MEDICAL POLICY STATEMENT
TrueCare

Policy Name & Number	Date Effective
Transcervical Radiofrequency Ablation-TrueCare-MM-1791	11/01/2026
Policy Type	
MEDICAL	

Medical Policy Statements are developed from a review of the available evidence-based, clinical information based on and supported by clinical guidelines from medical specialties, peer-reviewed medical and scientific studies, nationally recognized utilization and technology assessment guidelines, and other medical management industry standards to aid in determining the medical necessity of a service. Medically necessary services are defined in the plan-specific Evidence of Coverage, Member Handbooks, Provider Manuals, Medical Policy Statements, and/or other plan policies and procedures.

Medical Policy Statements do not guarantee an authorization or payment of services. Please refer to the plan contract (e.g., Evidence of Coverage, Member Handbook) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract and/or provider agreement, then the plan contract and/or provider agreement will be the controlling document. Reasonable discretion may be used in interpreting and applying this Policy Statement to services provided in a particular case, and the policy may be modified at any time. Medical Policy Statements may be superseded by federal and state laws and regulations, as applicable. In the case of a discrepancy between the Policy Statement's effective date and any applicable legal or regulatory requirement, the law or regulation will govern.

Coverage for mental health and substance use disorder (MH/SUD) benefits are provided at the same level as coverage for medical and surgical (M/S) benefits, as required by the Mental Health Parity and Addiction Equity Act (MHPAEA). MH/SUD benefits are not subject to limits or requirements that are more restrictive than those that apply to M/S benefits.

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A. Subject

Transcervical Radiofrequency Ablation

B. Background

Uterine leiomyomas (fibroids) are the most common solid benign tumors of the uterus, estimated to occur in up to 70% of women by menopause. Uterine fibroids are associated with heavy menstrual bleeding, dysmenorrhea, pelvic pain, quality of life, and difficulty in achieving pregnancy. The combined effect of the direct costs attributable to fibroid diagnosis and treatment, plus the indirect costs due to work absenteeism and loss of productivity, are responsible for a significant economic burden of $34 billion annually in the United States.

Hysterectomy and myomectomy are the most commonly performed surgical interventions for the treatment of uterine fibroids. Hysterectomy involves removal of the uterus (and generally, the cervix), with or without ovarian conservation. Myomectomy is an operation in which individual fibroids are removed, retaining the uterus and therefore potential for future pregnancy.

In recent years, leiomyoma ablation techniques have emerged as less invasive alternatives. Transcervical uterine ablation of leiomyomas combines reusable intrauterine ultrasound with a single-use intrauterine radiofrequency ablation (RFA) handpiece and needle electrode to facilitate targeted thermal ablation of symptomatic uterine leiomyomas creating coagulative necrosis within the treated leiomyoma.

The Sonata system (Gynesonics Inc.) is a minimally invasive, uterine-sparing, ultrasound-guided system for performing transcervical RFA of fibroids in the outpatient setting. It integrates intrauterine ultrasound imaging with a radiofrequency treatment device to provide a uterus-conserving, transcervical incisionless treatment for a range of leiomyoma types and sizes. Sonata has received clearance by the Food and Drug Administration (FDA) and has Conformité Européenne (CE) marking for use in the European Union.

C. Definitions

- **Leiomyomas** – Also called uterine fibroids, an extremely common benign neoplasm in women of reproductive age composed of smooth muscle cells and fibroblasts.
- **Myomectomy** – A surgical procedure to remove uterine fibroids while preserving the uterus.
- **Radiofrequency Ablation** – A minimally invasive technique that shrinks the size of tumors by using heat to destroy tissue.

D. Policy

I. Transcervical ultrasound guided radiofrequency ablation (Sonata) is considered medically necessary as an alternative to myomectomy or hysterectomy for treating symptomatic uterine fibroid(s) when **all** the following criteria are met:
   A. fibroid(s) diagnosis
   B. preference for uterine preservation
   C. uterine size < 16 gestational weeks

D. no history of gynecologic malignancy or pre-malignancy within the past 5 years
E. member has received counseling regarding the lack of data for individuals who may desire future pregnancy

II. Non-covered services
A. The use of transcervical radiofrequency ablation as a treatment for uterine fibroids is considered not medically necessary if the above criteria are not met.
B. The following treatments for uterine fibroids are considered experimental and investigational as safety and efficacy have not been established:
1. acupuncture
2. cryomyolysis
3. cryotherapy
4. electrical ablation
5. interstitial thermotherapy
6. laparoscopic uterine artery occlusion
7. lasers

E. Conditions of Coverage
NA

F. Related Policies/Rules
NA

G. Review/Revision History

	DATE	ACTION
Date Issued	06/18/2025	New policy. Approved at Committee.
Date Revised	11/05/2025 07/29/2026	Updated references. Approved at Committee. Minor edits for clarity. Approved at Committee.
Date Effective	11/01/2026	
Date Archived		

H. References
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