

MEDICA®

UTILIZATION MANAGEMENT POLICY

TITLE: BREAST IMPLANT REMOVAL, REVISION, OR REIMPLANTATION

Origination Date: May, 1996

Subsequent 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

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

PRODUCT APPLICATION

This policy provides general information concerning Medica’s administrative processes. It applies to all fully insured Medica Health Plans, Medica Insurance Company, and Medica Health Plans of Wisconsin products, unless a specific limitation or exception exists. For self-insured plans, consult individual plan sponsor benefit documents. If there is a discrepancy between a Utilization Management Policy and a self-insured benefit plan, the provisions of the benefit plan will govern. With respect to Medicare and Medicaid members, this policy will apply unless Medicare or Medicaid policies require different coverage.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

Medica updates its Utilization Management Policies regularly, and reserves the right to amend these policies without notice to Medica members. Medica also reserves the right to amend these policies without notice to contracted health care providers unless the amendment materially alters the policy. If the amendment materially alters the policy, Medica will disclose the change to contracted health care providers not less than 45 days prior to implementation of the policy. Medica’s Utilization Management Policies contain general information only and do not guarantee coverage. Receipt of benefits is subject to all terms and conditions of the member’s coverage document. Members should consult their Certificates of Coverage or Plan Documents/Summary Plan Descriptions to review the provisions relating to a specific coverage determination. If there is a conflict between a Utilization Management Policy and the applicable coverage document, the coverage document will govern. 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 Utilization Management Policy may call Medica’s Provider Service Center toll free at 1-800-458-5512.

Medica’s 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 Coverage Issues 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.

II. Comments

- A. The FDA has approved four breast implants for marketing in the United States:
 - 1. In May 2000, Mentor and Allergan (formerly named Inamed) received approval for saline-filled breast

implants. These implants were approved for breast augmentation in women 18 years or older and for breast reconstruction in women of any age.

2. In November 2006, Allergan and Mentor received approval for their silicone gel-filled breast implants. These implants were approved for breast augmentation in women 22 years or older and for breast reconstruction in women of any age.
- 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/cdrh/breastimplants/index.html> for more information.
- 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.

MEDICAL NECESSITY CRITERIA

- I. Indication for breast implant **reimplantation**:
Previous medically necessary implant, post mastectomy.
 - II. Indications for breast implant removal or revision:
 - A. If previous augmentation with a **saline** implant(s), at least one of the following criteria must be met:
 1. Previous medically necessary implant, post mastectomy, or
 2. Infection, not amenable to or unresponsive to other treatment, or
 3. Uncontrolled bleeding, or
 4. Extrusion of the implant, or
 5. Capsular contraction causing significant pain, or
 6. Capsular contraction that interferes with routine mammography, or
 7. Interference with the treatment of breast cancer, or
 8. Granuloma.
- OR**
- B. If previous augmentation with a **silicone** implant(s), at least one of the following criteria must be met:
 1. Previous medically necessary implant, post mastectomy, or
 2. Ruptured or leaking implant, or

3. Infection, not amenable to or unresponsive to other treatment, or
4. Uncontrolled bleeding, or
5. Extrusion of the implant, or
6. Capsular contraction causing significant pain, or
7. Capsular contraction that interferes with routine mammography, or
8. Interference with the treatment of breast cancer, or
9. Siliconoma or granuloma.

III. Written documentation from the medical record, specifying the medical necessity, according to the criteria above, may be required. Signs, symptoms, and clinical indications for removal, revision, or reimplantation should be documented in the medical record by the surgeon.

COVERAGE ISSUES

1. Prior authorization **is required** for breast implant removal, revision, or reimplantation.
2. Coverage may vary according to the terms of the member's coverage document.
3. For Medicare members, refer to the following, as applicable:
 - Centers for Medicare and Medicaid Services (CMS). *National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy (140.2)*. Available at: http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=140.2&ncd_version=1&basket=ncd%3A140%2E2%3A1%3ABreast+Reconstruction+Following+Mastectomy. Accessed April 26, 2010.
 - For Minnesota: Wisconsin Physicians Service Insurance Corporation. *Local Coverage Determination (LCD) for Cosmetic and Reconstructive Surgery (L17996)*. Available at: http://www.cms.gov/mcd/viewlcd.asp?lcd_id=17996&lcd_version=18&show=all. Accessed April 26, 2010.
 - For Wisconsin: Wisconsin Physicians Service Insurance Corporation. *Local Coverage Determination (LCD) for Cosmetic and Reconstructive Surgery (L17993)*. Available at: http://www.cms.gov/mcd/viewlcd.asp?lcd_id=17993&lcd_version=20&basket=lcd%3A17993%3A20%3ACosmetic+and+Reconstructive+Surgery%3ACarrier%3AWisconsin+Physicians+Service+Insurance+Corporation+%2800951%29%3A. Accessed April 26, 2010.
 - For North Dakota and South Dakota: Noridian Administrative Services, LLC. *Local Coverage Determination (LCD) for Plastic Surgery (L24349)*. Refer to the Medicare Coverage Database Search Page, available at: <http://www.cms.hhs.gov/mcd/search.asp>? Accessed April 26, 2010.
 - For other states, refer to the Medicare Coverage Database Search Page, available at: <http://www.cms.hhs.gov/mcd/search.asp>?
4. Cosmetic surgery is generally an exclusion in the member's coverage 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.
5. Reimplantation, when the original reason for implants was cosmetic, and not associated with a previous medically necessary mastectomy, is not covered.
6. Removal, revision, or reimplantation of saline or silicone implants for the following reasons are generally not considered medically necessary:
 - A. Breast implant malposition, or
 - B. Unsatisfactory aesthetic outcome, or
 - C. Patient desire for change of implant, or
 - D. Patient fear of impending negative effects on their health due to the presence of the implant.
7. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member's coverage 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 their Medica administrative handbook.

References:

1. American Society of Plastic and Reconstructive Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria for Third-Party Payers: *Breast Reconstruction Following Diagnosis and Treatment for Breast Cancer*. September 2004. Arlington Heights, IL. Available at: http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Key_Issues_in_Plastic_Surgery/Breast_Procedures.html. Accessed April 26, 2010.
2. American Society of Plastic Surgeons. *Policy Statement: Breast Augmentation in Teenagers*. December 2004. Arlington Heights, IL. Available at: http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Key_Issues_in_Plastic_Surgery/Breast_Procedures.html. Accessed April 26, 2010.
3. American Society of Plastic Surgeons. *Practice Parameter: Treatment Principles of Silicone Breast Implants*. March 2005. Arlington Heights, IL. Available at: http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Key_Issues_in_Plastic_Surgery/Breast_Procedures.html. Accessed April 26, 2010.
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16. Wisconsin Physicians Service Insurance Corporation. *Local Coverage Determination (LCD) for Cosmetic and Reconstructive Surgery (L17996)*. Available at: http://www.cms.gov/mcd/viewlcd.asp?lcd_id=17996&lcd_version=18&show=all. Accessed April 26, 2010.
17. Wisconsin Physicians Service Insurance Corporation. *Local Coverage Determination (LCD) for Cosmetic and Reconstructive Surgery (L17993)*. Available at: http://www.cms.gov/mcd/viewlcd.asp?lcd_id=17993&lcd_version=20&basket=lcd%3A17993%3A20%3ACosmetic+and+Reconstructive+Surgery%3ACarrier%3AWisconsin+Physicians+Service+Insurance+Corporation+%2800951%29%3A. Accessed April 26, 2010.
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