Name of Policy:
Autologous Fat Grafting to the Breast and Adipose-derived Stem Cells

Policy #: 476       Latest Review Date: April 2014
Category: Surgery      Policy Grade: C

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Autologous fat grafting to the breast has been used as an adjunct to reconstructive breast surgery, for post-mastectomy pain and in irradiated skin. Adipose derived stem cells have been proposed as a supplement to the fat graft in an attempt to improve graft survival.

Autologous fat grafting to the breast
History
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). Citing a lack of strong data and literature, 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 (eg, 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.

In 2012, the ASPS published recommendations limited to fat transfer to the postmastectomy breast with no native breast tissue present.
“The existing evidence suggests autologous fat grafting as an effective option in breast reconstruction following mastectomy while demonstrating moderate to significant aesthetic improvement. In addition, the available evidence also cites autologous fat grafting as a useful modality for alleviating post mastectomy pain syndrome. Furthermore, the evidence suggests
autologous fat grafting as a viable option for improving the quality of irradiated skin present in the setting of breast reconstruction.”

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. Small amounts (100-200 mL) of adipose tissue can be obtained under local anesthesia. The most common technique, called the Coleman technique, also involves a purification step, which involves centrifugation to remove blood, fluid, and ruptured adipocytes.

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. Other complications include oil cyst formation, indurations in either the subcutis or breast parenchyma, calcification, and severe breast deformity.

Indications for autologous fat grafting to the breast
Autologous fat grafting to the breast has been proposed for indications that include breast augmentation and following oncologic surgery. Proposed indications after oncologic surgery include as an adjunct to reconstruction postmastectomy or lumpectomy for contour deformities and improved shape and volume of the breast, for postmastectomy pain syndrome (neuropathic pain), and for irradiated skin to soften the skin and restore it to nonirradiated appearance and consistency.

NOTE: This policy does not address the use of autologous fat tissue in aesthetic breast augmentation (i.e., cosmesis).

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 one gram of adipose tissue yields approximately 5 x 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 (ADSC), 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 et al, 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 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.

**Policy:**
The use of autologous fat grafting to the breast, with or without adipose-derived stem cells, does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**
A literature search was performed through December 2013. The literature on the use of fat grafting to the breast, with or without adipose-derived stem cells, consists of retrospective cohort studies, case series, and case reports. Following is a summary of the key literature to date, including systematic reviews of the studies using fat grafting to the breast and all identified case series using fat grafting to the breast with the supportive use of adipose-derived stem cells. Several review articles summarize autologous fat grafting and adipose-derived stem cells.
Autologous Fat Grafting in Breast Reconstruction

A 2013 systematic review by Krastev et al examined the evidence of the oncologic risks associated with autologous fat grafting in breast cancer patients. The review included trials with female patients who underwent either mastectomy or breast conserving therapy and subsequent breast reconstruction including autologous fat grafting. The oncologic safety of the fat grafting procedure was assessed by locoregional recurrence rates. The trials included one retrospective cohort study, one multicenter study of case series without controls, two smaller cohorts, and several case series. No randomized controlled studies were identified. Although 20 trials met the inclusion criteria for the review, only nine reported oncologic recurrence rates. The level of evidence was rated as low due to lack of control groups, lack of randomization, their retrospective nature, and small sample sizes. Across the studies there was variation in invasive versus in situ carcinomas and the percentage of patients who underwent radiation therapy before fat grafting. The mean interval between surgery and fat grafting varied across studies between one and 6.5 years, and mean follow-up varied between one and five years. The largest study in the review by Petit et al was a multicenter study which reported locoregional recurrence rates of 1.35% and 2.19% per year for the mastectomy and breast-conserving therapy groups, respectively. The authors of the systematic review stated that the highest level of evidence currently available on the oncologic safety of fat grafting to the breast is a retrospective cohort analysis by Petit et al, which was included in the review, and deemed to be level 2b evidence. The cohort analysis included 321 consecutive patients operated for a primary breast cancer between 1997 and 2008 who subsequently underwent fat grafting for reconstructive purpose. For each patient, two matched controls with similar characteristics were selected who had not undergone fat transfer. There were no significant differences between the fat grafting and control groups in locoregional or distant cancer recurrence. The authors of the systematic review concluded that it is still unclear whether fat grafting to the breast promotes locoregional recurrence and that larger prospective trials with longer follow-up are needed.

A 2012 systematic review by Claro et al examined the clinical applicability and safety of autologous fat grafting to the breast for reconstruction by identifying clinical complications, radiographic changes, and incidence of primary or recurrent breast cancer. Although the review also included patients who underwent fat grafting for augmentation, there were 41 studies that included 3646 patients who underwent grafting for reconstruction. The reconstruction was mainly for partial breast reconstruction and/or correction of breast deformities, but also included patients who underwent total breast reconstruction and for postradiation radiodermatitis. Most of the studies were graded as low or very low quality. Complication results were not reported separately for the studies that included fat grafting for augmentation versus reconstruction. Clinical complications were 3.9% and consisted mainly of induration and/or palpable nodularity and radiographic abnormalities occurred in 13%, most commonly as cysts. Local recurrence of breast cancer was evaluated in three studies, only one was prospective. The three studies included 616 patients with a mean follow-up of 45.2 months. Fourteen recurrent cancers were reported (2.3%), all in women whose initial treatment was mastectomy. The authors concluded that fat grafting to the breast is associated with few complications with no evidence of interference with follow-up after treatment for breast cancer and that the rate of breast cancer recurrence in the women who had fat grafting to the breast was similar to published rates for patients undergoing mastectomy who did not receive fat grafting but that confirmation of the oncologic safety awaits the results of controlled trials.
A 2012 literature review by Saint-Cyr et al on the role of fat grafting in reconstructive and cosmetic breast surgery included articles published between 2001 and 2011. Due to the heterogeneity of the studies, a formal meta-analysis was not done. Of 19 chosen studies, 11 had patients receiving autologous fat transplantation as an adjunct to breast reconstruction, five studies enrolled patients receiving the procedure for strictly cosmetic purposes, and three studies used fat grafting for both reconstructive and cosmetic purposes. In the studies included in the review, follow-up intervals ranged from two weeks to 19.1 years. The number of sessions employed per patient ranged from one to seven, with the intervals of time between sessions, when reported, ranging from 21 to 263 days. The review found it difficult to correlate patient or surgeon satisfaction with volume stability or complication rate as there was not a standardized method of documenting clinical success, postoperative volume stability, or follow-up intervals used to report complications; however, most of studies yielded results that were satisfactory or better. For fat grafting used in the setting of radiation (four studies), two studies reported a significant decrease in the LENT-SOMA scores in 95% to 100% of patients. Postoperative volume analysis was only performed in three studies. Postoperative infections, all managed with antibiotics, were reported in four of the studies. Among the 19 selected studies in the literature review, the methods used in the harvesting, processing, and injection of the adipose tissue varied widely.

In 2011, Losken et al reported their experience in patients with a history of breast cancer and autologous fat grafting in secondary breast reconstruction for acquired breast deformities. A retrospective review was performed for 107 patients between 1996 and 2010. The indications for fat grafting were for improvement in contour, shape, and volume of the breast following transverse rectus abdominis myocutaneous flap reconstruction (n=55), latissimus dorsi with or without implant (n=20), implant reconstruction (n=20), and breast conservation therapy deformity (n=12). The average volume of injection was 40 mL (range, 5-150 mL). Eighty of the 107 patients had fat injection performed only once. Patients with a history of radiation therapy had a significantly increased need for repeat fat injections. The average follow-up was eight months (range, 1 month-2.5 years). Complications occurred in 11% of patients and included fat necrosis, erythema, keloid scarring, and pain. There were 23 patients who had follow-up of greater than six months and were contacted for overall satisfaction with the fat injections. Seventeen patients responded, and 83% felt that the fat injections made an improvement (significant improvement n=9, moderate improvement n=5). Three patients reported no improvement.

In 2009, Illouz and Sterodimas reported on their experience over 25 years with 820 patients using autologous fat transplantation to the breast. Patients included in the study were candidates for either breast reconstruction after tumor resection or breast augmentation and were divided into three groups: patients with asymmetry after mastectomy and breast reconstruction (n=381), patients with congenital breast asymmetry (n=54), and patients requesting bilateral breast augmentation (n=385). A total of 820 consecutive female patients were operated on between 1983 and 2007. Age distribution of the patients ranged from 19 to 78 years (mean 45.6 years). Twenty-five to 180 mL of fat was grafted into each breast in each session (mean, 145 mL). The number of sessions needed to achieve the desired result ranged from one to five (mean, three sessions). The total amount of fat transplanted in each breast ranged from 25 to 900 mL (mean,
540 mL). Complications included ecchymosis (n=76), striae (n=36), hematomas (n=12), and infections (n=5). Long-term breast asymmetry was seen in 34 cases. Six hundred seventy patients have undergone mammography and ultrasonography six months and one year after their first intervention, and the authors state that postoperative mammograms after autologous fat transplantation identified changes one would expect after a breast reduction surgical intervention.

In 2009, Delay et al reported the results of fat transplantation to the breast in 880 procedures over 10 years. The lipomodeling procedures were performed for breast reconstruction (n=734), correction of congenital deformities (n=106), aesthetic breast surgery (n=30), and correction of a previous surgical defect (n=10). To compensate for fat resorption, 140 mL of fat was injected for a desired final volume of 100 mL. Clinical follow-up showed that the morphologic results with regard to the volume obtained were stable three to four months postoperatively if the patient’s weight remained constant. The authors stated that the postoperative radiologic appearance was that of normal breasts, sometimes showing images of fat necrosis that would not confuse the differential diagnosis of cancer for radiologists experienced in breast imaging. Oncologic follow-up at 10 years postoperatively, for the first patients treated, showed no increased risk of local recurrence of cancer or development of a new cancer. The complications included one case of infection at the harvest site, six cases of infection at the injection site, and one case of intraoperative pneumothorax that was successfully treated in the recovery room with no further consequences. The incidence of fat necrosis was 3%.

**Autologous Fat Grafting and the Use of Adipose-derived Stem Cells**

Pérez-Cano et al conducted a single-arm, prospective, multicenter clinical trial of 71 women who underwent breast conserving surgery for breast cancer and autologous adipose derived regenerative cell (ADRC)-enriched fat grafting for reconstruction of defects ≤150 mL (the RESTORE-2 trial). Trial end points included patient and investigator satisfaction with functional and cosmetic results and improvement in overall breast deformity at 12 months after procedure. Female patients (18-75 years of age) presenting with partial mastectomy defects and without breast prosthesis were eligible. The RESTORE-2 protocol allowed for up to two treatment sessions, and 24 patients elected to undergo a second procedure following the six-month follow-up visit. Of the 67 patients treated, 50 reported satisfaction with treatment results through 12 months. Sixty-one patients underwent radiation therapy as part of their treatment; two patients did not receive radiation, and the status of radiation treatment was not known for the other four patients. Using the same metric, investigators reported satisfaction with 57 out of 67 patients. There were no serious adverse events associated with the ADRC-enriched fat graft injection procedure. There were no reported local cancer recurrences. The LENT-SOMA scale included investigator and patient assessment of postradiation signs and symptoms. The investigators of the trial found that LENT-SOMA was insufficiently sensitive to adequately reflect the clinical improvements seen in the trial population. Patients with LENT-SOMA III and IV scores (most severe symptoms) were excluded during screening, which may have contributed to the subtle LENT-SOMA score changes observed in the trial. The investigators reported improvement from baseline through 12 months in the degree of retraction or atrophy in 29 out of 67 patients, while 34 patients had no change and four patients reported worse symptoms. Postradiation fibrosis at 12 months was reported as improved in 29 patients, while 35 patients had no change and three patients had worse symptoms. Management of atrophy was reported as improved in 17 patients, with 48 patients having no change and two patients reporting worse symptoms. Improvement in
these measures reached statistical significance. The authors concluded that future comparative studies are needed to determine the incremental benefit of ADRC-enriched fat grafting compared with traditional fat grafting in various clinical circumstances. The follow-up of the study is inadequate to draw conclusions on long-term risk of cancer recurrence.

In 2011, Kamakura and Ito reported on the use of autologous adipose-derived stem cell (ADSC) enriched fat grafting for breast augmentation in a prospective, nonrandomized open-label study of 20 Japanese women. After the adipose tissue was harvested by liposuction, it was processed in the Celution 800 System® to wash and isolate the adipose derived regenerative cells and produce a fat graft enriched with the regenerative cells. The average number of cells per gram of harvested adipose tissue was $3.4 \times 10^5$, and mean cell viability as measured with an automated cell counting system before graft delivery was 85%. Clinical outcomes measured included improvement in circumferential breast measurement from baseline state. There was improvement in circumferential breast measurement in all patients, and breast measurements were stable by 3 months after grafting. At nine months, the mean breast measurement had increased 3.3 cm from preoperative measurements. Through nine months, overall patient satisfaction was 75%, and physician satisfaction 69%. The procedure was well-tolerated without any serious adverse events. Postoperative cyst formation was seen in two patients.

In 2008, Yoshimura et al reported on the development of a novel strategy known as cell-assisted lipotransfer (CAL), in which autologous ADSCs are used in combination with lipoinjection. From 2003 to 2007, the group performed CAL in 70 patients: in the breast in 60 patients (including eight who had breast reconstruction after mastectomy). They reported outcomes for 40 patients with healthy thoraxes and breasts who underwent CAL for purely cosmetic breast augmentation; patients undergoing breast reconstruction for an inborn anomaly or after mastectomy were not included. Nineteen of the 40 patients had been followed for more than six months, with a maximum follow-up of 42 months. The authors observed that the transplanted adipose tissue was gradually absorbed during the first two postoperative months, and the breast volume showed a minimal change thereafter. Final breast volume showed augmentation by 100 to 200 mL after a mean fat amount of 270 mL was injected. The difference in breast circumference (defined as the chest circumference at the nipple minus the chest circumference at the inframammary fold) had increased in all cases by 4 to 8 cm at six months. Cyst formation or microcalcification was detected in four patients. The authors concluded that their preliminary results suggest that CAL is effective and safe for soft tissue augmentation and superior to conventional lipoinjection but that additional study is necessary to further evaluate the efficacy of this technique.

In 2007, Rigotti et al reported the results of a pilot study on the presence and effectiveness of ADSCs in 20 consecutive patients undergoing therapy for side effects of radiation treatment to the breast, chest wall or supraclavicular region, with severe symptoms or irreversible function damage (LENT-SOMA scale Grade 3 and 4). (LENT-SOMA is one of the most common systems to assess the late effects of radiation therapy.) The mean patient age was 51 years (range 37-71 years). The rationale behind the study was that the ADSCs, which have been shown to secrete angiogenic and antiapoptotic factors and to differentiate into endothelial cells, could promote neovascularization in ischemic tissue such as irradiated tissue. Targeted areas included the supraclavicular region, the anterior chest wall after mastectomy with or without breast
prosthesis, and breast after quadrantectomy. A lipoaspirate purification procedure was performed by centrifugation to remove a large part of the triglyceride portion of the tissue and disrupt the cytoplasm of the mature adipocytes to favor their rapid clearance after injection. A stromal-vascular fraction was isolated by enzymatic digestion of extracellular matrix, centrifugation and filtration, and the fractions were cultured for two to three weeks to obtain a homogenous cell population. To assess the presence of mesenchymal stem cells, the stromal-vascular fraction derived from the adipose tissue was cultured and characterized by flow cytometry. The number of procedures was one in five patients, two in eight, three in six, and six in one patient. Clinical follow-up varied between 18 and 33 months (mean, 30 months). Clinical results after treatment with lipoaspirates were assessed by LENT-SOMA scoring. The 11 patients initially classified as LENT-SOMA Grade 4 (irreversible functional damage) progressed to Grade 0 (no symptoms), Grade 1 and Grade 2 in four, five and one cases, respectively. In one case, no improvements were observed. In the four patients who had undergone mastectomy and had breast prostheses and areas of skin necrosis, the necrosis showed complete remission. In the group of nine patients classified as LENT-SOMA Grade 3, fibrosis, atrophy, and retraction progressed to Grade 0 and 1 in five and four cases, respectively.

National Cancer Institute’s Clinical Trial Database
No randomized, controlled trials were identified.

Summary
Fat grafting to the breast has gained popularity with the development of improved harvesting and transplanting techniques. As an adjunct to reconstructive surgery, reported complication rates have been low; however, the clinical effectiveness, interference with screening mammography and the oncologic safety of fat grafting to the breast is still unclear.

The use of adipose-derived stem cells in conjunction with fat grafting to the breast represents a potential new advance in the field of regenerative medicine. Although there is a possible role that these stem cells could play a role in graft survival through both adipogenesis and angiogenesis, a complete understanding of the mechanisms of interactions among adipose stem cells and growth factors is lacking, as is the understanding of any possible role they may have in tumorigenesis. The way to control adipose-derived stem cell differentiation and the fate of the stem cells also remains unknown.

Controlled prospective trials are needed to further investigate the many unanswered questions relating to the application of autologous fat grafting to the breast, with or without the use of adipose derived stem cells in conjunction with this procedure. The impact of fat grafting to the breast and the use of adipose derived stem cells on net health outcome is unknown and therefore, is considered to be investigational.

Practice Guidelines and Position Statements
In 2012, the American Society of Plastic Surgeons (ASPS) issued updated recommendations for the use of fat transfer to the postmastectomy breast with no native breast tissue present. The recommendation states that the body of evidence available on autologous fat grafting following mastectomy with no remaining native breast tissue is comprised mostly of case series, which when combined, the studies provide consistent evidence, resulting in grade B recommendations.
“The existing evidence suggests autologous fat grafting as an effective option in breast reconstruction following mastectomy while demonstrating moderate to significant aesthetic improvement. In addition, the available evidence also cites autologous fat grafting as a useful modality for alleviating post mastectomy pain syndrome. Furthermore, the evidence suggests autologous fat grafting as a viable option for improving the quality of irradiated skin present in the setting of breast reconstruction.”

A joint task force of the American Society for Aesthetic Plastic Surgery (ASAPS) and the American Society of Plastic Surgeons released a position statement on the use of stem cells in aesthetic surgery during the 2011 annual meeting of ASAPS. Based on a systematic review of the peer-reviewed literature, the task force concluded that while there is potential for the future use of stem cells in aesthetic surgical procedures, the scientific evidence and other data are very limited in terms of assessing the safety or efficacy of stem cell therapies in aesthetic medicine. Available online at: http://www.surgery.org/media/news-releases/asaps-and-asps-issue-joint-position-statement-on-stem-cells-and-fat-grafting.

Key Words:
Fat grafting, autologous fat grafting, adipose-derived stem cells, Celution™ System, Cytori Therapeutics, breast reconstruction with fat grafting, breast reconstruction with adipose-derived stem cells, ADSC, autologous fat transplantation to the breast, autologous cell-enriched fat grafting, lipoaspirate transplant, cell-assisted lipotransfer, CAL, Celution 800 System®

Approved by Governing Bodies:
Cytori Therapeutics, Inc was awarded 510(k) marketing clearance in September 2006 from the U.S. Food and Drug Administration’s (FDA) 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.

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Coding:
There is no specific CPT code for this procedure. One of the following CPT codes might be used:
CPT Codes:
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<th>Description</th>
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<td>Subcutaneous injection of filling material (e.g., collagen); 1 cc or less</td>
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<tr>
<td>11952</td>
<td>Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc</td>
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<td>11954</td>
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<td>19366</td>
<td>Breast reconstruction with other technique</td>
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<td>20926</td>
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The following CPT code **should not be used:**

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<td>19380</td>
<td>Revision of reconstructed breast</td>
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**References:**


Policy History:
Medical Policy Panel, June 2011
Medical Policy Group, June 2011 (2): new policy
Medical Policy Administration Committee, June 2011
Available for comment June 23 – August 8, 2011
Medical Policy Group, July 2011: Added Code 20926
Medical Policy Group, March 2013 (1): Update to Codes with addition of code range 11950-11954 as potentially usable codes
Medical Policy Group, July 2013 (2): Update to Codes not to be used—19380 Revision of reconstructed breast
Medical Policy Panel, April 2014
Medical Policy Group, April 2014 (1): Rewording for clarification to policy statement, no change in intent of coverage; update to Description, Key Points and References

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.