KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Breast Reconstruction or Breast Prostheses

- Following Mastectomy/Lumpectomy

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 Prothesis (L33317)
Local Coverage Articles	External Breast Prosthesis (A52478)

For Non-Medicare Members

Breast Reconstruction or Breast Prosthesis

For breast reconstruction or breast prosthesis following a mastectomy or lumpectomy Plastic Surgery credentials are preferred. The above procedures may be medically necessary when criteria in both in A and B are met:

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

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d. Areolar and nipple reconstruction
e. Areolar and nipple tattooing
f. 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.
g. Capsulotomy
h. Capsulectomy

The following products are covered for breast reconstruction when medically necessity criteria are met:
1. Alloderm
2. AlloMax
3. DermaMatrix
4. FlexHD
5. Neoform 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 <u>not covered</u>:
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 cosmetic. Ongoing surgery for treatment of natural changes due to age or weight changes is considered cosmetic and not covered.
D. Breast MRI is not covered for routine surveillance of silicone breast implants. The FDA made a recommendation (not a requirement) when they re-approved silicone implant use that members receive periodic breast MRIs. The FDA did not fund this screening. The choice of silicone vs saline is a patient preference and the use of MRI in this case cannot be described as medically necessary.

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.

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information 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.

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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 construction 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

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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:. 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: 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

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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 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 trails 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-1β and postoperative pain: A double-blind, placebo-controlled, pilot study in breast reduction patients. Plast Reconst 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 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.*

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Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19361	Breast reconstruction; with latissimus dorsi flap
19364	Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap
19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)
19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19396	Preparation of moulage for custom breast implant
HCPC Codes	**Description**
C1789	Prosthesis, breast (implantable)
L8000	Breast prosthesis, mastectomy bra, without integrated breast prosthesis form, any size, any type
L8001	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral, any size, any type
L8002	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, bilateral, any size, any type
L8015	External breast prosthesis garment, with mastectomy form, post mastectomy
L8020	Breast prosthesis, mastectomy form
L8030	Breast prosthesis, silicone or equal, without integral adhesive
L8031	Breast prosthesis, silicone or equal, with integral adhesive
L8032	Nipple prosthesis, prefabricated, reusable, any type, each
L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each
L8035	Custom breast prosthesis, post mastectomy, molded to patient model
L8039	Breast prosthesis, not otherwise specified
L8600	Implantable breast prosthesis, silicone or equal

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
05/13/2011	08/02/2011[MPC], 09/006/2011[MPC], 06/05/2012[MPC], 07/03/2012[MPC], 08/07/2012[MPC], 04/02/2013[MPC], 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], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC], 06/04/2024[MPC], 06/03/2025[MPC]	02/04/2025

[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
4/14/2020	Added non-covered statement for routine surveillance of silicone breast implants
07/31/2020	Added CPT codes 15769, 15771 and 15772
04/06/2021	Updated applicable codes
02/07/2023	MPC approved to adopt the modified changes to remove the indication for *one reconstructive procedure to produce a symmetrical appearance*. Requires 60-Day notice, effective 07/01/2023.
06/12/2023	Removed S codes due to the payment policy that states they are not reimbursable and must be billed with the other codes.
02/04/2025	MPC approved to endorse credentialing preferences for Mastectomy. 60-day notice is not required.

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