



**Kaiser Foundation Health Plan
of Washington**

Clinical Review Criteria

Breast Reconstruction or Breast Prostheses

- Following Mastectomy/Lumpectomy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Breast Reconstruction Following Mastectomy (140.2)
Local Coverage Determinations (LCD)	Plastic Surgery (L37020) External Breast Prosthesis (L33317)

For Non-Medicare Members

For breast reconstruction or breast prosthesis following a mastectomy or lumpectomy member must qualify both in A and B:

A. **ONE of the following** must be met:

1. Medically necessary lumpectomy or complete or partial mastectomy due to disease, injury or illness (such as breast cancer, chronic and severe fibrocystic disease, or infection unresponsive to medical therapy, chest wall surgery, or trauma) resulting in significant deformity;

OR

2. Prophylactic mastectomy to prevent the onset of breast cancer when a clinical determination has been made that there is a high risk for breast cancer;

B. And must be **ONE of the following** procedures:

1. **For the diseased/ injured/affected breast** must meet **ONE of the following:**

- a) Tissue/muscle reconstruction procedures (flaps)
- b) Capsulotomy
- c) Capsulectomy
- d) Implantation of tissue expander
- e) Implantation of U.S. Food and Drug Administration (FDA) approved internal breast prosthesis
- f) Areolar and nipple reconstruction
- g) Areolar and nipple tattooing
- h) Breast implant removal and subsequent re-implantation

2. **For the non-diseased/non-injured/unaffected/contralateral breast** to produce symmetry in appearance must meet **ONE of the following:**

- a) Breast reduction by mammoplasty or mastopexy
- b) Augmentation mammoplasty

- c) Augmentation with implantation of FDA internal breast prosthesis when unaffected breast is smaller than the smallest available internal prosthesis
- d) Areolar and nipple reconstruction
- e) Areolar and nipple tattooing
- f) One reconstructive procedure to produce a symmetrical appearance
- g) Breast implant removal and subsequent re-implantation performed to produce a symmetrical appearance when the original implant was in the unaffected breast prior to the disease in the affected breast.
- h) Capsulotomy
- i) Capsulectomy

The following products are covered for breast reconstruction when medically necessity criteria are met:

1. Alloderm
2. AlloMax
3. DermaMatrix
4. FlexHD
5. Neoforn Dermis
6. Strattice tissue matrix
7. SurgiMend

Autologous fat injections for post-mastectomy breast reconstruction (autologous fat grafting, autologous fat transfer, breast fat grafting, lipoinjection, lipofilling)

- A. Autologous fat injection coverage is covered only for breast reconstruction (dimpling and contouring), if medical necessity criteria for breast reconstruction is met.
- B. Total breast reconstruction is not covered using the Brava system (autologous fat injection for complete reconstruction).

The following are not covered:

- A. All other bioengineered skin substitutes other than listed above - see Wound Care criteria
- B. Suction lipectomy or ultrasonically assisted suction lipectomy for correction of donor site asymmetry.
- C. Reconstructive surgical revisions are for restoration and not for cosmesis. Ongoing surgery for treatment of natural changes due to age or weight changes is considered cosmetic and not covered.

Pulsed electromagnetic field (PEMF) for pain reduction after breast reconstruction surgery

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies

External breast prostheses and bras - If the member has not undergone breast reconstruction, external breast prostheses and bras are covered after a medically necessary mastectomy or a lumpectomy, when surgery results in significant deformity.

- External prosthesis (one silicone every 2 years or one foam every 6 months) Post-mastectomy bras/forms, limited to 2 every 6 months. Replacements within this 6 month period are covered when medically necessary due to a change in the Member's condition.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

While breast reconstructive surgery can be considered a cosmetic procedure, under both state and federal law, carriers must provide coverage for this type of surgery in certain clinical circumstances.

The Women's Health and Cancer Rights Act (WHCRA) of 1988 (also known as Janet's Law) is a federal law that requires Kaiser Permanente plans and carriers offering coverage in connection with group or individual plans to provide benefits for mastectomy-related services, including breast reconstruction surgery. WHCRA states that a Kaiser Permanente plan or carrier (in a manner determined in consultation with the attending physician and the patient), must provide coverage 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 physical complications of mastectomy, including lymphedema.

U.S. Code – Title 29 Chapters - § 1185b, § 300gg-27, and § 300gg-52.

Washington state law also has provisions for the coverage of reconstructive surgery following a mastectomy. Both RCW 48.46.280 (HMOs) and RCW 48.330 (Health Care Service Contractors) require that carriers shall provide coverage for:

- Reconstructive breast surgery resulting from a mastectomy which resulted from disease, illness, or injury.
- All stages of one (1) reconstructive breast reduction on the non-diseased breast to make it equal in size with the diseased breast after definitive reconstructive surgery on the diseased breast has been performed.

In addition to the above statutes, guidance for interpretation of these state statutes is found in Carr v. Blue Cross of Washington and Alaska, 93 Wash. App. 941 (1999).

Kaiser Permanente has developed the criteria above with these laws as a guide.

Evidence and Source Documents

[Autologous Fat Injections for Post-Mastectomy Breast Reconstruction](#)

[BRAVA® Breast Expansion System](#)

[Pulsed Electromagnetic Field \(PEMF\) for Pain Reduction After Breast Reconstruction Surgery](#)

[SERI® Surgical Scaffold for Breast Reconstruction](#)

Medical Technology Assessment Committee (MTAC)

Autologous Fat Injections for Post-Mastectomy Breast Reconstruction

BACKGROUND

Autologous fat transfer, also known as breast fat grafting (BFG), fat transplantation, lipofilling, or lipoinjection, is a process in which fat cells from one area of the body are transferred to another. Fat transfer was first performed by Neuber in 1893 for the correction of a depressed face scar, and two years later it was performed by Czerny for breast reconstruction after excision of a large fibroadenoma. Since then, several surgeons have used free fat grafts for the reconstruction of breast defects. Autologous fat is considered an ideal injectable agent for soft tissue augmentation; it is easily available for most patients, easy to use, inexpensive, nontoxic, biocompatible, and potentially long lasting, and removable (Mu 2009, Fraser 2011, Bucky 2011). Breast fat grafting is a promising technique to correct contour deformities in breasts reconstructed with either prosthesis or autologous tissues. The value of the procedure is controversial due concerns about its safety and efficacy. The degree of reabsorption of the adipose tissue transplanted is unpredictable. The mechanism underlying the survival of dissected autologous fat after grafting is unknown, but is believed to be dependent on revascularization of fat granules. The lipogenic activity may vary by donor site (e.g. abdomen, thigh, and flank), patient age, weight, smoking habits, co-morbidities, condition of recipient site (scarring, radiation, previous surgery) and other factors. One of the main concerns with autogenous fat grafting for the breast is the development of fat necrosis leading to liponecrotic cysts and microcalcifications that could be mistaken for cancerous calcifications. Compression of the breast tissue by the transferred fat may also make it difficult to identify subtle changes in architectural patterns seen with early breast cancer presentation. Another concern relates to the potential oncologic risks of breast fat grafting, as fat transfer into a previous breast-cancer area may potentially stimulate local recurrence. Other complications with autologous fat transfer include edema, hematoma, induration, infection, granuloma formation, oil cyst formation, fat liquefaction, sclerosis and resorption (Pulagam 2006, Mu 2009, Mizuno 2010, Fraser 2011, Bucky 2011, Rietjens 2011, Serra-Renom 2011). After gaining much popularity, the interest in autologous fat transfers waned in the 1950s and 1960s due to low rates of graft survival and the increased use of artificial material. The interest in autologous fat grafting for aesthetic and reconstructive purposes was renewed in the 1980s with the introduction of liposuction that provided a minimally invasive means of obtaining large amounts of adipose tissue in a semiliquid form. However, the procedure was again discontinued for some time due to concerns over post-operative calcifications and risk of obscuring developing malignant lesions. More recently, autologous fat transfer re-emerged after a number of surgeons introduced “lipomodelling” and used the technique alone or with in combination with other reconstructive procedures. Several

harvesting and transplantation techniques have been developed and refined, yet no standard procedures have been adopted by all practitioners. There is no consensus on the ideal cannula, technique for harvesting, processing, or grafting the fat. Harvesting approaches include syringe aspiration and lipoaspiration. Once harvested, the fat is prepared for injection by one of several methods including: washing with physiological buffers, centrifugation for separating the cells from the debris, decantation, or concentrating it using cotton towels or other adsorbent media. For grafting, the fat is injected with a variety of delivery methods using sharp or blunt needles. It is reported that the fat “takes” if it is obtained using atraumatic methods, but it does not acquire the shape of the breast and remains flattened. It is difficult to remodel the grafted fat to acquire the desired cone shape. The procedure is not simple and should be performed by skilled and trained surgeons. It requires careful calculation of the amounts of fat injected at one time, number of injections needed, appropriate sites for injections, and proper administration of the transferred fat (Hyakusoku 2008, Mu 2009, Fraser 2011, Bucky 2011, Parrish 2010). In 1987, the American Society of Plastic and Reconstructive Surgeons (ASPRS) Ad-Hoc committee on New Procedures issued a position statement recommending that autologous fat transfer to the breast be prohibited due to its complications that may compromise breast cancer screening. In 2007, the ASPS and the American Society for Aesthetic Plastic Surgery (ASAPS) again determined that fat grafting for breast augmentation is not recommended due to the lack of clinical data on the efficacy and safety of the procedure, and also because it may interfere with the detection of breast cancer. In 2009, the ASPS Fat Graft Task Force took a more lenient position stating that, “Fat grafting may be considered for breast augmentation and correction of defects associated with medical conditions and previous breast surgeries.” This Task Force based the recommendation on low quality evidence from case series, and/or expert opinion and the gave it a B grade. They emphasized that the patients should be made aware of the potential risks and complications of the procedure, and indicated that physicians should be cautious when considering high-risk patients (Gutowski 2009, Mizuno 2010).

08/15/2001: MTAC REVIEW

Autologous Fat Injections for Post-Mastectomy Breast Reconstruction

Evidence Conclusion: The published studies are limited to case series and case reports which do not provide sufficient evidence to determine the efficacy, safety, and durability of autologous fat transfer for breast reconstruction after a mastectomy. The studies used different techniques, donor site, volume of fat transplant, as well as various outcome measures and follow-up durations. The majority of the series included patients undergoing the procedure for breast augmentation, reconstructive surgery after mastectomy, as well as other indications. The largest published series of 880 patients over 10 years was reported by Delay, et al in 2009. The majority (83.4%) of the patient population underwent autologous fat grafting for breast reconstruction, the rest were for correction of congenital deformities, aesthetic breast surgeries, or to correct previous surgeries. The intervention was not compared to another procedure, and the study had several limitations including, but not limited to, lack of reporting inclusion/exclusion criteria, patient characteristics, and lack of clearly defined outcomes and reporting of duration or completeness of follow-up. The authors indicate that the procedure was successful to the patients and surgeons, but did not clearly define success other than comparison of photographs. They reported that the incidence of fat necrosis was 15% for the first 50 patients, and declined to 3% for the last 100 patients suggesting a surgical learning curve. The authors concluded, “None of the imaging results are likely to confuse the diagnosis of cancer for radiologists who are experienced in breast imaging. Oncologic follow-up (now at 10 years for our first patients) shows no increased risk of local recurrence or of development of a new cancer”. Illouz and Sterodimas (2009), reported on a series of 820 consecutive patients who underwent autologous fat transplantation over 25 years. These included patients undergoing the procedure for breast reconstruction after a mastectomy, patients with congenital asymmetry, or women requesting breast augmentation. A total amount of fat transplanted in each breast ranged from 25-900 ml (mean 540 ml), and a mean of 3 sessions (range 1-5) were needed to achieve the desired results. The authors indicated that the majority of patients were satisfied with the results. They did not measure the longevity of the transplantation, did not discuss loss of follow-up, injected fat survival, or necrosis. They indicate that calcifications, cysts, and cancer were not apparent in the first year after the procedure, and thought that they may not be directly associated with the procedure. Long-term follow-up data that ranged from 2-25 years (mean 113.3 years) were only available for 28% of the patients. In conclusion, data from published studies do not provide sufficient evidence to determine the components of a successful, consistent, durable, and safe autologous fat transplantation for breast reconstruction. The Breast Reconstruction and Augmentation With Brava Enhanced Autologous Fat Micro Grafting (BRAVA) trial is an ongoing nonrandomized study on fat grafting of the breast post-mastectomy as well as other indications.

Articles: Assessment objective: To determine the safety and efficacy of autologous fat grafting for post-mastectomy breast reconstruction. Screening of articles: The literature search revealed around 100 articles on autologous fat grafting for post-mastectomy breast reconstruction and/or augmentation. No published meta-analyses or randomized

controlled trials were identified; only case series and case reports. The majority of the published literature was on breast augmentation. The two largest published series of patients who underwent autologous fat transplantation to the breast, mainly for reconstruction after mastectomy, were selected for critical appraisal. 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;29:360-376.

See [Evidence Table](#) Illouz YG, Sterodimas A. Autologous fat transplantation to the breast: A personal technique with 25 years of experience *Aesth Plast Surg*. 2009;33:706-715. See [Evidence Table](#)

The use of autologous fat grafting does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

BRAVA® Breast Expansion System

10/21/2013: MTAC REVIEW

Evidence Conclusion: The developer of the Brava device (Brava LLC, Miami, Fla.) conducted a multicenter, prospective, magnetic resonance imaging-documented study to determine the safety and efficacy of single-stage large-volume autologous fat transfer to the breast treated with the Brava external breast expander. The population included 81 women between the ages of 17 and 63 years who desired breast augmentation. It is not clear from the study if patients seeking reconstruction following mastectomy were included or excluded (Khouri, Eisenmann-Klein et al. 2012). Currently, the evidence on the use of BRAVA® Breast Expansion System is limited and provided insufficient evidence to determine the safety and efficacy for use superficially in breast reconstruction surgery with autologous fat transfer. Conclusion: There is no evidence to permit conclusions concerning the safety and efficacy of the BRAVA Breast Expansion System used in breast reconstructive surgery with fat implants.

Articles: A search of PubMed and the National Institute of Health Clinical Trials records was completed for the period through September 2013 for studies on BRAVA® Breast Expansion System used for the treatment of patients following mastectomy for breast cancer. The search strategy used the terms *Brava, breast expansion, reconstructive surgery, fat implants, flap surgery* and *mastectomy* with variations. Articles were limited to those published in English language and enrolling human subjects. The search was supplemented by an examination of article bibliographies in addition to the PubMed *related* articles function. Screening of Articles: A literature search was conducted and revealed one publication (funded by the manufacturer) on the use of the Brava system plus autologous fat transfer in breast augmentation. There are no current publications on the use of the BRAVA Breast Expansion System in breast reconstruction. One ongoing clinical trial was discovered (Breast Reconstruction and Augmentation with the BRAVA Enhanced Autologous Fat Micro Grafting) with an estimated completion date of April 2014. No studies were selected for review.

The use of the BRAVA® Breast Expansion System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Pulsed Electromagnetic Field (PEMF) for Pain Reduction After Breast Reconstruction Surgery

BACKGROUND

Pulsed electromagnetic field (PEMF) therapy, also known as electromagnetic therapy uses an electromagnet to generate electric current, and nonthermal pulsed electromagnetic energy to deliver the current. PEMF utilize generators designed to create radiofrequency signals that are delivered through coils which do not come in direct contact with the skin. The electric current is generated in short bursts into in the injured tissue without the production of heat or interfering with nerve or muscle function. Unlike electrical stimulation, FEMF therapy does not involve the use of current, leads, or electrodes. The FEMF devices are noninvasive and can be applied over or as part of the dressing in the wound healing area directly following a procedure for the postoperative management of a surgical wound (Kinney 2005, Gupta 2009, Strauch 2009). The mechanism of action of PEMF on tissue growth and repair is not completely known. In vitro and animal research showed that PEMF can increase blood flow, enhance circulation, induces collagen synthesis, granulocyte infiltration, and inhibit growth of some wound pathogens. The literature also suggests that this modality of therapy can modify the inflammatory process, reduce edema, and enhance tissue repair. The effects of PEMF are immediate and are not limited by pharmacokinetics because the induced currents are instantaneously present when the coil is transmitting into the affected area (Kinney 2005, Gordon 2007, Strauch 2009). Electromagnetic therapy is currently being used in physical medicine, orthopedic and sports injuries, and other musculoskeletal conditions. PEMF therapy use is proposed for other conditions as the reduction of pain and edema after facial surgery, breast surgery, and abdominoplasty. Several trials are currently underway or planned to study the use of PEMF in several other fields of medicine (Kinney 2005, Gupta 2009).

06/18/2012: MTAC REVIEW**Pulsed Electromagnetic Field (PEMF) for Pain Reduction After Breast Reconstruction Surgery**

Evidence Conclusion: The two published trials on the use of pulsed electromagnetic field therapy (PEMF) to reduce pain and the use of pain medications after breast reconstruction surgery were small pilot studies with valid methodology. Both trials were randomized, blinded, used sham therapy as a control, and had sufficient power to detect statistically significant differences between PEMF and the sham therapy. Hedén and Pilla's trial randomized 42 women to receive bilateral active PEMF therapy, bilateral breast sham therapy, or one of the two therapies on each breast. The results of the study showed a significant difference between the active and sham therapies in the pain experienced and in the use of postoperative pain medication. Those who received PEMF on one breast and sham therapy on the other breast showed no significant differences between the two breasts or between them and the active treatment. This was attributed to the fact that the breast randomized to sham treatment received 40- 60% of signal amplitude delivered to the active treatment breast due to the propagation of PEMF signal from the coil application. Based on this observation, Rohde and colleagues (2009) randomized their study participants to receive either bilateral active therapy or bilateral sham therapy. The trial included 24 patients and reported outcomes for only 48 hours. Similar to Hedén and Pilla's results, women who received PEMF therapy experienced less pain and used fewer narcotics in the 48 postoperative hours. Conclusion: The overall results of the published small pilot studies show that PEMF therapy may reduce pain and use of pain medication after breast reconstruction surgery. Both trials noted that no adverse events were reported, but neither studied the effect of PEMF on the reduction of postoperative edema, or on the speed and quality of wound repair

Articles: The literature search revealed two relatively small randomized controlled trials that evaluated the use of PEMF therapy after breast reconstruction therapy. Both trials were critically appraised.

Hedén P and Pilla AA. Effects of pulsed electromagnetic fields on postoperative pain: A double-blind randomized pilot study in breast augmentation patients. *Aesth Plast Surg.*2008;32:660-666. See [Evidence Table](#)

Rohde C, Chiang A, Adipoju O, et al. Effects of pulsed electromagnetic fields on interleukin-1 β and postoperative pain: A double-blind, placebo-controlled, pilot study in breast reduction patients. *Plast Reconstr Surg.*2010;125:1620-1629. See [Evidence Table](#)

The use of Pulsed electromagnetic field (PEMF) therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

SERI® Surgical Scaffold for Breast Reconstruction**04/20/2015: MTAC REVIEW**

Evidence Conclusion: There is a lack of published evidence on the use of SERI® Surgical Scaffold for breast reconstruction after mastectomy. The largest published study to date, SURE-001 (Fine et al, 2014, Evidence table 1) was a prospective observational study with no comparison or control group. It included 139 patients undergoing two-stage, implant-based breast reconstruction using SERI® Surgical Scaffold in multiple centers in the US. The study is planned to follow the patients for 2 years, but the published article reports the interim data for 71 patients followed for 1 year after surgery. The patients underwent tissue expander placement during stage one of reconstruction, with SERI® sutured into place for soft-tissue support of the lower-breast mound. Once expansion was complete with drain placement, the second stage of surgery was performed, where the expander was replaced with a permanent breast implant. The primary outcome of the study was the investigator satisfaction at 6 months. Other outcomes included the investigator satisfaction at 12 months after stage 1 surgery; ease to use of SERI®; visibility and palpability of SERI® through the skin at first postoperative visit, and during follow-up; patient satisfaction, and adverse events associated with the implant. The interim results of the study showed that the mean investigator satisfaction scores were 9.2 at 6 months where a score of 10 indicates being very satisfied with results. The mean patient satisfaction with the treated breast was 4.3 at 6 months and 4.5 at 12 months with a score of 5 signifying very satisfied with results. Adverse events occurred in 18 of the 71 patients with 1 year follow-up after stage 1 surgery, and most occurred within the first 6 months. Tissue necrosis occurred in 8.5% of the patients, seroma in 7%, hematoma in 7%, cellulitis in 4.2%; implant loss in 4.2%, capsular contracture in 1.4% and breast infection occurred in 1.4%. These results have to be interpreted with caution as the study was only observational with no control or comparison group, and had a subjective primary outcome. The study was sponsored by Allergan, Inc. and all the investigators had financial ties to the manufacturer of SERI® Surgical Scaffold. Conclusion: There is insufficient evidence to determine the efficacy and safety of SERI surgical scaffold in women undergoing breast reconstructive surgery after mastectomy.

Articles: The literature search did not reveal any randomized controlled trials that compared the use of SERI® Surgical Scaffold versus currently used practices or alternative material used for tissue support. To date, the published empirical studies consist of one prospective case series with 139 women undergoing breast reconstruction

after mastectomy (SURE-001 study, Fine et al, 2014), a very small retrospective case series, and case reports on the use of SERI® for other indications as abdominoplasty and brachioplasty.

The prospective case series was selected for critical appraisal. Fine NA, Lehfeldt M, Gross JE, et al. SERI Surgical Scaffold, Prospective Clinical Trial of a Silk-Derived Biological Scaffold in Two-Stage Breast Reconstruction: 1-Year Data. *Plast Reconstr Surg.* 2015; 135(2):339-351. [See Evidence Table 1](#)

The use of the SERI® Surgical Scaffold for Breast Reconstruction does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Date Reviewed	Date Last Revised
05/13/2011	08/02/2011 ^{MDCRPC} , 09/06/2011 ^{MDCRPC} , 06/05/2012 ^{MDCRPC} , 07/03/2012 ^{MDCRPC} , 08/07/2012 ^{MDCRPC} , 04/02/2013 ^{MDCRPC} , 11/05/2013 ^{MPC} , 12/03/2013 ^{MPC} , 09/02/2014 ^{MPC} , 12/02/2014 ^{MPC} , 10/06/2015 ^{MPC} , 08/02/2016 ^{MPC} , 06/06/2017 ^{MPC} , 04/03/2018 ^{MPC}	06/02/2015

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
06/02/2015	MPC approved MTAC recommendation of insufficient evidence for Seri Surgical Scaffolding for Breast Reconstruction
09/01/2015	Added language per that external prosthesis and bras are covered “before, during and after” surgery per WHCRA regs
11/2/2015	Aligned external prosthesis language with contract policy
03/08/2018	Added Plastic Surgery LCD

Codes

CPT: 11970, 11971, 19316, 19318, 19324, 19325, 19328, 19330, 19340, 19342, 19350, 19355, 19357, 19361, 19364, 19366, 19367, 19368, 19369, 19370, 19371, 19380, 19396

HCPCS: L8000, L8001, L8002, L8015, L8020, L8030, L8031, L8032, L8035, L8039