

ASPS Insurance Coverage Criteria for Third-Party Payers – BIA-ALCL

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 2,207 to 1 in 86,000 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 augmentation and for reconstruction after breast cancer. To date, most cases have been associated with a history of textured implant placement.

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 or chest wall 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 the surrounding reactive fibrous tissues that develop around of the breast implant, which may contract and put pressure on the implant and at the same time the breast implant is removed.

Contracture is a condition of shortening or retraction of certain tissues such as 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 Explained
Anthem	N/A	N/A
Aetna	Yes	Aetna considers the removal of breast implants medically necessary for members who meet the following selection criteria. 1. Breast cancer in the implanted breast or remnant, or in the contralateral breast, where implant removal is necessary to excise the breast cancer; <i>or</i> 2. Breast implant-associated anaplastic large cell lymphoma; <i>or</i>

		3. Extrusion of implant through skin, <i>or</i> 4. Implants complicated by recurrent infections, <i>or</i> 5. Implants with Baker Class IV contracture Footnotes* (see Appendix) associated with severe pain, <i>or</i> 6. Implants with severe contracture Footnotes* that interferes with mammography, <i>or</i> 7. Intra- or extra-capsular rupture of silicone gel-filled implants, <i>or</i> 8. Members who exhibit cutaneous hypersensitivity-like reactions associated with breast implants and who have failed conventional treatments (e.g., antibiotics, oral corticosteroids, and topical corticosteroids); <i>or</i> 9. Persons with textured implants who exhibit persistent symptoms such as pain, lumps, swelling, or asymmetry that occur after the surgical incision has fully healed.
Blue Cross Blue Shield	Yes	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	N/A	N/A
Cigna	Yes	<p>The removal of EITHER a silicone gel-filled OR saline-filled breast implant is considered medically necessary for at least ONE of the following indications:</p> <ul style="list-style-type: none"> • The implant is interfering with EITHER of the following: <ul style="list-style-type: none"> ☐ diagnostic evaluation of a suspected breast cancer ☐ adequate treatment of known breast cancer (e.g., obstructing radiation therapy) • ANY of the following: <ul style="list-style-type: none"> ☐ persistent or recurrent local or systemic infection secondary to a breast implant refractory to medical management, including antibiotics ☐ Baker Stage IV capsular contracture resulting in EITHER of the following: <ul style="list-style-type: none"> o pain o interference with standard breast cancer screening ☐ tissue necrosis secondary to the implant ☐ diagnosed breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) ☐ current use of Allergan BIOCELL textured breast implants and tissue expanders <p>Removal of an intact silicone gel-filled breast implant when performed solely for suspected autoimmune disease or connective tissue disease or breast cancer prevention is considered experimental, investigational or unproven.</p>
Health Net	N/A	N/A
Humana	N/A	N/A
Magellan	N/A	N/A
Molina	Varies by state	Please check individual state health plan regulations and benefit contracts before applying this MCP. Coverage of breast implant removal is applicable to individual State and Federal Health Plan Medicaid regulations and benefit

		<p>contracts that define cosmetic procedures that supersedes this policy.</p> <p>1. Breast implant removal (silicone or saline) may be considered medically necessary due to complications of the implant when one of the following clinical conditions are present: [ONE]</p> <p><input type="checkbox"/> Baker Classification* Class III visible contracture without pain to IV visible contracture that is causing pain and refractory to medical management; or <input type="checkbox"/> Breast implant-associated anaplastic large cell lymphoma;</p>
United Healthcare	Yes	<p>Indications for Coverage The following are eligible for coverage as Reconstructive and medically necessary: <input type="checkbox"/> Correction of inverted nipples is considered reconstructive when one of the following criteria are met: o Member meets the Women’s Health and Cancer Rights Act (WHCRA) criteria (refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy for details); or o Documented history of chronic nipple discharge, bleeding, scabbing or ductal infection; or o For correction of an inverted nipple(s) resulting from a Congenital Anomaly. <input type="checkbox"/> Anaplastic Lymphoma of the breast: o Removal of a breast implant and capsulectomy is covered, regardless of the indication for the initial implant placement, for: <input type="checkbox"/> Treatment of Anaplastic Lymphoma of the breast when there is pathologic confirmation of the diagnosis by cytology or biopsy; or <input type="checkbox"/> Individuals with an increased risk of implant-associated Anaplastic Lymphoma of the breast due to use of Allergan BIOCELL textured breast implants and tissue expanders.</p>
Wellcare	N/A	N/A
Wellpoint	N/A	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 are 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, , 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)

C84.70-84.79	Anaplastic large cell lymphoma, ALK-negative, extranodal, solid organ sites
N63	Unspecified lump in breast, nodule, mass, or swelling of the breast
64.4	Mastodynia
R52	Pain
T85.49XA	Other mechanical complication of breast prosthesis and implant, initial encounter
T85.79XA	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts
T85.848A	Pain due to internal prosthetic devices, implants and grafts
T85.44XA	Contracture of Breast Prosthesis
T85.43XA	Rupture of Breast Prosthesis
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
19330	Removal of mammary implant material
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19371	Breast periprosthetic capsulectomy
38525	Biopsy/excisions, lymph node; open or deep axillary node

Table A – NCCN Guidelines for Breast Implant-Associated ALCL

	National Comprehensive Cancer Network®	NCCN Guidelines Version 1.2020 Breast Implant-Associated ALCL	NCCN Guidelines Index Table of Contents Discussion
CLINICAL PRESENTATION ^a	INITIAL WORKUP	PATHOLOGIC WORKUP ^e	
Physical signs ^b (effusion, enlargement, mass, ulceration) >1 year post implantation (Average 7-9 years post-implantation)	Ultrasound of breast or Breast MRI in selected cases or PET/CT scan ^c in selected cases <div> Any effusion → FNA of fluid^d around breast implant </div> <div> Mass → Biopsy of mass </div> <div> Ultrasound inconclusive → Breast MRI, if not previously done </div>	<div> ESSENTIAL: <ul style="list-style-type: none"> • Cytology with cell block preparation^d • IHC and/or flow cytometry^d for CD2, CD3, CD4, CD5, CD7, CD8, CD30, CD45, and ALK^f </div> <div> USEFUL UNDER CERTAIN CIRCUMSTANCES: <ul style="list-style-type: none"> • If there is solid mass associated with the implant, biopsy (excisional or incisional or core needle) may be required for diagnosis </div> <div> If indeterminate of lymphoma → Second pathology consultation by tertiary cancer center </div> <div> Negative for lymphoma → Refer to plastic surgeon for management </div> <div> Histologic confirmation or suspicious of BIA-ALCL^g → See BIAA-2 </div>	
See References on BIAA-A			

^a Rare 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.

^b A majority of cases have been seen in textured implants (Miranda RN, et al. J Clin Oncol 2014;32:114-120).

^c Patients with T-cell lymphomas often have extranodal disease, which may be inadequately imaged by CT. PET scan may be preferred in these instances.

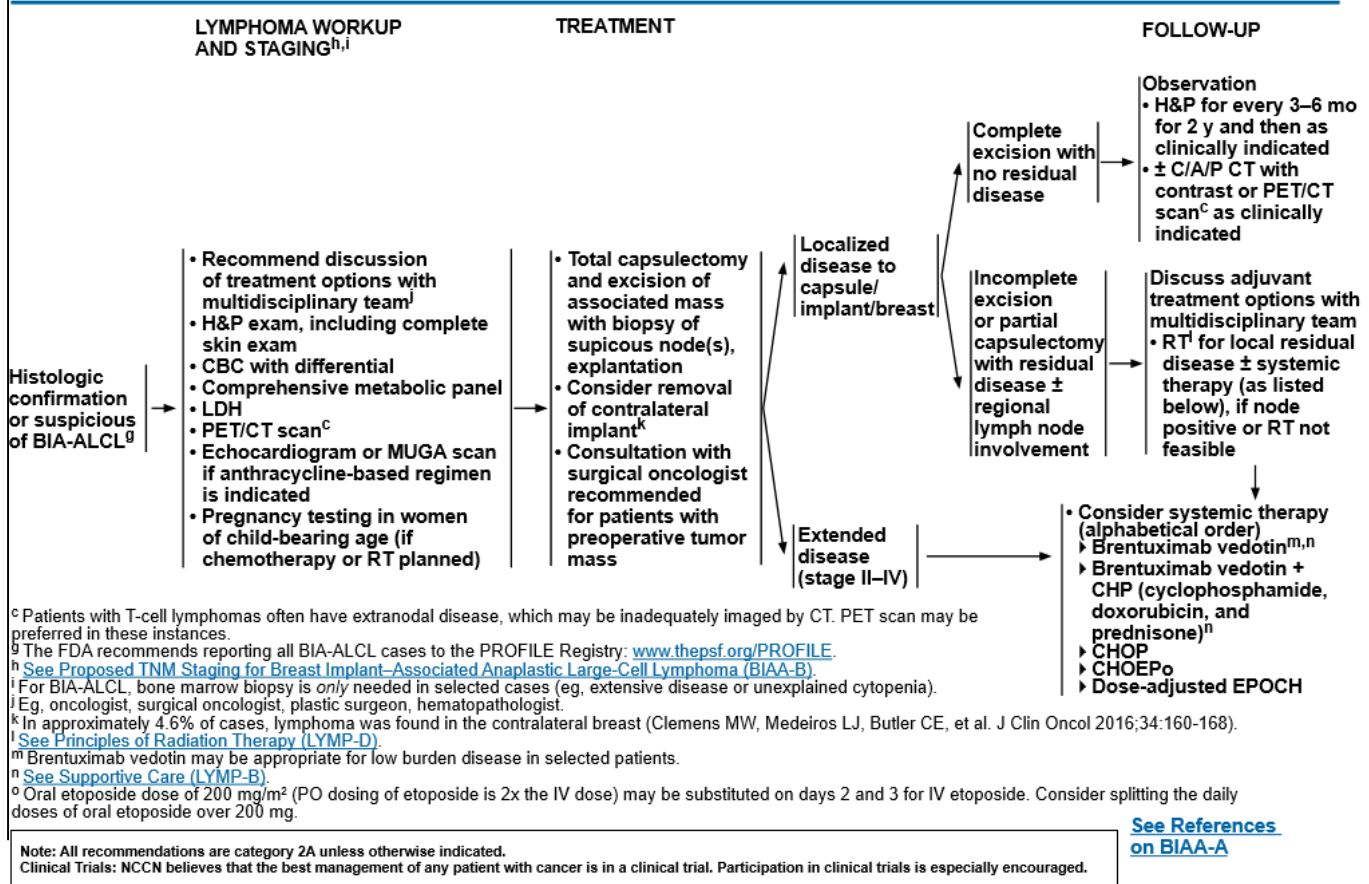
^d Larger volume of fluid yields a more accurate diagnosis. If possible, obtain >50 mL for cytology and cell block; >10 mL for flow cytometry immunophenotype.

^e [See Principles of Molecular Analysis in T-Cell Lymphomas \(LYMP-A\)](#).

^f Breast implant-associated ALCL (BIA-ALCL) is usually ALK-negative but has a good prognosis.

^g The FDA recommends reporting all BIA-ALCL cases to the PROFILE Registry: www.thepsf.org/PROFILE.

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.



REFERENCES

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