Coverage Summary

Incontinence: Urinary and Fecal Incontinence, Diagnosis and Treatments

Policy Number: I-001  
Products: UnitedHealthcare Medicare Advantage Plans  
Original Approval Date: 11/27/2006

Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  
Last Review Date: 07/21/2020

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)
- Non-Implantable Pelvic Floor Electrical Stimulator (NCD 230.8)
- Sacral Nerve Stimulation for Urinary Incontinence (NCD 230.18)
- Urological Supplies

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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 is 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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I. COVERAGE

**Coverage Statement**: 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 for Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.

**Guidelines/Notes**:  
1. **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

2. **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. See the NCD for Incontinence Control Devices (230.10). (Accessed March 9, 2020)

3. **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.  
   See the NCD for Uroflowmetric Evaluations (230.2). (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 http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

4. **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. 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.  
   b. Home use of biofeedback is not covered.
See the NCD for Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1). (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 http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

5. Collagen Implant Therapy
Collagen implant therapy is covered when coverage criteria are met.
See 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 http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

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

6. 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.
See the NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18). (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 http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

7. 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.
See the NCD for Non-Implantable Pelvic Floor Electrical Stimulator (230.8). (March 9, 2020)

8. 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.

See the NCD for Electrical Continence Aid (230.15). (Accessed March 9, 2020)

Note: This electrical stimulator device is used in the treatment of fecal incontinence.
9. **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. See the **NCD for Bladder Stimulators (Pacemakers) (230.16)**. (Accessed March 9, 2020)

10. **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, see the **LCD Availability Grid (Attachment A)**.
- 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)**. (IMPORTANT NOTE: After checking the LCD/LCA Availability Grid and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the above referenced policy.)
- Committee approval date: March 17, 2020
- Accessed July 13, 2020

11. **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 for Omnibus Codes. (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the above referenced policy.)
- Committee approval date: March 17, 2020
- Accessed March 9, 2020

12. **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, see the **LCD/LCA Availability Grid (Attachment B)**.
- For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy for Botulinum Toxins A and B. (IMPORTANT NOTE: After checking the LCD/LCA Availability Grid and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the above referenced policy.)
- Committee approval date: March 17, 2020
- Accessed July 13, 2020

**II. 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 Stimulation (PTNS); available at** [http://www.cms.gov/medicare-coverage](http://www.cms.gov/medicare-coverage)
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 for Sacral Nerve Stimulation; available at [http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx). (Accessed March 9, 2020)

### III. REFERENCES

See above

### IV. REVISION HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Guideline/Revised Section</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>07/21/2020</td>
<td>Guideline 4</td>
<td>[Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™) (CPT code 53860)]</td>
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<td>Guideline 11</td>
<td>[Posterior Tibial Nerve Stimulation (PTNS) (CPT code 64566)]</td>
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<tr>
<td></td>
<td>Guideline 13</td>
<td>(Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence)</td>
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<td></td>
<td></td>
<td>Replaced reference to “states with no LCDs/LCAs” with “states/territories with no LCDs/LCAs”</td>
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### Attachments

- Removed LCD/LCA Availability Grid for Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™) (CPT code 53860)

### V. ATTACHMENTS

#### Attachment A – LCD/LCA Availability Grid

**Posterior Tibial Nerve Stimulation (PTNS)**

<table>
<thead>
<tr>
<th>ID #</th>
<th>Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States/Territories</th>
</tr>
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<tbody>
<tr>
<td>L33406</td>
<td>Posterior Tibial Nerve Stimulation (PTNS)</td>
<td>A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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<tr>
<td>L33396</td>
<td>Posterior Tibial Nerve Stimulation for Voiding Dysfunction</td>
<td>MAC Part A and B</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>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>A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
<td>AS, CA, GU, HI, MP, NV</td>
</tr>
</tbody>
</table>
### Attachment A – LCD/LCA Availability Grid

**Posterior Tibial Nerve Stimulation (PTNS)**

CMS website accessed July 13, 2020

<table>
<thead>
<tr>
<th>ID #</th>
<th>Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States/Territories</th>
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<tbody>
<tr>
<td>L35011</td>
<td>Surgery: Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control</td>
<td>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</td>
<td>Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control</td>
<td>A and B MAC</td>
<td>Palmetto GBA</td>
<td>AL, GA, NC, SC, TN, VA, WV</td>
</tr>
</tbody>
</table>

End of Attachment A

### Attachment B – LCD/LCA Availability Grid

**Botulinum toxin type A for Overactive Bladder/Urinary Incontinence**

CMS website accessed July 13, 2020

<table>
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<tr>
<th>ID #</th>
<th>Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States/Territories</th>
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<tbody>
<tr>
<td>L33949</td>
<td>Botulinum Toxins</td>
<td>A and B MAC</td>
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<td>FL, PR, VI</td>
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<td>Botulinum Toxin</td>
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<td>National Government Services, Inc.</td>
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<td>L35172</td>
<td>Botulinum Toxin Types A and B</td>
<td>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>L35170</td>
<td>Botulinum Toxin Types A and B Policy</td>
<td>A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
<td>AS, CA, GU, HI, MP, NV</td>
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<td>L33458</td>
<td>Chemodenervation</td>
<td>A and B MAC</td>
<td>Palmetto GBA</td>
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<td>(Note: States notated with an asterisk should follow the other available state-specific LCD/LCA listed on this grid. This WPS LCD/LCA only applies to states without asterisk.)</td>
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<td>L34635</td>
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<td>MAC Part B</td>
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<td>IN, IA, KS, MI, MO, NE</td>
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End of Attachment B