

OHCA Guideline

Medical Procedure Class:	Transcervical Ablation of Uterine Fibroid(s) – the Sonata System
Initial Implementation Date:	February 1, 2026
Last Review Date:	January 2026
Effective Date:	February 1, 2026
Next Review/Revision Date:	February 2029

* This document is not a contract, and these guidelines do not reflect or represent every conceived situation. Although all items contained in these guidelines may be met, this does not reflect or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.

New Criteria

Revision of Existing Criteria

Summary

Purpose: To provide guidelines to assure medical necessity and consistency in the prior authorization process.

Definitions

Ablation – the removal or destruction of a body part or tissue or its function; may be performed by surgery, hormones, drugs, radiofrequency, heat, or other methods

Adenomyosis – a condition where the tissue that lines the uterus grows into the muscular wall of the uterus, causing it to thicken and enlarge

Intramural – a common type of non-cancerous tumor that grows within the muscular wall (myometrium) of the uterus

Pedunculate – a non-cancerous uterine growth attached to the uterus by a slender stalk, or peduncle, allowing it to grow outward from the uterine wall or inward into the uterine cavity

Radiofrequency – high-frequency electrical energy used in minimally invasive procedures to create heat, destroying abnormal tissues

Sonata System – aka Sonata fibroid treatment – a minimally invasive procedure to treat symptomatic uterine fibroids without surgery, using radiofrequency energy to shrink fibroids while preserving the uterus

Submucous – a non-cancerous growth that develops just beneath the endometrium, the inner lining of the uterus

Transcervical radiofrequency ablation – a minimally invasive procedure that integrates intrauterine ultrasound imaging with radiofrequency transcervical incisionless treatment to destroy uterine fibroids

Transmural – a type of uterine fibroid that grows through the entire thickness of the uterine wall, extending from the outer surface (serosa) to the inner lining (endometrium)

Description

The Sonata System uses a handpiece with a miniature high-resolution ultrasound tip that allows the provider to see the fibroids from inside the uterus during the procedure and then treat each fibroid with a process called an ablation.

Ultrasound waves from the handpiece tip are used to locate the fibroid. The sonata treatment handpiece then delivers radiofrequency energy to shrink the fibroid over time and reduce symptoms.

CPT Codes Covered Requiring Prior Authorization (PA)

58580 – transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency

Approval Criteria

I. GENERAL

Medical Necessity must be met. All documentation submitted to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the member's needs for the service in accordance with the **OAC 317:30-3-1(f)(2)**.

II. INDICATIONS

A. Ultrasound-guided radiofrequency ablation (RFA) is indicated for the treatment of symptomatic uterine fibroids and may be considered medically necessary when **ALL** the following criteria are met:

1. Member is 18 years of age and over;
2. Currently not pregnant;
3. Individual fibroids are no greater than 7 cm in any diameter;
4. Uterine size does not exceed 14 cm on ultrasound;
5. Low suspicion of leiomyosarcoma (a type of uterine cancer);

AND

One or more symptoms directly caused by fibroids, including:

- Excessive or prolonged bleeding (menorrhagia);
- Anemia from blood loss;
- Pelvic discomfort (severe pain, chronic pain, painful intercourse);
- Bladder pressure with urinary frequency (not due to UTI);
- Low back pain;
- Gastrointestinal symptoms (abdominal bloating, constipation).

B. Sonata is designed for non-pedunculated (submucous, intramural, transmural) fibroids and fibroid clusters.

Contraindications

The Sonata System should not be used in women who:

- Are currently pregnant;
- Have an active pelvic infection;
- Have known or suspected gynecologic cancer or precancerous conditions, such as atypical endometrial hyperplasia;
- Have a permanent birth control implant in their fallopian tubes;
- Have known hip implants, other metal implants located near the ablation site, or along the path where the radiofrequency (RF) current returns to the dispersive electrodes;
- Have an intrauterine device (IUD), unless it is taken out before the Sonata treatment begins.

ALLERGY WARNING: The Sonata System should be used with caution in patients who have a known nickel allergy.

Additional Information

- **Fertility and Pregnancy:** The safety and effectiveness of the Sonata System concerning future fertility and the ability to conceive (fecundity) have not been established. Since this treatment is

designed as a uterus-conserving alternative to a hysterectomy, it is important to understand that it does not prevent the possibility of pregnancy.

- **Adenomyosis:** The effectiveness of the Sonata System has not been established in women who have a clinically significant diagnosis of adenomyosis.

References

Oklahoma Health Care Authority, Policies and Rules, OAC 317:30-3-1(f)(2).

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