

**Policy: MP237**

**Section: Medical Benefit Policy**

**Subject: Transurethral/Transvaginal Radiofrequency Tissue Remodeling**

**Applicable line of business:**

<b>Commercial</b>	<b>x</b>	<b>Medicaid</b>	<b>x</b>
<b>Medicare</b>	<b>x</b>	<b>ACA</b>	<b>x</b>
<b>CHIP</b>	<b>x</b>		

**I. Policy:** Transurethral/Transvaginal Radiofrequency Tissue Remodeling

**II. Purpose/Objective:**

To provide a policy of coverage regarding Transurethral/Transvaginal radiofrequency tissue remodeling

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**Commercial**

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicare**

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

**CHIP**

Geisinger Health Plan Kids (GHP Kids) is a Children’s Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicaid**

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

### **Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

### **DESCRIPTION:**

Transurethral and transvaginal radiofrequency tissue remodeling has been proposed as a treatment of urinary stress incontinence. Unlike traditional radiofrequency which causes tissue necrosis, this procedure utilizes lower temperatures and has been proposed to shrink and stabilize the endopelvic fascia, thus improving the support for the urethra and bladder neck.

### **EXCLUSIONS:**

The Plan does **NOT** provide coverage for the use of transurethral or transvaginal radiofrequency tissue remodeling as a treatment of urinary stress incontinence because it is considered **experimental, investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

### **Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

### **CODING ASSOCIATED WITH: Transurethral/Transvaginal radiofrequency tissue remodeling**

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.*

- 53860** Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
- 0672T** Endovaginal cryogen-cooled monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence

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

**Associated Key Words:** ReNessa®, SURx®

### **LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

**REFERENCES:**

Vianello, A, Costantini, E, Del, ZM, and Porena, M. Mini-invasive techniques for the treatment of female stress urinary incontinence. *Minerva Ginecol.* 2007;59(6):557-569.

Appell, RA, Juma, S, Wells, WG, Lenihan, JP, Klimberg, IW, Kanellos, A, and Reilley, SF. Transurethral radiofrequency energy collagen micro-remodeling for the treatment of female stress urinary incontinence. *Neurourol Urodyn.* 2006;25(4):331-336.

ECRI Institute Hotline (online). Nonsurgical, transurethral radiofrequency collagen denaturation for female stress urinary incontinence. Lansdale: ECRI Institute. Current as of March 3, 2009.

California Technology Assessment Forum (CTAF). Radiofrequency micro-remodeling for the treatment of female stress urinary incontinence 2008 Oct.

Highmark Medicare Services. LCD L30547 – Radiofrequency treatment for urinary incontinence.

Hayes Health Technology Brief Transurethral Radiofrequency Micro-Remodeling Using the Renessa® System (Novasys Medical Inc.) for Female Stress Urinary Incontinence. 3/19/10. Accessed 1/3/13

Kang D, Han J, Neuberger MM, Moy ML, Wallace SA, Alonso-Coello P, Dahm P. Transurethral radiofrequency collagen denaturation for the treatment of women with urinary incontinence. *Cochrane Database of Systematic Reviews*, Issue 3, 2015.

Razzaghi M, et al Intravaginal Pulsed Contractile Radiofrequency for Stress Urinary Incontinence Treatment; A Safety Study. *J Lasers Med Sci* 2021;12:e56

Abdelaziz, A., Blusewicz, T A., Coley, K P., & Karram, M. Safety, tolerability and short-term efficacy of transvaginal fractional bipolar radiofrequency therapy for symptoms of stress and or mixed incontinence in conjunction with genitourinary syndrome of menopause. *Neurology and Urodynamics*, 2023;42 (4):807-813

Er-Rabiai, Y., Torres-Lacombe, M., Casaña, J., López-Bueno, R., Núñez-Cortés, R., & Calatayud, J. The effectiveness of adding transvaginal radiofrequency to pelvic floor muscle training for 6 weeks in women with stress urinary incontinence. A double-blind randomised controlled trial. *International Urogynecology Journal*, 2024;10 (1007).

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 02/10

**Revised:** 2/11 (coding), 1/18 (add transvaginal RF exclusion)

**Reviewed:** 2/12, 2/13, 2/14, 2/15, 2/16, 1/17, 1/19, 1/20, 1/21, 1/22, 1/23, 1/24, 1/25

**CMS UM Oversight Committee Approval:** 12/23, 5/24, 2/25

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health

Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.