Medicare Advantage Medical Policy

MA: BIOENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES

EFFECTIVE 01/01/2024

Description
Bioengineered skin and soft tissue substitutes may be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenographic), synthetic materials, or a composite of these materials.

Bioengineered skin and soft tissue substitutes are being evaluated for a variety of conditions, including breast reconstruction and healing lower extremity ulcers and severe burns.

Autologous cell harvesting device (RECELL Sytem) is a device that enables point-of-care preparation and application using the patient's own skin for treatment of burns. The FDA approved indications are treatment of acute thermal burn wounds.

Policy
Related Policies

I.200 Amniotic Membrane and AmnioticFluid

Bioengineered Skin and Soft Tissue Subsitutes

I. The use of bioengineered skin and soft tissue substitutes is considered **scientifically validated** for the following indications:

A. Breast reconstruction **OR**

B. Diabetic lower extremity ulcers **OR**

C. Venous insufficiency lower extremity ulcers **OR**

D. Dystrophic epidermolysis bullosa **OR**

E. Second- or third-degree burns.

II. The use of bioengineered skin and soft tissue substitutes is considered **investigational** for all other indications.

Autologous Cell Harvesting Device

I. Autologous cell harvesting device (e.g., RECELL system) is considered **scientifically validated** for the treatment of 2nd and 3rd degree burns when the following criteria is met:

A. **ONE** of the following:

1. acute partial thickness (2nd and 3rd degree burns in patients 18 years of age and older **OR**

2. in combination with meshed autografting for acute full thickness thermal burn wounds in pediatric or adult patients with 3rd degree burns.

AND

B. The member has **NONE** of the following contraindications.

1. wounds clinically diagnosed as infected or with necrotic tissue present in the wound bed **AND**

2. patients with a known hypersensitivity to trypsin or compound sodium lactate solution (e.g., Hartmann's Solution **AND**

3. patients with a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine or chlorhexidine solutions **AND**

II. All other uses of autologous cell harvesting device (RECELL system) is considered **investigational.**

Background

Skin and Soft Tissue Substitutes

Bioengineered skin and soft tissue substitutes may be either acellular or cellular. Acellular products (eg, dermis with cellular material removed) contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. Acellular dermal matrix (ADM) products can differ in a number of ways, including as species source (human, bovine, porcine), tissue source (eg dermis, pericardium, intestinal mucosa), additives (eg antibiotics, surfactants), hydration (wet, freeze-dried), and required preparation (multiple rinses, rehydration).

Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within the matrix may be autologous, allogeneic, or derived from other species (eg, bovine, porcine). Skin substitutes may also be composed of dermal cells, epidermal cells, or a combination of dermal and epidermal cells, and may provide growth factors to stimulate healing. Bioengineered skin substitutes can be used as either temporary or permanent wound coverings.

Applications

There are a large number of potential applications for artificial skin and soft tissue products. One large category is nonhealing wounds, which potentially encompasses diabetic neuropathic ulcers, vascular insufficiency ulcers, and pressure ulcers. A substantial minority of such wounds do not heal adequately with standard wound care, leading to prolonged morbidity and increased risk of mortality. For example, nonhealing lower-extremity wounds represent an ongoing risk for infection, sepsis, limb amputation, and death. Bioengineered skin and soft tissue substitutes have the potential to improve rates of healing and reduce secondary complications.

Other situations in which bioengineered skin products might substitute for living skin grafts include certain postsurgical states (eg, breast reconstruction) in which skin coverage is inadequate for the procedure performed, or for surgical wounds in patients with compromised ability to heal. Second- and third-degree burns are another indication in which artificial skin products may substitute for auto- or allografts. Certain primary dermatologic conditions that involve large areas of skin breakdown (eg, bullous diseases) may also be conditions in which artificial skin products can be considered as substitutes for skin grafts. ADM products are also being evaluated in the repair of other soft tissues including rotator cuff repair, following oral and facial surgery, hernias, and other conditions.

Codes

A2002	**A2003**	**A2004**	**A2005**	**A2006**	**A2007**	**A2008**
A2009	**A2010**	**A2011**	**A2012**	**A2013**	**A2014**	**A2015**
A2016	**A2017**	**A2018**	**A2019**	**A2020**	**A2021**	**A4100**
C1832	**C1849**	**C9354**	**C9356**	**C9358**	**C9360**	**C9363**
C9364	**Q4100**	**Q4101**	**Q4102**	**Q4103**	**Q4104**	**Q4105**
Q4106	**Q4107**	**Q4108**	**Q4110**	**Q4111**	**Q4112**	**Q4113**
Q4114	**Q4115**	**Q4116**	**Q4117**	**Q4118**	**Q4121**	**Q4122**
Q4123	**Q4124**	**Q4125**	**Q4126**	**Q4127**	**Q4128**	**Q4130**
Q4134	**Q4135**	**Q4136**	**Q4141**	**Q4142**	**Q4143**	**Q4146**
Q4147	**Q4149**	**Q4152**	**Q4158**	**Q4161**	**Q4164**	**Q4165**
Q4166	**Q4167**	**Q4175**	**Q4182**	**Q4193**	**Q4195**	**Q4196**
Q4197	**Q4200**	**Q4202**	**Q4203**	**Q4220**	**Q4226**	

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