MEDICAL COVERAGE POLICY	
SERVICE:	**Incontinence Treatment**
Policy Number:	**052**
Effective Date:	**05/01/2024**
Last Review:	**04/08/2023**
Next Review:	**04/08/2024**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

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

PRIOR AUTHORIZATION: Required for Sacral Nerve Stimulator

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) NCD 230.18 Sacral Nerve Stimulation For Urinary Incontinence or LCD (Local Coverage Determination). Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

For all other lines of business use the criteria set forth in InterQual®. When the InterQual® criteria-set only includes Medicare sources (i.e., National or Local Coverage Determinations), those sources will be used to review requests for all lines of business.

Urinary Incontinence/Retention

1. **Biofeedback** is not a covered benefit under many BSWHP 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). BSWHP 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.
2. **Sacral nerve stimulation (SNS)** - Use InterQual® as directed above.
3. **BSWHP considers Transurethral RF Therapy (Renessa Procedure) experimental, investigational and/or unproven and therefore NOT medically necessary** for the treatment of stress urinary incontinence.
4. **Posterior Percutaneous Tibial Nerve Stimulation** (PTNS)
   a. PTNS 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.

b. **PTNS may be considered medically necessary** for the treatment of medically diagnosed overactive bladder which has failed standard pharmacotherapy.
   i. BSWHP considers an initial treatment plan of up to 12 weekly, 30-minute sessions, medically necessary.
   ii. Patients must report an improvement in symptoms within 12 weeks (i.e., 12 sessions) of initiation of PTNS for continued coverage.
   iii. 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
   iv. Treatments after 12 months are considered experimental/investigational

5. **Bedwetting Alarms** are commercially available without a prescription and therefore are not covered by the health plan.

Fecal Incontinence

1. Sacral Nerve Stimulator for Fecal Incontinence: Use InterQual® as directed above.
2. Interventions that are NOT considered medically necessary include:
   a. Solesta - an injectable gel, is considered experimental and investigational.
   b. Botox - is considered experimental and investigational.

BACKGROUND:

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: None

CODES:
Important note: *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.*

CPT Codes	53444 - Insertion of tandem cuff (dual cuff) 53445 - Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff 64561 - Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, 64566 – Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming, 64581 – Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement), 64585 - Revision or removal of peripheral neurostimulator electrode array 64590 –Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, director or inductive coupling, 64595 – Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver, 95970 – Electronic analysis of implanted neurostimulator pulse generator system; simple or complex brain, spinal cord, or peripheral neurostimulator pulse generator/transmitter, without reprogramming 95971 - Electronic analysis of implanted neurostimulator pulse generator system; simple spinal cord, or peripheral neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, 95972 - 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
CPT Codes NOT Covered	53860 - Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
HCPCS Codes	A4290 - Sacral nerve stimulation test lead, each C1767 - Generator, neurostimulator (implantable), nonrechargeable E0745 - Neuromuscular stimulator, electronic shock unit L8679 - Implantable neurostimulator, pulse generator, any type L8681 - Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only L8682 - Implantable neurostimulator radiofrequency receiver 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
ICD-10 Codes	N31.0 - N31.9 - Bladder atony N39.4 – N39.498 – Other specified urinary incontinence N36.44 - Muscular disorders of urethraN39.4 – 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

POLICY HISTORY:

Status	Date	Action
New	12/6/2010	New policy
Reviewed	12/6/2011	Reviewed.
Reviewed	11/15/2012	Reviewed.
Reviewed	11/14/2013	ICD10 codes added.
Reviewed	09/25/2014	Updated LCD information and SNS and PTNS criteria accordingly
Reviewed	10/22/2015	New LCD. Coverage for fecal incontinence added.

Reviewed	12/02/2015	Reviewed with pelvic surgery team and made mild modifications.
Reviewed	10/27/2016	Minor format changes
Reviewed	09/19/2017	Policy language clarification
Reviewed	03/13/2017	Corrected indications to include retention.
Updated	10/01/2018	Added one HCPCS code C1767
Reviewed	06/27/2019	No significant changes
Updated	05/28/2020	Transitioned to IQ and aligned for FirstCare and SWHP
Reviewed	05/27/2021	No major change. Codes updated
Reviewed	04/21/2022	No changes
Reviewed	04/27/2023	No changes
Reviewed	04/08/2024	Formatting changes, added hyperlinks to NCD and TMPPM, beginning and ending note sections updated to align with CMS requirements and business entity changes

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.

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