MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
Transcervical Radiofrequency Ablation-OH MCD-MM-1563	03/01/2025-01//31/2026
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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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 the potential for 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. This creates 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 FDA and has CE marking for use in the European Union.

C. Definitions

- **Leiomyomas** – also called uterine fibroids, are an extremely common benign neoplasm in women of reproductive age. They are 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. uterine preservation is desired
   B. fibroid(s)
   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 that want to become pregnant

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. These following treatments for uterine fibroids are considered experimental and investigational as their 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	01/16/2024	New policy. Approved at Committee.
Date Revised	12/04/2024	Updated references. Approved at Committee.
Date Effective	03/01/2025	
Date Archived	01/31/2026	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Brooks E, Mihalov L, Delvadia D, et al. The inspire comparative cost study: 12-month health economic and clinical outcomes associated with hysterectomy, myomectomy, and treatment with the Sonata System. *Clinicoecon Outcomes Res.* 2020;12:1-11. doi:10.2147/CEOR.S214755

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

2. Cardozo ER, Clark AD, Banks NK, et al. The estimated annual cost of uterine leiomyomata in the United States. *Am J Obstet Gynecol*. 2012;206(3):211.e1-211.e2119. doi:10.1016/j.ajog.2011.12.002
3. Christoffel L, Römer T, Schiermeier S. Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE): Study Protocol and Preliminary Results [published correction appears in Med Devices (Auckl). 2021 Mar 15;14:85. doi: 10.2147/MDER.S309722]. Med Devices (Auckl). 2021;14:77-84. Published 2021 Mar 3. doi:10.2147/MDER.S301166.
4. Chudnoff S, Guido R, Roy K, et al. Ultrasound-guided transcervical ablation of uterine leiomyomas. *Obstet Gynecol*. 2019;133(1):13-22. doi:10.1097/AOG.0000000000003032
5. Health Technology Evaluation. Transcervical Radiofrequency Ablation with the Sonata System for Symptomatic Uterine Fibroids. Hayes; 2023. Accessed November 5, 2024. www.evidence.hayesinc.com
6. Lukes A, Green MA. Three-Year Results of the SONATA Pivotal Trial of Transcervical Fibroid Ablation for Symptomatic Uterine Myomata. *J Gynecol Surg*. 2020;36(5):228-233. doi:10.1089/gyn.2020.0021
7. Shirin G, Engelhardt M, Gee P, Pschadka G. Transcervical fibroid ablation with the Sonata™ system for treatment of submucous and large uterine fibroids. *Int J Gynaecol Obstet.* 2021;155(1):79-85. doi:10.1002/ijgo.13638
8. Transcervical Uterine Ablation of Leiomyomas. A-1039 (AC). MCG Health. 28th ed. 2024. Accessed November 5, 2024. www.careweb.careguidelines.com
9. Yu S, Silverberg K, Bhagavath B, et al. Post-market safety of laparoscopic ultrasound-guided radiofrequency ablation. *JSLS*. 2020;24(4):e2020.00050. doi:10.4293/JSLS.2020.00050

Independent medical review – October 2023

Approved by ODM 12/12/2024