Provider Partners Health Plans

Medical Coverage Policy

Effective Date 10/7/2024
Next Review Date 10/2025
Policy Number: 26C.002

Biosynthetic Wound Care Products

Overview

This Coverage Policy addresses the use of Biosynthetic wound care products used in the non-healing wounds for Provider Partners Health Plan members.

Instructions for Use

Medical Coverage Policies are reviewed by the Provider Partners Utilization Management Committee (UMC) and provide assistance in interpreting Provider Partners benefit plans. Our medical policies are intended to be used in connection with the independent professional medical judgement of a qualified health care provider. Provider Partners may also use various National and Local Coverage guidelines, Local Coverage Articles as well as the tools developed by third parties, such as the InterQual® criteria, as well as the PPHP specific policies, to assist us in administering health benefits.

Description

This Coverage Policy defines the criteria of medical necessity for coverage of biosynthetic wound care products. Biosynthetic wound care products are used to treat non-healing chronic wounds and to provide a biological foundation for tissue regeneration. These products can be used in various clinical settings, including but not limited to, diabetic ulcers, venous ulcers, pressure ulcers, and burn injuries. This policy outlines the medical necessity criteria for the use of biosynthetic wound care products for Medicare Advantage beneficiaries. The policy aims to ensure that these products are used in appropriate clinical scenarios to improve wound healing, prevent infection, and avoid complications such as amputation or prolonged hospitalization.

Application

This Medical Policy applies to all Provider Partners Health Plans.

Criteria/Coverage Rationale

Biosynthetic wound care products may be considered medically necessary for Medicare Advantage members when the following conditions are met:

Diagnosis: The provider must document a wound diagnosis for which biosynthetic wound care products are indicated: partial- and full-thickness wounds, pressure ulcers, diabetic foot ulcers, venous leg ulcers, burns (particularly partial thickness, surgical wounds, skin graft donor sites, abrasions, and large traumatic wounds where tissue regeneration needs support. The fundamental basis for non-healing of a wound is of paramount importance and must be corrected prior to consideration of additional therapy.

Appropriate treatment prior to consideration of biosynthetic wound care products must include:

a. Control of edema, venous hypertension or lymphedema
b. Control of any nidus of infection or colonization with bacterial or fungal elements
c. Elimination of underlying cellulitis, osteomyelitis, foreign body, or malignant process
d. Appropriate assessment of arterial blood flow to affected area, including, where necessary, comprehensive vascular consultation.
e. Appropriate debridement of necrotic tissue or foreign body (exposed bone or tendon)
f. For diabetic foot ulcers, appropriate non-weight bearing or pressure off-loading.
g. For venous stasis ulcers, compression therapy provided with documented diligent use of multilayer dressings, compression stockings of > 20mmHg pressure, or pneumatic compression.
h. For pressure wounds, adequate off-loading
i. Provision of wound environment to promote healing (protection from trauma and contaminants, elimination of inciting or aggravating processes)
j. Demonstration of adequate nutrition and protein stores to support healing

Failure of Standard Wound Care: The wound must not be healing adequately with traditional or standard wound care measures (e.g., saline or hydrocolloid dressings, compression therapy, antibiotics, etc.), has increased in size or depth, or has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing). Documentation of at least 4 weeks of prior standard care treatment is required.

Wound Characteristics: The wound must meet the following characteristics:

k. Full-thickness or partial-thickness wound
l. Presence of tissue necrosis or significant risk for infection or complications
m. Chronic wounds that have shown no signs of healing despite at least 30 days of appropriate therapy
n. A wound that is expected to benefit from a biosynthetic dressing, such as in cases where there is delayed wound healing, large surface area involvement, or significant tissue loss

Treatment Plan: The wound care treatment plan, including the use of biosynthetic wound care products, must be designed by a licensed healthcare professional and should be part of a comprehensive wound management strategy, including proper nutrition, infection

control, and ongoing monitoring. It is neither reasonable nor medically necessary to continue a given type of wound care in the absence of wound improvement, it is expected that the response a current course of therapy will be documented and reassessed, in the medical record at least once every 30 days for each episode of wound treatment and made available upon request

Specific Product Criteria

Biosynthetic wound care products may be considered medically necessary when they meet the following product-specific criteria:

a. **FDA Approval**: The biosynthetic wound care product must be approved by the U.S. Food and Drug Administration (FDA) for use in wound healing applications.
b. **Clinical Efficacy**: Documentation from clinical trials or scientific evidence must support the use of the product for the specific type of wound the beneficiary is experiencing.
c. **Appropriate Indication**: The product must be used in accordance with the FDA-approved indications or guidelines for use in wound care, as well as professional clinical recommendations.

Documentation Requirements

The following documentation must be provided to justify the medical necessity of biosynthetic wound care products:

a. **Patient History**: A detailed history of the wound, including onset, diagnosis, and any relevant medical conditions (e.g., diabetes, venous insufficiency).
b. **Treatment History**: Documentation of previous wound care treatments, including any failure of traditional wound care measures (e.g., bandages, antibiotics, debridement).
c. **Wound Assessment**: A current wound assessment, including size, depth, stage, and signs of infection or complications.
d. **Physician's or another qualified licensed healthcare professional Treatment Plan**: A comprehensive wound care treatment plan from the treating healthcare provider, detailing the use of the biosynthetic product and expected healing outcomes.

Exclusions

Biosynthetic wound care products will **not** be considered medically necessary under the following conditions:

a. The wound is deemed to be healing or improving with standard treatment methods, and there is no evidence of failure or progression.

b. The wound is classified as a superficial wound that does not meet the medical necessity criteria outlined above.

c. The biosynthetic product is being used for cosmetic purposes or in a non-covered scenario (e.g., for prevention or elective purposes).

d. The wound is non-healing due to patient non-compliance or inability to comply with necessary care, such as failure to follow the prescribed treatment plan.

Definitions

- **Non-healing wound or chronic wounds:** A wound that fails to show evidence of healing by contraction and advancement of epithelial margins following 4 weeks of optimization, including all aspects of standard therapy, is considered a chronic non-healing wound and falls into the auspices of this policy
- **Biosynthetic Wound Care Products:** These products include but are not limited to bioengineered dressings, skin substitutes, and other advanced wound care products that combine synthetic or biological materials to promote wound healing and tissue regeneration.
- **Autografts/tissue cultured autografts:** Include the harvest or application of an autologous skin graft.
- **CTP grafts:** Include non-autologous human cellular and/or tissue products (e.g., dermal or epidermal, cellular and acellular, homograft or allograft), non-human cellular and/or tissue products (i.e., xenograft), and biological products (synthetic or xenogeneic) that are applied in a sheet over an open wound to augment wound closure or skin growth.

Medicare Coverage Determinations

Provider Partners follows the Local Coverage Determination (LCD) noted on the CMS website at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36690&ver=34&

The specific clinical criteria are noted on this link.

Coverage Type	Jurisdiction Medicare Administrative Contractors (MACs)	Determination Name/Number	Revision Effective Date	Applicable States/Territories
NCD	N/A	Not Developed	N/A	
LCD	CGS Administrators, LLC	Wound Care Application of Cellular and/or Tissue	9/5/2024	KY, OH

		Based Products, Lower Extremities (L36690) (A56696). **Will retire 02/11/2025**		

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD= National Coverage Determinations; LCD = Local Coverage Determination
LCA=Local Coverage Article

Coding

https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56696

Policy History/Revision Information

Date	Summary of Changes
02/10/2025	**Revised to reflect the retirement of LCD on 02/11/2025**