

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

Effective Date: April 15, 2018

Related Policies: None

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.

FDA REGULATORY STATUS

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

In September 2006, Celution™ Cell Concentration System (Cytori Therapeutics; San Diego, CA) was cleared for marketing by the U.S. Food and Drug Administration 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.

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).

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. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. 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

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uncertainty about the possible oncologic influence ADSC may have on the fat grafting procedure. 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 released a joint position statement on the use of stem cells in aesthetic surgery in 2011.⁷ 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

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POLICY HISTORY

Date	Action	Description
March 2018	New Policy	The use of adipose-derived stem cells in autologous fat grafting to the breast is considered investigational .