

# **Radiofrequency Ablation Treatment for Benign Tumors**

LOB(s): Commercial	State(s): ⊠ Idaho ⊠ Montana ⊠ Oregon ⊠ Washington □ Other:
🛛 Medicare	
🖾 Medicaid	🖾 Oregon 🔲 Washington

## **Enterprise Policy**

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

## Background

Radiofrequency ablation (RFA) destroys cells (cancerous and normal) by applying a heat-generating rapidly alternating radiofrequency current through probes inserted into the tumor. The cells ablated by RFA are not removed but are gradually replaced by fibrosis and scar tissue. If there is local recurrence, it occurs at the edge of this scar tissue and, in some cases, may be retreated. RFA can be performed as an open surgical procedure, laparoscopically, or percutaneously with ultrasound or computed tomography (CT) guidance.

Uterine fibroids (i.e., leiomyomas or myomas) are noncancerous growths that develop from the smooth muscular tissue of the uterus usually during childbearing years. The size and growth pattern of uterine fibroids vary. They may be found as subserosal, intramural, submucosal, or pedunculated masses. They may also be located in the cervix or broad ligament.

Thyroid nodule refers to an abnormal growth of thyroid cells that forms a lump within the thyroid gland. Most are asymptomatic and benign but should be evaluated for potential cancer. Although surgical treatment is well-established and primary treatment for patients whose symptoms indicate removal is required. Radiofrequency Ablation offers an alternative to surgery in certain conditions or high-risk patients.

## Commercial

## Prior authorization is required

#### I. Uterine Fibroid

- A. PacificSource considers the use of laparoscopic (e.g., Acessa®) or transcervical (e.g., Sonata®) radiofrequency ablation as a treatment for uterine fibroids to be medically necessary when ALL of the following criteria are met:
  - 1. Persistence of one or more symptoms directly attributed to uterine fibroids (e.g., excessive menstrual bleeding unresponsive to conservative management (menorrhagia), bulk-related pelvic pain, pressure or discomfort, urinary symptoms referable to compression of the ureter or bladder, and/or dyspareunia)
  - 2. Premenopausal status
  - 3. Uterine preservation is desired
  - 4. Fibroids are less than 10 cm in any diameter
  - 5. Other potential causes for symptoms (e.g., infection, malignancy) have been ruled out

#### II. Benign Thyroid Nodule(s)

- **A.** PacificSource considers radiofrequency ablation as a treatment for benign thyroid nodules(s) to be medically necessary when **ALL** the following criteria is met:
  - 1. Member is 18 years or older
  - 2. Thyroid nodule(s) are greater than 2 cm in diameter
  - **3.** Thyroid nodule(s) are cytologically benign per fine needle aspiration biopsy
  - 4. Member is a high-risk surgical candidate, as defined below;
    - **a.** American Society of Anesthesiologists Physical Status classification system (ASA) level 3 or higher
    - **b.** Increased risk for complications due to severe comorbidity (e.g., unstable angina, uncontrolled diabetes, congestive heart failure, end stage renal disease, respiratory failure, morbid obesity (list is not all inclusive))

#### Medicaid

PacificSource Community Solutions follows the hierarchical process detailed in the "Clinical Criteria Used in UM Decisions" policy when determining coverage for the treatment of benign tumors with radiofrequency ablation (RFA). PCS evaluates services based on the relevant coverage guidelines, limitations, and restrictions specified in the OHP Prioritized List of Health Services and its guidelines, as well as any applicable Oregon Administrative Rules (OARs).

PCS follows the "Unlisted and Unspecified Procedure Codes" policy for requests for unlisted codes.

PacificSource follows the "Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)" criteria for members under 21 and Young Adults with Special Health Care Needs (YSHCN).

#### Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow internal policy for determination of coverage and medical necessity.

## Experimental/Investigational/Unproven

PacificSource considers the following treatments for uterine fibroids to be experimental, investigational, or unproven:

- Acupuncture
- Cryomyolysis
- Cryotherapy
- Electrical ablation
- Interstitial thermotherapy
- Lasers
- Ultrasound ablation, with or without magnetic resonance imaging (MRI) guidance

## **Coding Information**

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

- 58580 Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency
- 58674 Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
- 58999 Unlisted procedure, female genital system (non-obstetrical)
- 60660 Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency
- 60661 Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging guidance, radiofrequency (List separately in addition to code for primary procedure)
- 0071T Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue
- 0072T Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue
- 0673T Ablation, benign thyroid nodule(s), percutaneous, laser, including imaging guidance
- 60699 Unlisted procedure, endocrine system

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

## Definitions

Fibroids - Fibrous tissue collected in the uterine wall; also referred to as leiomyomas or myomas.

- **Laparoscopic -** A surgical procedure performed using a laparoscope, a thin fiberoptic scope introduced into a body cavity for diagnostic and surgical purposes.
- **Magnetic resonance imaging (MRI)** The use of a nuclear magnetic resonance spectrometer to produce electronic images of specific atoms and molecular structures in solids, especially human cells, tissues, and organs.
- **Percutaneous -** A medical procedure in which access to inner organs or other tissue is achieved via puncture of the skin.

Transcervical - A medical procedure performed through the cervical opening of the uterus.

#### References

American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Gynecology (2021). Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. Obstetrics and gynecology, 137(6), e100–e115.

American Society of Anesthesiologist. (December 13, 2020). Standards and Practice Parameters: Statement on ASA Physical Status Classification System. Retrieved April 20, 2023, from <a href="https://www.asahg.org/standards-and-quidelines/asa-physical-status-classification-system">https://www.asahg.org/standards-and-quidelines/asa-physical-status-classification-system</a>

Arnreiter, C., & Oppelt, P. (2021). A Systematic Review of the Treatment of Uterine Myomas Using Transcervical Ultrasound-Guided Radiofrequency Ablation with the Sonata System. Journal of minimally invasive gynecology, 28(8), 1462–1469.

Bradley, L. D., Pasic, R. P., & Miller, L. E. (2019). Clinical Performance of Radiofrequency Ablation for Treatment of Uterine Fibroids: Systematic Review and Meta-Analysis of Prospective Studies. Journal of laparoendoscopic & advanced surgical techniques. Part A, 29(12), 1507–1517.

Hayes Knowledge Center. (June 21, 2024). Health Technology Assessment: Radiofrequency Ablation for Benign Thyroid Nodules. <u>https://evidence.hayesinc.com/report/dir.rfabenign5089</u>

Lin, L., Ma, H., Wang, J., Guan, H., Yang, M., Tong, X., & Zou, Y. (2019). Quality of Life, Adverse Events, and Reintervention Outcomes after Laparoscopic Radiofrequency Ablation for Symptomatic Uterine Fibroids: A Meta-Analysis. Journal of minimally invasive gynecology, 26(3), 409–416.

Miller, C. E., & Osman, K. M. (2019). Transcervical Radiofrequency Ablation of Symptomatic Uterine Fibroids: 2-Year Results of the SONATA Pivotal Trial. Journal of gynecologic surgery, 35(6), 345–349.

Muhammad, H., Santhanam, P., Russell, J. O., & Kuo, J. H. (2021). RFA and benign thyroid nodules: Review of the current literature. Laryngoscope investigative otolaryngology, 6(1), 155–165. Retrieved April 21, 2023, from <u>https://onlinelibrary.wiley.com/doi/full/10.1002/lio2.517</u>

National Institute for Health and Care Excellence (NICE). (June 29, 2016). Ultrasound-guided percutaneous radiofrequency ablation for benign thyroid nodules. Retrieved April 21, 2023, from <a href="https://www.nice.org.uk/Guidance/IPG562">https://www.nice.org.uk/Guidance/IPG562</a>

National Institute of Child Health and Human Development. Surgical treatments for fibroids. Available at: <u>https://www.nichd.nih.gov/health/topics/uterine</u>.

National Library of Medicine. Medline Plus Health Topics: Uterine fibroids. Available at: <u>https://medlineplus.gov/uterinefibroids.html</u>

Ross, D. S. (June 7, 2022). Diagnostic approach to and treatment of thyroid nodules. UpToDate. Retrieved April 20, 2023, from <u>https://www.uptodate.com/contents/diagnostic-approach-to-and-treatment-of-thyroid-nodules?search=benign+thyro</u>

Yu, S., Silverberg, K., Bhagavath, B., Shobeiri, S. A., Propst, A., & Eisenstein, D. (2020). Post-Market Safety of Laparoscopic Ultrasound-Guided Radiofrequency Ablation. JSLS : Journal of the Society of Laparoendoscopic Surgeons, 24(4), e2020.00050.

The Health Evidence Review Commission (HERC) Prioritized List of Health Services https://www.oregon.gov/oha/HSD/OHP/Pages/Prioritized-List.aspx

Oregon Administrative Rules (OARs). Oregon Health Authority. Health Systems: Medical Assistance Programs – Chapter 410 <u>https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=87</u>

## **Related Policies**

Clinical Criteria Used in UM Decisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)

Unlisted and Unspecified Procedure Codes

## Appendix

Policy Number:		
Effective: 1/1/2023	Next review:	7/1/2026
Policy type: Enterprise		
Author(s):		
Depts: Health Services		

**Applicable regulation(s):** OARs 410-120-1200, 410-141-3820, 410-141-3825, 410-151-0001, 410-151-0002, 410-151-0003. **Applicable regulation(s):** OARs 410-120-1200, 410-141-3820 through 3830, 410-151-0000 through 0003, and Guideline 40 of the OHP Prioritized List of Health Services

Commercial OPs: 6/2025

Government OPs: 6/2025