FEP Medical Policy Manual

FEP 7.01.153 Adipose-Derived Stem Cells in Autologous Fat Grafting to the Breast

Effective Policy Date: April 1, 2021

Original Policy Date: March 2018

Related Policies:

None

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

Description

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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.

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 and are undergoing reconstructive surgery.

POLICY STATEMENT

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

POLICY GUIDELINES

None

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 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. In May of 2020, the Revolve Envi 600 System underwent various design modifications (K163647). FDA product code: MUU.

RATIONALE

Summary of Evidence

For individuals who have breast cancer who receive autologous fat grafting to the breast with adipose derived stem cells (ADSC) enrichment of the graft, the evidence includes small single-arm studies, some of which are prospective. 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

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.[8.] 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2018	New policy	The use of adipose-derived stem cells in autologous fat grafting to the breast is considered investigational.
March 2019	Replace policy	Policy updated with literature review through October 30, 2018; reference 5 added. Policy statement unchanged.
March 2020	Replace policy	Policy updated with literature review through December 4, 2019; no references added. Policy statement unchanged.
March 2021	Replace policy	Policy updated with literature review through November 13, 2020; no references added. Policy statement unchanged.