

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

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Autologous fat grafting (may also be referred to as autologous fat transplant, lipoinjection, lipofilling, or lipomodelling) to the breast has been used 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. Autologous fat grafting generally involves the transfer of fat from the abdomen or thighs into the breast, with multiple sessions performed, depending on their condition.

Adipose-derived stem cells have been proposed as a supplement to the fat graft in an attempt to improve graft survival. 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. Along with potential necrosis, other complications include oil cyst formation, indurations in either the subcutis or breast parenchyma, calcification, and severe breast deformity.

Research demonstrates that subcutaneous fat contains many stem and regenerative cells, including cells that play a role in tissue survival and vascularization. This is the basis for the proposal that autologous adipose-derived regenerative cells (ADRCs) may increase graft survival. However, ADSCs are prone to unpredictability and low rates of fat graft survival.

MEDICARE ADVANTAGE 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).

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None While the NCD 140.2 does support medical necessity for breast reconstruction following a mastectomy, it does not provide guidance for the various techniques that may be used for breast reconstruction procedures. Therefore, additional criteria references are required.
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	<i>Medicare coverage guidance is not available for autologous fat grafting or adipose-derived stem cell transplant to the breast. Therefore, the health plan's medical policy is applicable.</i> Adipose-derived Stem Cell Enrichment in Autologous Fat Grafting to the Breast, Surgery, Policy No. 182 (see "NOTE" below)
NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (Medicare IOM Pub. No. 100-04, Ch. 23, §30 A). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to	

make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence.** ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

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.

CROSS REFERENCES

[Investigational \(Experimental\) Services and New and Emerging Medical Technologies and Procedures](#), Medicine, Policy No. M-149

[Gender Affirming Interventions for Gender Dysphoria](#), Medicine, Policy No. M-153

[Cosmetic and Reconstructive Surgery](#), Surgery, Policy No. M-12

[Reconstructive Breast Surgery, Mastopexy, and Management of Breast Implants](#), Surgery, Policy No. M-40

[Reduction Mammoplasty \(Mammoplasty\)](#), Surgery, Policy No. M-60

REFERENCES

None

CODING

NOTE: There is no specific code to report the use of the additional adipose-derived stem cell enrichment in autologous fat grafting. CPT indicates code 20926 is the code to report for all autologous fat grafting including reconstructive breast surgery, with or without additional adipose-derived stem cells (aka, stem cell enrichment). This code includes harvest and placement of the graft, and encompasses harvesting the fat graft material by any method, closing the donor site (if indicated) and applying the appropriate dressing, processing the fat graft material, injecting the fat graft into the recipient site, and dressing the recipient site. The procedure involves a donor site, preparation of the graft, and a recipient site. This code may be reported for any site when performed and is the only code needed to report the autogenous fat grafting procedure. (*CPT Assistant Coding, October, 2016*)

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
	19366	Breast reconstruction with other technique
	19380	Revision of reconstructed breast
	19499	Unlisted procedure, breast
	20926	Tissue grafts, other (e.g., paratenon, fat, dermis)
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.