Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus
covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific
provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits
under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD)
to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy
between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state
mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards,
church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked
plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case
Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for
under Medicare rules, and not to any other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the
CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes
coverage guidelines in this policy where applicable.

SERVICE: Urinary and Fecal Incontinence: Biofeedback, Sacral Nerve Stimulation, Posterior Tibial Nerve Stimulation

PRIOR AUTHORIZATION: Required for Sacral Nerve Stimulator

POLICY:

Urinary Incontinence/Retention:

Biofeedback:
Biofeedback is not a covered benefit under many SWHP policies, however, if the contract does provide coverage, prior authorization is NOT required. Biofeedback for urinary incontinence is not a treatment; it is a tool to help patients learn how to perform pelvic muscle exercises (Kegel exercises). SWHP may cover physical therapy which includes instruction in performance of pelvic muscle exercise when medically appropriate. Once proficiency is achieved further biofeedback therapy would not be covered.

Sacral nerve stimulation (SNS): (e.g. Interstim)
SWHP may consider SNS medically necessary as a last resort therapy when the patient has 1) urinary urge incontinence (UI) or 2) urinary urgency-frequency syndrome, or 3) urinary retention, and meets ALL of the following criteria:

1. 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. Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50 percent or greater improvement through test stimulation. Improvement is measured through voiding diaries.

3. 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.

4. The requesting provider documenting the need for SNS is a urologist or uro-gynecologist.
Excluded: Patients with stress incontinence, urinary obstruction and specific neurologic disease (e.g., diabetes with peripheral nerve involvement) that are associated with secondary manifestations of the above three indications.

SWHP considers the SNS experimental and investigational for all other indications.

SNS requires PRIOR AUTHORIZATION.

Transurethral RF Therapy (Renessa Procedure)

SWHP considers transurethral radiofrequency therapy (Renessa procedure) for the treatment of stress urinary incontinence experimental, investigational and/or unproven.

Posterior Percutaneous Tibial Nerve Stimulation: (PTNS)

Posterior Tibial Nerve Stimulation 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.

Posterior Percutaneous Tibial Nerve Stimulation may be considered medically necessary for the treatment of medically diagnosed overactive bladder which has failed standard pharmacotherapy.

- SWHP considers an initial treatment plan of up to 12 weekly, 30-minute sessions, medically necessary.
- Patients must report an improvement in symptoms within 12 weeks (i.e., 12 sessions) of initiation of PTNS for continued coverage.
- Treatment beyond the initial 12 sessions will be allowed at a frequency of 1 every 1 to 2 months for up to 12 months IF there is documentation of 50% decrease in symptoms as evidenced by a daily uro-log (i.e., record of bladder events, voiding diary) and an improvement in quality of life
- Treatments after 12 months are considered experimental/investigational

Bedwetting Alarms:

These are commercially available without a prescription and therefore are not covered by the health plan.

Fecal Incontinence

Sacral Nerve Stimulator for Fecal Incontinence

SWHP may consider a nerve stimulator medically necessary when ALL of the following conditions are met:

1. Chronic fecal incontinence with greater than two incontinent episodes on average per week; AND
2. Documented failure or intolerance to not less than 3 months of conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); AND
3. A successful percutaneous test stimulation lasting not less than one week, defined as at least 50% sustained improvement in symptoms; AND
4. Condition is not related to anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter; visible sequelae of pelvic radiation; active anal abscesses and fistulae) and/or chronic inflammatory bowel disease; **AND**

5. Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

**Interventions that are NOT considered medically necessary:**

- Sacral nerve stimulation is considered experimental/investigational for the following indications, including, but not limited to:
  - Rectal surgery for conditions other than cancer, performed within the past 12 months; or
  - Rectal surgery for cancer performed within the past 24 months; or
  - Anorectal malformation (for example, congenital anorectal malformation); or
  - Visible sequelae of pelvic radiation; or
  - Active anal abscesses and fistulae; or
  - Chronic inflammatory bowel disease (IBD); or
  - Peripheral neuropathy; or
  - Complete spinal cord injury (no motor or sensory function at sacral segments S4-S5); or
  - Chronic constipation
  - Chronic pelvic pain

- Solesta - an injectable gel, is considered experimental and investigational.

- Botox - is considered experimental and investigational.

**OVERVIEW:**

**URINARY INCONTINENCE:**

Urinary incontinence, defined as the involuntary loss of urine, is common, particularly in women.

There are four prevalent types of UI in adults: a) stress incontinence (urine loss that occurs with an increase in abdominal pressure, and is often due to urethral hypermobility.), b) urge incontinence (which is thought to be related to detrusor over activity.), c) overflow incontinence (dribbling or leaking associated with incomplete bladder emptying), and d) mixed stress and urge incontinence.

Treatments for UI pelvic muscle exercises (Kegel exercise), behavioral therapies such as bladder training and/or biofeedback, pharmacotherapies (e.g., anticholinergic agents, musculotropic relaxants, calcium channel blockers, tricyclic antidepressants, or a combination of anticholinergic, antispasmodic medications and tricyclic antidepressants), and a variety of surgical procedures including intraurethral injection of Coaptite, and implantation of an artificial urinary sphincter.

Specifically, urge incontinence is more effectively managed with peripherally acting receptor agonists or antagonists while stress incontinence is better controlled by pelvic muscle exercises, behavioral therapies, or corrective surgery.

**FECAL INCONTINENCE:**
Fecal incontinence (FI) is loss of control of the bowels resulting in involuntary excretion of liquid or solid feces. The prevalence of FI ranges from 1% to 8% in healthy individuals and approaches 30% in institutionalized patients. FI affects 20 million non-institutionalized adults in the United States. FI has a negative impact on activities of daily living and quality of life. Current treatments for FI range from conservative measures aimed at reducing symptoms to surgical interventions intended to correct anal sphincter or pelvic floor abnormalities.

Sacral nerve stimulation, also called sacral nerve modulation, involves the application of a mild electrical pulse to the sacral nerves through a surgically implanted neuromodulation system to treat fecal incontinence. The electrical pulses modulate the sacral nerves that influence the functioning of the bladder, bowel, urinary, and anal sphincters, and the pelvic floor muscles. The InterStim Therapy System is manufactured by Medtronic.

MANDATES: There are no mandated benefits or regulatory requirements.

CODES:  

Important note:  

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed,</td>
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<tr>
<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming,</td>
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<td>64581</td>
<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement),</td>
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<tr>
<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrode array</td>
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<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, director or inductive coupling,</td>
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<tr>
<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver,</td>
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<tr>
<td>95970</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system; simple or complex brain, spinal cord, or peripheral neurostimulator pulse generator/transmitter, without reprogramming</td>
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<tr>
<td>95971</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system; simple or complex spinal cord, or peripheral neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming,</td>
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<tr>
<td>95972</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system; complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
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CPT Codes NOT covered:  

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<tr>
<th>HCPCS Codes</th>
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<tr>
<td>A4290</td>
<td>Sacral nerve stimulation test lead, each</td>
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<tr>
<td>C1767</td>
<td>Generator, neurostimulator (implantable), nonrechargeable</td>
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<tr>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
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<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
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<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
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<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
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MEDICAL COVERAGE POLICY
SERVICE: Incontinence Treatment
Policy Number: 052
Effective Date: 08/01/2019
Last Review: 06/27/2019
Next Review Date: 06/27/2020

L8683 - Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8684 - Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
L8689 - External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

ICD10:
N31.0 - N31.9 - Bladder atony
N39.4 – N39.498 – Other specified urinary incontinence
N36.44 Muscular disorders of urethra
N39.4 – N39.498 – Other specified urinary incontinence
N36.44 Muscular disorders of urethra
N39.3 Stress incontinence (female) (male)
N39.41 Urge incontinence
N39.46 Mixed incontinence
R15.x Incontinence of feces
R30.1 Vesical tenesmus
R32 Unspecified urinary incontinence
R33.0 - R33.9 - Urinary retention
R35.0 Frequency of micturition
R39.11 Hesitancy of micturition
R39.14 Feeling of incomplete bladder emptying
R39.2 Extrarenal uremia
R39.81 Functional urinary incontinence
R39.89 Other symptoms and signs involving the genitourinary system
R39.9 Unspecified symptoms and signs involving the genitourinary system


LCD L35011 “Posterior Tibial Nerve Stimulation for Urinary Control,” (eff 04/18/2019)

POLICY HISTORY:

<table>
<thead>
<tr>
<th>Status</th>
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<tr>
<td>New</td>
<td>12/6/2010</td>
<td>New policy</td>
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<tr>
<td>Reviewed</td>
<td>12/6/2011</td>
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<td>Reviewed</td>
<td>11/15/2012</td>
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<td>Reviewed</td>
<td>11/14/2013</td>
<td>ICD10 codes added.</td>
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<tr>
<td>Reviewed</td>
<td>09/25/2014</td>
<td>Updated LCD information and SNS and PTNS criteria accordingly</td>
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<tr>
<td>Reviewed</td>
<td>10/22/2015</td>
<td>New LCD. Coverage for fecal incontinence added.</td>
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<tr>
<td>Reviewed</td>
<td>12/02/2015</td>
<td>Reviewed with pelvic surgery team and made mild modifications.</td>
</tr>
<tr>
<td>Reviewed</td>
<td>10/27/2016</td>
<td>Minor format changes</td>
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<tr>
<td>Reviewed</td>
<td>09/19/2017</td>
<td>Policy language clarification</td>
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<td>Reviewed</td>
<td>03/13/2017</td>
<td>Corrected indications to include retention.</td>
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<tr>
<td>Updated</td>
<td>10/01/2018</td>
<td>Added one HCPCS code C1767</td>
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<tr>
<td>Reviewed</td>
<td>06/27/2019</td>
<td>No significant changes</td>
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</table>
REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.


**InterStim Continence Control Therapy/Sacral Nerve Stimulation:**

**Solesta references:**

**Fecal Incontinence references:**


