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 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**

<table>
<thead>
<tr>
<th>Insurance Company</th>
<th>Implant Removal Coverage</th>
<th>Implant Removal Coverage Criteria Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthem</td>
<td>No information Available</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| 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  
2. Extrusion of implant through skin, or |
3. Implants complicated by recurrent infections, or
4. Implants with Baker Class IV contracture* (see Appendix) associated with severe pain, or
5. Implants with severe contracture* that interferes with mammography, or
6. Intra- or extra-capsular rupture of silicone gel-filled implants, or
7. Breast cancer in the implanted breast or remnant, or in the contralateral breast, where implant removal is necessary to excise the breast cancer.

<table>
<thead>
<tr>
<th>Health Plan</th>
<th>Information Available</th>
<th>Coverage Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Cross Blue Shield</td>
<td>No information Available</td>
<td>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.</td>
</tr>
<tr>
<td>Centene Corp</td>
<td>No information Available</td>
<td>N/A</td>
</tr>
<tr>
<td>Cigna</td>
<td>No</td>
<td>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.</td>
</tr>
<tr>
<td>Health Net</td>
<td>No information Available</td>
<td>N/A</td>
</tr>
<tr>
<td>Humana</td>
<td>No information Available</td>
<td>N/A</td>
</tr>
<tr>
<td>Magellan</td>
<td>No information Available</td>
<td>N/A</td>
</tr>
<tr>
<td>Molina</td>
<td>Yes</td>
<td>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.</td>
</tr>
<tr>
<td>Health Insurance Provider</td>
<td>Information Available</td>
<td>Coverage</td>
</tr>
<tr>
<td>---------------------------</td>
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<tr>
<td>United Healthcare</td>
<td>No information Available</td>
<td>N/A</td>
</tr>
<tr>
<td>Wellcare</td>
<td>No information Available</td>
<td>N/A</td>
</tr>
<tr>
<td>Wellpoint</td>
<td>No information Available</td>
<td>N/A</td>
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</tbody>
</table>

**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 need 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

<table>
<thead>
<tr>
<th>CLINICAL PRESENTATION&lt;sup&gt;a&lt;/sup&gt;</th>
<th>INITIAL WORKUP</th>
<th>PATHOLOGIC WORKUP&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical signs&lt;sup&gt;c&lt;/sup&gt; (effusion, enlargement, mass, ulceration) &gt; 1 year post-implantation (Average 8–10 years post-implantation)</td>
<td>Any effusion</td>
<td>FNA of fluid&lt;sup&gt;d&lt;/sup&gt; around breast implant</td>
</tr>
<tr>
<td>Ultrasound of breast or Breast MRI in selected cases</td>
<td>Mass</td>
<td>Biopsy of mass</td>
</tr>
<tr>
<td>Ultrasound inconclusive</td>
<td>Breast MRI, if not previously done</td>
<td>If indeterminate of lymphoma</td>
</tr>
</tbody>
</table>

**ESSENTIAL:**
- Cytology with cell block preparation<sup>e</sup>
- IHC and/or flow cytometry<sup>f</sup> for CD2, CD3, CD4, CD5, CD7, CD8, CD30, CD45, and ALK<sup>g</sup>

**USEFUL UNDER CERTAIN CIRCUMSTANCES:**
- If there is solid mass associated with the implant, biopsy (excisional or incisional or core needle) may be required for diagnosis

**Histologic confirmation or suspicious of BIA-ALCL<sup>i</sup>**

- Negative for lymphoma
- Refer to plastic surgeon for management
- See BIAA-2
- Second pathology consultation by tertiary cancer center

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<sup>a</sup>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.

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

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

<sup>d</sup>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.

<sup>e</sup>See Principles of Molecular Analysis in T-Cell Lymphomas (LYMPH-A).

<sup>f</sup>Breast implant-associated ALCL (BIA-ALCL) is usually ALK-negative but has a good prognosis.

<sup>i</sup>The FDA recommends reporting all BIA-ALCL cases to the PROFILE Registry: www.thefst.org/PROFILE.

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Note: All recommendations are category 3A unless otherwise indicated.
Clinical Trial: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

**BIAA-1**
# NCCN Guidelines Version 2.2019

## Breast Implant-Associated ALCL

### LYMPHOMA WORKUP AND STAGING

- **Recommend discussion of treatment options with multidisciplinary team**
- **H&P exam, including complete skin exam**
- **CBC with differential**
- **Comprehensive metabolic panel**
- **LDH**
- **PET/CT scan**
- **Echocardiogram or MUGA scan if anthracycline or anthracycline-based regimen is indicated**
- **Pregnancy testing in women of child-bearing age (if chemotherapy or RT planned)**

### TREATMENT

- **Total capsulectomy and excision of associated mass with biopsy of suppurative node(s), explantation**
- **Consider removal of contralateral implant**
- **Consultation with surgical oncologist recommended for patients with preoperative tumor mass**

### FOLLOW-UP

- **Complete excision with no residual disease**
- **Localized disease to capsule/implant/breast**
- **Incomplete excision or partial capsulectomy with residual disease & regional lymph node involvement**
- **Extended disease (stage II-IV)**

### References


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

Updates made to NCCN Guidelines- August 2019.