviewed literature, there is no evidence that Extracorporeal Magnetic Innervation demonstrates sustained improvement in patient outcomes. Therefore, ExMI is considered investigational for the treatment of urinary incontinence in both men and women.

Refer to Corporate Medical Policy #1.01.19 regarding Pelvic Floor Electrical Stimulation as a Treatment of Urinary or Fecal Incontinence.

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 which are female.

Extracorporeal Magnetic Innervation (ExMI) is a technology reported for use in the treatment of urinary incontinence. ExMI “provides non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence.”

The NeoControl Pelvic Floor Therapy System consists of a specially designed chair with a power/control unit which drives the system. When the patient sits in the NeoControl therapy chair, the perineum is naturally placed on the central axis of the pulsing therapeutic field, which is imbedded in the seat. This allows all tissues in the perineal region to be penetrated by the magnetic flux. Magnetic flux, not electricity, enters the patients’ body. The patient remains fully clothed throughout the treatment session. A treatment session takes less than 30 minutes and is typically done twice a week for six to eight weeks. Magnetic stimulation of the sacral nerves by positioning a circular coil over the sacrum has also been investigated as a non-invasive alternative to electrical sacral stimulation.

RATIONALE:
The FDA has approved the NeoControl Pelvic Floor Therapy System for the treatment of urinary incontinence in women only. Other FDA approved devices include the Cadwell High Speed Magnetic Stimulator and Magstim® Rapid Stimulator. The evidence from peer-reviewed literature is limited in support of the efficacy of ExMI. Studies are hampered by small patient samples, lack of control groups, inconsistent procedural protocols and lack of long-term results. There is limited evidence that ExMI is equal to or superior to established treatment methods. Some case series do demonstrate initial, short-term improvement in the number of incontinence episodes, but its long-term effects have not been established. (Choe, et al 2007, Voorham-van der Zalm, et al, 2006).

Recent systematic reviews (KF Hunter, et al., 2007 and R McDonald, et al. 2007) found no long-term benefit in magnetic stimulation/innervation in decreasing the episodes of urinary incontinence in men following prostatectomy.
In 2012, the European Association of Urology (EAU) published clinical guidelines on the management of urinary incontinence. (15) The guidelines do not recommend treatment or urinary incontinence with electrical stimulation using surface electrodes alone, and do not recommend treatment with magnetic stimulation.

**CODES:**

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<td>Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.</td>
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**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:**

There are no specific CPT codes for pulsed magnetic neuromodulation.

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**HCPCS:**

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<td>G0295 (E/I)</td>
<td>Electromagnetic stimulation, to one or more areas, for wound care other than described in G0329 or for other uses</td>
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**ICD9:**

| 788.30-788.39 | Urinary incontinence (code range) |
| 625.6 | Stress incontinence, female |

**ICD10:**

| N39.3 | Stress incontinence (female) (male) |
| N39.41-N39.498 | Other specified urinary incontinence (code range) |
| R32 | Unspecified urinary incontinence |

**REFERENCES:**


KEY WORDS:
ExMI, Magnetic stimulation, NeoControl chair.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Extracorporeal Magnetic Innervation.