Incontinence: Urinary and Fecal Incontinence, Diagnosis and Treatments

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Related Medicare Advantage Policy Guidelines
- Biofeedback Therapy (NCD 30.1)
- Biofeedback Therapy for the Treatment of Urinary
  Incontinence (NCD 30.1.1)
- Bladder Stimulators (Pacemakers) (NCD 230.16)
- Electrical Continence Aid (NCD 230.15)
- Incontinence Control Devices (NCD 230.10)
- Sacral Nerve Stimulation for Urinary Incontinence
  (NCD 230.18)
- Urological Supplies

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 Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.

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 March 5, 2021)

Urodynamic Studies (Uroflowmetry or Cystometrogram)
Uroflowmetric evaluations (also referred to as urodynamic voiding or urodynamic flow studies) are covered under Medicare for diagnosing various urological dysfunctions, including bladder outlet obstructions.

Refer to the NCD for Uroflowmetric Evaluations (230.2). (Accessed March 5, 2021)

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.

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). (Accessed March 5, 2021)

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 June 7, 2021)

Collagen Implant Therapy
Collagen implant therapy is covered when coverage criteria are met.

Refer to the NCD for Incontinence Control Devices (230.10). (Accessed March 9, 2020)

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 June 7, 2021)
Note: The member’s copayment for collagen implantation injection treatment is the office visit plus the injectable medication copayment, if any.

Sacral Nerve Stimulation (SNS)
Sacral nerve stimulation (SNS) 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). (Accessed March 5, 2021)

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 June 7, 2021)

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.
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 March 5, 2021)

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 March 5, 2021)

Posterior Tibial Nerve Stimulation (PTNS) (CPT Code 64566)

Medicare does not have a National Coverage Determination for PTNS for urinary control. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Posterior Tibial Nerve Stimulation (PTNS).

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the Novitas LCD for Surgery: Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control (L35011).

Note: After checking the Posterior Tibial Nerve Stimulation (PTNS) table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

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 at this time.

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

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

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 and compliance with these policies required where applicable. For specific LCDs/LCAs, refer to the Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence table.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled Botulinum Toxins A and B.

Note: After checking the Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
Definitions

**Posterior Tibial Nerve Stimulation (PTNS):** A minimally invasive procedure, consists of insertion of a percutaneous needle above the medial malleolus into a superficial branch of the posterior tibial nerve. An adjustable low voltage electrical impulse (10mA, 1-10 Hz frequency) travels via the posterior tibial nerve to the sacral nerve plexus to alter pelvic floor function by neuromodulation. Multiple LCDs for Posterior Tibial Nerve Stimulations (PTNS); available at [https://www.cms.gov/medicare-coverage-database/new-search/search.aspx](https://www.cms.gov/medicare-coverage-database/new-search/search.aspx). (Accessed June 7, 2021)

**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](https://www.cms.gov/medicare-coverage-database/new-search/search.aspx). (Accessed June 7, 2021)

Supporting Information

**Important Note:** When searching the Medicare Coverage Database, if no LCD/LCA is found, then use the applicable referenced default policy below for coverage guidelines.

<table>
<thead>
<tr>
<th>LCD/LCA ID</th>
<th>LCD/LCA Title</th>
<th>Contractor Type</th>
<th>Contractor Name</th>
<th>Applicable States/Territories</th>
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<tbody>
<tr>
<td>L33406 (A57770)</td>
<td>Posterior Tibial Nerve Stimulation (PTNS)</td>
<td>Part A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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<td>L33396 (A57453)</td>
<td>Posterior Tibial Nerve Stimulation for Voiding Dysfunction</td>
<td>Part A and B MAC</td>
<td>National Government Services, Inc</td>
<td>CT, IL, MN, WI, VT, NY, MA, ME, NH, RI</td>
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<tr>
<td>A52965</td>
<td>Posterior Tibial Nerve Stimulation Coverage</td>
<td>Part A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
<td>AK, AZ, ID, MT, ND, OR, SD, WA, UT, WY</td>
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<tr>
<td>A55104</td>
<td>Posterior Tibial Nerve Stimulation Coverage</td>
<td>Part A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
<td>AS, CA, GU, HI, MP, NV</td>
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<td>L35011 (A57712)</td>
<td>Surgery: Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control</td>
<td>Part A and B MAC</td>
<td>Novitas Solutions, Inc.</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
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<tr>
<td>L33443 (A56719)</td>
<td>Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control</td>
<td>Part A and B MAC</td>
<td>Palmetto GBA</td>
<td>AL, GA, NC, SC, TN, VA, WV</td>
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**Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence**

<table>
<thead>
<tr>
<th>LCD/LCA ID</th>
<th>LCD/LCA Title</th>
<th>Contractor Type</th>
<th>Contractor Name</th>
<th>Applicable States/Territories</th>
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<tr>
<td>L33949 (A56472)</td>
<td>Botulinum Toxins</td>
<td>Part A and B MAC</td>
<td>CGS Administrators, LLC</td>
<td>KY, OH</td>
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<td>L33274 (A57715)</td>
<td>Botulinum Toxins</td>
<td>Part A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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</table>
Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence
Accessed June 7, 2021

<table>
<thead>
<tr>
<th>LCD/LCA ID</th>
<th>LCD/LCA Title</th>
<th>Contractor Type</th>
<th>Contractor Name</th>
<th>Applicable States/Territories</th>
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<tr>
<td>L33646</td>
<td>Botulinum Toxins</td>
<td>Part A and B MAC</td>
<td>National Government Services, Inc.</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, WI, VT</td>
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<tr>
<td>L35172</td>
<td>Botulinum Toxin Types A and B</td>
<td>Part A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
<td>AK, AZ, ID, MT, ND, OR, SD, WA, UT, WY</td>
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<td>L35170</td>
<td>Botulinum Toxin Types A and B Policy</td>
<td>Part A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<td>L33458</td>
<td>Chemodenervation</td>
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<td>L34635</td>
<td>Botulinum Toxin Type A &amp; Type B</td>
<td>Part A MAC</td>
<td>Wisconsin Physicians Service</td>
<td>AK*, AL*, AR, AZ*, CA*, CO, CT*, DE, FL*, GA*, HI*, IA, ID*, IL*, IN, KS, KY*, LA, MA*, MD, ME*, MI, MO, MS, MT*, NC*, ND*, NE, NH*, NJ, NM, NV*, OH*, OK, OR*, PA, RI*, SC, SD*, TN*, TX, UT*, VA*, VT*, WA*, WI*, WV*, WY* Note: States notated with an asterisk (*) should follow the other available state-specific LCD/LCA listed in this table. This WPS LCD/LCA only applies to states without asterisk.</td>
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L34635       | Botulinum Toxin Type A & Type B                    | Part B MAC      | Wisconsin Physicians Service        | IN, IA, KS, MI, MO, NE                         |

Policy History/Revision Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Changes</th>
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<tr>
<td>05/01/2021</td>
<td>Template Update</td>
</tr>
<tr>
<td></td>
<td>Reformed policy; transferred content to new template</td>
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<tr>
<td>03/16/2021</td>
<td>Related Medicare Advantage Policy Guidelines</td>
</tr>
<tr>
<td></td>
<td>Removed reference link to the policy titled Non-Implantable Pelvic Floor Electrical Stimulator (NCD 230.8)</td>
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Instructions for Use

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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.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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