HEALTH INSURER

123 Insurance Way

Anywhere, IL 012345

DATE

RE: Claim # XXXXXXXXXXX

Insured: NAME (ID# XXXXXXXXXXX)

Claimant: NAME (DOB Mo-Day-Year)

To Whom It May Concern:

I am writing to appeal [Health Plan Name]’s decision to deny coverage of removal [and exchange] of my breast implants which were used in reconstruction following a bilateral mastectomy. My implants are textured [and part of the Allergan **BIOCELL product** recall announced in July 2019] [Exhibit A]. These implants are associated with an increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

The Women’s Health and Cancer Rights Act (WHCRA) requires most group and individual health plans to pay for breast reconstruction following a mastectomy. Any woman undergoing a mastectomy deemed to be medically necessary is entitled to “all stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prostheses and treatment of physical complications of the mastectomy, including lymphedema.” [Exhibit B]

Breast reconstruction following mastectomy can significantly impact a woman’s body image, self-esteem, and quality of life. WHRCA exists to help ensure that women have a choice and some sense of control in conjunction with a mastectomy, allowing them to work with their health care providers to choose the type of reconstruction best suited for them. In addition to reconstruction, the law mandates coverage of care related to “physical complications of all stages of the mastectomy.” As such, coverage of reconstructive revisions and/or replacement of breast implants is required by law.

My surgeons and I have determined that explant is medically necessary due to [list any symptoms/complications and/or the risk of BIA-ALCL]. The vast majority of insurers cover explant and/or exchange of breast implants as indicated. BIA-ALCL can be a very serious illness. As such, explant is the best way to ensure my continued health.

Thank you for your consideration. Your prompt attention to this appeal is greatly appreciated.

Sincerely,

[Signature]

**Exhibit A**

# Image result for fda logo

# **The FDA Requests Allergan Voluntarily Recall Natrelle BIOCELL Textured Breast Implants and Tissue Expanders from the Market to Protect Patients: FDA Safety Communication**

To protect individuals from the increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), associated with Allergan BIOCELL textured breast implants, the Food and Drug Administration (FDA) requested that Allergan recall its BIOCELL textured breast implants and tissue expanders. Allergan agreed and is removing these products from the global market.

The FDA requested that Allergan recall all BIOCELL textured breast implants and tissue expanders marketed in the U.S. based on newly submitted Medical Device Reports (MDRs) reporting worldwide cases of BIA-ALCL and BIA-ALCL-related deaths associated with these devices. Allergan has notified the FDA that it will recall its BIOCELL textured breast implants and tissue expanders from the global market.

Based on the currently available information, including the newly submitted data, our analysis demonstrates that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences and potentially death from BIA-ALCL.

**Affected Products**

**Allergan Natrelle Saline-Filled Breast Implants** (formerly McGhan RTV Saline-Filled Mammary Implant) approved under P990074. The following are the textured styles:

* Style 163 – BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants
* Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile)
* Style 363 – BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection
* Style 468 – BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants

**Allergan Natrelle Silicone-Filled Textured Breast Implants** (formerly Inamed Silicone-Filled Breast Implants) approved under P020056. The following are the textured styles:

* Style 110 – BIOCELL Textured Round Moderate Projection Gel Filled Breast Implants
* Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants
* Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants
* Style TRL - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
* Style TRLP - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
* Style TRM - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
* Style TRF - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
* Style TRX - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
* Style TCL – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
* Style TCLP – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants

**Exhibit A** (continued)

* Style TCM – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
* Style TCF – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
* Style TCX – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
* Style TSL – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
* Style TSLP – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
* Style TSM – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
* Style TSF – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
* Style TSX – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants

**Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants** approved under P040046. The following are the textured styles:

* Style 410FM
* Style 410FF
* Style 410MM
* Style 410 MF
* Style 410 FL
* Style 410 ML
* Style 410 LL
* Style 410 LM
* Style 410 LF
* Style 410 FX
* Style 410 MX
* Style 410 LX

Allergan tissue expanders for the breast that have BIOCELL texturing originally cleared as:

* Natrelle 133 Plus Tissue Expander (K143354)
* Natrelle 133 Tissue Expander with Suture Tabs (K102806)

Source: www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue

**Exhibit B**



**Women's Health and Cancer Rights Act (WHCRA)**

The Women's Health and Cancer Rights Act of 1998 (WHCRA) is a federal law that provides protections to patients who choose to have breast reconstruction in connection with a mastectomy.

If WHCRA applies to you and you are receiving benefits in connection with a mastectomy and you elect breast reconstruction, coverage must be provided for:

* All stages of reconstruction of the breast on which the mastectomy has been performed;
* Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
* Prostheses and treatment of physical complications of all stages of the mastectomy, including lymphedema.

This law applies to two different types of coverage:

1. Group health plans (provided by an employer or union);
2. Individual health insurance policies (not based on employment).

Group health plans can either be “insured” plans that purchase health insurance from a health insurance issuer, or “self-funded” plans that pay for coverage directly.  How they are regulated depends on whether they are sponsored by private employers, or state or local (“non-federal”) governmental employers.  Private group health plans are regulated by the Department of Labor.  State and local governmental plans, for purposes of WHCRA, are regulated by CMS.  If any group health plan buys insurance, the insurance itself is regulated by the State’s insurance department.

Contact your employer’s plan administrator to find out if your group coverage is insured or self-funded, to determine what entity or entities regulate your benefits.

Health insurance sold to individuals (not through employment) is primarily regulated by State insurance departments.

WHCRA requires group health plans and health insurance companies (including HMOs), to notify individuals regarding coverage required under the law. Notice about the availability of these mastectomy-related benefits must be given:

1. To participants and beneficiaries of a group health plan at the time of enrollment, and to policyholders at the time an individual health insurance policy is issued; and
2. Annually to group health plan participants and beneficiaries, and to policyholders of individual policies.

Contact your State's insurance department to find out whether additional state law protections apply to your coverage if you are in an insured group health plan or have individual (non-employment based) health insurance coverage.  
WHCRA does not apply to high risk pools since the pool is a means by which individuals obtain health coverage other than through health insurance policies or group health plans.

WHCRA does NOT require group health plans or health insurance issuers to cover mastectomies in general. If a group health plan or health insurance issuer chooses to cover mastectomies, then the plan or issuer is generally subject to WHCRA requirements.

Note: A non-Federal governmental employer that provides self-funded group health plan coverage to its employees (coverage that is not provided through an insurer) may elect to exempt its plan (opt out) from the requirements of WHCRA by following the “Procedures & Requirements for HIPAA Exemption Election” posted on the Self-Funded Non-Federal Governmental Plans webpage at http://cms.gov/cciio/resources/files/hipaa\_exemption\_election\_instructions\_04072011.html. This includes a requirement to issue a notice of opt-out to enrollees at the time of enrollment and on an annual basis.  For a list of plans that have opted out of WHCRA, go to http://cms.gov/cciio/resources/other/index.html#nonfed and click on “List of HIPAA Opt-out Elections for Self-funded Non-Federal Governmental Plans.”

If you have concerns about your plan’s compliance with WHCRA, contact our help line at 1-877-267-2323 extension 6-1565 or at [phig@cms.hhs.gov](mailto:info@ephox.com).

Source: www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra\_factsheet.html