

UnitedHealthcare® Medicare Advantage Coverage Summary

Urinary and Fecal Incontinence, Diagnosis, and Treatments

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☐ Instructions for Use

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Related Policies

None

Coverage Guidelines

Diagnosis and treatment of urinary incontinence are covered in accordance with Medicare coverage criteria.

DME Face to Face Requirement: Effective July 1, 2013, Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including incontinence treatment systems, pelvic floor stimulator, monitor, sensor and/or trainer). For DME Face to Face Requirement information, refer to the Coverage Summary titled <u>Durable Medical Equipment (DME)</u>, <u>Prosthetics</u>, <u>Corrective Appliances/Orthotics (Non-Foot Orthotics)</u>, <u>Nutritional Therapy</u>, and <u>Medical Supplies Grid</u>.

Conservative Treatments

Conservative treatments of urinary incontinence are covered. Examples include, but are not limited to:

- Habit training
- Prompted voiding
- Routine/scheduled toileting
- Kegel exercises

Mechanical or Hydraulic Incontinence Control Devices

Mechanical or hydraulic incontinence control devices for the management of urinary incontinence are covered for members with permanent anatomic and neurologic dysfunctions of the bladder (e.g., artificial sphincter). This class of devices achieves control of urination by compression of the urethra. Refer to the National Coverage Determination (NCD) for Incontinence Control Devices (230.10). (Accessed February 15, 2023)

Urodynamic Studies (CPT Codes 51725, 51726, 51727, 51728, 51729, 51736, 51741, 51792, and 51797)

Uroflowmetric evaluations (also referred to as urodynamic voiding or urodynamic flow studies) are covered for diagnosing various urological dysfunctions, including bladder outlet obstructions. Refer to the NCD for Uroflowmetric Evaluations (230.2).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.

(Accessed February 15, 2023)

Urodynamic Studies - Non-Invasive (e.g., UroCuff®) (CPT Code 55899)

Medicare does not have a National Coverage Determination (NCD) for non-invasive urodynamics studies. Local Coverage Determinations (LCDs/Local Coverage Articles (LCAs) exists and compliance with these policies required where applicable. For specific LCDs/LCAs, refer to the <u>Urodynamic Studies - Non-invasive (e.g., UroCuff*)</u> table.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Medical Policy titled Omnibus Codes.

Note: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

(Accessed October 24, 2023)

Biofeedback Therapy

Biofeedback is a method of treatment for urinary incontinence used as a tool to help patients learn how to perform pelvic muscle exercise (PME). Biofeedback-assisted PME involves the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone with the goal of improving awareness of pelvic floor musculature.

Biofeedback is covered for the treatment of stress and/or urges urinary incontinence for 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.
- Home use of biofeedback is not covered.

Refer to the NCD for Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.

(Accessed February 15, 2023)

Collagen Implant Therapy

Collagen implant therapy is covered when coverage criteria are met.

Refer to the NCD for Incontinence Control Devices (230.10).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.

Note: The member's copayment for collagen implantation injection treatment is the office visit plus the injectable medication copayment, if any.

(Accessed February 15, 2023)

Sacral Nerve Stimulation (SNS) for Urinary Incontinence

Sacral nerve stimulation is covered_for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention when criteria are met.

Refer to the NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.

(Accessed February 15, 2023)

Sacral Nerve Stimulation (SNS) for Fecal Incontinence

Medicare does not have a National Coverage Determination (NCD) for sacral nerve stimulation for the treatment of fecal incontinence. Local Coverage Determinations (LCDs/Local Coverage Articles (LCAs) exist and compliance with these policies required where applicable. For specific LCDs/LCAs, refer to the <u>Sacral Nerve Stimulation for Fecal Incontinence</u> table.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Medical Policy for <u>Sacral Nerve Stimulation for Urinary and Fecal Indications</u>.

Note: After checking the <u>Sacral Nerve Stimulation for Fecal Incontinence</u> table and searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines. (Accessed December 7, 2023)

Non-implantable Pelvic Floor Electrical Stimulator

Non-implantable pelvic floor electrical stimulators for stress and/or urge urinary incontinence are covered when criteria are met.

Refer to the NCD for Non-Implantable Pelvic Floor Electrical Stimulator (230.8). (Accessed February 15, 2023)

Electrical Continence Aid

Electrical continence aid is a device consisting of a plastic plug, molded into the shape of the patient's anal canal, which contains two implanted electrodes that are connected by a wire to a small portable generator. An electrical current is produced which stimulates the anal musculature to cause a contraction sufficient to hold the plug in while allowing the patient to ambulate without incontinence.

Electrical continence aids are in the experimental stage of development and there is no valid scientific documentation of their effectiveness and safety. Therefore, they are not covered under Medicare since they cannot be considered to be reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member as required by §1862(a)(1) of the Act.

Refer to the NCD for Electrical Continence Aid (230.15). (Accessed February 15, 2023)

Note: This electrical stimulator device is used in the treatment of fecal incontinence.

Bladder Stimulators (Pacemakers)

Bladder stimulators (pacemakers) are not covered. The use of spinal cord electrical stimulators, rectal electrical stimulators, and bladder wall stimulators is not considered reasonable and necessary. Therefore, no program payment may be made for these devices or for their implant. Refer to the NCD for Bladder Stimulators (Pacemakers) (230.16). (Accessed February 15, 2023)

PureWick™ Urine Collection System (HCPCS Code K1006)

Medicare does not have a National Coverage Determination (NCD) for PureWick™ Urine Collection System. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

For coverage guidelines, refer to the UnitedHealthcare Medical Policy titled Omnibus Codes.

Note: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

(Accessed September 15, 2023)

Solesta® for Fecal Incontinence (HCPCS Code L8605)

Medicare does not have a National Coverage Determination (NCD) for Solesta[®]. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist, however, CGS has published an article for Solesta[™] Treatment for Fecal Incontinence with coverage criteria.

For coverage guidelines, refer to the CGS Article titled Solesta™ Treatment for Fecal Incontinence.

Note: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

(Accessed December 7, 2023)

Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence

Medicare does not have a National Coverage Determination (NCD) for botulinum toxin type A. Local Coverage Determinations (LCDs/Local Coverage Articles (LCAs) exist for all states/territories and compliance with these policies required where applicable. For specific LCDs/LCAs, refer to the <u>Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence</u> table.

Definitions

Sacral Nerve Stimulation: Implantation of a permanent device that modulates the neural pathways controlling bladder function. This treatment is one of several alternative modalities for patients with urge urinary incontinence whose incontinence has been refractory to behavioral and pharmacologic treatment. This treatment involves electrical stimulation of the sacral nerves in the lower region of the spine via a totally implantable system. System components include a lead, an implantable pulse generator and an extension that connects the lead to the pulse generator. It is expected that the physician performing this service has completed a training course in the use and implantation of the device. Multiple LCDs/LCAs for Sacral Nerve Stimulation; available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. (Accessed February 15, 2023)

Supporting Information

Urodynamic Studies - Non-invasive (e.g., UroCuff®) Accessed December 7, 2023				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
A58543	Billing and Coding: Urodynamic Services - Non-invasive	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI

Urodynamic Studies - Non-invasive (e.g., UroCuff°) Accessed December 7, 2023				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
A58541	Billing and Coding: Urodynamic Services - Non-invasive	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L34056 (A56802)	<u>Urodynamics</u>	Part A and B MAC	National Government Services, Inc.	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
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Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence Accessed December 7, 2023				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L33949 (A56472)	Botulinum Toxins	Part A and B MAC	CGS Administrators, LLC	KY, OH
L33274 (A57715)	Botulinum Toxins	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L33646 (A52848)	Botulinum Toxins	Part A and B MAC	National Government Services, Inc.	CT, IL, MA, ME, MN, NH, NY, RI, WI, VT
L35172 (A57186)	Botulinum Toxin Types A and B	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, WA, UT, WY
L35170 (A57185)	Botulinum Toxin Types A and B Policy	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L38809 (A58423)	Botulinum Toxins	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L33458 (A56646)	Chemodenervation	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L34635 (A57474)	Botulinum Toxin Type A & Type B	Part B MAC	Wisconsin Physicians Service	IN, IA, KS, MI, MO, NE
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Sacral Nerve Stimulation for Fecal Incontinence Accessed December 7, 2023				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
A55835	Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence	A and B MAC	CGS Administrators, LLC	KY, OH
A53017	Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence	A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, WA, UT, WY
A53359	Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence	A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
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Policy History/Revision Information

Date	Summary of Changes
11/08/2023	Template Update Updated Instructions for Use Coverage Guidelines
	 Urodynamic Studies - Non-Invasive (e.g., UroCuff®) (CPT Code 55899) Revised language to indicate Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable
	 Sacral Nerve Stimulation (SNS) for Fecal Incontinence Revised default guidelines for sacral nerve stimulation for the treatment of fecal incontinence: Added reference link to the UnitedHealthcare Commercial Medical Policy titled Sacral Nerve Stimulation for Urinary and Fecal Indications Removed reference link to the Noridian LCA for Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53017)
	 Supporting Information Updated list of available LCDs/LCAs to reflect the most current information Archived previous policy version MCS049.06

Instructions for Use

This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the Member's Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member's EOC/SB, the member's EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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