# Coverage Summary

## Incontinence: Urinary and Fecal Incontinence, Diagnosis and Treatments

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<tr>
<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 01/16/2018</td>
</tr>
</tbody>
</table>

### 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

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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.

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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 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 14, 2018)

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 14, 2018)
   Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. See the LCDS for Urodynamics. (Accessed April 30, 2018)

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 LCDs for Non-covered Services (L33629) for coverage guideline. (IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.)
   - Committee approval date: January 16, 2018
   - Accessed April 30, 2018
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.


Local Coverage Determinations (LCDs) and compliance with these policies is required where applicable. These LCDs 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 April 30, 2018)

6. **Collagen Implant Therapy**

A collagen implant, which is injected into the submucosal tissues of the urethra and/or bladder, neck and tissues adjacent to the urethra, is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers.

a. Collagen implants are **limited** to the following types of patients with stress urinary incontinence due to intrinsic sphincter deficiency (ISD):

- Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- Male patients following trauma, including prostatectomy and/or radiation; and
- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H$_2$O or less

b. Evaluation of the member for collagen implant therapy must include all of the following:

   **Men**:
   - A complete history and physical examination
   - A simple cystometrogram to determine whether the bladder fills and stores properly
   - A bladder stress test maneuver to determine whether the bladder can contract and generate sufficient pressure resistance

   **Women**:
   - A complete history and physical examination that must include a pelvic examination
   - A simple cystometrogram to identify any existing bladder or urethral support abnormalities
   - An abdominal leak point pressure (ALLP) test

c. Prior to any collagen implantation injection treatments a skin test for collagen sensitivity must be administered and evaluated over a 4-week period
d. Members whose incontinence does not improve with 5 injection procedures (5 separate treatment sessions) are considered treatment failures, and no further treatment of urinary incontinence by collagen implant is covered. Members who have a reoccurrence of incontinence following successful treatment with collagen implants in the past (e.g., 6-12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification.

See the NCD for Incontinence Control Devices (230.10). (Accessed March 14, 2018)

Also see the available Local Articles for clarification and coding. See the LCA for Collagen Implantation for Urinary Incontinence - Medical Policy Article (A52374). (Accessed April 30, 2018)

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)
   a. Sacral nerve stimulation (SNS) is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention when the following criteria are met:
      1) The patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur
      2) The patient must have had successful test stimulation in order to support subsequent implantation
      3) Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation (improvement is measured through voiding diaries)
      4) The patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated
   b. Sacral nerve stimulation is not covered for members with stress incontinence, urinary obstruction and specific neurological diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of urinary urge incontinence, urgency-frequency syndrome and urinary retention.

See the NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18). (Accessed March 14, 2018)

Local Policy Articles exist and compliance with these policies is required where applicable. See the LCDs for Sacral Nerve Stimulation for Urinary Incontinence and Fecal Incontinence. (Accessed April 30, 2018)

8. Non-implantable Pelvic Floor Electrical Stimulator

Non-implantable pelvic floor electrical stimulator is a device that provides neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator. The methods of pelvic floor electrical stimulation vary in location, stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration (duty cycle), treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use, and between clinic and home settings. In general, the stimulus frequency and
other parameters are chosen based on the patient's clinical diagnosis.

Non-implantable pelvic floor electrical stimulators for stress and/or urge urinary incontinence are covered when both of the following criteria are met:

a. Member is cognitively intact
b. Member has 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 PME designed to increase periurethral muscle strength)

See the NCD for Non-Implantable Pelvic Floor Electrical Stimulator (230.8). (Accessed March 14, 2018)

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 14, 2018)

*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 14, 2018)

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) for all 50 states exist and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, see the LCD Availability Grid (Attachment B).
- Committee approval date: January 16, 2018
- Accessed April 30, 2018

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 Medical Policy for Omnibus Codes.
II. 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 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 April 30, 2018)

III. REFERENCES

See above

IV. REVISION HISTORY

01/16/2018 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.

03/21/2017 Annual review; no updates.

06/21/2016 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 Disorders.

- 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.”
- 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. ATTACHMENT(S)

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### Attachment A - LCD Availability Grid

**Radiofrequency (RF) Micro-remodeling for Stress Urinary Incontinence (e.g., Renessa™)**
(CPT code 53860)

[CMS website accessed April 30, 2018](https://www.cms.gov)

**IMPORTANT NOTE:** Use the applicable LCD based on member’s residence/place of service AND type of service.

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
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<tr>
<td>L33629</td>
<td>Non-covered Services</td>
<td>A and B MAC</td>
<td>National Government Services, Inc</td>
<td>CT, IL, MN, WI, VT, NY, MA, ME, NH, RI</td>
</tr>
<tr>
<td>L36954</td>
<td>Noncovered Services other than CPT® Category III Noncovered Services</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

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### Attachment B - LCD Availability Grid

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

[CMS website accessed April 30, 2018](https://www.cms.gov)

**IMPORTANT NOTE:** Use the applicable LCD based on member’s residence/place of service AND type of service.

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
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</tr>
</thead>
<tbody>
<tr>
<td>L34436</td>
<td>Posterior Tibial Nerve Stimulation (PTNS)</td>
<td>MAC – Part A and B</td>
<td>Wisconsin Physicians Service</td>
<td>IN, IA, KS, MI, MO, NE</td>
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<tr>
<td>L34436</td>
<td>Posterior Tibial Nerve Stimulation (PTNS)</td>
<td>MAC Part A</td>
<td>Wisconsin Physicians Service</td>
<td>AK, AL, AR, AZ, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, OH, OR, RI, SC, SD, TN, UT, VA, VI, VT, WA, WI, WV, WY</td>
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<tr>
<td>L33396</td>
<td>Posterior Tibial Nerve Stimulation for Voiding Dysfunction</td>
<td>A and B MAC</td>
<td>National Government Services, Inc</td>
<td>CT, IL, MN, WI, VT, NY, MA, ME, NH, RI</td>
</tr>
</tbody>
</table>
### Attachment B - LCD Availability Grid

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

CMS website accessed April 30, 2018

**IMPORTANT NOTE:** Use the applicable LCD based on member’s residence/place of service AND type of service.

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
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<tr>
<td>L33443</td>
<td>Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control</td>
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<td>Palmetto GBA</td>
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<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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<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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<td>A52965</td>
<td>Posterior Tibial Nerve Stimulation Coverage</td>
<td>A and B MAC</td>
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<td>AK, AZ, ID, MT, ND, OR, SD, WA, UT, WY</td>
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<td>Posterior Tibial Nerve Stimulation Coverage</td>
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<td>Noridian Healthcare Solutions, LLC</td>
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</tbody>
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**End of Attachment B**

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### Attachment C - LCD Availability Grid

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

CMS website accessed April 30, 2018

**IMPORTANT NOTE:** Use the applicable LCD based on member’s residence/place of service AND type of service.

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
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<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>A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
<td>AS, CA, GU, HI, MP, NV</td>
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<td>L33646</td>
<td>Botulinum Toxin</td>
<td>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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<td>L34635</td>
<td>Botulinum Toxin Type A &amp; Type B</td>
<td>MAC Part A and B</td>
<td>Wisconsin Physicians Service</td>
<td>IN, IA, KS, MI, MO, NE</td>
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<tr>
<td>L34635</td>
<td>Botulinum Toxin Type A &amp; Type B</td>
<td>MAC Part A</td>
<td>Wisconsin Physicians Service</td>
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**End of Attachment C**