Skin and Soft Tissue Substitutes (for North Carolina Only)

Policy Number: CSNCT0592.09
Effective Date: February 1, 2025

Instructions for Use

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Related Policies

- Breast Reconstruction (for North Carolina Only)
- Prolotherapy and Platelet Rich Plasma Therapies

Application

This Medical Policy only applies to the State of North Carolina.

Coverage Rationale

For medical necessity clinical coverage criteria, refer to the North Carolina Medicaid (Division of Health Benefits) Clinical Coverage Policy, Burn Treatment and Skin Substitutes: 1G-2, Skin Substitutes.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
Q4101	Apligraf, per sq cm
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm
Q4106	Dermagraft, per sq cm
Q4116	AlloDerm, per sq cm
Q4121	TheraSkin, per sq cm
Q4128	FlexHD, or AllopatchHD, per sq cm
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4151	AmnioBand or Guardian, per sq cm
Q4186	Epifix, per sq cm

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Depending on their function and purpose, skin substitutes are regulated by the FDA through one of the following regulatory pathways:

- Premarket Approval (PMA): Devices that support or sustain human life or have the potential to cause risk of illness or injury are approved through the PMA process. These devices require clinical data to support their claims for use. Refer to the following website (search by product or applicant name): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.
- Premarket Clearance or 510(k) Process: Devices that are substantively equivalent to legally marketed predicate devices that do not require PMA can be marketed under this designation. Refer to the following website (search by product or applicant name): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
- FDA's Definition under the Code of Federal Regulations (CFR) of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) addressed in Public Health Service 361 (Title 21, CFR 1270 & 1271): This pathway is available for biological tissue derived from human sources considered to be "minimally manipulated". Products that reach the market through the HCT/P process do not require any testing to prove clinical safety or efficacy. However, the manufacturer must meet specific FDA regulations for the collection, processing, and selling of HCT/Ps. Human amniotic membrane and amniotic fluid are included in these regulations. Human-derived tissue considered to be more than minimally manipulated require FDA premarket approval or 510(k) clearance. Refer to the following website for more information: https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products.
- Humanitarian Device Exemption (HDE): The regulatory pathway for products intended for diseases or conditions that affect small populations, or are rare. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm. (Accessed October 24, 2024)

References

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policies, Skin Substitutes, No: 1G-2. https://medicaid.ncdhhs.gov/1g-2-skin-substitutes/download?attachment. Accessed October 24, 2024.

Policy History/Revision Information

Date	Summary of Changes
02/01/2025	• Routine review; no change to coverage guidelines • Archived previous policy version CSNCT0592.08

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.