Title 23: Division of Medicaid

Part 203: Physician Services

Chapter 10: Implantable Medical Devices

Rule 10.1: Skin and Soft Tissue Substitutes

A. The Division of Medicaid defines skin and soft tissue substitutes as types of wound coverage materials composed of human tissue, non-human tissue, synthetic materials, or a composite of these materials which mimic or substitute for some aspect of the skin's structure, either permanently or temporarily, for the treatment of acute and chronic non-healing wounds and soft tissue grafting.

B. The Division of Medicaid covers skin and soft tissue substitute procedures, products, and services for medically accepted conditions and indications approved by the Food and Drug Administration (FDA) when medically necessary and when the procedures, products, and services are:

1. Individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs,

2. Safely applied within the scope of FDA indications and according to manufacturer's instructions, and

3. No equally effective or more conservative or less costly treatment is available statewide.

C. The Division of Medicaid covers skin and soft tissue substitutes for the following, including, but not limited to:

1. Acute wounds,

2. Chronic non-healing wounds,

3. Soft tissue grafting,

4. Second and third degree burns,

5. Dermatological conditions which involve large areas of skin breakdown,

6. Post-surgical states in which skin coverage is inadequate or ability to heal is compromised,

7. Diabetic foot ulcers, and

8. Venous stasis ulcers.

D. The Division of Medicaid does not cover skin and soft tissue substitutes for experimental, investigational uses or clinical trials or for the following conditions or circumstances, including, but not limited to:

1. Infected ulcers,

2. Wounds or ulcers healing with traditional wound care dressings and treatment,

3. Underlying osteomyelitis,

4. Surrounding cellulitis,

5. Uncontrolled diabetes,

6. Vasculitis,

7. Eschar or any necrotic material,

8. Wound bed with exposed bone,

9. Uncontrolled rheumatoid arthritis, rheumatoid ulcers, or both,

10. Known hypersensitivity to:

    a) Collagen,

    b) Bovine-derived products, or

    c) Porcine-derived products,

11. Active Charcot's arthropathy of the ulcer extremity,

12. Arterial disease with an ankle brachial index (ABI) of less than .65 in respect to venous stasis ulcers or a lack of pedal pulses in respect to diabetic foot ulcers,

13. Ulcers with sinus tracts or tunnels,

14. Uncontrolled collagen vascular diseases,

15. Radiation and/or chemotherapy treatment within the month immediately preceding proposed skin substitute treatment, or

16. Current treatment with high-dose corticosteroids or immunosuppressants.

E. The provider must maintain auditable records that substantiate the services provided which must include, but are not limited to, the following:

1. The diagnosis supporting medical necessity,

2. Previous conservative wound management which has failed to induce healing,

3. Exact location, size, including width, length, circumference, and depth, of the wound prior to initial treatment and prior to each subsequent treatment,

4. Response to wound treatment,

5. Appropriate adjunctive wound care measures,

6. The handling, application, and immobilization of the product in accordance with the manufacturer's instructions,

7. Amount of skin or soft tissue product used and wasted, and

8. Manufacturer's serial/lot/batch or other unit identification number of graft material, or documentation sufficient to demonstrate that the manufacturer does not supply unit identification.

Source: Social Security Act §§ 1862(a)(1)(A) and (D); 21 CFR Part 1271.

History: New Rule eff. 10/01/2014.