Medical Policy

Non-Implantable Pelvic Floor Electrical Stimulator

WellSense Health Plan Members (All Products): See SPECIAL COVERAGE INFORMATION PER PLAN box below for policy guidelines.

Description

A pelvic floor electrical stimulator is a device which is used in the treatment of urinary incontinence by delivering an electrical current to the muscles of the pelvic floor, causing them to contract.

Policy

For Medicare Members
A pelvic floor electrical stimulator may be considered reasonable and necessary when the following criteria are met:

- Must be ordered by the member's treating practitioner.
- The member is cognitively intact with a diagnosis of stress and/or urge incontinence who has failed a documented trial of pelvic muscle exercise training. A failed trial is defined as the completion of a four-week plan of pelvic muscle exercises that are designed to increase periurethral strength with no clinically significant improvement.

Home use of **(E0746 Electromyography (EMG), biofeedback device)** biofeedback therapy is not covered for Medicare members.

For Non-Medicare Members

New Hampshire Medicaid Members:
A pelvic floor electrical stimulator may be considered reasonable and necessary when the following criteria are met:

- Must be ordered by the member's treating practitioner.
- The member is cognitively intact with a diagnosis of stress and/or urge incontinence who has failed a documented trial of pelvic muscle exercise training. A failed trial is defined as the completion of a four-week plan of pelvic muscle exercises that are designed to increase periurethral strength with no clinically significant improvement.

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Commercial Members:
The E0740 Non-implanted Pelvic Floor Stimulator is considered experimental and investigational for all indications, therefore, a non-covered item.

HCPCS Level II Codes and Description

E0740	Non-implanted Pelvic Floor Electrical Stimulator, complete system.
E0746	Electromyography (EMG), biofeedback device

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Northwood follows all CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

References

Blue Cross Blue Shield of Massachusetts, Policy Number : 470. BCBSA Reference Number: 1.01.17 Accessed November 25, 2024.

Centers for Medicare and Medicaid Services, "NCD for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)," Publication 100.3, Manual Section 230.8, Version 2, CIM 60-24, effective 6/19/2006. Last accessed and reviewed 11-25-24.

WellSense Health Plan Medical Policy, Biofeedback in an Outpatient Setting to Treat Incontinence or Constipation Policy Number: OCA 3.969, Version Number: 20, Version Effective Date: 11/01/24. Accessed and reviewed 10/22/24.

SPECIAL COVERAGE INFORMATION PER PLAN: For (E0746) Electromyography (EMG), biofeedback device

Biofeedback in an Outpatient Setting to Treat Incontinence or Constipation

Policy Number: OCA 3.969
Version Number: 20
Version Effective Date: 11/01/24

All WellSense Products:

- NH Clarity plans
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Clarity plans/Employer Choice Direct
- MA Senior Care Options

Policy Summary

The Plan considers biofeedback provided in the outpatient setting for the treatment of urinary incontinence (stress, urgency, mixed, or overflow urinary incontinence), fecal incontinence, and/or dyssynergia-type constipation to be medically necessary when clinical criteria are met for New Hampshire (NH) Medicaid adult members age 21 or older, adult and pediatric MA and NH Clarity members, NH Medicare Advantage members, and MA Senior Care Options members. For a MassHealth member age 20 or younger or a NH Medicaid member age 20 or younger,

outpatient biofeedback used to treat urinary incontinence, fecal incontinence, and/or dyssynergia-type constipation is only covered when the service is requested by the treating provider as part of an EPSDT service and clinical criteria included in this policy are met. Plan prior authorization is required. This is NOT a covered, payable service for MassHealth members age 21 or older on the date of service.

Clinical Criteria

ALL criteria in items 1 through 4 must be met and documented in the member's medical record:

1. Member has failed a documented trial of 4 weeks of pelvic muscle exercise (PME) training with no significant improvement in symptoms; AND

2. Member is cognitively intact; AND

3. At least ONE (1) of the criteria in items a through c is met:

   a. Member with stress, urgency, mixed, or overflow urinary incontinence; OR

   b. Member with fecal incontinence and has some degree of rectal sensation and ability to contract the sphincter voluntarily; OR

   c. Member is 18 years of age or older on the date of service with chronic dyssynergic-type constipation and failed 3 months of conventional treatment that includes the use of laxatives, dietary changes (e.g., high-fiber diet), and attempting defecation after meals; AND

4. Biofeedback training will be used to manage the member's symptom(s) for up to 4 sessions.

Limitations and Exclusions

Biofeedback is considered experimental and investigational or NOT medically necessary when Plan criteria are NOT met, for other indications, or when used in the home setting due to limited evidence documenting the clinical utility and clinical validity of treatment.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, CMS NCD 30.1.1 includes medically necessary indications for biofeedback therapy rendered by a practitioner in an office or other facility setting for the treatment of urinary incontinence. Home use of biofeedback therapy is not covered by CMS. No guideline was

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found related to the treatment of a defecatory dysfunction (e.g., idiopathic constipation, fecal incontinence, dyssynergic defecation). Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Change/Authorization History

Revision Number	Date	Description of Change	Prepared/Reviewed by	Approved by	Review Date:	Effective Date:
A	Nov.2006	Initial Release	Rosanne Brugnoni	Ken Fasse	n/a	
01		Annual Review / no changes	Susan Glomb	Ken Fasse	Dec.2008	
02	12-22-09	Annual Review/ no changes	Susan Glomb	Ken Fasse	Dec. 2009	
03	12-03-10	Annual Review – No changes	Susan Glomb	Ken Fasse	Dec.2010	
04	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri		
05	11-18-11	Annual Review. Added Reference to Policy	Susan Glomb	Dr. B. Almasri	Nov. 2011	
06	04-04-12	Added reference to NH Medicaid	Susan Glomb	Dr. B. Almasri		
07	11-29-12	Annual Review – No changes	Susan Glomb	Dr. B. Almasri	Nov 12	
08	12-18-13	Annual review. No changes	Susan Glomb	Dr. B. Almasri		
09	11-24-14	Annual Review. No changes	Susan Glomb	Dr. B. Almasri		
10	12-04-15	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2015	
11	12-02-16	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2016	
12	12-18-17	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2017	

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13	12-12-18	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2018	
14	1-28-19	Updated to indicate that for Commercial members the E0740 is experimental/investigational and non-covered. Added references.	Carol Dimech	Dr. C. Lerchin	January 2019	
15	12-06-19	Annual review. No additional changes.	Carol Dimech	Dr. C. Lerchin	December 2019	December 2019
16	11-23-20	Annual Review. No Changes.	Lisa Wojno	Dr. C. Lerchin	November 2020	November 2020
17	11-24-21	Annual Review. Added NCD/LCD verbiage to "Important Note". Changed physician to treating practitioner.	Carol Dimech/Susan Glomb	Dr. C. Lerchin	November 24, 2021	
18	11-15-22	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	11-15-22	11-15-22
19	11-15-23	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	11-15-23	11-15-23
20	10-22-24	Added WellSense criteria for Biofeedback device. Also, added the (E0746) is not covered for home use for Medicare members.	Carol Dimech	Dr. C. Lerchin	10-22-24	11-1-24
21	11-25-24	Annual review no changes since 10-22-24 entry.	Carol Dimech/Susan Glomb	Dr. C. Lerchin	11-25-24	11-25-24