Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

Policy #: 296
Latest Review Date: July 2023
Category: Medical
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **transvaginal radiofrequency bladder neck suspension** and/or **transurethral radiofrequency tissue remodeling** as a treatment of urinary stress incontinence as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Urinary stress incontinence (SUI), defined as the involuntary loss of urine from the urethra due to an increase in intra-abdominal pressure, is a common condition, affecting 6.5 million women in the United States. Conservative therapy includes behavior modifications, pelvic floor muscle exercises, or periurethral bulking agents such as collagen. Various surgical options are considered when conservative therapy fails, including most prominently various different types of bladder suspension procedures, which intends to reduce bladder neck and urethra hypermobility by tautening the endopelvic fascia.

The use of nonablative levels of radiofrequency energy has been investigated as a non-surgical technique to shrink and stabilize the endopelvic fascia, thus improving the support for the urethra and bladder neck. An incision is made through the vagina lateral to the urethra, exposing the endopelvic fascia. Radiofrequency energy is then applied over the endopelvic fascia in a slow, sweeping manner, resulting in blanching and shrinkage of the tissue. The procedure is also known as radiofrequency mirco-remodeling or radiofrequency collagen denaturation.

KEY POINTS:

The most recent update was with a review of the literature through July 5, 2023.

Summary of Evidence

For individuals receiving transvaginal or transurethral radiofrequency for tissue remodeling for urinary stress incontinence, the evidence includes small prospective and retrospective studies, and one RCT. Relevant outcomes include quality of life, improvement of symptoms, and treatment morbidity There remains insufficient evidence from well-conducted randomized controlled trials that either transvaginal or transurethral radiofrequency improves the net health outcome compared to a sham procedure or another treatment for stress urinary incontinence. Larger studies with long-term follow-up, identification of the patient population that might benefit from the procedure and independent replication are needed. There is minimal evidence within the peer-reviewed literature that provides support for the use of transvaginal radiofrequency surgery or transurethral radiofrequency tissue micro-remodeling. The efficacy

and long-term effectiveness of these modalities for the treatment of urinary incontinence has not been determined. The evidence is insufficient to determine the health effects of this technology.

Practice Guidelines and Position Statements
The American College of Obstetricians and Gynecologists (ACOG)
In 2015 (reaffirmed in 2018), ACOG published practice bulletin Number 155 – Urinary Incontinence in Women. The recommendations on treating urinary incontinence in women do not mention transvaginal or transurethral radiofrequency remodeling.

American Urological Association (AUA) / Society of Urodynamics and Female Pelvic Medicine & Urogenital Reconstruction (SUFU).
In 2017 (Amended 2023), the AUA and SUFU published a guideline for the Surgical Treatment of Female Stress Urinary Incontinence. The recommendations do not mention transvaginal or transurethral radiofrequency remodeling.

U.S. Preventive Task Force Recommendations
N/A

KEY WORDS:
Transvaginal radiofrequency bladder neck suspension, transurethral radiofrequency tissue remodeling, urinary stress incontinence, SUI, radiofrequency, micro-remodeling, radiofrequency collagen denaturation

APPROVED BY GOVERNING BODIES:
The SURx Transvaginal System received clearance to market through the U.S. Food and Drug Administration (FDA) 510(k) process in 2002. According to the FDA, the device "is indicated for shrinkage and stabilization of female pelvic tissue for treatment of Type II stress urinary incontinence due to hypermobility in women not eligible for major corrective surgery". This device is no longer marketed in the United States.

Novasys Medical received clearance to market the Renessa transurethral RF system through the U.S. FDA 510(k) process in July 2005. The device "is indicated for the transurethral treatment of female stress urinary incontinence due to hypermobility in women who have failed conservative treatment and who are not candidates for surgical therapy."

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

53899	Unlisted procedure, urinary system
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

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POLICY HISTORY:

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Medical Policy Group, February 2009
Medical Policy Group, March 2010
Medical Policy Group, December 2010
Medical Policy Group, February 2011
Available for comment February 2 – March 18, 2011
Medical Policy Group, July 2011
Medical Policy Group, March 2013
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated effective March 24, 2020.
Medical Policy Group, August 2021
Medical Policy Group, July 2022
Medical Policy Group, July 2023: Reviewed by consensus. No change to policy statement.
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