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

Description
Following a mastectomy, patients 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.

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 evidence review does not address the use of autologous fat tissue in aesthetic breast augmentation (i.e., cosmetic).

OBJECTIVE
The objective of this evidence review is to determine whether autologous fat grafting to the breast with adipose-derived stem cell enrichment improves the net health outcome in individuals who have breast cancer.

POLICY STATEMENT
The use of adipose-derived stem cells in autologous fat grafting to the breast is considered investigational.

BENEFIT APPLICATION
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS
In September 2006, Celution™ Cell Concentration System (Cytori Therapeutics; San Diego, CA) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process as a...
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cell saver device. The system is cleared for the collection, concentration, washing, and reinfusion of a patient’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 a patient’s own adipose tissue from one part of the patient’s body to another. FDA product code: CAC.

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. FDA product code: MUU.

RATIONALE

Summary of Evidence
For individuals who have breast cancer who receive of 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. 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. In addition, no studies were identified which demonstrated incremental benefits of using ADSC enrichment with autologous fat grafting over autologous fat grafting alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
American Society for Aesthetic Plastic Surgery and American Society of Plastic Surgeons
The American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons (2011) released a joint position statement on the use of stem cells in aesthetic surgery. 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.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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POLICY HISTORY

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>March 2018</td>
<td>New Policy</td>
<td>The use of adipose-derived stem cells in autologous fat grafting to the breast is considered investigational.</td>
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<tr>
<td>March 2019</td>
<td>Update Policy</td>
<td>Policy updated with literature review through October 30, 2018; reference 5 added. Policy statement unchanged.</td>
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