Medical Policy Manual Surgery, Policy No. 182

Adipose-derived Stem Cell Enrichment in Autologous Fat Grafting to the Breast

Effective: December 1, 2024

Next Review: October 2025
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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Autologous fat grafting to the breast has been used as an adjunct to reconstructive breast surgery to address issues such as post-mastectomy pain and irradiated skin. Adipose-derived stem cells have been proposed as a supplement to the fat graft in an attempt to improve graft survival.

MEDICAL POLICY CRITERIA

Notes:

- This policy does not address the use of autologous fat grafting without adipose stem cell enrichment for breast reconstruction, which may be considered medically necessary.
- This policy does not address free flap autologous fat grafting with micro vascularization.
- This policy does not address the use of autologous fat tissue in aesthetic breast augmentation (i.e., cosmesis).

The use of autologous fat grafting to the breast with supplemented adipose-derived stem cells is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Gender Affirming Interventions for Gender Dysphoria, Medicine, Policy No. 153
2. Endometrial Ablation, Surgery, Policy No. 01
3. Cosmetic and Reconstructive Surgery, Surgery, Policy No. 12
4. Reconstructive Breast Surgery/Mastopexy, and Management of Breast Implants, Surgery, Policy No. 40
5. Reduction Mammaplasty, Surgery, Policy No. 60

BACKGROUND

AUTOLOGOUS FAT GRAFTING TO THE BREAST

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

ADIPOSE-DERIVED STEM CELLS (ADSCS)

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 x 10^3 stem cells, which is up to 500 times greater than the number of mesenchymal stem cells in 1 gram of bone marrow.[1] 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.[1] 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.[1]

Current methods for isolating ADSCs can involve various 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,[2] 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 (2008), 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.[3] 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-enriched fat.

REGULATORY STATUS

A point-of care system is available for concentrating ADSCs 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. The system received 510(k) marketing clearance from the U.S. Food and Drug Administration 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.

In 2017, the Revolve Envi 600 Advanced Adipose System (LifeCell Corporation, Branchburg, NJ) was cleared for marketing by the FDA through the 510(k) process. The system harvests, filters, and transfers autologous adipose tissue for fat grafting. Uses include reconstructive surgery. In May of 2020, the Revolve Envi 600 System underwent various design modifications (K163647). FDA product code: MUU.

EVIDENCE SUMMARY

The literature on the use of fat grafting to the breast with the use of adipose-derived stem cell (ADSC) enrichment consists of retrospective cohort studies, case series, and case reports. The following is a summary of the key literature to date, including all identified case series using fat grafting to the breast with the supportive use of ADSCs.

Systematic Reviews

A 2021 SR published by Li and Chen compared the efficacy of CAL and conventional lipotransfer in breast augmentation.[4] Six studies including 353 patients met inclusion criteria. Of these, one was a randomized trial, four were retrospective observational case-series, and one was a prospective controlled trial. No evaluation of study quality was reported. The fat survival rate was significantly higher in the CAL group than in the control group (standard mean difference [SMD]=1.79, 95% CI 0.28 to 3.31; p=0.02). No statistically significant differences in complication rates between groups (SMD=1.79, 95% CI 0.28 to 3.31; p=0.02). There were also no statistically significant differences identified in the subgroup analyses between the groups in fat survival rate (SMD=1.52, 95% CI -0.21 to 3.24; p=0.08).

In 2017, Lazole conducted a SR to evaluate the safety and efficacy of CAL. Twenty-five studies addressing fat grafting to the breast and face were included in the systematic review and 16 in the meta-analysis.[5] The fat survival rate was significantly higher with CAL than non-CAL fat graft, only for injection volumes < 100 mL. There was no significant difference between groups in frequency of multiple procedures after fat grafting. The incidence of complications

was significantly higher in the CAL group.

In 2016, Zhou conducted a SR with the same purpose as the above systematic review, and included seventeen articles (n=387) for all indications, including breast.[6] For all indications combined, the pooled fat survival rate was significantly higher in the CAL group than in the nonlipotransfer group (60% vs. 45%, p=0.0096). Complication incidence was similar in the two groups. In breast fat grafting fat survival was improved by only 9% in the CAL group, which was not statistically significant. In addition, lipotransfer in breast cases was associated with a higher complication incidence compared with other indications (p<0.001).

Randomized Control Trial

Vester-Glowinski (2022) published a randomized control trial (RCT) trial aimed to investigate whether ADSCs improve fat graft volume retention in patients undergoing breast augmentation with lipofilling.[7] This was a double-blind, randomized controlled trial of breast augmentation with ADSC-enriched fat grafting. Healthy women aged 30 to 45 years were enrolled. First, the participants underwent liposuction to obtain fat for culture expansion of ASCs. Then, the participants were randomly assigned to undergo a 300- to 350-mL breast augmentation with ADSC-enriched fat grafting (10 × 106 ASCs/mL fat graft) to 1 of their breasts and placebo-enriched fat grafting of identical volume to the contralateral breast. Fat graft volume retention after one year was 54.0% (95% CI, 30.4%-77.6%) in the breasts treated with ASC-enriched fat grafting (n = 10) and 55.9% (95% CI, 28.9%-82.9%) in the contralateral breasts treated with placebo-enriched fat grafting (n = 10) (p=0.566). The authors concluded that the findings of this trial do not support that ASC-enriched fat grafting is superior to standard fat grafting for breast augmentation.

Nonrandomized Studies

Jørgensen (2021) performed a phase I trial aimed to assess whether ADSCs can alleviate lymphedema in clinical reality with long-term follow-up in patients with breast cancer-related lymphedema (BCRL).[8] They treated 10 patients with BCRL using ADSCs and a scar-releasing lipotransfer to the axillary region, and all patients were followed one, three, six, twelve, and forty-eight months after treatment. There was no significant decrease in BCRL volume after treatment. However, self-reported upper extremity disability and arm heaviness and tension improved. The authors reported that in this phase I study with four years of follow-up, axillary delivered ADRCs and lipotransfer were safe and feasible and improved BCRL symptoms and upper extremity function. The authors also recommended more RCTs to confirm the results of this study.

Jeon et al (2020) evaluated the efficacy of CAL on the fat graft retention rate in patients with volume deficit after undergoing autologous breast reconstruction following total mastectomy.[9] This 12-month prospective study included 20 patients (20 breasts) between 2017 and 2019. Patients were divided into two groups: autologous fat graft without stromal-vascular fraction (i.e., without ADSC) or autologous fat graft with stromal-vascular fraction of ADSC. The retention rate of the fat graft was higher in the group with ADSC than in the group without at both postoperative 6 months (73.8% vs 62.2%; p=0.03) and 12 months (65.4% vs 48.4%; p=0.03). Based on a modified BREAST-Q questionnaire at 12 months, the group who received fat graft with ADSC reported higher patient satisfaction (49.4 points out of 55 compared to 44.2 points out of 55), although this was not statistically significant. Fat necrosis occurred in one patient each in both groups, however, locoregional recurrence was not observed in any patient during follow-up. The authors concluded that CAL with stromal-vascular fraction provided

better outcomes in terms of volume retention compared to CAL without ADSC.

Mazur (2018) evaluated the risk of cancer recurrence in 56 patients having the breast reconstructed with autologous ASC (transplanted as the subpopulation present in the stromal vascular fraction [SVF]).[10] Tumor recurrence in these patients was compared with tumor recurrence in 252 matched patients that did not receive breast reconstruction. Cancer recurrence in the ASC and control groups was 3.7% and 4.13%, respectively, which was not significantly different (p=1.0).

In 2016, Jung conducted a small single-arm, prospective study to evaluate the impact of ADSCs, using CAL, on graft survival, including five patients.[11] One year after CAL, breast volume had decreased to 47% of the initial postoperative volume. The ratio of ADSC cell count to grafted fat volume showed no correlation with graft survival. The addition of SVF cells did not appear to improve the retention of grafted fat in these patients. Skin tension may be an important factor influencing the absorption pattern of grafted fat.

In 2013, Peltoniemi conducted a prospective comparative study to evaluate if stem cell enrichment is important for success in lipofilling for cosmetic breast augmentation.[12] A total of 18 women underwent breast augmentation, with 10 of the cases including transferred lipoaspirate enriched with ADSCs using the Cytori Celution(®) system MRI-based volumetric analysis was done preoperatively and six months post-procedure. MRI analysis revealed mean graft survival was not significantly different between groups (54% in nonADSC group vs. 50% in the ADSC-enrichment patients). After centrifugation survival was not significantly different between groups (79% in nonADSC group vs. 74% in the ADSC-enrichment patients. The investigators concluded that they did not see any advantage in stem cell enrichment by the Celution(®) system in cosmetic fat transplantation to the breast.

In 2012, Pérez-Cano 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).[13] Trial endpoints included patient and investigator satisfaction with functional and cosmetic results and improvement in overall breast deformity at 12 months post-procedure. Female patients (18 to 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 post-radiation 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. Post-radiation 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 as compared to traditional fat grafting in various clinical circumstances.

In 2011, Kamakura and Ito reported on the use of ADSC enriched fat grafting for breast augmentation in a prospective, nonrandomized open-label study of 20 Japanese women.[14] 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. 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 three months after grafting. At nine months, the mean breast measurement had increased 3.3 cm from preoperative measurements. The procedure was well-tolerated without any serious adverse events. Postoperative cyst formation was seen in two patients.

In 2008, Yoshimura and colleagues reported on the development of CAL, in which autologous ADSCs are used in combination with lipoinjection.[3] 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 reported the results of a pilot study on the presence and effectiveness of ADSCs in 20 consecutive patients undergoing therapy for adverse 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 radiotherapy.[15] The mean patient age was 51 years (range, 37 to 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 patients, three in six patients, 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.

PRACTICE GUIDELINE SUMMARY

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE)

In 2012 NICE published an evidence-based clinical practice guideline addressing breast reconstruction using lipomodelling after breast cancer treatment. Regarding the use of stem cell enrichment, it states, “Further information about the outcomes of this and other adaptations of the technique of lipomodelling is desirable for guiding their future use in clinical management.”[16]

AMERICAN SOCIETY OF AESTHETIC PLASTIC SURGERY AND AMERICAN SOCIETY OF PLASTIC SURGEONS[17]

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.[17] 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.

SUMMARY

The current research on the use of supplemented adipose-derived stem cells in combination with fat grafting to the breast has many limitations. In addition, the research is starting to show that the use of these cells does not increase graft survival or decrease resorption rates. More research is needed on the long-term effectiveness and safety of enrichment of adipose-derived stem cells in fat grafting to the breast. In addition, no evidence-based clinical practice guidelines recommend the use of adipose-derived stem cell enrichment in fat grafting to the breast. Therefore, the use of adipose-derived stem cell enrichment in conjunction with fat grafting to the breast is considered investigational.

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CODES

NOTE: There is no specific code to report the use of the additional adipose-derived stem cell enrichment in autologous fat grafting.

Codes	Number	Description
CPT	11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
	11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
	11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
	11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc
	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)
	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)
	19499	Unlisted procedure, breast
HCPCS	None	

Date of Origin: *November 2011*