



ASPS Recommended Insurance Coverage Criteria for Third-Party Payers

Breast Implant Associated Anaplastic Large Cell Lymphoma

BACKGROUND

Anaplastic Large Cell Lymphoma (ALCL) is a rare type of cancer of the immune system that is estimated to affect 1 in half a million women. It usually develops in the lymph nodes, skin, lung, or liver. However, the World Health Organization has recently identified a new disease, breast implant associated ALCL (BIA-ALCL) which can develop in the breast area around textured breast implants. BIA-ALCL is a rare lymphoma, and is not a breast cancer. BIA-ALCL has been estimated to affect 1 in 1,000 to 1 in 30,000 women with textured breast implants.

In 2011, the Food and Drug Administration (FDA) reported a safety communication, alerting women of the possible association between breast implants and a very rare form of ALCL, based on a reported cluster of cases of lymphoma in women with breast implants. At that time, the limited number of reported cases made it impossible to determine which factors increased the risk.

In subsequent studies, the understanding of BIA-ALCL has grown. The World Health Organization defines BIA-ALCL as a rare type of T-Cell Lymphoma that arises around breast implants. It is characterized by abnormal growth of large anaplastic cells with a strong expression of CD30 surface proteins that arises within the breast capsule and predominantly presents as a seroma or effusion with a sudden swelling of the breast. This form of ALCL has been tied to both saline and gel implants, placed both for enlargement and for reconstruction after breast cancer. To date, it has only been found in cases with textured implants.

The exact mechanism by which ALCL develops around breast implants remains unknown. When present, BIA-ALCL is most always found in the fluid and scar surrounding the implant, and only in advanced cases infiltrating into the breast tissue itself. It has been reported in women both with and without capsular contracture.

In 2016, the World Health Organization identified BIA-ALCL as a cancer that is most commonly a “noninvasive disease associated with excellent outcome.” Treatment for BIA-ALCL differs from the standard treatment used for most lymphomas and follows standardized guidelines by the National Comprehensive Cancer Network (NCCN). Early stage disease can be successfully treated by surgery alone, and typically involves removal of the implant and the scar tissue (e.g., capsule) surrounding the

implant. More advanced cases have been treated by chemotherapy and radiation. A delay in appropriate treatment of patients with BIA-ALCL can result in progression, with advanced features such as lymphadenopathy and organ metastasis.

In patients without symptoms or other abnormalities, the FDA does not recommend screening tests or prophylactic breast implant removal.

DEFINITIONS

Anaplastic Large Cell Lymphoma (ALCL) is an aggressive (fast growing) type of non-Hodgkin Lymphoma that is of the T-cell type. The cancer cells express a cell surface protein called CD30 on immunohistochemistry and may appear in the lymph nodes, skin, bones, soft tissue, lungs or liver.

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare T-cell lymphoma that can develop following breast implantation. It is not a breast cancer.

Capsular Contracture is the tightening of a normal membrane around a prosthetic implant, most likely due to proliferation of myofibroblasts. This results in deformation of the implant or its soft tissue covering, or both, and in variable symptoms.

Capsulectomy is the surgical removal of breast implant (or any capsular implant) and the surrounding reactive fibrous tissues that develop around it, which may contract and put pressure on the implant.

Contracture is a condition of shortening and hardening of muscles, tendons or other tissues.

Cosmetic Surgery is performed to reshape normal structures of the body in order to improve the patient’s appearance and self-esteem.

Effusion is a fluid collection that develops from the escape of fluid from the blood vessels or lymphatics into the tissues or a cavity.

Lymphadenopathy is the abnormal enlargement of lymph nodes.

Reconstructive Surgery is performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is general performed to improve function, but may also be done to approximate a normal appearance.

CURRENT COVERAGE POLICY - BY INSURANCE COMPANY

Insurance Company	Implant Removal Coverage	Implant Removal Coverage Criteria Explanation
Anthem	No information Available	N/A
Aetna	Yes	Aetna considers the removal of breast implants medically necessary for members who meet ANY of the following indications: 1.Breast implant-associated anaplastic large cell lymphoma; or

		<p>2.Extrusion of implant through skin, or</p> <p>3.Implants complicated by recurrent infections, or</p> <p>4.Implants with Baker Class IV contracture* (see Appendix) associated with severe pain, or</p> <p>5.Implants with severe contracture* that interferes with mammography, or</p> <p>6.Intra- or extra-capsular rupture of silicone gel-filled implants, or</p> <p>7.Breast cancer in the implanted breast or remnant, or in the contralateral breast, where implant removal is necessary to excise the breast cancer.</p>
Blue Cross Blue Shield	No information Available	While cosmetic procedures are generally not covered, medically necessary cancer treatments including removal of implants, chemotherapy, and radiation as related to BIA-ALCL are covered.
Centene Corp	No information Available	N/A
Cigna	No	Cigna does not cover removal of an intact silicone gel-filled breast implant when performed solely for suspected autoimmune disease or connective tissue disease or breast cancer prevention, because these indications are considered experimental, investigational or unproven.
Health Net	No information Available	N/A
Humana	No information Available	N/A
Magellan	No information Available	N/A
Molina	Yes	Breast implant removal for cosmetic purposes is not covered. Breast implant removal deemed medically necessary as a result of medical complications is covered. Prior authorization required.
United Healthcare	No information Available	N/A
Wellcare	No information Available	N/A
Wellpoint	No information Available	N/A

POLICY

Most women approach their doctor with symptoms such as pain, lumps, swelling, regional lymphadenopathy, or asymmetry in their breasts years after getting implants. BIA-ALCL most often arises within the fluid or capsular tissue around the implant, and is commonly associated with an

effusion. Timely diagnosis and treatment is the optimal approach for the management of patients with suspected BIA-ALCL.

Per the National Comprehensive Cancer Network Guidelines (see Table A), an ultrasound of the breast or in selected cases, a breast MRI, should be performed. If an effusion is seen on imaging, physicians should perform fine needle aspiration, sending specimens for pathologic review, including cytology, CD-30 Immunohistochemistry and flow cytometry, if there is a reasonable clinical suspicion of BIA-ALCL. When a mass or adenopathy are discovered, specimen collection is also essential.

If results are indeterminate of lymphoma, a second pathology consultation by a tertiary cancer center should be performed. Diagnosis is made by large anaplastic cells on cytology, positive CD30 immunohistochemistry expression, and a T cell clone on flow cytometry. If there is histologic confirmation, the patient should undergo a complete history and physical exam, including blood work and pregnancy testing in women of child-bearing age.

Preoperative workup may include an oncology consultation, surgical oncology consultation, bone marrow biopsy, ALK gene translocation testing, and/or PET-CT scan to determine extent of disease.

Management of the BIA-ALCL patient includes complete surgical excision of the implant, total capsulectomy and removal of any disease or mass with biopsy of suspicious nodes. Pathological review of specimens should be performed. The surgeon should also consider removal of any contralateral implant as approximately 4.6% of patients have been found to have bilateral disease incidentally found at time of surgery.

Depending on surgical findings, residual or extended disease may require adjuvant treatment. Therefore, referral to an oncologist is recommended prior to surgery for oncologic staging and evaluation.

Typical follow-up for patients with no residual disease includes observation every 3-6 months for 2 years and then as clinically indicated. NCCN recommends advanced diagnostic imaging such as PET or CT scan every 6 months for the first two years, and then only as clinically indicated.

It is important that a woman who had breast implants placed for cosmetic reasons understands that the evaluation and treatment of a cancer is a covered benefit of her health insurance plan. Evaluation should not be delayed for fear of out-of-pocket expense.

Of note, ASPS/PSF and the FDA are collaborating to conduct research and have developed a Breast Implant-Associated ALCL Registry, the PROFILE Registry, to increase the scientific data on ALCL in women with breast implants. Data is collected retrospectively and prospectively on confirmed cases of BIA-ALCL (including localized or systemic disease, and of any anatomic site and ALCL cell phenotype) in women with breast implants. The primary goal of this collaboration is to better understand the role of breast implants in the etiology of ALCL in women with breast implants. The research will also focus on identifying potential risk factors and criteria detection and management of this disease. In addition to providing health care practitioners and patients with information they need about breast implants and

treatment of ALCL, the confirmed cases in the Registry of BIA-ALCL in women with breast implants will be available for analytical epidemiological studies.

CODING

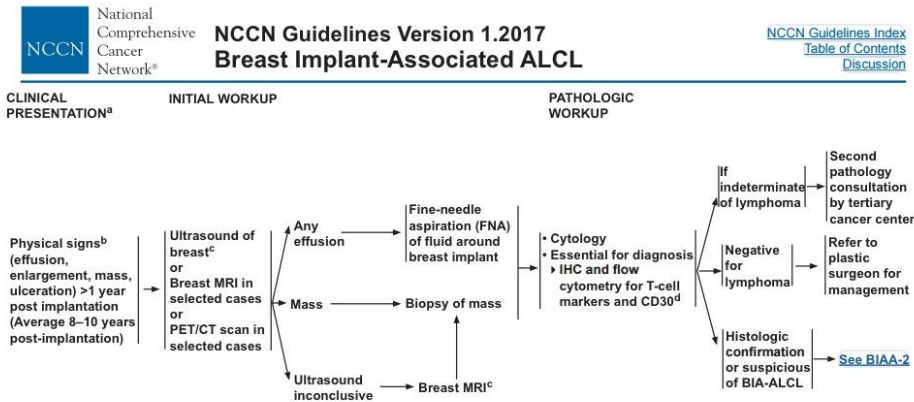
Diagnosis (ICD-10)

- C84.79 Anaplastic large cell lymphoma, ALK-negative, extranodal, solid organ sites
- N63 Unspecified lump in breast, nodule, mass, or swelling of the breast
- R59.9 Enlarged lymph node
- N64.89 Other specified disorders of breast

Procedure (CPT)

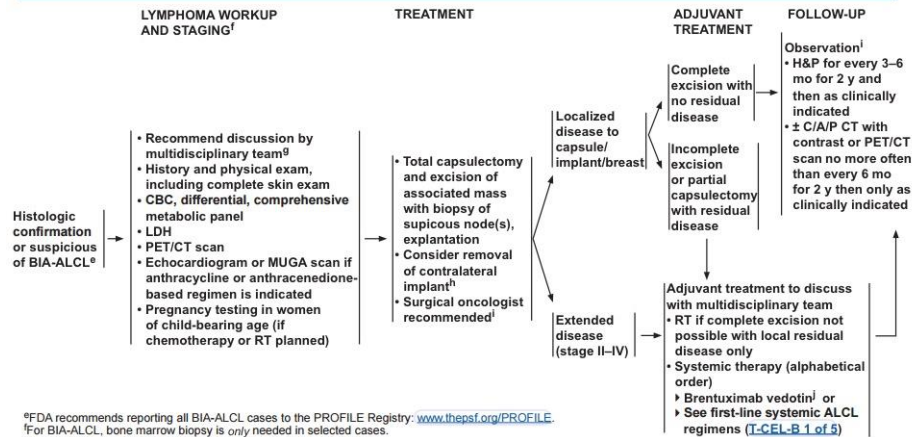
- 10022 Fine needle aspiration with imaging guidance
- 19101 Breast biopsy, open, incisional
- 19260 Excision of chest wall tumor
- 19328 Removal intact mammary implant
- 19371 Breast periprosthetic capsulectomy
- 38525 Biopsy/excisions, lymph node; open or deep axillary node

Table A – NCCN Guidelines for Breast Implant-Associated ALCL



^aRare cases with parenchymal breast or nodal involvement may have an aggressive course more in line with systemic ALK-positive ALCL (See TCEL-3). Optimal treatment of these cases is not well defined and management should be individualized.
^bA majority of cases have been seen in textured implants (Miranda RN, et al. Breast implant-associated anaplastic large-cell lymphoma: long-term follow-up of 60 patients. J Clin Oncol 2014;32:114–120).
^cAdrada BE, et al. Breast implant-associated anaplastic large cell lymphoma: sensitivity, specificity, and findings of imaging studies in 44 patients. Breast Cancer Res Treat 2014;147:1–14.
^dMiranda RN, et al. Breast implant-associated anaplastic large-cell lymphoma: long-term follow-up of 60 patients. J Clin Oncol 2014;32:114–120.

Note: All recommendations are category 2A unless otherwise indicated.
 Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.



^fFDA recommends reporting all BIA-ALCL cases to the PROFILE Registry: www.thespf.org/PROFILE.

^gFor BIA-ALCL, bone marrow biopsy is only needed in selected cases.

^hEg, oncologist, surgical oncologist, plastic surgeon, hemepathologist.

ⁱIn approximately 4.6% of cases, lymphoma was found in the contralateral breast (Clemens MW, Medeiros LJ, Butler CE, et al. Complete surgical excision is essential for the management of patients with breast implant-associated anaplastic large-cell lymphoma. *J Clin Oncol* 2016; 34:160-168).

^jClemens MW, Medeiros LJ, Butler CE, et al. Complete surgical excision is essential for the management of patients with breast implant-associated anaplastic large-cell lymphoma. *J Clin Oncol* 2016; 34:160-168.

^kPro B, Advani R, Brice P, et al. Brentuximab vedotin (SGN-35) in patients with relapsed or refractory systemic anaplastic large-cell lymphoma: results of a phase II study. *J Clin Oncol* 2012;30:2190-2196. Pro B, Advani R, Brice P, et al. Four-year survival data from an ongoing pivotal phase 2 study of brentuximab vedotin in patients with relapsed or refractory systemic anaplastic large cell lymphoma [abstract]. *Blood* 2014 124:Abstract 3095.

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Approved by the Executive Committee of the American Society of Plastic Surgeons®, October 2017.