



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

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Urinary Incontinence Treatment

Policy Number: HS-080

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2/2/2012

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Urinary incontinence is the involuntary loss of urine that is a social or hygienic problem. Urinary incontinence is categorized as transient, urge, stress, overflow, mixed, and functional. It affects at least 13 million Americans and is twice as common in women as in men. Urinary incontinence affects 10% to 52% of adult women and is severe in 3% to 17%. For noninstitutionalized persons aged 60 years or older, the prevalence ranges from 15% to 30%, and for nursing home residents, the prevalence is 50% or higher. The following are risk factors for the development of urinary incontinence in women, including childbirth, mode of delivery, pregnancy, increased parity, hysterectomy, recurrent urinary tract infections, and other gynecologic factors; gastrointestinal factors; medications such as diuretics, sedatives and beta-blockers; smoking; alcohol and caffeine use; presence of two or more chronic diseases such as chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), and diabetes; advanced age; white race; and high body mass index. Other causes of incontinence in both men and women include diseases that damage the cortical and subcortical inhibitory centers, such as dementia, Alzheimer's disease, normal pressure hydrocephalus, and multi-infarct disease from Hayes, 2006).

Treatment options for urinary voiding disorders include: behavioral strategies, pharmacological interventions, temporary electrical stimulation, and reconstructive surgery. Usually, the less invasive, first-tier behavioral and pharmacological interventions are advised and are often combined with temporary electrical stimulation before irreversible, reconstructive surgery is considered as a treatment choice.

Sacral Nerve Stimulation

Sacral nerve stimulation (SNS) is currently intended for the treatment of intractable urinary urge incontinence, non-obstructive urinary retention, and urgency/frequency syndrome in adults. SNS is generally indicated in members who demonstrate at least 50% incontinence symptom relief during percutaneous test stimulation and who have failed or not tolerated more conservative treatments (e.g., behavioral strategies, pharmacological interventions).

When the screening trial demonstrates successful results, permanent SNS system placement can be performed. The implantable pulse generator (IPG) is positioned surgically in the upper buttock region. Once the IPG is placed, it is then connected to an extension that passes underneath the skin to an electrical lead that has been placed through an incision over the lower back in contact with one side of the appropriate sacral nerve root, most often the S3 vertebra. Implantation is considered to be a reversible, minimally invasive procedure and is performed under general anesthesia. The IPG can be externally adjusted to optimal settings by a physician using a microprocessor-based console programmer. Members can operate a hand-held programmer to adjust levels of stimulation within physician-prescribed limits. The battery is expected to last approximately 7–9 years. When the battery loses power, another procedure is required to replace it.

Pelvic Floor Electrical Stimulation

Pelvic floor electrical stimulation can be performed in a clinical setting or at home. Electrodes can be placed either externally and internally; the treatment varies in stimulus frequency, stimulus intensity, treatment duration, number of sessions, and treatment days per week. During each treatment session, a frequency of 5 to 100 hertz (Hz) is used for 15 to 20 minutes once or twice daily. In most cases, vaginal, anal, and surface electrodes are used; removable electrodes are placed in the vagina or rectum (plug electrodes) or around the dorsum of the penis (butterfly electrodes). Electrodes may also be placed on the presacral skin to convey electrical impulses to the nerve roots that supply the pudendal and pelvic nerves to the bladder.

In cases of urge incontinence, the objective of electrical stimulation is to reinforce the inhibitory system. Since these inhibitory neurons operate at low frequencies, stimulation is generally administered at 5 to 20 Hz. Electrical stimulation may also be transmitted percutaneously with surface electrodes to inhibit detrusor activity. Surface electrodes may be applied to the hamstring and quadriceps muscles of one or both legs. In these cases, electrical

stimulation is applied with pulse duration of 0.2 milliseconds (ms) and a frequency of 30 Hz. The hamstrings and quadriceps are stimulated alternately for 4 seconds each with an intervening 4-second duration in which no stimulation is applied. In another variation of the technique, an electrode is placed on the presacral skin over the S2/3/4 nerve roots and a second electrode is placed over the perineal skin.

For stress incontinence, the goal of electrical stimulation is the activation of the motor neurons. In these cases, stimulation is generally administered at 20 to 50 Hz. For patients with mixed incontinence, the treatment sessions generally alternate between stimulation parameters for urge incontinence and stress incontinence (Hayes, 2006).

Collagen Implant

A collagen implant, which is injected into the submucosal tissues of the urethra and/or the bladder neck and into 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.

Transurethral Radiofrequency Micro-Remodeling

The Renessa® System (Novasys Medical Inc.) consists of an RF generator and probe. The probe is inserted through the urethra into the bladder, and is anchored in the bladder outlet by inflation of a balloon at its tip. A series of 4 needles arranged concentrically around the probe shaft just beneath the balloon are deployed into the tissue after which pulses of RF energy lasting 60 to 90 seconds are administered. The RF energy raises the temperature in the vicinity of the needle tips to 65°C to 75°C. These temperatures are high enough to break down tissue proteins in the region of the needle tip but do not lead to tissue destruction. As these small lesions heal, the urethral tissue becomes firmer and less likely to open involuntarily under pressure. The process, which is also called micro-remodeling, is performed by a gynecologist or urologist, takes around 20 minutes, and has a recovery time of around 2 hours. The procedure has been carried out under conscious sedation, but preliminary data indicate it can also be performed in the office.

The available evidence on the efficacy and safety of transurethral RF therapy with the Renessa system for treatment of SUI is very limited. Only two manufacturer-sponsored studies were identified that were conducted by a single group of researchers. There is some evidence of efficacy among patients with the most severe symptoms of SUI, but analysis and interpretation of the results is complicated by a high rate of placebo responses and lack of blinded assessment of outcomes. Moreover, there has been no evaluation of the long-term health outcomes or complications following this procedure, and it is unknown how it compares with alternative technologies. Further studies incorporating blinded assessment of objective outcomes and longer follow-up are needed to confirm the efficacy and safety of this procedure.

POSITION STATEMENT

- 1) Sacral nerve stimulation **is considered medically necessary** and a covered benefit if ALL of the following criteria are met:
 - Member has a diagnosis of 788.31 urinary urge incontinence, 788.20 non-obstructive urinary retention OR 788.31, 788.32, 788.33, 788.41 Urinary Urgency-Frequency Syndrome; AND,
 - The member has shown a documented positive response to a percutaneous trial of sacral stimulation*;
AND,
 - The member has not responded to conventional therapy, including documented behavioral,

pharmacologic, and/or surgical corrective therapy.

*Before a member is eligible for permanent implantation, the member must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through a voiding diary.

2) Non-implantable pelvic floor electrical stimulation **is considered medically necessary** if ALL of the following criteria are met:

- Member has a diagnosis of 625.6 Stress and/or 788.31, 788.33 Urinary Urge Incontinence; AND,
- Member is cognitively intact; AND,
- 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 incontinence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

3) Injectable urethral bulking agents (i.e., collagen) **are considered medically necessary** for members who:

- have not responded to conventional treatments; AND,
- have 599.82 Intrinsic Sphincter Deficiency (ISD)

Injections of bulking agents have been shown to have NO clinical value in ANY of the following circumstances and, therefore, are NOT a covered benefit:

- Previous V15.3 Pelvic Radiation Therapy; OR,
- 596.59 Unstable or Noncompliant Bladder; OR,
- Members with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies; OR,
- Members with an acute condition involving 595.0 Cystitis, 593.89 Urethritis, or 595.9 Infection; OR,
- Members undergoing or planning to undergo desensitization injections to meat products.

NOTE: Prior to collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4 week period.

In male members, the evaluation must include a complete history and physical examination and a simple cystometrogram to determine that the bladder fills and stores properly. The member then is asked to stand upright with a full bladder and to cough or otherwise exert abdominal pressure on his bladder. If the member leaks, the diagnosis of ISD is established.

In female members, the evaluation must include a complete history and physical examination (including a pelvic exam) and a simple cystometrogram to rule out abnormalities of bladder compliance and abnormalities of urethral support. Following that determination, an abdominal leak point pressure (ALLP) test is performed. Leak point pressure, stated in cm H₂O, is defined as the intra-abdominal pressure at which leakage occurs from the bladder (around a catheter) when the bladder has been filled with a minimum of 150 cc fluid. If the patient has an ALLP of less than 100 cm H₂O, the diagnosis of ISD is established.

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 recurrence 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.

- 4) Vaginal cones **are considered medically necessary** and a covered benefit if ALL of the following criteria are met:
 - When used in combination with pelvic muscle exercises (Kegel's exercise); AND,
 - Member has a diagnosis of 625.6 or 788.32 Simple (pure) Stress Urinary Incontinence
- 5) Pessary (bladder neck support prosthesis), a plastic device that fits into the vagina to help support the uterus and bladder, **is considered medically necessary** and a covered benefit if ALL of the following criteria are met:
 - Member is female and has a diagnosis of 625.6 Stressed or 788.33 Mixed Urinary Incontinence
- 6) Tension-free vaginal tape procedures **are considered medically necessary** and a covered benefit if ALL of the following criteria are met:
 - Member is female; AND,
 - Has failed behavioral and pharmacological treatments; AND,
 - Has a diagnosis of 625.6 Stress Urinary Incontinence
- 7) Colposuspension and sling procedures **are considered medically necessary** and a covered benefit if ALL of the following criteria are met:
 - Member has a diagnosis of 625.6 or 788.32 or 788.33 Stress Urinary Incontinence; AND,
 - Member is refractory to conservative management

The following treatments for urinary incontinence **are considered experimental and investigational** and NOT a covered benefit:

- Transurethral radiofrequency micro-remodeling using the Renessa® system (Novasys Medical Inc)
- Transvaginal radiofrequency bladder neck suspension
- Percutaneous tibial nerve stimulation
- Extracorporeal magnetic stimulation (Neocontrol™ System)
- Transurethral Macroplastique injection
- Transobturator tape procedure
- Implantable pelvic floor electrical stimulation

CODING

Covered CPT® Codes when the above criteria has been met:

- | | |
|--------------|--|
| 11950 | Subcutaneous injection of filling material (e.g. collagen), 1 cc or less |
| 11951 | Subcutaneous injection of filling material (e.g. collagen), 1.1 to 5.0 cc |
| 11952 | Subcutaneous injection of filling material (e.g. collagen), 5.1 to 10.0 cc |
| 11954 | Subcutaneous injection of filling material (e.g. collagen), over 10.0 cc |
| 51715 | Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck |
| 51840 | Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); simple |
| 51841 | Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); complicated (eg, secondary repair |
| 51990 | Laparoscopy, surgical; urethral suspension for stress incontinence |

- 51992** Laparoscopy, surgical; sling operation for stress incontinence (e.g., fascia or synthetic)
- 53440** Sling operation for correction of male urinary incontinence (e.g., fascia or synthetic)
- 53442** Removal or revision of sling for male urinary incontinence (e.g., fascia or synthetic)
- 53444** Insertion of tandem cuff (dual cuff)
- 53445** Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
- 53446** Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
- 53447** Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
- 53448** Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff through an infected field at the same operative session including irrigation and debridement of infected tissue
- 53449** Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
- 57160** Fitting and insertion of pessary or other intravaginal support device
- 57287** Removal or revision of sling for stress incontinence (e.g., fascia or synthetic)
- 57288** Sling operation for stress incontinence (e.g., fascia or synthetic)
- 64550** Application of surface (transcutaneous) neurostimulator
- 64561** Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
- 64581** Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
- 64585** Revision or removal of peripheral neurostimulator electrodes
- 95970** Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
- 95971** Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
- 95972** Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex brain, spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
- +95973** Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour

Covered ICD-9-CM Procedure Codes when the above criteria has been met:

- 04.92** Implantation or Replacement of Peripheral Neurostimulator Leads, i.e., Sacral Nerve
- 58.93** Implantation of artificial urinary sphincter (AUS); i.e. urethral
- 59.71** Levator muscle operation for urethrovesical suspension
- 59.72** Injection of implant into urethra and/or bladder neck, i.e. Collagen implant
- 59.79** Repair of Stress Incontinence NOS
- 96.18** Insertion of other vaginal pessary

Non Covered CPT® Codes

53860 - Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

Non Covered CPT® Category III Codes

0193T Has been deleted effective 2011, to report use 53860

Covered HCPC® Codes when the above criteria has been met:

- A4290** Sacral nerve stimulation test lead, each
 - A4335** Incontinence Supply, miscellaneous (assign for Vaginal Cones, Tension Free Vaginal Tape as there are no specified codes to date)
 - A4561** Pessary, rubber, any type
 - A4562** Pessary, non-rubber, any type
 - C1767** Generator, neurostimulator (implantable)
 - C1771** Repair device, urinary, incontinence, with sling graft
 - C1778** Lead, neurostimulator (implantable)
 - C1787** Patient programmer, neurostimulator
 - C1815** Prosthesis, urinary sphincter (implantable)
 - C1816** Receiver and/or transmitter, neurostimulator (implantable)
 - C1883** Adaptor/extension, pacing lead or neurostimulator lead (implantable)
 - C1897** Lead, neurostimulator test kit (implantable)
 - C2631** Repair device, urinary, incontinence, without sling graft
 - E0740** Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer
 - L8603** Collagen Implant, Injectable bulking agent, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
 - L8606** Synthetic implant, Injectable bulking agent, urinary tract, 1 ml syringe, includes shipping and necessary supplies
 - L8680** Implantable neurostimulator electrode, each
 - L8681** Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
 - 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
 - L8685** Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
 - L8686** Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
 - L8687** Implantable neurostimulator pulse generator, dual array, rechargeable, include extension
 - L8688** Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
 - L8689** External recharging system for implanted neurostimulator, replacement only
 - L8695** External recharging system for battery (external) for use with implantable neurostimulator
 - Q3031** Collagen skin test
 - S8270*** Enuresis alarm, using auditory buzzer and/or vibration device
- *S- Codes are NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes**

Covered ICD-9-CM Diagnosis Codes when the above criteria has been met:

- 599.82** ISD – Intrinsic (Urethral) Sphincter Deficiency
- 625.6** Female Stress Incontinence
- 788.20** Retention of Urine, unspecified
- 788.31** Urge incontinence
- 788.32** Male Stress Incontinence

788.33 Mixed incontinence (female) (male)
788.41 Urinary Frequency

*Current Procedural Terminology (CPT) 2012 American Medical Association: Chicago, IL.®©

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Government Agencies, Professional and Medical Organizations

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HISTORY AND REVISIONS

Date	Action
2/2/2012	<ul style="list-style-type: none">• Approved by MPC. No changes.
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
2/26/2011	<ul style="list-style-type: none">• Approved by MPC.