Protocol

Reconstructive Breast Surgery/Management of Breast Implants

(701129)

Medical Benefit		**Effective Date**: 04/01/14	**Next Review Date**: 01/15
Preauthorization	Yes	**Review Dates**: 02/07, 02/08, 01/09, 01/10, 01/11, 01/12, 01/13, 01/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Reconstructive breast surgery is defined as a surgical procedure that is designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. Breast reconstruction is distinguished from purely cosmetic procedures by the presence of a medical condition, e.g., breast cancer or trauma, which leads to the need for breast reconstruction.

Recent advances and innovations in surgical techniques and radiology and the discovery that multipotent adult stem cells are present in human adipose tissue have contributed to renewed interest in performing autologous fat grafting to the breast for aesthetic and reconstructive purposes.

The most common indication for reconstructive breast surgery is a prior mastectomy; in fact, benefits for reconstructive breast surgery in these patients are a mandated benefit in many states. In contrast, cosmetic breast surgery is defined as surgery designed to alter or enhance the appearance of a breast that has not undergone surgery, accidental injury, or trauma. Reduction mammaplasty is a common example of cosmetic breast surgery, but surgery to alter the appearance of a congenital abnormality of the breasts, such as tubular breasts, would also be considered cosmetic in nature.

There is a broadening array of surgical approaches to breast reconstruction. The most common is insertion of a breast implant, either a silicone gel-filled or saline-filled prosthesis. The implant is either inserted immediately at the time of mastectomy or sometime afterward in conjunction with the previous use of a tissue expander.

The breast may also be reconstructed using autologous tissues, such as a free flap, a latissimus dorsi flap, or more commonly using a transverse rectus abdominis flap (TRAM procedure). Nipple areola reconstruction or nipple tattooing may also be considered reconstructive breast surgery. Since the purpose of reconstructive breast surgery is to restore the normal appearance of the breast, on some occasions procedures are performed on the contralateral, normal breast to achieve symmetry, such as mastopexy and reduction mammaplasty. These procedures fall into the category of reconstructive breast surgery only when performed in conjunction with a contralateral mastectomy for cancer with associated reconstruction. Except for medically necessary reduction mammoplasty, these procedures are considered cosmetic in other circumstances.

The following protocol describes different types of reconstructive breast surgery and reviews the evidence on efficacy for the different approaches. It also establishes criteria for the explantation of breast implants based on whether the original implant was cosmetic or reconstructive in nature, and whether the implant is silicone gel-filled or saline-filled.

Background on Fat Grafting and Adipose-derived Stem Cells

Autologous fat grafting to the breast

Transplantation of autologous fat has been performed for over 100 years, primarily in cosmetic facial surgery. Since the 1980s, there has been an increased interest in autologous fat transfer for breast augmentation; however, variability in long-term results and oncologic concerns have limited its application in the breast. In 1987, the American Society of Plastic and Reconstructive Surgeons (ASPRS) Ad-Hoc Committee on New Procedures determined that fat grafting to the breast region could impede breast cancer detection because of possible complications including fat necrosis, cyst formation and calcifications, and that fat grafting to this area should be avoided. This position was supported by several subsequent studies that reported severe complications due to fat grafting for breast augmentation. Until 2005, most physicians refrained from performing fat grafting to the breast.

Technical advances in fat grafting such as the development of devices like liposuction cannulae and more sophisticated methods to detect breast cancer, which can provide a relatively precise distinction between microcalcifications associated with fat grafting and those associated with cancer, led physicians to develop improved fat grafting techniques. However, in 2007, the American Society of Plastic Surgeons (ASPS) and the American Society for Aesthetic Plastic Surgery (ASAPS) announced that fat grafting for breast augmentation was still not recommended based on a lack of available clinical data on the safety and efficacy of the procedure and the possibility that the procedure might interfere with cancer detection.

In 2009, the ASPS issued a new position on fat transfer, grafting, and injection to the body, which was based on a review of the literature of patients who had undergone fat grafting (238 of whom underwent fat grafting to the breast). The ASPS task force concluded that fat grafting could be considered for breast augmentation and to correct defects associated with medical conditions and previous breast operations, although it cautioned that the results are largely dependent on technique and surgeon expertise and that because the lifetime of fat grafts is unknown, additional treatments may be necessary. Although no scientific evidence was found that specifically addressed patient selection, physicians were advised to exercise caution when considering patients at high risk for developing breast cancer (e.g., BRCA-1, BRCA-2, and/or a personal or family history of breast cancer) when determining whether a patient is an appropriate candidate for autologous fat grafting to the breast.

Adipose tissue physiology in fat grafting

Harvesting of adipose tissue by liposuction is technically easy, minimally invasive, and associated with little patient discomfort and morbidity, and small amounts (100-200 mL) can be obtained under local anesthesia.

Adipose tissue is a highly vascularized tissue, and adipocytes are in direct contact with adjacent capillary vessels. In free fat grafting, direct diffusion of nutrients from plasma in the surrounding bed and subsequent revascularization usually occurs within 48 hours and are essential for graft survival. If the local environment does not undergo revascularization, the grafted fat tissue eventually undergoes necrosis, one complication after fat grafting. There is general unpredictability and a low rate of graft survival due to partial necrosis. Other complications include oil cyst formation, indurations in the subcutis or breast parenchyma, calcification, and severe breast deformity.

Adipose-derived stem cells

Stem cell biology, and the related field of regenerative medicine, involves multipotent stem cells that exist within a variety of tissues, including bone marrow and adipose tissue. Studies have shown that 1 gram of adipose tissue yields approximately 5×10^3 stem cells, which is up to 500 times greater than the number of mesenchymal stem cells in one gram of bone marrow. Stem cells, because of their pluripotentiality and unlimited capacity for self-renewal, offer promise for tissue engineering and advances in reconstructive procedures.

Adipose tissue in particular represents an abundant and easily accessible source of adipose-derived stem cells (ADSCs), which can differentiate along multiple mesodermal lineages. ADSCs may allow for improved graft survival and generation of new fat tissue after transfer from another site.

This identification of several potentially beneficial therapeutic properties of ADSC has led to proposed novel techniques of fat grafting in conjunction with ADSC therapy for breast fat grafting, including the differentiation of ADSC into adipocytes as a reservoir for adipose tissue turnover, the differentiation of ADSC into endothelial cells and the subsequent increase in blood supply to the grafted fat tissue, thereby decreasing the rate of graft resorption, the release of angiogenic growth factors by ADSC and the induction of angiogenesis, protection of the graft from ischemic reperfusion injury by ADSC and acceleration of wound healing at the recipient site.

Current methods for isolating ADSCs can involve a variety of processes which may include centrifugation and enzymatic techniques that rely on collagenase digestion followed by centrifugal separation to isolate the stem cells from primary adipocytes. Isolated ADSCs can be expanded in monolayer on standard tissue culture plastic with a basal medium containing 10% fetal bovine serum, and newly developed culture conditions provide an environment within which the study of ADSCs can be done without the interference of animal serum. They also allow rapid expansion of autologous ADSCs in culture for use in human clinical trials. A standard expansion method has not yet been established.

Yoshimura and colleagues, in an effort to address the problems of unpredictability and low rates of fat graft survival, developed a technique known as cell-assisted lipotransfer (CAL), which produces autogenous fat rich in ADSCs. In CAL, half of the lipoaspirate is centrifuged to obtain a fraction of concentrated ADSCs while the other half is washed, enzymatically digested, filtered and spun down to an ADSC-rich pellet. The latter is then mixed with the former, converting a relatively ADSC-poor aspirated fat to ADSC-rich fat.

A point-of care system is available for concentrating ADSC from mature fat. The Celution™ system (Cytori Therapeutics, Inc.) is designed to transfer a patient's own adipose tissue from one part of the body to another in the same surgical procedure.

Regulatory Status

Cytori Therapeutics, Inc. was awarded 510(k) marketing clearance in September 2006 from the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH) for the Celution™ Cell Concentration System as a cell saver device. The system is cleared for the collection, concentration, washing and re-infusion of a patient's own cells for applications that may include, but are not limited to, cardiovascular, plastic and reconstructive, orthopedic, vascular, and urological surgeries and procedures.

Related Protocols

Bio-Engineered Skin and Soft Tissue Substitutes

Cosmetic vs. Reconstructive Surgery or Services

Reduction Mammoplasty

Policy (Formerly Corporate Medical Guideline)

Reconstructive breast surgery may be considered **medically necessary** after a medically necessary partial (including but not limited to lumpectomy) or full mastectomy, or following accidental injury~~,~~ or trauma when there is functional impairment. Medically necessary mastectomies are most typically done as treatment for cancer. Reconstruction may be performed by an implant-based approach or through the use of autologous muscle tissue. However the uses of autologous fat grafting and adipose-derived stem cells for augmentation or reconstruction of the breast is considered **investigational**.

Explantation of a *silicone* gel-filled breast implant may be considered **medically necessary** in all cases for a documented implant rupture, infection, extrusion, Baker class IV contracture, or surgical treatment of breast cancer.

Explantation of a ruptured *saline*-filled breast implant may be considered **medically necessary** only in those patients who had originally undergone breast implantation for reconstructive purposes. Otherwise, indications for the explantation of a saline-filled implant are similar to those of a silicone-filled implant.

Explantation of a breast implant associated with a Baker class III contracture may be considered **medically necessary** only in those patients who had originally undergone breast implantation for reconstructive purposes.

Reconstructive breast surgery after explantation of an implant is considered **medically necessary** only in those patients who had originally undergone breast implantation for reconstructive purposes.

The following indications for explantation of implants are considered **not medically necessary**:

- Systemic symptoms, attributed to connective tissue diseases, autoimmune diseases, etc.;
- Patient anxiety;
- Baker class III contractures in patients with implants for cosmetic purposes;
- Rupture of a saline implant in patients with implants for cosmetic purposes;
- Pain not related to contractures or rupture.

After reconstructive breast surgery on one side, insertion of an implant on the contralateral, normal side is rarely necessary to achieve symmetry.

Policy Guideline

Application of the above policy regarding explantation of implants requires documentation of the original indication for implantation and the type of implant, either saline- or silicone gel-filled, and the current symptoms, either local or systemic. The following chart should facilitate determination of the medical necessity of explantation. Yes indicates that the explantation would be considered **medically** necessary, given the symptoms, type of implant, and original indication for implantation.

Indication/Type of Implant

Indication for Explantation	Reconstruction/silicone	Reconstruction/saline	Cosmetic/silicone	Cosmetic/saline
Systemic Illness				
Connective tissue disease	no	no	no	no
Autoimmune disease	no	no	no	no
Rheumatic conditions	no	no	no	no
Neurologic symptoms	no	no	no	no
Fibromyalgia	no	no	no	no
Chronic fatigue syndrome	no	no	no	no
Patient Anxiety	no	no	no	no
Absolute Medical Indications				
Rupture*	yes	yes	yes	no
Baker class IV contracture	yes	yes	yes	yes

Indication for Explantation	Reconstruction/silicone	Reconstruction/saline	Cosmetic/silicone	Cosmetic/saline
Recurrent infection	yes	yes	yes	yes
Extruded implant	yes	yes	yes	yes
Surgery for breast cancer	yes	yes	yes	yes
Other Indications				
Baker class III contractures	yes	yes	no	no
Pain**	no	no	no	no
Post-Explantation Procedures				
Reimplantation of implants	yes	yes	no	no
Autologous reconstruction	yes	yes	no	no

*Rupture of implants requires documentation with an imaging study, such as mammography, magnetic resonance imaging, or ultrasonography. Lack of imaging confirmation of rupture in association with persistent local symptoms requires case by case consideration.

**Pain as an isolated symptom is an inadequate indication for explantation. The pain should be related to the Baker classification or a diagnosis of rupture.

Reconstructive breast surgery may consist of any of the following procedures:

- Immediate or delayed insertion of breast prosthesis with or without associated tissue expansion;
- Autologous reconstruction using autologous tissue, e.g., latissimus dorsi flap, transverse rectus abdominis myocutaneous flap, or free flap;
- Revision of reconstructed breast;
- Nipple/areola reconstruction and nipple tattooing when the breast reconstruction is considered eligible for coverage;
- Mastopexy or reduction mammoplasty on the contralateral breast to achieve symmetry.

Protocol called Cosmetic vs. Reconstructive Services may also be applicable for other than post medically necessary mastectomy reasons for breast reconstruction.

Benefit Application

For general business, the existence of Legislative Mandates, such as New York State Legislation which is regarding reconstruction after a mastectomy, may impact whether a service could be considered not medically necessary or investigational.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Atisha D, Alderman AK, Lowery JC et al. Prospective analysis of long-term psychosocial outcomes in breast reconstruction: two-year postoperative results from the Michigan Breast Reconstruction Outcomes Study. Ann Surg 2008; 247(6):1019-28.
2. Serletti JM, Fosnot J, Nelson JA et al. Breast reconstruction after breast cancer. Plast Reconstr Surg 2011; 127(6):124e-35e.
3. DSouza N, Darmanin G, Fedorowicz Z. Immediate versus delayed reconstruction following surgery for breast cancer . Cochrane Database Syst Rev 2011; (7):CD008674.
4. Barry M, Kell MR. Radiotherapy and breast reconstruction: a meta-analysis. Breast Cancer Res Treat 2011; 127(1):15-22.
5. Winters ZE, Benson JR, Pusic AL. A systematic review of the clinical evidence to guide treatment recommendations in breast reconstruction based on patient- reported outcome measures and health-related quality of life. Ann Surg 2010; 252(6):929-42.
6. Brandberg Y, Malm M, Blomqvist L. A prospective and randomized study, "SVEA," comparing effects of three methods for delayed breast reconstruction on quality of life, patient-defined problem areas of life, and cosmetic result. Plast Reconstr Surg 2000; 105(1):66-74; discussion 75-6.
7. Gabriel SE, Woods JE, O'Fallon WM et al. Complications leading to surgery after breast implantation. The New England journal of medicine 1997; 336(10):677-82.
8. Chung KC, Wilkins EG, Beil RJ, Jr. et al. Diagnosis of silicone gel breast implant rupture by ultrasonography. Plast Reconstr Surg 1996; 97(1):104-9.
9. Netscher DT, Weizer G, Malone RS et al. Diagnostic value of clinical examination and various imaging techniques for breast implant rupture as determined in 81 patients having implant removal. South Med J 1996; 89(4):397-404.
10. Samuels JB, Rohrich RJ, Weatherall PT et al. Radiographic diagnosis of breast implant rupture: current status and comparison of techniques. Plast Reconstr Surg 1995; 96(4):865-77.
11. Baker JL. Augmentation mammoplasty. In: Owsley JQ, Jr., Peterson RA, eds. Symposium on aesthetic surgery of the breast. St. Louis: CV Mosby; 1978.
12. American Society of Plastic and Reconstructive Surgeons. American Society of Plastic and Reconstructive Surgeons Citizens' Petition to the Food and Drug Administration which requests that silicone gel-filled implants remain available because the device is necessary for the public health. Arlington Heights, IL November 29, 1991.
13. Gabriel SE, O'Fallon WM, Kurland LT et al. Risk of connective-tissue diseases and other disorders after breast implantation. N Engl J Med 1994; 330(24):1697-702.
14. Hennekens CH, Lee IM, Cook NR et al. Self-reported breast implants and connective-tissue diseases in female health professionals. A retrospective cohort study. JAMA 1996; 275(8):616-21.
15. Sanchez-Guerrero J, Colditz GA, Karlson EW et al. Silicone breast implants and the risk of connective-tissue diseases and symptoms. N Engl J Med 1995; 332(25):1666-70.
16. Silverman BG, Brown SL, Bright RA et al. Reported complications of silicone gel breast implants: an epidemiologic review. Ann Intern Med 1996; 124(8):744-56.

17. National Comprehensive Cancer Network. Invasive Breast Cancer: Principles of breast reconstruction following surgery Version 3:2013 http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf last accessed November 2013.
18. Mizuno H, Hyakusoku H. Fat grafting to the breast and adipose-derived stem cells: recent scientific consensus and controversy. Aesthtic Surg J 2010; 30(3):381-9.
19. Gutowski KA. Current applications and safety of autologous fat grafts: A report of the ASPS Fat Graft Task Force. Plast Reconstr Surg 2009; 124:272-80.
20. Sterodimas A, de Faria J, Nicaretta B et al. Tissue engineering with adipose-derived stem cells (ADSCs): Current and future applications. J Plast Reconstr Aesthet Surg 2010; 63(11):1886-92.
21. Yoshimura K, Sato K, Aoi N et al. Cell-assisted lipotransfer for cosmetic breast augmentation: supportive use of adipose-derived stem/stromal cells. Aesth Plast Surg 2008; 32(1):48-55.
22. Parrish JN, Metzinger SE. Autogenous fat grafting and breast augmentation: A review of the literature. Aesthet Surg J 2010. 30(4):549-56.
23. Wilson A, Butler PE, Seifalian AM. Adipose-derived stem cells for clinical applications: a review. Cell Prolif 2011; 44(1):86-98.
24. Chan CW, McCulley SJ, Macmillan RD. Autologous fat transfer- a review of the literature with a focus on breast cancer surgery. J Plast Reconstr Aesthet Surg 2008; 61(12):1438-48.
25. Losken A, Pinell X, Sikoro K et al. Autologous fat grafting in secondary breast reconstruction. Ann Plast Surg 2011; 66(5):518-22.
26. Illouz YG, Sterodimas A. Autologous fat transplantation to the breast: a personal technique with 25 years of experience. Aesth Plast Surg 2009; 33(5):706-15.
27. Delay E, Garson S, Tousson G et al. Fat injection to the breast: technique, results, and indications based on 880 procedures over 10 years. Aesthet Surg J 2009; 29(5):360-78.
28. Kamakura T, Ito K. Autologous cell-enriched fat grafting for breast augmentation. Aesthetic Plast Surg 2011 Apr 30. [Epub ahead of print]
29. Rigotti G, Marchi A, Galiè M et al. Clinical treatment of radiotherapy tissue damage by lipoaspirate transplant: A healing process mediated by adipose-derived adult stem cells. Plast Reconstr Surg 2007; 119(5):1409-22.
30. National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy (140.2), Effective Date of this version 1/1/1997.