Cryoablation of Breast Fibroadenomas

Date of Origin: 10/2006 **Last Review Date: 12/27/2023** **Effective Date: 1/1/2024**

Dates Reviewed: 10/2007, 10/2008, 02/2011, 05/2011, 05/2012, 03/2013, 02/2015, 02/2016, 02/2017, 12/2018, 12/2019, 12/2020, 12/2021, 11/2022, 12/2023

Developed By: Medical Necessity Criteria Committee

I. Description

Breast fibroadenomas are common benign lesions that often affect women during their reproductive years. Fibroadenomas can cause physical deformity due to large size and may produce discomfort. Previously, standard treatment options for fibroadenomas included observation or surgical excision. A newer treatment approach for fibroadenomas is cryoablation. Cryoablation of fibroadenomas involves the localized freezing and destruction of the breast mass. This procedure can be performed in a physician's office, under local anesthesia with only a small incision. The technique of cryoablation involves ultrasound guidance for three-dimensional probe placement within the center of the lesion. Once the probe is in place, the fibroadenoma is frozen. Usually two freeze/thaw cycles are performed. Cryoablation continues until a frozen ball encompasses all of the tumorous area. Once the tissue is destroyed, the body should reabsorb it in approximately 3-6 months.

II. Criteria: CWQI HCS-0024

A. Cryoablation of breast fibroadenomas is considered experimental, investigational, or unproven. There is insufficient evidence in peer-reviewed literature to demonstrate the effectiveness of the procedure.

III. Information Submitted with the Prior Authorization Request:

1. None

IV. Applicable CPT or HCPC codes NOT covered:

Codes	Description
19105	Ablation, cryosurgical of fibroadenoma, including ultrasound guidance, each fibroadenoma

V. References

1. Kaufman CS, Bachman B, Littrup PJ, et al. Cryoablation treatment of benign breast lesions with 12-month follow-up. Am J Surg. 2004 Oct;188(4):340-8.
2. Kaufman CS, Littrup PJ, Freeman-Gibb LA. Et al. Office-based cryoablation of breast fibroadenomas with long-term follow-up. Breast J. 2005 Sep-Oct;11(5):344-50.
3. Littrup PJ, Freeman-Gibb L, Andea A, et al. Cryotherapy for breast fibroadenomas. Radiology. 2005 Jan;234(1):63-72.
4. Morin J, Traore A, Dionne G, et al. Magnetic resonance-guided percutaneous cryosurgery of breast carcinoma: technique and early clinical results. Can J Surg. 2004 Oct;47(5):347-51.
5. National Comprehensive Cancer Network (NCCN). In: Clinical practice guidelines in oncology: Breast
6. Sklair-Levy M, Sella T, Alweiss T, Craciun I, Libson E, Mally B. Incidence and management of complex fibroadenomas. AJR Am J Roentgenol. 2008 Jan;190(1):214-8.
7. The American Society of Breast Surgeons. Official Statement: Management of fibroadenomas of the breast. Accessed on May 17, 2012 at: http://www.breastsurgeons.org/statements/PDF_Statements/Fibroadenoma.pdf.
8. Whitworth PW, Rewcastle JC. Cryoablation and cryolocalization in the management of breast disease. J Surg Oncol. 2005 Apr 1;90(1):1-9.
9. Physician Advisors

VI. Annual Review History

Review Date	Revisions	Effective Date
03/2013	Annual Review: Added table with review date, revisions, and effective date.	04/03/2013
04/03/2014	Annual Review: No changes	04/03/2014
02/25/2015	Annual Review: No changes	02/25/2015
02/2016	Annual Review: No changes. Added ICD-10 codes; deleted ICD-9	02/24/2016
02/23/2017	Annual Review: Updated to new template	02/23/2017
12/2018	Annual Review: No changes	01/01/2019
12/2019	Annual Review: No changes	01/01/2020
12/2020	Annual Review: No changes	01/01/2021
12/2021	Annual Review: No changes	01/01/2022
11/2022	Annual Review: No changes	12/1/2022
12/2023	Annual Review: No changes	1/1/2024

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D24.1	Benign neoplasm of right breast
D24.2	Benign neoplasm of left breast

ICD-10	ICD-10 Description
D24.9	Benign neoplasm of unspecified breast
N60.21	Fibroadenosis of right breast
N60.22	Fibroadenosis of left breast
N60.29	Fibroadenosis of unspecified breast

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
N/A	

NCD/LCD Document (s):
N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC