

Mentor BIA-ALCL Patient Financial Assistance Policy for Mentor Breast Implants and Tissue Expanders

OVERVIEW

This policy outlines the handling of financial assistance for patients who incur costs associated with the diagnosis and treatment of Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA-ALCL) with a history of implantation of Mentor breast implants or Mentor tissue expanders in North America including the United States of America, Puerto Rico, and Canada.

POLICY

Although Mentor products have consistently shown a low representation of Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA-ALCL), our aim is to provide Mentor patients added peace of mind.

This process is triggered through a product complaint placed by a surgeon on behalf of a newly diagnosed patient. Upon submission of proof of diagnosis, via pathology report confirming BIA-ALCL, and proof of last known breast implant or breast tissue expander implantation being that of a Mentor breast implant or breast tissue expander, Mentor will provide the affected patient with up to \$7,500 in financial assistance to go toward the patient's out of pocket BIA-ALCL costs for diagnosis and medical treatment.

To be eligible for the Mentor BIA-ALCL Patient Financial Assistance Policy, patients must be diagnosed on or after January 1st 2019. At the time of diagnosis, the patient must also present documentation of having been last previously implanted with a breast implant or a breast tissue expander manufactured by Mentor. The previously implanted Mentor breast implant or breast tissue expander can have been implanted before January 1st 2019 but must be the last known device implanted in the patient before diagnosis with BIA-ALCL.

REPLACEMENT PRODUCT POLICY

In addition to financial assistance, the patient may be eligible for replacement product to the affected and contralateral breast, as per the Mentor Product Replacement Policy. To qualify for product replacement under the Replacement Policy, implantation of the affected Mentor implants, as well as any subsequent procedures, must be in accordance with current MENTOR product literature and accepted plastic surgical procedures by appropriately qualified licensed physicians. There is no additional charge for the replacement product even if the requested replacement product is in a more expensive product family than the originally affected product.

The explanted product must be returned to the Mentor Product Evaluation Department within sixty (60) days of its explant in order to qualify for the free-of-charge replacement product. In the event that the explanted product is not returned to the Mentor Product Evaluation Department within sixty (60) days of its explantation, the ordering customer will be invoiced for the price of the replacement product.

At the surgeon's request, Mentor will also provide a replacement breast implant or breast tissue expander to use to replace the contralateral implant, provided that the contralateral breast implant is a Mentor product. There will be no charge for this courtesy except as outlined in this policy.

Qualifying replacement product (limit 2) will be sent without shipping charges if the order is received in the Mentor Product Evaluation Department at least three (3) business days prior to scheduled delivery date; otherwise, freight charges will be invoiced to the ordering customer. All "backup" replacement product requested will be invoiced at customer's established pricing and shipping terms and will follow Mentor's standard return policy. Mentor will neither provide nor pay for a replacement with a non-Mentor product under the terms of this Replacement Policy, nor in any event provide money for or in lieu of a Mentor replacement product. Any replacement MENTOR® Saline Filled Breast Implant, MENTOR® MemoryGel® Breast Implant, MENTOR® MemoryGel® Xtra Implant or MENTOR® MemoryShape® Breast Implant automatically includes new coverage under any eligible warranty program currently available at time of implant.

The following information are required to verify eligibility for financial assistance or product replacement under the Mentor BIA-ALCL Patient Financial Assistance Policy:

- Information to document the patient's implant information (catalogue, serial #) and the patient's experience
- The operative report for the original implantation surgery to document date of implant
- Proof of diagnosis via pathology report confirming BIA-ALCL
- A copy of the operative report for the revision surgery
- Copies of bills showing diagnosis, operating room, anesthesia, and surgeon fees incurred for BIA-ALCL treatment and the replacement surgery
- Copies of forms showing any relevant insurance reimbursements (explanation of benefits forms)

LIMITATION ON THE REPLACEMENT POLICY:

If Mentor's obligation to provide a replacement product under the Replacement Policy is prevented, restricted, or interfered with by reason of fire, flood, earthquake, explosion, or other casualty or accident, strikes or labor disputes, inability to procure supplies or power, war or other violence, any law, order, proclamation, regulation, ordinance, demand, or requirement of any government agency, or any other act or condition whatsoever beyond the reasonable control of Mentor, the performance of that obligation shall be excused without penalty. For purposes of this provision, excuse of performance shall mean that Mentor is neither obligated to provide nor pay for a replacement product, regardless of the product's source. Despite the excuse of Mentor's obligation to provide a replacement product under this provision, Mentor shall continue to perform its obligation to provide financial assistance for treatment of BIA-ALCL as per the Mentor BIA-ALCL Patient Financial Assistance Policy.

THE BIA-ALCL PATIENT FINANCIAL ASSISTANCE POLICY AND REPLACEMENT POLICY, ARE LIMITED WARRANTIES ONLY, AND ARE SUBJECT TO THE TERMS AND CONDITIONS SET FORTH IN THIS DOCUMENT. ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS, ARE EXCLUDED. THIS REMEDY IS THE SOLE AND EXCLUSIVE REMEDY AVAILABLE. MENTOR SHALL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL LOSS, DAMAGE, OR EXPENSE ARISING, DIRECTLY OR INDIRECTLY, FROM THE USE OF THESE PRODUCTS. MENTOR NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER, OR ADDITIONAL LIABILITY, OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. MENTOR DOES NOT WARRANT OR OTHERWISE ASSUME LIABILITY FOR MENTOR PRODUCTS THAT HAVE NOT BEEN PROCURED DIRECTLY FROM MENTOR BY THE TREATING PHYSICIAN (OR THEIR AUTHORIZED BUYING AGENT).

This policy shall not be construed in any way as an admission of liability or of general or specific medical causation between implants or expanders and BIA-ALCL.