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Removal of the Phrase “Usual” with Respect to Frequency of Dressing Changes

Multiple comments noted that removal of the term “usual” with respect to frequency of wound dressings is ambiguous, lacks clarity, and removes a clinician’s ability to use their clinical judgement to provide appropriate wound care - leading to a restriction of coverage. The recommendation was to continue the prior LCD language, specifically by reinstating usage of the term “usual” regarding the frequency of dressing changes.

Response: The statutorily-based coverage requirements regarding the specific types of wounds and sites that are eligible for reimbursement are unchanged in the posted draft policy. Likewise, none of the policy-based criteria pertaining to the choice of dressing were changed in this draft. Removal of the term “usual” does not remove or restrict the use of clinical judgment, but rather serves to clarify utilization parameters by removing ambiguous terminology.

Honey, Silver, Copper and Iodine Dressings are Safe and Efficacious

Multiple comments that there is sufficient evidence that honey, silver, copper and iodine dressings are safe and efficacious, and that the assignment of A4649 to these products ignores FDA approval of these dressings.

Response: The primary action of these substances is widely perceived to be antimicrobial agents. Claims by the manufacturer for direct antimicrobial effect in the wound would require these substances to receive FDA clearance as a drug rather than as a substance included in a surgical dressing. In the 510(k) process the FDA does not directly assess safety and efficacy of individual surgical dressing materials.

Longstanding statutory requirements exclude antiseptics, antimicrobials and numerous other substances from Medicare coverage as surgical dressings. This LCD revision separates dressings that are primarily composed of these non-covered materials from dressings primarily composed of covered material(s) to allow for more precise HCPCS coding and for correct claim processing.

Use of Clinically Predominant Component of a Dressing Instead of the 50% by Weight Classification in the Coding Guidelines Section of the Related Policy Article

Multiple comments were received that the assignment of A4649 to products containing honey should not be based on the weight-based standard, but rather on the clinically predominant component of the product.

Response: The DME MACs appreciate the comments on the coding guideline for multi-component dressings. Coding Guidelines, documentation requirements and non-medical necessity coverage and payment rules contained in the LCD-related Policy Articles are not subject to LCD notice and comment requirements. This information was included in the published draft policy to provide relevant contextual information necessary for complete understanding of the reasonable and necessary provisions in the draft LCD.

Inpatient Facilities Will not be Able to Provide Care to Prevent Pressure Ulcers

Multiple comments were received that skilled nursing facilities (SNFs) and Long Term Care Facilities (LTCs) will not be able to provide needed care to prevent pressure ulcers, thus becoming non-compliant with relevant Surveyor Guidelines to prevent pressure ulcers.

Response: Medicare is a defined benefit program. For any item to be eligible for payment, the item must first be eligible for inclusion into one of the statutorily-established benefit categories. The Medicare Surgical Dressings Benefit provides the definition of covered dressings that are eligible for dressing reimbursement (see CMS Internet Only Manual (IOM), Publication 100-02, *Benefit Policy Manual*, Chapter 15, Section 100). The Surgical Dressings Benefit does not provide coverage of surgical dressings once a wound is healed or for the prevention of pressure ulcers.

In addition, prevention of pressure ulcers involves a multi-factorial approach which includes bedside care such as ensuring adequate nutrition and hydration, frequent repositioning, use of specialized pressure-reducing mattresses, and addressing moisture and continence. These care measures are not impacted by the Surgical Dressing Draft LCD.

The Bibliography was Incomplete and Should be Exhaustive

Several comments were received that stated the bibliography was inadequate since it was not an exhaustive listing of references. Several commenters included references to published articles.

Response: CMS provides guidance to contractors on the development of LCDs in the *Program Integrity Manual* (see CMS IOM 100-08, Chapter 13). CMS does not require that a bibliography be exhaustive, but rather should reflect the relevant articles, clinical guidelines, and other scientific publications which inform the authors when writing LCDs. The revised bibliography section in the final LCD incorporates references cited by commenters, together with an updated literature review.

Mugard® Mucoadhesive Oral Wound Rinse Should be Covered in the Surgical Dressings LCD Because of its Clinical Effectiveness in Treating Oral Mucositis

Multiple comments and testimonial letters were received supporting this was effective in treating oral mucositis and that it should be covered in the surgical dressings LCD.

Response: Oral mucositis is not considered to be a “qualifying wound” under the Medicare Surgical Dressings Benefit. The DME MACs published a Correct Coding and Coverage article entitled “*Oral Suspensions Used in The Treatment of Oral Mucosal Injuries*” on July 20, 2016 which explains the coverage requirements in more detail. The article can be found on the DME MACs web sites.

Coverage of Dressings Should be Based on the Clinical Stage of the Wound

Multiple comments that coverage of surgical dressings should be based on the clinical staging of the wound

Response: Wound staging as a clinical classification tool only applies to pressure ulcers. The Medicare Surgical Dressings Benefit includes surgically-created wounds, surgically- modified wounds, as well as any wound that requires debridement as qualifying wounds. Although pressure ulcers are among the most commonly debrided wounds, there are other wound types such as venous stasis ulcers and arterial insufficiency ulcers that may require surgical intervention and/or debridement. Describing coverage only in terms of pressure ulcer staging would not include these other eligible wound types.

Restricting Usage of Dressings to Stage 3 and 4 Ulcers

Several comments were made that the language regarding foam, collagen, and hydrogel dressings restricted their use to stage 3 and 4 ulcers.

Response: Coverage criteria related to wound staging for foam, collagen, and hydrogel dressings in the draft policy are unchanged from the current long-standing active LCD.

Clarify Language on Recommended Frequency of Dressing Change

One comment was made that the change frequencies of recommended dressing changes should be modified from “the change frequencies of the individual products should be considered and ideally help to extend the wear of the individual dressings.” to instead read “the change frequencies of the individual products should be considered and ideally help to extend the wear-time of the individual products.”

Response: Language in the draft LCD, which is unchanged from the current active LCD, does take into consideration the variance of change frequency among different products. Specifically, the draft LCD states:

“When combinations of primary dressings, secondary dressings, and wound filler are used, the change frequencies of the individual products should be similar. For purposes of this policy, **the product in contact with the wound determines the change frequency**. It is not reasonable and necessary to use a combination of products with differing change intervals.”
[Emphasis added]

Zinc Paste-Impregnated Bandage Coverage Should Align with Clinical Practice, Language Change “Up to Three Times Per Week with Clinically Supportive Documentation”

One comment was received that zinc paste-impregnated bandage coverage should align with clinical practice with recommended language change “up to three times per week with clinically supportive documentation”.

Response: Weekly coverage of wounds using zinc paste-impregnated bandages reflects general frequency changes as per usual clinical practice and manufacturers’ recommendations. For those situations where a greater frequency of dressing changes is necessary, an individual consideration process is available.

The LCD Increases the Administrative Burden on Providers.

Several comments were received that the documentation requirements in the LCD would increase the administrative burden on providers.

Response: Documentation requirements, as described in Section 1833(e) of the Social Security Act, precludes payment to any provider of services unless “there has been furnished such information as may be necessary to determine the amounts due such provider.” The draft LCD does not introduce new requirements nor change any of the long-standing documentation requirements present in the current active LCD.

Use of Compression Bandages and Stockings for Venous Ulcers

Several comments were received that coverage of elastic bandages and compression stockings be available for venous ulcers to prevent recurrence and therapy for lymphedema.

Response: Compression dressings are covered for use on qualified wounds. A venous ulcer that meets the statutory benefit requirements to be classified as a qualifying wound would be eligible for dressing coverage. Compression items used for the treatment of edema often associated with venous ulcers are outside of the scope of the Medicare Surgical Dressings Benefit.

Choice of Secondary Dressing

One comment that the LCD provides no coverage for secondary dressings for minimally draining wounds other than gauze and thin films, which does not follow NPUAP Practice Guidelines

Response: The draft LCD does not introduce new requirements nor change any of the long-standing coverage requirements present in the current active LCD.

Use of HCPCS Codes to Determine Coverage

One comment that the existence or absence of HCPCS codes identify specific products or ingredients in their descriptions is not determinative of coverage and should not be used as such.

Response: We agree. HCPCS codes, by themselves, do not determine coverage. HCPCS codes describe products. These codes are used by payors for billing. Medicare, and other payors, assign their own payment rules and pricing to HCPCS codes to allow for automation during claim processing. When a product is assigned to an existing HCPCS code, it inherits the payor’s payment rules associated with the code.

Documentation Requirements do not Comply with Medicare Program Instructions

One comment that neither the Program Integrity Manual nor all four DME MACs' Supplier Manuals address the need for the order (both detailed and preliminary) or the provider's medical record to specify the size of the dressing. Hence, we request the language requiring "the size of the dressing" under Policy Specific Documentation be removed.

Response: Medicare requires that all items billed must have a prescription before delivery and a detailed order that specifies the item or HCPCS code for the item before billing. Many of the surgical dressing HCPCS codes include long descriptors that specify specific dressing size. Consequently, it is expected the provider's medical record justifies the dressing quantity and sizes, based on the clinical characteristics of the wound

Alternate Methods to Determine the "Clinically Predominant" Component for Multi-Component Products

One comment that there are recognized standardized tests which can be performed to evaluate the clinically predominant component for coding decisions. Offer is given to share their expertise.

Response: The DME MACs are always willing to entertain alternatives to existing policy requirements. Refer to the DME MAC web sites for information about how to request changes.

Note

Since the posting of the Draft LCD, the Open Public Meeting and the Notice-and-Comment period in 2015, a major format change has been made to all DME MAC LCDs. This change involves removing standard documentation language from the LCD and moving the Policy Specific Documentation language to the related Policy Article. The standard documentation information has been moved to a stand-alone article (A55426), which is attached to each LCD. The final version of the Surgical Dressings LCD incorporates these changes to be consistent with other DME MAC LCDs for all 4 DME jurisdictions.