Medical Policy
Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

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Policy Number: 523
BCBSA Reference Number: 2.01.60
NCD/LCD: Local Coverage Determination (LCD): Non-covered Services (L33629)

Related Policies
- Periurethral Bulking Agents for the Treatment of Urinary Incontinence, #471
- Biofeedback as a Treatment of Urinary Incontinence in Adults, #173
- Pelvic Floor Stimulation as a Treatment of Urinary Incontinence, #470

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Transvaginal radiofrequency bladder neck suspension as a treatment of urinary stress incontinence is INVESTIGATIONAL.

Transurethral radiofrequency tissue remodeling as a treatment of urinary stress incontinence is INVESTIGATIONAL.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

This is not a covered service.

Local Coverage Determination (LCD): Non-covered Services (L33629)

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO Blue℠</td>
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<td>Medicare PPO Blue℠</td>
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</tbody>
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CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following CPT code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>53860</td>
<td>Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence</td>
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Description

Urinary stress incontinence, defined as the involuntary loss of urine from the urethra due to an increase in intra-abdominal pressure, is a common condition affecting women in the U.S. Conservative therapy usually includes pelvic floor muscle exercises. Biofeedback, pelvic electrical stimulation, or periurethral bulking agents such as collagen might also be tried. Various surgical options are considered when conservative therapy fails, including most prominently various types of bladder suspension procedures.

Radiofrequency (RF) tissue remodeling with specially designed devices has been explored as a minimally invasive treatment option for urinary stress incontinence. It involves using nonablative levels of RF energy to shrink and stabilize the endopelvic fascia, thus improving the support for the urethra and bladder neck.

Examples of RF devices for the treatment of urinary stress incontinence include the SURx Transvaginal System and Renessa® transurethral radiofrequency system from Novasys Medical Inc. All RF devices for the treatment of urinary stress incontinence are considered investigational regardless of the commercial name, the manufacturer, or FDA approval status.

Summary

There remains insufficient evidence from well-conducted, randomized, controlled trials that either transvaginal or transurethral radiofrequency tissue remodeling improves the net health outcome compared to a sham procedure or another treatment for stress urinary incontinence. Thus, the treatments are considered investigational.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>12/2015</td>
<td>Clarified coding information.</td>
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<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>5/2013</td>
<td>New references from BCBSA National medical policy.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References