

MEDICAL POLICY – 7.01.153

Adipose-Derived Stem Cells in Autologous Fat Grafting to the Breast

BCBSA Ref. Policy: 7.01.153

Effective Date: Apr. 1, 2025

Last Revised: Mar. 10, 2025


Replaces: N/A

RELATED MEDICAL POLICIES:

None

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [CODING](#) | [RELATED INFORMATION](#)[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

Introduction

As part of breast reconstruction, a person's own fat can be taken from other parts of the body and placed in the breast(s). There are risks of this fat transfer, including death of the fat cells and the chance that some of the transferred fat will migrate away from the breast area. Stem cells concentrated from the fat tissue are known as adipose-derived stem cells or ADSCs. Using ADSCs is proposed as a way to try to increase the success of a fat transfer to the breast. Medical studies have not yet determined whether injecting ADSCs could play a role in creating new tumors. The studies that have been done involve only a few individuals who have been followed for a short time. For these reasons, using ADSCs as part of grafting a person's own fat to the breast is considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Adipose-derived stem cells	<p>The use of adipose-derived stem cells in autologous fat grafting to the breast is considered investigational.</p> <p>Note: Autologous fat grafting to the breast without the use of adipose-derived stem cells is not subject to medical review.</p>

Coding

Code	Description
CPT	
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
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)
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
19380	Revision of reconstructed breast (e.g., 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

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Related Information

N/A

Evidence Review

Description

Following a mastectomy, individuals often experience pain and irradiated skin; as an adjunct to reconstructive breast surgery, surgeons will sometimes graft autologous fat to the breast. Adipose-derived stem cells (ADSCs) have been proposed as a supplement to the fat graft, in an attempt to improve graft survival; however, whether ADSCs play a role in tumorigenesis is still relatively unknown.

Background

Fat Grafting to the Breast

Autologous fat grafting to the breast has been proposed for indications that include breast augmentation following oncologic surgery. Grafting would be performed as an adjunct to reconstruction after mastectomy or lumpectomy, and it would be of benefit in the following areas: for contouring purposes, improving breast shape and volume, and for alleviating post mastectomy pain syndrome (neuropathic pain) and irradiated skin (thereby reducing complication and failure rates of implant reconstruction). Variability in long-term results and oncologic concerns have limited application of autologous fat grafting in the breast.

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. A single gram of adipose tissue yields approximately 5000 stem cells; this is 100 to 500 times the number of mesenchymal stem cells found in an equivalent amount 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. In particular, adipose tissue represents an abundant and easily accessible source of ADSCs, which can differentiate along multiple mesodermal lineages. ADSCs may allow for improved graft survival and the generation of new fat tissue after transfer from another site.^{1,2}

The potentially therapeutic properties of ADSC have led to novel techniques of fat grafting in conjunction with ADSC therapy for breast fat grafting. Differentiation of ADSC into adipocytes may provide a reservoir for adipose tissue turnover. Differentiation of ADSC into endothelial cells, with the release of angiogenic growth factors by ADSC, may decrease the rate of graft resorption by increasing blood supply to the grafted fat tissue. Further, ADSC may serve to accelerate wound healing and protect the graft from ischemia reperfusion injury.¹ Current methods for isolating ADSCs can involve various processes, which may include centrifugation and enzymatic techniques that rely on collagenase digestion, which, in turn, is followed by centrifugal separation to isolate the stem cells from primary adipocytes. Isolated ADSCs can be expanded in a monolayer on standard tissue culture plastic surfaces with a basal medium containing 10% fetal bovine serum.³ Newly developed culture conditions provide an environment in which the study of ADSCs can be done without the interference of animal serum and may also allow rapid expansion of autologous ADSCs in culture for use in human clinical trials. A standard expansion method has not yet been established.

To address the problems of unpredictability and low rates of fat graft survival, Yoshimura et al (2008) developed a technique known as cell-assisted lipotransfer, which produces autogenous fat rich in ADSCs.⁴ In cell-assisted lipotransfer, half of the lipoaspirate is centrifuged to obtain a fraction of concentrated ADSCs; meanwhile, the other half is washed, enzymatically digested, filtered, and spun down to an ADSC-rich pellet. The latter is then mixed with the former, converting a relatively ADSC-poor aspirated fat to ADSC-rich fat.

A point-of-care system is available for concentrating ADSC from mature fat. The Celution System is designed to transfer an individual's own adipose tissue from one part of the body to another in the same surgical procedure.



Summary of Evidence

For individuals who have breast cancer who receive autologous fat grafting to the breast with ADSC enrichment of the graft, the evidence includes small single-arm studies, some of which are prospective. The relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. The observational studies were heterogeneous in the patient selection, methods in harvesting stem cells, number of procedures, and outcomes measured. Studies have mainly reported patient and investigator satisfaction and functional and cosmetic results. One small, prospective study found that the use of ADSC enrichment with autologous fat grafting over autologous fat grafting alone improved the retention rate of the fat graft postoperatively at 6 and 12 months. Larger clinical trials are needed to confirm this benefit. Limitations of the data include sample sizes, short-term follow-up, and uncertainty about the possible oncologic influence ADSC may have on the fat grafting procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

No relevant ongoing clinical trials were identified as of November 2024.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society for Aesthetic Plastic Surgery and American Society of Plastic Surgeons



In 2011, the American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons released a joint position statement on the use of stem cells in aesthetic surgery.⁹ Based on a systematic review of the peer-reviewed literature, the societies 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.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In September 2006, Celution Cell Concentration System (Cytori Therapeutics; San Diego, CA) was cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process as a cell saver device. The system is cleared for the collection, concentration, washing, and reinfusion of an individual's cells for applications that may include, but are not limited to, cardiovascular, plastic and reconstructive, orthopedic, vascular, and urologic surgeries and procedures. In 2007, Cytori Therapeutics received the FDA 510(k) clearance to market the Autologous Fat Transfer system, which transfers an individual's own adipose tissue from one part of the individual's body to another.

FDA product code: CAC.

References

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6. Rigotti G, Marchi A, Galiè M, et al. Clinical treatment of radiotherapy tissue damage by lipoaspirate transplant: a healing process mediated by adipose-derived adult stem cells. *Plast Reconstr Surg*. Apr 15 2007; 119(5): 1409-1422. PMID 17415234
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8. Jeon HJ, Choi DH, Lee JH, et al. A Prospective Study of the Efficacy of Cell-Assisted Lipotransfer with Stromal Vascular Fraction to Correct Contour Deformities of the Autologous Reconstructed Breast. *Aesthetic Plast Surg*. Jun 2021; 45(3): 853-863. PMID 32995982
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History

Date	Comments
12/08/15	New Policy. Policy created with literature review through September 13, 2015; the use of adipose-derived stem cells (ADSC) in autologous fat grafting to the breast is considered investigational. (Note: The former policy addressing both autologous fat grafting and ADSC has been archived. This policy only addresses ADSC. Policy statement regarding ADSC remains investigational.)
06/01/16	Annual Review, approved May 10, 2016. Policy updated with literature search. Reference added. No change to the policy statement.
11/01/17	Annual Review, approved October 19, 2017. Policy updated with literature review through July 20, 2017; no references added. Policy statement unchanged. Added CPT codes 11950, 11951, 11952, and 11954.
04/01/18	Annual Review, approved March 20, 2018. Policy updated with literature review through July 2017; no references added. Policy statement unchanged.
04/01/19	Annual Review, approved March 19, 2019. Policy updated with literature review through October 2018; reference 5 added. Policy statement unchanged.
01/01/20	Coding update, added CPT codes 15769, 15771, 15772, 15773, and 15774 (new codes effective 1/1/20, replacing CPT code 20926 which terminated 1/1/20).
01/10/20	Coding update, removed CPT codes 15773 and 15774 which were added in error.
04/01/20	Annual Review, approved March 19, 2020. Policy updated with literature review through December 2019; no references added. Policy statement unchanged.
07/02/2020	Coding update. Added CPT's 15773 and 15774.
12/01/20	Coding update, added note that CPT code 19366 terminated 1/1/21.



Date	Comments
04/01/21	Annual Review, approved March 2, 2021. Removed CPT codes 15769 and 20926. Policy updated with literature review through November 13, 2020; no references added. Policy statement unchanged.
04/01/22	Annual Review, approved March 7, 2022. Policy updated with literature review through November 19, 2021; reference added. Policy statement unchanged. Removed termed CPT 19366.
04/01/23	Annual Review, approved March 6, 2023. Policy updated with literature review through November 11, 2022; no reference added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. Updated code description for CPT code 19380.
03/01/24	Annual Review, approved February 26, 2024. Policy updated with literature review through November 28, 2023; no references added. Policy statement unchanged.
04/01/25	Annual Review, approved March 10, 2025. Policy updated with literature review through December 6, 2024; no references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

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