Allergan Breast Implant Warranty Programme

This document describes Allergan's Saline-Filled and Silicone-Filled Breast Implant Warranty Program effective May 1, 2019. The Breast Implant Limited Warranties consist of the *ConfidencePlus*™ Warranty, and are described in Table I below:

Table 1

Warranty Program	Events Covered	Events not covered/ Limitations
Natrelle® ConfidencePlus™ Warranty Program	For all Allergan Textured Breast Implants including CUI®, McGhanand BRST® - Lifetime product replacement for rupture, plus up to USD 3,500 for surgical fees within 10 years for surgeries performed after January 1, 2019 - 10 years of guaranteed product replacement for capsular contracture Baker grade III/IV for surgeries performed after January 1, 2019 - 10 years of guaranteed product replacement for patients diagnosed with late seroma for surgeries performed after January 1, 2019 - Free contralateral breast implant replacement at the surgeon's request - Uncommon events coverage for BIA-ALCL lifetime product replacement, up to USD 7,500 for out-of-pocket expenses not covered by insurance - Late seroma diagnostic testing performed after 1 October 2019, up to USD 1,000 for out-of-pocket expenses not covered by insurance - Implanted in Australia or New Zealand Note: Amounts stated in USD in this document will be converted and paid in local currency based on the foreign exchange (FX) rates at the time of processing.	Asymptomatic, elective or preventative removal Patient dissatisfaction with implant size or aesthetics Adverse reactions other than implant rupture, capsular contracture or late seroma Removal of implants due to wrinkling or rippling. Loss of product integrity caused by cosmetic revision surgery Loss of product integrity caused by open or closed capsulotomy Gel deformation / gel fracture Other manufacturers' products Financial reimbursement for a non-Natrelle replacement product in lieu of a Natrelle replacement product

* Deflation, rupture, capsular contracture and late seroma are among the known risks of breast implants. Capsular contracture is defined as the tightening of the tissue capsule around an implant, resulting in firmness or hardening of the breast and squeezing of the implant. Late seroma is defined as a pocket of serous fluid that develops at least 12 months after breast augmentation and presents with clinically evident swelling.

The plastic surgeon, as learned intermediary, is responsible for providing the patient with appropriate risk information before surgery, including (but not limited to) the risk of deflation, rupture and Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Allergan makes available to all plastic surgeons and patients a copy of the device appropriate informed decision brochure describing the benefits and risks of surgery with either its Saline-Filled or Silicone Gel-Filled breast implants. Copies can also be obtained by contacting Allergan directly, or through the Allergan website. The plastic surgeon should also advise the patient about possible adverse reactions and complications associated with Saline-Filled and Silicone Gel-Filled breast implants. **This document is not intended to, and cannot, take the place of a full and candid discussion between plastic surgeon and patient or the informed decision brochure for patients.**

Qualified Allergan Breast Implants are the following (hereinafter referred to as "Allergan Breast Implants"):

- CUI MHP, MLP, SHD
- Natrelle Saline breast implant styles 168, 363, 468
- Natrelle and McGhan 410 breast implant styles LL, LM, LF, LX, ML, MM, MF, MX, FL, FM, FF, FX
- Natrelle and McGhan 410 *Soft Touch* breast implant styles LL, LM, LF, LX, ML, MM, MF, MX, FL, FM, FF, FX
- Natrelle 510 Dual-Gel styles LX, MX, FX
- Natrelle INSPIRA breast implants styles TRL, TRLP, TRM, TRF, TRX, TSL, TSLP, TSM, TSF, TSX, TCL, TCLP, TCM, TCF, TCX
- Natrelle and McGhan Round Gel Implants, styles 110, 110 Soft Touch, 115, 120, 120 Soft Touch
- Natrelle Komuro breast implants styles KML, KMM, KLL, and KLM
- Natrelle Ritz Princess breast implant styles RML, RMM, RFL, RFM
- Natrelle 150 Full Height and Short Height double lumen implants

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I. APPLICATION OF THE ALLERGAN WARRANTIES

A. WARRANTY

1. **Timeline**: The Allergan Warranty applies automatically to Allergan Breast Implants implanted in all Allergan markets outside the United States of America on or after May 1, 2019 (or as set out in Table I above), and supersedes any previous Allergan Warranty Program previously applicable.

2. **Covered Events:** The Allergan Warranty applies only to the following covered events (each a "Covered Event") if they require surgical intervention:

   (a) For NATRELLE® Silicone-Filled Breast Implants:

      (i) rupture of Allergan Silicone-Filled Breast Implants due to crease fold failure; or

      (ii) loss of shell integrity from unknown cause; or

      (iii) removal of implants for capsular contracture Baker grade III/IV (product replacement only within ten years of augmentation surgery); or

      (iv) removal of implants for late seroma (product replacement only within ten years of augmentation surgery).

      (v) BIA-ALCL diagnosis

      The Allergan Warranty may also apply to other event-related losses of shell integrity not specifically excluded, subject to review and approval by Allergan.

3. **Events Not Covered:** The Allergan Warranty does not apply to:

   (a) removal of implants for size alteration;

   (b) removal of implants due to wrinkling or rippling;

   (c) loss of shell integrity caused by operative procedures; or

   (d) loss of shell integrity resulting from open capsulotomy or closed compression capsulotomy procedures.

   The Allergan Warranty excludes other events outside the covered events listed in section A(I)(2) above.

4. **Cost:** No cost.

5. **What Allergan will provide under the Allergan Warranty:**

   (a) **Product Replacement:** If patient has a Covered Event, Allergan will replace the qualifying Allergan product with another Allergan product, of the same or similar type as the qualifying product, free of charge for the lifetime of the implant. Implantation of the replacement Allergan product, as well as any subsequent procedures, must be in strict accordance with current Allergan product literature and accepted plastic surgical

procedures by appropriately qualified licensed plastic surgeons for such product to qualify for replacement. As an alternative to providing free replacement, Allergan may reimburse the cost that the patient paid for the qualifying Allergan product.

The explanted product must be returned to the Allergan Device Analysis Laboratory within 90 days of its explant in order to qualify for the free of charge replacement product. For claims where both devices are explanted, both explanted devices must be returned. In the event that the explanted product is not returned to the Allergan Device Analysis Laboratory within 90 days of its explantation, the ordering customer will be invoiced for the price of the replacement product. Qualifying replacement product will be sent without shipping charges. Subject to this clause, Allergan will neither provide nor pay for a non-Allergan product, nor in any event provide money for or in lieu of an Allergan replacement product. Any replacement NATRELLE® Style, Saline-Filled or Silicone-Filled Breast Implant, automatically includes a new Allergan Warranty covering the replacement implant only.

(b) For NATRELLE® Silicone-Filled Breast Implants:

(i) When a qualifying replacement surgery for a Covered Event occurs from the date of implantation within the timelines set out in Table I above, Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of the respective amounts set out in Table I. Upon submission of a qualifying request, Allergan will provide a general release in favor of Allergan.

(ii) Allergan will not pay for any re-operative expenses until receipt of the release signed by the patient. In addition, Allergan may require a copy of bills or receipts associated with the revision surgery before payment will be made. Other documentation, such as operative notes and photos, may be required prior to payment. Request for financial assistance under the Allergan Warranty must be made to the Allergan Warranty Department prior to the date of qualifying revision surgery.

(iii) Should a more expensive Allergan product be requested by the plastic surgeon, Allergan will invoice the ordering customer for the list price difference between the qualified product to be replaced and the requested replacement product.

The customer will not be credited or reimbursed for the list price difference between the qualified product to be replaced and the requested replacement product should the plastic surgeon request a less expensive replacement product.

At the surgeon's request, Allergan will also provide a replacement of a NATRELLE® Silicone-Filled Breast Implant to use to replace the contralateral implant. Upon submission of a qualifying request for financial assistance, Allergan will provide a general release in favor of Allergan.

(c) For BIA-ALCL diagnosis

(i) When documentation of a positive diagnosis of BIA-ALCL is provided by a pathology report confirming CD30 positive, ALK negative cytology and/or histology as per the NCCN [National Comprehensive Cancer Network] guidelines, Allergan will pay out-of-pocket expenses for surgical fees, operating room, and anesthesia expenses directly related to revision surgery and not covered by insurance, up to a maximum aggregate amount of USD 7,500 Upon submission of a qualifying request, Allergan will provide a general release in favor of Allergan.

(ii) Allergan will not pay for any re-operative expenses until receipt of the release signed by the patient. In addition, Allergan may require a copy of bills or receipts associated with the revision surgery before payment will be made. Other documentation, such as operative notes and photos, may be required prior to payment. Request for financial assistance under the Allergan Warranty must be made to the Allergan Warranty Department upon confirmation of a positive diagnosis.

(iii) Should a more expensive Allergan product be requested by the plastic surgeon, Allergan will invoice the ordering customer for the list price difference between the qualified product to be replaced and the requested replacement product.

The customer will not be credited or reimbursed for the list price difference between the qualified product to be replaced and the requested replacement product should the plastic surgeon request a less expensive replacement product.

At the surgeon's request, Allergan will also provide a replacement of a NATRELLE® Silicone-Filled Breast Implant to use to replace the contralateral implant. Upon submission of a qualifying request for financial assistance, Allergan will provide a general release in favor of Allergan.

B. PATIENT INFORMATION ON THE ALLERGAN WARRANTY

Before implantation surgery, the plastic surgeon should explain the details of the Allergan Warranty terms and conditions, including product replacement, to the patient, and direct the patient to the Allergan website where they can view the terms and conditions document. In addition to explaining the terms of the Allergan Warranty and Product Replacement, the plastic surgeon should also advise the patient about possible adverse reactions and complications associated with Saline-Filled and Silicone-Filled Breast Implants, including the risk of BIA-ALCL, and review with the patient the device appropriate informed decision brochure provided by Allergan, describing the benefits and risks of surgery with either its Saline-Filled or Silicone Gel-Filled breast implants.

C. FILING A CLAIM

If a Covered Event occurs within ten years of the date of an implantation/or at any time for BIA-ALCL coverage under the Allergan Warranty, the plastic surgeon should contact Allergan's Medical Device Complaint Center at MedDeviceComplaintsAPAC@Allergan.com to report the event(s) (see form on Schedule 1) and forward the following documents in advance of the revision surgery in order for a subsequent claim to be considered for approval:

(i) **Rupture**: a copy of the MRI and/or US report - If revision surgery is planned based on reliance of Magnetic Resonance Imaging (MRI) and/or Ultrasound (US) findings of suspected rupture of an ALLERGAN® Silicone-Filled Breast Implant

(ii) **Capsular Contracture Baker grade III or IV**: medical report stating the capsular contracture grade and need for surgery.

(iii) **Seroma Late**: In the case of a claim under a late seroma event for patients with textured implants only, a diagnosis qualifies as > 50 cc of fluid presented at least 12 months after surgery, upon a confirm diagnosis by a surgeon and confirmed by photographs, pathology, or other reports deemed acceptable by Allergan.

(iv) **BIA-ALCL**: a pathology report confirming BIA-ALCL diagnosis through confirmation of a CD-30 positive, ALK-negative cytology and/or histology.

Allergan will organise the return of the explanted implant(s). Upon receipt of the returned product, and of the properly signed release and claim form, payment will be issued to the appropriate party or parties in accordance with limitations outlined in this document.

Replacement products may be ordered before surgery by contacting **Device Technologies** (Allergan's Distributor) at:

Phone: 1300 338 423

D. **Limitation on Product Replacement**

If Allergan's obligation to provide a replacement product under the Allergan Warranty 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 Allergan, the performance of that obligation shall be excused without penalty. For purposes of this provision, excuse of performance shall mean that Allergan is neither obligated to provide nor pay for a replacement product, regardless of the product's source. Despite the excuse of Allergan's obligation to provide a replacement product under this provision, Allergan shall continue to perform its obligation to provide financial assistance for operating room, anesthesia, and surgical fee costs to the extent described under the Allergan Warranty.

Allergan reserves the right to cancel, change, or modify the terms of the Allergan Warranty. Any such cancellation, change, or modification will not affect the currently stated terms for those already enrolled in the Program.

Schedule 1

Allergan

Ref.: DOP-004

(Please complete and e-mail form to MedDeviceComplaintsAPAC@Allergan.com within 24 hours of complaint receipt.)

ORIGIN OF COMPLAINT		
Date Allergan Was First Notified:	Name of Allergan Representative Contacted:	Method of Contact: Email ☐ Phone ☐ Fax ☐ Other ☐ If Other, please specify:
Reporter Name:		Reporter Type: Implant MD ☐ Explant MD ☐ Other ☐ If Other, please specify:
Institution:		
Address:		Phone:
City, Postal Code, Country:		Email/Fax:
Implant MD name:		Explant MD name:

EVENT DESCRIPTION (LEFT SIDE)	EVENT DESCRIPTION (RIGHT SIDE)
Complaint?: YES ☐ NO ☐; If YES, please list events below:	Complaint?: YES ☐ NO ☐; If YES, please list events below:
Did the device cause or contribute to the reported event(s)? YES ☐ NO ☐; If NO, please provide the cause:	Did the device cause or contribute to the reported event(s)? YES ☐ NO ☐; If NO, please provide the cause:
Date of Symptom Onset:	Date of Symptom Onset:
Treatment (excluding implant removal) (Left)	Treatment (excluding implant removal) (Right)

PATIENT INFORMATION			
Full Name or Initials:		Race:	
Date of Birth:		Sex: Male ☐ Female ☐	
Implant Date:	Implant Surgery Type: Primary Augmentation ☐ Primary Reconstruction ☐ Revision Augmentation ☐ Revision Reconstruction ☐ Unknown ☐	If Implant Surgery Type is Revision, please provide the initial silicone implant date:	Implant Placement: Subglandular ☐ Submuscular ☐ Subcutaneous ☐ Unknown ☐
Explant Date:	Replacement Date (If different from explant date):		

AFFECTED DEVICE INFORMATION (Device(s) involved in the reported event(s))			
Left side Serial #		Right side Serial #	
Left side Lot #		Right side Lot #	
Left side Catalog #		Right side Catalog #	

REPLACEMENT DEVICE INFORMATION (If applicable and available) ☐ BACK-UP DEVICE INFORMATION (For out-of-box/broken device events only) ☐			
Left side Serial #		Right side Serial #	
Left side Lot #		Right side Lot #	
Left side Catalog #		Right side Catalog #	

DEVICE RETURN STATUS	FOR OUT-OF-BOX/BROKEN DEVICE EVENTS ONLY
Device to be returned? YES ☐ NO ☐ If NO, please provide a reason:	Did the inner silicone gel touch the patient? YES ☐ NO ☐

ADMINISTRATIVE DATA	
Form Completed by / Company	Date:

ALLERGAN EMPLOYEE/AUTHORIZED REPRESENTATIVE USE ONLY
Reportable to Local Regulatory Body? YES ☐ NO ☐; (If YES, please send a copy of the initial/follow-up/final /combined initial and final report when available)

ADDITIONAL INFORMATION