



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Cryosurgical Ablation of Breast Fibroadenomas

Policy # 00235

Original Effective Date: 03/18/2009

Current Effective Date: 03/19/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider cryosurgical ablation of benign breast fibroadenomas to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for cryosurgical ablation of benign breast fibroadenomas may be considered **eligible for coverage** when all of the following criteria are met:

- The lesion must be identified by mammography or ultrasound; and
- The lesion must be histologically confirmed as fibroadenoma; and
- The lesion must be \leq 4cm in diameter.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of cryosurgery ablation of benign breast fibroadenomas when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers cryosurgical ablation as a treatment of malignant breast cancer to be **investigational.***

Background/Overview

Cryosurgical ablation (hereafter referred to as cryosurgery) involves freezing of target tissues, most often by inserting into the tumor a probe through which coolant is circulated. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

The hypothesized advantages of cryosurgery include improved local control and benefits common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization). Potential complications of cryosurgery include those caused by hypothermic damage to normal tissue adjacent to the tumor, structural damage along the probe track, and secondary tumors, if cancerous cells are seeded during probe removal.

Cryosurgical treatment of various tumors including renal cell carcinomas, malignant and benign breast disease, pancreatic cancer, and lung cancer has been reported in the literature.

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Breast tumors. Early stage primary breast cancers are treated surgically. The selection of lumpectomy, modified radical mastectomy, or another approach is balanced against the patient's desire for breast conservation, the need for tumor-free margins in resected tissue, and the patient's age, hormone receptor status, and other factors. Adjuvant radiation therapy decreases local recurrences, particularly for those who select lumpectomy. Adjuvant hormonal therapy and/or chemotherapy are added, depending on presence and number of involved nodes, hormone receptor status, and other factors. Treatment of metastatic disease includes surgery to remove the primary lesion and combination chemotherapy.

Fibroadenomas are common benign tumors of the breast that can either present as a palpable mass or a mammographic abnormality. These benign tumors are frequently surgically excised to rule out a malignancy.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

There are several cryoablation devices cleared for marketing by the FDA through the 510(k) process for use in open, minimally invasive or endoscopic surgical procedures in the areas of general surgery, urology, gynecology, oncology, neurology, dermatology, proctology, thoracic surgery and ear; nose; and throat. Examples include:

- Cryocare Surgical System by Endocare;
- CryoGen Cryosurgical System by Cryosurgical, Inc.;
- CryoHit by Galil Medical for the treatment of breast fibroadenoma;
- SeedNet System by Galil Medical; and
- Visica System by Sanarus Medical.

Centers for Medicare and Medicaid Services (CMS)

No national coverage determination.

Rationale/Source

A variety of case series have focused on the role of cryosurgery as an alternative to surgical excision of benign fibroadenomas. Kaufman and colleagues have published several case series reports on office-based ultrasound-guided cryoablation as a treatment of breast fibroadenomas. These case series reported on a range of 29-68 patients followed for periods of six months to up to 2.6 years. It is likely that these case series include overlapping patients. At one year, patients reported 91% patient satisfaction and fibroadenomas became nonpalpable in 75% of cases. At follow-up averaging 2.6 years in 37 patients, the authors noted only 16% out of 84% of palpable fibroadenomas remained palpable after treatment and of the fibroadenomas that were initially 2 cm or less in size, only 6% remained palpable. In this series of patients, the authors also noted that cryoablation did not produce artifact that might interfere with interpretation of mammograms. These small case series from the same group of investigators is inadequate to permit scientific conclusions. In addition, it is unclear whether "nonpalpability" is the most appropriate medical outcome. Fibroadenomas are benign lesions with only a very remote chance of malignant conversion, and thus complete surgical excision may be recommended primarily to allay patients' concerns regarding harboring a palpable lesion.

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Nurko and colleagues reported on outcomes at 6 and 12 months for 444 treated fibroadenomas reported to the FibroAdenoma Cryoablation Treatment (FACT) registry involving 55 different practice settings. In these patients, before cryoablation, 75% of fibroadenomas were palpable by the patient. Follow-up at 6- and 12-month intervals showed palpable masses in 46% and 35%, respectively. When fibroadenomas were grouped by size, for lesions 2 cm or less, the treatment area was palpable in 28% at 12 months. For lesions more than 2 cm, the treatment area was palpable in 59% at 12 months. The authors noted they would continue to follow up these patients to better define resolution of the treatment-induced physical and radiographic findings. Comparative trials with adequate long-term follow-up are needed to assess this technology and determine how this approach compares with surgery, as well as with vacuum-assisted excision and with observation (approximately one-third regrowth over several years' time).

References

1. Blue Cross and Blue Shield Association, *Medical Policy Reference Manual*, "Cryosurgical Ablation of Miscellaneous Solid Tumors Other than Liver, Prostate, or Dermatologic Tumors", 7.01.92, 7:2013.
2. Kaufman CS, Bachman B, Littrup PJ et al. Office-based ultrasound-guided cryoablation of breast fibroadenomas. *Am J Surg* 2002;184(5):384-400.
3. Kaufman CS, Littrup PJ, Freeman-Gibb LA et al. Office-based cryoablation of breast fibroadenomas: 12-month follow-up. *J Am Coll Surg* 2004; 198(6):914-23.
4. Kaufman CS, Bachman B, Littrup PJ et al. Cryoablation treatment of benign breast lesions with 12 months follow up. *Am J Surg* 2004; 188(4):340-8.
5. Littrup PJ, Freeman-Gibb L, Andea A et al. Cryotherapy for breast fibroadenomas. *Radiology* 2005; 234(1):63-72.
6. The American Society of Breast Surgeons. Consensus Statement: Management of Fibroadenomas of the Breast. <http://www.breastsurgeons.org>
7. The American Society of Breast Surgeons. Consensus Statement: Management of Fibroadenomas of the Breast. http://www.breastsurgeons.org/officialstmts/Management_of_Fibroadenomas_of_the_Breast_4-29-08.pdf

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	19105
HCPCS	C2618
ICD-9 Diagnosis	217, 610.2
ICD-9 Procedure	No codes

Policy History

Original Effective Date: 03/18/2009

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03/04/2009 Medical Director review

03/18/2009 Medical Policy Committee approval. Cryosurgical ablation of benign breast fibroadenomas is now considered eligible with criteria instead of investigational. This topic was separated from "Cryosurgery Ablation of Miscellaneous Solid Tumors Other Than Liver or Prostate Tumors" and a new policy was created for breast fibroadenomas.

03/05/2010 Medical Policy Committee approval

03/19/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/03/2011 Medical Policy Committee review

03/16/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/01/2012 Medical Policy Committee review

03/21/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/07/2013 Medical Policy Committee review

03/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/06/2014 Medical Policy Committee review

03/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;



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- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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