



THE AMERICAN SOCIETY FOR
AESTHETIC PLASTIC SURGERY, INC.



AMERICAN SOCIETY OF
PLASTIC SURGEONS



THE AESTHETIC SURGERY EDUCATION
AND RESEARCH FOUNDATION



THE PLASTIC SURGERY
FOUNDATION™

The BIA-ALCL Patient Assistance Fund

The American Society for Aesthetic Plastic Surgery (ASAPS) and the American Society of Plastic Surgeons (ASPS), in conjunction with the Aesthetic Surgery Education and Research Foundation (ASERF) and the Plastic Surgery Foundation (PSF), are pleased to announce funding for patients diagnosed with breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). These funds are intended to help underinsured or uninsured patients who are seeking surgical treatment of BIA-ALCL, total capsulectomy and explantation, and excision of associated mass with biopsy of suspicious node(s) and implant-based reconstruction, if indicated. The goal of this Fund is for ASAPS, ASPS, ASERF, and PSF members to help patients obtain treatment when insurance limitations would have otherwise restricted their ability to do so. The Fund is made possible by generous contributions from Allergan, Mentor Worldwide, LLC and Sientra, Inc.

Patient Selection Criteria for Consideration

- Patient's health insurance must be either exhausted or unavailable.
- Patient must have no health insurance through any other source, such as a partner/spouse or a second employer.
- Patient must reside within the United States.
- Following National Comprehensive Cancer Network (NCCN) treatment guidelines, patient must have been diagnosed with ALCL. Submit the diagnostic tests performed to make the diagnosis with the application (see Appendix 1 for diagnostic guidelines).

Implant Criteria

- Implant must have an unknown manufacturer, or a manufacturer no longer in existence, or have been manufactured by Allergan, Mentor or Sientra. (Where the implantation procedure took place is immaterial.)

Surgeon Criteria

- Patient's own plastic surgeon, or an ASAPS, ASPS, ASERF, and/or PSF member volunteer, must be available to perform the procedure.
- Surgeon must have access to either an accredited in-office surgery center or a hospital with an available charity care program.
- Surgeon must be familiar with NCCN guidelines for diagnosis and management of ALCL.
- Surgeon must have a working relationship, and be willing to consult, with an oncologist and hematopathologist who are both familiar with ALCL.
- Surgeon must be willing to donate his/her surgical services.
- If the surgeon owns the surgical facility, surgeon must be willing to donate the facility fees.

Fund Uses

- Total capsulectomy and excision of associated mass with biopsy of suspicious node(s) and explantation, with implant-based breast reconstruction, if indicated and determined by the treating surgeon on a case-by-case basis.
- Staged implant replacement/reconstruction will be covered by the Fund but requires pre-approval.
- Associated surgical costs, such as anesthesia and fees for facilities not owned by the surgeon.
- Pre-approved travel expenses when a local plastic surgeon is not available.
- Follow-up appointments for 6 months based on surgeon(s) recommendations.

Exclusions

- Patients who have not been diagnosed with ALCL.
- Patients who are staff of either the original or volunteer plastic surgeon.
- Patients who are related to either the original or volunteer plastic surgeon.
- Diagnostic tools, such as ultrasound, CD30 testing or pathologic evaluation.
- Treatment of ALCL, including initial workup, pathologic workup, lymphoma workup and staging, chemotherapy, radiation or other disease treatment modalities, and adjuvant treatment in the event of incomplete excision with residual disease.
- Implants which are known to have been manufactured by entities other than Allergan, Mentor or Sientra. (Even if that entity is still in existence.)
- Non-surgical expenses (except for pre-approved travel)
- Any Manufacturer's implant warranty to which a patient may be entitled shall not be considered insurance, and, by itself, shall not thereby render a patient ineligible for participation in the Fund
- Requests for funds exceeding \$6,500.00 U.S. dollars.

Patient/Physician Agreements

- Patient and Surgeon will report details of the case to all registries requested, including PROFILE and FDA MAUDE Database.
- Patient and Surgeon will share pathology specimens for centralized tissue banking on IRB approved studies.
- Patient and Surgeon will share the medical procedure details, including deidentified photographs, with ASAPS, ASPS, ASERF, and PSF for physician and patient education and research, which will include journal articles and scientific presentations, in person, in print and online.
- Patient will waive medical confidentiality, but as to physician and patient education and research only. Patient will not waive medical confidentiality for any commercial advertising or promotions.
- Surgeon will submit written confirmation that each hospital and treating physician will not bill the eligible Fund patient or any other third party for services and/or products provided.

Process

- The patient and the patient's plastic surgeon will submit a request to ASERF for review by the ALCL Patient Assistance Fund Task Force.
- ALCL Patient Fund Task Force will evaluate each request as expeditiously as circumstances permit.
- Patient and/or Surgeon will be promptly notified whether their case will be funded, and if so, how much.
- Following the procedure, and upon approval of provider invoices, ASERF will issue checks to each provider, not to the patient, and only in the amounts pre-approved.

If you are an ASAPS, ASPS, ASERF, and/or PSF member who has a patient that meets the qualifications above and would like their case to be considered for a grant, please present ASERF with the following information/documentation:

- Submit a written request for financial support up to \$6,500.00 on behalf of your patient. In this request please briefly outline why you feel your patient is a good candidate. Please provide the following:
 - 1) Brief Clinical History: Date of ALCL diagnosis, prior surgeries and reconstructions, therapeutic treatments, and current ALCL status. Please submit copies of all key reports: laboratory, pathology, and radiologic tests that confirmed the diagnosis.
 - 2) Surgical plan and goals.
 - 3) Amount of funds requested, the designated use of funds, and the contact information for each ultimate recipient of the funds.
 - 4) Acknowledgement that Patient and Surgeon will report details of the case to all registries requested, including PROFILE and FDA MAUDE Database, and will share pathology specimens for centralized tissue banking on IRB approved studies.
 - 5) Submit an original signed copy of the ASERF Patient Photographic Authorization and Release.
 - 6) Submit written confirmation that each hospital and treating physician will not bill the eligible Fund patient or any other third party for services and/or products provided.



ASERF PATIENT PARTICIPATION AGREEMENT TO REPORT DETAILS, SHARE PATHOLOGY SPECIMENS, AND PHOTOGRAPHIC AUTHORIZATION AND RELEASE

In consideration of the Aesthetic Surgery Education and Research Foundation (“ASERF”) providing a grant, in conjunction with my doctor donating all or a portion of his/her services, for all or a portion of the cost of my breast procedure(s), I hereby agree to report details of my case to all registries requested, including PROFILE and FDA MAUDE Database, and share pathology specimens for centralized tissue banking on IRB approved studies, which have been explained to me by my doctor. I further consent to the taking of deidentified photographs or videotapes of me or parts of my body, by my doctor or designee, and to the release by my doctor to ASERF of such deidentified photographs, videotapes, and case histories.

I understand that such deidentified photographs, videotapes or case histories may be published by my doctor and ASERF and/or any party acting under their express license and authority in any print, visual or electronic media including, but not limited to, medical journals and textbooks, scientific presentations and teaching courses, and Internet web sites, for the purpose of informing the medical profession or the general public about plastic surgery methods and benefits. I also agree to be interviewed by my doctor or ASERF about the procedure and “my story” for purposes of such public and medical profession education.

- My first name, case history and procedure photos may be used as stated above.
- My first name, case history, procedure photos *and my face* may be used as stated above.

In either case, I understand that the photographs may portray features that shall make my identity recognizable.

I understand that the information disclosed may be protected by state law, which privacy protections I hereby waive. I understand that once given, I waive the right to revoke this authorization. I further understand that, because ASERF is not receiving the information in the capacity of a health care provider or health plan covered by HIPAA, nor is any information being transmitted electronically for the purpose of insurance confirmation or reimbursement, the information described above will not be protected by the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and may be redisclosed by ASERF.

I release and discharge my doctor, ASERF, and all parties acting under their express license and authority from all rights that I may have in the photographs, videotapes or case histories and from any claim that I may have relating to such use in publication, including any claim for payment in connection with distribution or publication of these materials in any medium. I further release, discharge and will hold harmless and defend at my own expense ASERF from any medical claims I may have against my doctor.

I grant this consent as a voluntary contribution in the interest of public education and certify that I have read the above Authorization and Release and fully understand its terms.

Patient signature

Printed Name

Date

Doctor signature

Printed Name

Date



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The BIA-ALCL Patient Assistance Fund Surgery Grant Request Form

For the grant to be reviewed by the Committee, please use the following checklist and complete the items below to ensure your application is complete.

- Written request for grant
- ASERF photo release and hold harmless agreement

ALL APPLICATIONS MUST BE MAILED TO:

ASERF

Attn: BIA-ALCL Patient Assistance Fund

11262 Monarch St.

Garden Grove, CA 92841-1441

DO NOT SEND THIS APPLICATION ELECTRONICALLY

Surgeon Name: _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Email: _____

APPLICATION CHECKLIST

- 1) Provide a brief clinical history of the patient. [Date of ALCL diagnosis, prior surgeries and reconstructions, therapeutic treatments, and current ALCL status.] Also submit copies of all key reports: laboratory, pathology, and radiologic tests that confirmed the diagnosis.

(Insert text here)

2) Surgical Plan and Goals for the patient.

(Insert text here)

3) Amount of funds requested and the designated use of funds.

Amount Requested (\$6,500.00 maximum): \$ _____

(Designated use of funds)

- 4) Provide acknowledgement that the Patient has agreed to report details of the case to all registries requested, including PROFILE and FDA MAUDE Database, and share pathology specimens for centralized tissue banking on IRB approved studies.
- 5) Submit an original signed copy of the ASERF Patient Photographic Authorization and Release.
- 6) Submit written confirmation that each hospital and treating physician will not bill the eligible Fund patient or any other third party for services and/or products provided.

By signing below, I acknowledge that all the information in this grant application is true to the best of my knowledge. I certify that the any funds awarded will be applied to the purpose presented in this grant request.

Signature

Date

Appendix 1



Management of Suspected and Confirmed BI-ALCL

