

# Natrelle®



Actual *Natrelle* INSPIRA® patient.  
Individual results may vary.

*Natrelle*® *ConfidencePlus*®  
warranty program

More COVERAGE  
for peace of mind

November 2021 update

Please see back cover for Important Safety Information,  
including Boxed Warning.



## GEL BREAST IMPLANT WARRANTY

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**MORE** coverage.  
**MORE** confidence.

The *Natrelle*® ConfidencePlus® warranty offers you more coverage for your breast implants—designed for your satisfaction and peace of mind.

Choose ANY style and size of *Natrelle*® gel breast implant for replacement in the case of any covered event with *Natrelle*® gel breast implants.

## ConfidencePlus® gel warranty

**FREE** coverage and automatic enrollment

### Rupture

- Implant replacement: Lifetime for both affected and contralateral implants
- Out-of-pocket financial assistance: Up to \$3,500 for 10 years

### Capsular contracture Baker Grade III/IV

- Implant replacement: 10 years for both affected and contralateral implants
- Out-of-pocket financial assistance: Up to \$2,000 for 2 years (augmentation patients only)\*

### Late seroma

Implant replacement: 20 years for both affected and contralateral textured implants.

### Late seroma diagnostic testing coverage

If you have textured gel or textured saline breast implants, Allergan® will cover up to \$1,000 of out-of-pocket fees toward diagnostic testing for late seroma to rule out breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

### BIA-ALCL treatment coverage

In the event of a BIA-ALCL diagnosis, you are eligible for up to \$7,500 out-of-pocket financial assistance toward the removal of the breast implant(s) and the associated scar tissue (complete capsulectomy).

Allergan® will also provide replacement implant(s) at no charge. For coverage eligibility, surgeons are directed to contact Allergan® and provide appropriate documentation.

\*Covers one incident per patient; recurring capsular contracture is not covered.



## SALINE BREAST IMPLANT WARRANTY

**MORE** coverage.  
**MORE** confidence.

For patients with *Natrelle*® saline implants, *ConfidencePlus*® warranty offers the peace of mind to upgrade to even more comprehensive coverage.

### **Late seroma**

Implant replacement: 20 years for both affected and contralateral textured implants.

### **Late seroma diagnostic testing coverage**

If you have textured gel or textured saline breast implants, Allergan® will cover up to \$1,000 of out-of-pocket fees toward diagnostic testing for late seroma to rule out breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

\*Covers one incident per patient; recurring capsular contracture is not covered.

## ConfidencePlus® saline warranty

**FREE** coverage and automatic enrollment

### Deflation

- Implant replacement: Lifetime for both affected and contralateral implants

### Saline to Gel Upgrade

- Only *Natrelle*® offers free saline-filled implants to gel-filled implants replacement, including the contralateral replacement<sup>1</sup>
- Upgrade from saline-filled implants to *Natrelle* INSPIRA® Responsive Gel Breast Implants at no charge
- Upgrade from saline-filled implants to *Natrelle* INSPIRA® SoftTouch or *Natrelle* INSPIRA® Cohesive Gel Breast Implants for only \$100 per implant

## ConfidencePlus® Premier saline warranty



You may choose to upgrade the above coverage within 45 days by enrolling at [cpp.natrelle.com](http://cpp.natrelle.com).

### Enrollment fee

- \$200 within 45 days of surgery

### Deflation

- Out-of-pocket financial assistance: Up to \$2,400 for 10 years

### BIA-ALCL treatment coverage

In the event of a BIA-ALCL diagnosis, you are eligible for up to \$7,500 out-of-pocket financial assistance toward the removal of the breast implant(s) and the associated scar tissue (complete capsulectomy).

Allergan® will also provide replacement implant(s) at no charge. For coverage eligibility, surgeons are directed to contact Allergan® and provide appropriate documentation.

# Important **TERMS** and **CONDITIONS** to know

## Products covered

The *ConfidencePlus*® warranty program applies to all FDA-approved *Natrelle*® breast implants, provided the products have been used:

- As intended by appropriately qualified and licensed surgeons and in accordance with current and accepted plastic surgery techniques
- In accordance with the current *Natrelle*® Breast Implant Directions for Use, found at [www.allergan.com/products](http://www.allergan.com/products)

## Events covered

- **Loss of shell integrity** resulting in **implant rupture of gel implants** that requires surgical intervention
- **Loss of shell integrity** resulting in **implant deflation of saline-filled implants** that requires surgical intervention
- **Capsular contracture (Baker Grade III/IV)** with *Natrelle*® gel implants that requires surgical intervention
  - Allergan® has the right to request photographs to confirm diagnosis
- **Late seroma** for patients with textured implants only. Previous Allergan® textured implants that have since been replaced with smooth implants are not covered
  - A diagnosis qualifies as > 50 cc of fluid presented at least 12 months after surgery
  - Cases must be diagnosed by a surgeon and confirmed by photographs, pathology, or other reports deemed acceptable by Allergan®
- **BIA-ALCL** diagnosis that requires surgical intervention
- **Late seroma diagnostic testing to rule out BIA-ALCL** when suspected, which may include one or more of cell cytology, CD30 immunohistochemistry, or flow cytometry testing

## Special considerations

Each *Natrelle*<sup>®</sup> breast implant is covered individually. So in the case of any covered event, you may choose to replace both implants or only the damaged implant. Coverage of the opposite (contralateral) implant will continue for the remaining life of the warranty.

## Events not covered

- Removal for capsular contracture for saline implants
- Dissatisfaction with implant size or aesthetics
- Adverse reactions other than the covered events listed on the previous page
- Loss of product integrity caused by cosmetic revision surgery
- Loss of product integrity caused by open or closed capsulotomy
- Other manufacturers' products
- Financial reimbursement for a replacement product that is not a *Natrelle*<sup>®</sup> style breast implant in lieu of a *Natrelle*<sup>®</sup> style replacement product

## To submit a claim

For coverage eligibility, your surgeon must contact the Allergan<sup>®</sup> Product Surveillance team prior to surgery at 1-800-624-4261 and provide the appropriate documentation. The surgeon is required to return the explanted, disinfected *Natrelle*<sup>®</sup> breast implant(s) within 3 months of the date of explantation. Allergan<sup>®</sup> requests the return of all explanted breast implants associated with a complaint to assist with evaluating and maintaining the quality and safety of *Natrelle*<sup>®</sup> breast implants. Where applicable, financial assistance will be issued upon receipt and verification of the explanted product(s), the Returned Goods Authorization (RGA), and the patient's warranty general release.

Insurance may cover procedures related to breast implants. Please contact your insurance provider to understand what may be included in your coverage.

## **Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION AND APPROVED USES**

Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.

Breast implants have been associated with the development of a cancer of the immune system called breast implant–associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.

Patients receiving breast implants have reported a variety of systemic symptoms, such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases, and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

### **Who can get breast implants?**

Natrelle® Breast Implants are approved for the following:

- **Breast augmentation for women at least 22 years old for silicone-filled implants and for women at least 18 years old for saline-filled implants.** Breast augmentation includes primary breast augmentation to increase the breast size and revision surgery to correct or improve the result of a primary breast augmentation
- **Breast reconstruction.** This includes primary breast reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. This also includes revision surgery to correct or improve the result of a primary breast reconstruction

### **Who should NOT get breast implants?**

Breast implant surgery should NOT be performed in:

- Women with active infection anywhere in their body
- Women with existing cancer or precancer of their breast who have not received adequate treatment for those conditions
- Women who are currently pregnant or nursing

### **What should I tell my doctor?**

Tell your doctor if you have any of the following conditions, as the risks of breast implant surgery may be higher:

- Autoimmune diseases (eg, lupus and scleroderma)
- A weakened immune system (eg, taking medications to decrease the body's immune response)
- Planned chemotherapy or radiation therapy following breast implant placement
- Conditions or medications that interfere with wound healing and blood clotting
- Reduced blood supply to breast tissue
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders
- Those with a diagnosis of depression or other mental health disorders should wait for resolution or stabilization of these conditions prior to undergoing breast implantation surgery

### **What else should I consider?**

- There is a Boxed Warning for breast implants. Please see bold text at beginning
- Many changes to your breasts following implantation are irreversible. If you later choose to have your implants removed and not replaced, you may experience dimpling, puckering, wrinkling, or other cosmetic changes, which may be permanent
- Breast implantation is likely not a one-time surgery. The longer implants are in place, the greater the potential risk for complications. You will likely need additional surgeries on your breasts due to complications or unacceptable cosmetic results. Thus, you should also consider the complication rates for later (revision) surgery since you may experience these risks in the future
- Cancer treatments and surgery will affect the outcome and timing of breast reconstruction
- Breast implants may affect your ability to breastfeed, either by reducing or eliminating milk production
- Rupture of a silicone-filled breast implant is most often silent. Even if you have no symptoms, you should have your first ultrasound or MRI at 5 to 6 years after your initial implant surgery and then every 2 to 3 years thereafter regardless of whether your implants are for augmentation or reconstruction. If you have symptoms of or uncertain ultrasound results for breast implant rupture, an MRI is recommended. Additional imaging may be required depending on your medical history and status. The health consequences of a ruptured silicone gel-filled breast implant have not been fully established
- Routine screening mammography for breast cancer will be more difficult, and implants may rupture during the procedure. Perform self-examination every month for cancer screening and ask your surgeon to help you distinguish the implant from your breast tissue. Lumps, persistent pain, swelling, hardening, or changes in implant shape should be reported to your surgeon and possibly evaluated with imaging

### **What are key complications with breast implants?**

Key complications include reoperation, implant removal with or without replacement, implant rupture with silicone-filled implants, implant deflation with saline-filled implants, and capsular contracture (severe scar tissue around the implant). Other complications include breast pain, swelling, asymmetry, wrinkling/rippling, implant malposition nipple complications, hypertrophic scarring, and implant palpability/visibility.

Talk to your doctor about other complications.

For more information, see the patient brochures at [www.allergan.com/products](http://www.allergan.com/products).

To report a problem with *Natrelle®* Breast Implants, please call Allergan® at 1-800-624-4261.

The sale and distribution of *Natrelle®* Breast Implants is restricted to licensed physicians who provide information to patients about the risks and benefits of breast implant surgery.

**Reference:** 1. MentorPromise and MentorPromise Enhanced Protection Plan for Saline-Filled Breast Implants. Mentor website. [https://www.jnjmedicaldevices.com/sites/default/files/2021-01/MentorPromise%20Saline%20TandC%202021%20Final\\_0.pdf](https://www.jnjmedicaldevices.com/sites/default/files/2021-01/MentorPromise%20Saline%20TandC%202021%20Final_0.pdf).

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*Natrelle*

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