

MEDICA®
UTILIZATION MANAGEMENT POLICY

TITLE: BREAST IMPLANT REMOVAL, REVISION, OR REIMPLANTATION

EFFECTIVE DATE: August 20, 2018

This policy was developed with input from specialists in plastic surgery and general surgery, and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing criteria that generally determines the medical necessity of breast implant removal, revision, or reimplantation. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions

- A. **Breast implants** are bags or pouches filled with a saline or silicone gel solution and placed under the skin, under the breast, or under the pectoral muscle. Breast implants are used for breast contour outline reconstruction following mastectomy or for cosmetic breast size augmentation.
- B. **Capsular contracture** occurs when the scar tissue or capsule that normally forms around the implant tightens and squeezes the implant. The degree of contracture is often classified by using the **Baker grading system**. The four Baker classes/stages follow:
 - Grade I: the breast is normally soft and looks natural
 - Grade II: the breast is a little firm but looks normal
 - Grade III: the breast is firm and looks abnormal (visible distortion)
 - Grade IV: the breast is hard, painful, and looks abnormal.

II. Comments

- A. The FDA has approved multiple breast implants for marketing in the United States, including products manufactured by Mentor, Allergan, and Sientra.
- B. The long-term physiological effects of breast implants are unknown. Some women with breast implants have reported health problems that they believe are related to their implants, but most studies of these diseases have failed to show an association with breast implants. There also have been concerns about possible, but unproven, effects on health. Most of the health concerns about breast implants are related to the body reacting to a foreign material, such as silicone gel.
See <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/default.htm> for more information. Accessed April 30, 2018.
- C. Complications of breast implants may include:
 - 1. Reoperations, with or without removal of the implant
 - 2. Capsular contracture

3. Breast pain
4. Changes in nipple and breast sensation
5. Excessive bleeding
6. Infection
7. Implant rupture or loss of shell integrity
 - a. Rupture or leakage of silicone may lead to a variety of other related complications, such as:
 - 1) Enlarged lymph nodes
 - 2) Scar formation
 - 3) Inflammation
 - 4) Granulomatous foreign body reaction
 - 5) Presence of foamy histiocytes
 - 6) Silicone mastopathy
 - 7) Nodule formation
 - 8) Migration of silicone gel to adjacent or other tissue
 - b. Rupture or leakage of saline implants has not been shown to be harmful to the body. If a saline-filled implant ruptures, the implant will deflate in a few hours and the body will harmlessly absorb the salt water.
- D. The Food and Drug Administration (FDA) panel advises that women with implants see their physicians regularly and, if an implant is found to have ruptured, discuss the need to have it removed. The FDA also advises that women who are not experiencing problems with their implants need not have their implants removed. The normal risk associated with any surgical procedure is likely to be greater than any real or speculative risk from retaining the implant. Periodic checkups are advised. Occasionally it is necessary for a woman to have her breast implants surgically revised, either by complete removal, or removal with reimplantation.

BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for breast implant removal, revision, or reimplantation (unless associated with breast reconstruction following mastectomy AND the procedure will be coded as such). Please see the prior authorization list for product specific prior authorization requirements.
2. Coverage may vary according to the terms of the member's plan document.
3. Cosmetic surgery is generally an exclusion in the member's plan document. However, coverage of all stages of reconstruction of the breast on which a mastectomy was performed and surgery and reconstruction of the other breast to produce a symmetrical appearance is required by state and federal law.
4. Reimplantation, when the original reason for implants was cosmetic, and not associated with a previous medically necessary mastectomy, *is cosmetic and therefore, not covered*.
5. Removal, revision, or reimplantation of saline or silicone implants for the following reasons are generally not considered medically necessary:
 - A. Breast implant malposition
 - B. Unsatisfactory aesthetic outcome
 - C. Patient desire for change of implant
6. If the medical necessity criteria for removal of a breast implant are met unilaterally, Medica will cover removal of the implant in the other breast if both implants are removed at the same time.
7. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member's plan document.
8. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in the Medica Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA

- I. Prior authorization **is not required** for breast implantation removal, revision or reimplantation when it is associated with breast reconstruction following mastectomy AND the procedure is coded as such.
- II. Breast implant **removal** or **revision** is considered medically necessary when documentation in the medical record indicates that **one of the following** criteria are met:
 - A. If previous augmentation with a **saline** implant(s), **one of the following** criteria must be met:
 1. Previous medically necessary implant, post mastectomy
 2. Recurrent infection, not amenable to or unresponsive to treatment

3. Uncontrolled bleeding
 4. Extrusion of the implant through the skin
 5. Baker Class IV capsular contraction causing severe pain
 6. Severe capsular contraction that interferes with routine mammography
 7. Interference with the diagnostic evaluation of a suspected breast cancer or treatment of known breast cancer
 8. Granuloma
 9. Tissue necrosis secondary to the implant
 10. Breast implant-associated anaplastic large cell lymphoma.
- B. If previous augmentation with a **silicone** implant(s), **one of the following** criteria must be met:
1. Previous medically necessary implant, post mastectomy
 2. Ruptured or leaking implant, confirmed on imaging studies (i.e., mammography, ultrasound, or magnetic resonance imaging (MRI))
 3. Recurrent infection, not amenable to or unresponsive to treatment
 4. Uncontrolled bleeding
 5. Extrusion of the implant through the skin
 6. Baker Class IV capsular contraction causing severe pain
 7. Severe capsular contraction that interferes with routine mammography
 8. Interference with the diagnostic evaluation of a suspected breast cancer or treatment of known breast cancer
 9. Siliconoma or granuloma
 10. Tissue necrosis secondary to the implant
 11. Breast implant-associated anaplastic large cell lymphoma.

DOCUMENT HISTORY

Original effective date	May 1996
MPC Endorsement Date(s)	06/1997, 06/1998, 05/1999, 05/2000, 05/2001, 06/2002, 05/2003, 06/2004, 06/2005, 06/2006, 06/2007, 06/2008, 06/2009, 06/2010, 06/2011, 06/2012, 06/2013, 06/2014, 6/2015, 6/2016, 6/2017, 06/2018
Administrative Update(s)	05/01/2017

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