Coverage Summary

Incontinence: Urinary and Fecal Incontinence, Diagnosis and Treatments

<table>
<thead>
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<tr>
<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 03/19/2019</td>
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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)

- Non-Implantable Pelvic Floor Electrical Stimulator (NCD 230.8)
- Posterior Tibial Nerve Stimulation
- Sacral Nerve Stimulation for Urinary Incontinence (NCD 230.18)
- Uroflowmetric Evaluations (NCD 230.2)
- Urological Supplies

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 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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4. Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™)
5. Biofeedback Therapy
6. Collagen Implant Therapy
7. Sacral Nerve Stimulation (SNS)
8. Non-implantable Pelvic Floor Electrical Stimulator
9. Electrical Continence Aid
10. Bladder Stimulators (Pacemakers)
11. Posterior Tibial Nerve Stimulation (PTNS)
12. Solesta® for Fecal Incontinence
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II. DEFINITIONS

III. REFERENCES
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 6, 2019)

3. Urodynamic Studies (Uroflowmetry or Cystometry)
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 6, 2019)

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. (Accessed March 6, 2019)

4. Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™) (CPT code 53860)
   • Medicare does not have a National Coverage Determination (NCD) for radiofrequency micro-remodeling for stress urinary incontinence.
   • Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, see the LCD Availability Grid (Attachment A).
   • For states with no LCDs/LCAs, refer to the National Government Services LCD for Non-
5. **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 6, 2019)*

*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](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx). (Accessed March 6, 2019)*

6. **Collagen Implant Therapy**

Collagen implant therapy is covered when coverage criteria are met.

*See the NCD for Incontinence Control Devices (230.10). (Accessed March 6, 2019)*

*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](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx). (Accessed March 6, 2019)*

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

7. **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 6, 2019)*

*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](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx). (Accessed March 6, 2019)*
8. **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)**. (Accessed March 6, 2019)

9. **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 6, 2019)

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

10. **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 6, 2019)

11. **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 for all 50 states and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, see the **LCD Availability Grid (Attachment B)**.
    - **Committee approval date:** March 19, 2019
    - Accessed November 6, 2019

12. **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 guideline, refer to the **UnitedHealthcare Commercial Medical Policy for Omnibus Codes**.
      (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy).
    - **Committee approval date:** March 19, 2019
    - Accessed November 6, 2019
13. **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 state-specific LCDs/LCAs, see the LCD Availability Grid (Attachment C).*
- *For states with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy for Botulinum Toxins A and B for coverage guidelines.*

**IMPORTANT NOTE:** After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LC/LCA is found, then use the above referenced policy.

- **Committee approval date:** March 19, 2019
- **Accessed November 6, 2019**

### 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 Stimulations (PTNS); 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 6, 2019)**

**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 6, 2019)**

### III. REFERENCES

See above

### IV. REVISION HISTORY

04/01/2019

- Updated policy introduction; added language to clarify:
  - There are instances where [the Coverage Summary] 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*)
- Retitled reference links that direct users to UnitedHealthcare *Commercial* policies
Annual review with the following updates:

Guideline 6 (Collagen Implant Therapy) - Deleted detailed guideline from the Coverage Summary; same guideline are outlined in the referenced NCD for Incontinence Control Devices (230.10).

Guideline 7 [Sacral Nerve Stimulation (SNS)] - Deleted detailed guideline from the Coverage Summary; same guideline are outlined in the referenced NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18).

Guideline 8 (Non-implantable Pelvic Floor Electrical Stimulator) - Deleted detailed guideline from the Coverage Summary; same guideline are outlined in the referenced NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18).

Updated Local Coverage Determination (LCD) Availability Grids; removed instruction to “use the applicable LCD based on member’s residence/place and type of service” (this note only applies when selecting the appropriate DME LCD Policy)

Re-review with the following updates:

Guideline 3 [Urodynamic Studies (Uroflowmetry or Cystometrogram)] – Replaced reference to specific LCDs/LCAs with link to the general CMS search page.

Guideline 6 (Collagen Implant Therapy) – Replaced reference to specific LCDs/LCAs with link to the general CMS search page.

Guideline 7 [Sacral Nerve Stimulation (SNS)] - Replaced reference to specific LCDs/LCAs with link to the general CMS search page.

Annual review with the following updates:

Guideline 4 (Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence) - Updated the applicable LCDs to include the most recent website links and effective dates related to the Cahaba-Palmetto jurisdiction transition; no change in guideline.

Guideline 11 (Posterior Tibial Nerve Stimulation) - Updated the applicable LCDs to include the most recent website links and effective dates related to the Cahaba-Palmetto jurisdiction transition; no change in guideline.

Guideline 12 Solesta® for Fecal Incontinence – Updated guideline to state that there are no longer available LCDs. The only available LCD was retired.

Guideline 13 (Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence) - Updated the applicable LCDs to include the most recent website links and effective dates related to the Cahaba-Palmetto jurisdiction transition; no change in guideline.

Annual review; no updates.

Re-review with the following update:

Guideline 4 (Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence) - changed the default policy for states with no LCDs from Wisconsin Physicians Services LCD for Radiofrequency Treatment for Urinary Incontinence (L34642) (now retired) to National Government Services LCD for Non-covered Services (L33629); L33629 is the only available LCD; no available UHC MP or MCG.
03/15/2016  Annual review with the following updates:
- Guideline #4 [Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™)] - Removed verbiage “for Radiofrequency Micro-remodeling for Stress Urinary Incontinence” from 2nd bullet point.
- Guideline #9 (Sling Procedures) - Deleted from guidelines; unable to find current CMS reference.
- Guideline #13 (Botulinum Toxin Type A for Overactive Bladder/Urinary Incontinence) - Removed verbiage “for Botulinum Toxins which address the treatment of Overactive Bladder/Urinary Incontinence” from 2nd bullet point.
- Updated reference link(s) of the applicable LCDs to reflect the condensed link.

06/16/2015  Guideline 4 [Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™)]
- Changed default policy for states with no LCDs from United Healthcare Medical Policy for and Tibial Nerve Stimulation For Urinary Disorders Radiofrequency Therapy (retired effective June 1, 2015) to Wisconsin LCD for Radiofrequency Treatment for Urinary Incontinence (L31615)

Guideline 12 [Posterior Tibial Nerve Stimulation (PTNS) (CPT Code 64566)]
- Updated to indicate that all 50 states now have LCDs
- Removed reference link to the UnitedHealthcare Medical Policy for Radiofrequency Therapy and Tibial Nerve Stimulation For Urinary Incontinence which was retired effective June 1, 2015

03/12/2015  Formatting change only.

02/17/2015  Annual review with the following updates:
- Guideline #4 [Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™)] - Revised guideline for states with no Local Coverage Determinations (LCDs); replaced Wisconsin LCD for Radiofrequency Treatment for Urinary Incontinence (L31516) to UnitedHealthcare Medical Policy for Radiofrequency Therapy and Tibial Nerve Stimulation For Urinary Incontinence.
- Guideline #6 (Collagen Implant Therapy) – Update language to match updated LCD language.
- Guideline #13 [Solesta® for Fecal Incontinence (HCPCS code L8605)] – Added following language “Coverage guidelines of the available LCAs align (proven) and cover less than 80% of the geographic area. The UnitedHealthcare Medical Policy guidelines does not align (unproven) with the available LCAs guidelines.” to show individual consideration (IC) process used to determine default for states without LCDs.
- Guideline #14 (Botulinum toxin type A for Overactive Bladder/Urinary Incontinence) – Added applicable guideline based on the UnitedHealthcare Drug Policy for Botulinum Toxins A and B; new to the policy.

10/21/2014  Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.
03/18/2014  Annual review with the following updates:

- Guideline #4 Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™) Revised guideline for states with no Local Coverage Determinations (LCDs); replaced Novitas LCD for Radiofrequency Treatment for Urinary Incontinence (L30547) to Wisconsin LCD for Radiofrequency Treatment for Urinary Incontinence (L31516).
- Guideline #10 Electrical Continence Aid - Updated guideline based on the NCD for Electrical Incontinence Aid (230.15).
- Guideline #11 Bladder Stimulators (Pacemakers) - Updated guideline based on the NCD for Bladder Stimulators (Pacemaker) (230.16).
- Revised the definitions of Posterior Tibial Nerve Stimulation and Sacral Nerve Stimulation.
- Deleted the definitions of Renessa™, Sling Procedures and Urinary Incontinence.

08/20/2013  Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g).

04/29/2013  Annual review with the following updates:

- Guidelines #4 (Radiofrequency Micro-remodeling for Stress Urinary Incontinence, e.g., Renessa™) - Added reference to CPT code 53860
- Guidelines #12 (Posterior Tibial Nerve Stimulation) - Added reference to CPT code 64566
- Guidelines #13 (Solesta® for Fecal Incontinence) - Added applicable coverage guidelines (new to policy).

04/23/2012  Annual review; Guidelines #4 (Renessa™) was updated to include the additional LCDs that are now available (i.e., Wisconsin L31617) and deleted retired local articles (i.e., CIGNA A46177); no change in default guidelines for states with no LCDs.

10/31/2011  LCD Availability Grid for PTNS (Attachment A) updated, i.e., deleted retired LCDs, L27267 and L29544 and added L31391.

04/26/2011  Annual review with the following updates:

- Guidelines #4 (Renessa™) - (1) changed the LCD guidelines for states with no LCDs from NHIC L24914 (retired) to Highmark L30547; and (2) updated the LCD and Local Articles availability and links.
- Guidelines #12 Posterior tibial nerve stimulation (PTNS) - Updated the link to the UHC MP for Radiofrequency Therapy and Tibial Nerve Stimulation for Urinary Incontinence; deleted “states unproven” as the coverage rationale had changed. Attachment A - PTNS LCD Availability Grid was updated.

10/21/2010  Updated the links of the LCDs and Local Articles for Guidelines #4 (Renessa™).

09/20/2010  PTNS LCD Availability Grid updated.

04/21/2010  Updated to include Guidelines #4 (Renessa™) using the standard CS format and using the NHIC L24914 guidelines for states with no LCDs.
### V. ATTACHMENTS

#### Attachment A - LCD Availability Grid

**Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™)**

(CPT code 53860)

CMS website accessed November 6, 2019

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<td>Non-covered Services</td>
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<td>AL, GA, NC, SC, TN, VA, WV</td>
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End of Attachment A

#### Attachment B - LCD Availability Grid

**Posterior Tibial Nerve Stimulation (PTNS)**

(CPT Code 64566)

CMS website accessed November 6, 2019

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<td>Posterior Tibial Nerve Stimulation (PTNS) Billing &amp; Coding Guidelines</td>
<td>MAC - Part A and B</td>
<td>Wisconsin Physicians Service</td>
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<td>Posterior Tibial Nerve Stimulation (PTNS) Billing &amp; Coding Guidelines</td>
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<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</td>
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End of Attachment B
## Attachment C - LCD Availability Grid

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

CMS website accessed November 6, 2019

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<td>L33949</td>
<td>Botulinum Toxins</td>
<td>A and B MAC</td>
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**End of Attachment C**