

Suggestions for LCD Region 4 Revisions

General suggestions:

1. "Surgical dressings must be tailored to the specific needs of an individual patient." (LCD , paragraph 1, pg 4/20). This is a salient point, in that the frequency of change of most dressings is hard to time-stamp as multiple factors must be considered. For example, in an outpatient wound clinic, if the wound is not heavily draining and the patient is relatively healthy, a 3 times a week frequency for a primary dressing may be appropriate. In contrast, if the wound is draining large volumes, the same primary dressing may require daily changes in the acute care or long term care environment. Further, the overall status of the individual, the acuity of their illness or illnesses and all the associated comorbidities that can make wound healing a challenge. Regulations for long term care (Guidance to Surveyors, F314) require daily assessment of the wound. Proper assessment involves visual inspection of the wound and periwound. This raises two issues: The LCD states "dressing size must be based on and appropriate to the size of the wound. For wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound..." (LCD, paragraph 9, pg 3/20) In order to effectively view the periwound, which is determined to extend 3-4 cm beyond the wound edge, one must remove the dressing as the periwound is typically covered and not visible when the dressing is in place. The second issue pertains to exudate or drainage. In the LCD (paragraph 11, pg 3/20) it states, "dressing needs may change frequently (e.g., weekly) in the early phases of wound treatment and/or with heavily draining wounds..." The concept of a heavily draining wound has never been quantified and is based exclusively on clinical judgment. However, it is paramount to remove soiled or wet dressings from the wound, because a wet or moist dressing permits bacterial entrance to the wound surface. Therefore, the amount of wound fluid should not be the only qualifier justifying more frequent dressing changes. The frequency of dressing changes should be based upon the clinical decision making of the clinician and/or wound specialist and not on a pre-set time period, nor exclusively predicated on level of exudate or wound fluid. A wound may be dry or desiccated, but based on the clinical presentation of the wound and patient, it may require daily visualization to promote wound healing. Once a wound has been stabilized and a clean, healthy wound bed has been achieved (concurrent with the overall stability of the patient) then less frequent dressing changes may be warranted. Once all nonviable tissue has been removed, and the wound base, edge and periwound are stable, only then is it best practice to reduce dressing change frequency for proper assessment and care planning. Subtle changes must be detected through

assessment to ensure that the proper interventions are being provided given the multitude of challenges an elderly or compromised individual may have; and to address any deleterious changes that can occur due to co-morbid factors such as nutrition/hydration status, associated illnesses and medications, functional and cognitive status. All these factors singularly or jointly can impact, impair and alter the healing process.

2. "An adhesive border is usually more binding than that obtained with separate taping and is therefore indicated for use with wounds requiring less frequent dressing changes." (LCD, paragraph 5, pg 3/20). Technically, this statement is not correct. One must consider the actual adhesive surface area and the type of adhesive being used in the dressing. The only function of an adhesive border is to help secure the dressing in place. Outside of hydrocolloids, most adhesive borders are fairly gentle and these often require picture-framing with tape to ensure proper adherence; particularly in areas on the body subjected to movement, moisture and other sources of wear and tear. Dressings with an adhesive border are very useful to help maintain a dressing in place but they often need additional support to protect the wound bed from the environment as well as from displacement from activity/mobility. Therefore, the method of adhering the dressing should not predicate a specific dressing change frequency.
3. "Use of more than one type of wound filler or more than one type of wound cover in a single wound is rarely medically necessary and the reasons must be well documented..." (LCD, paragraph 6, pg 3/20) This statement does not account for wounds with undermining, tunneling, sinus tracts or deep cavernous cavities where certain fillers would be indicated for those areas and other dressings/covers may be needed for the wound bed/base. For example, Stage III and IV pressure ulcers typically have undermining, tunneling and/or sinus tracts that require certain fillers compared to the wound base which may not need a filler. The determining factor should be the unique etiology, presentation of the wound, safe retraction of packing materials based on tensile strength and dressing decisions based upon those characteristics.
4. "Because composite dressings, foam and hydrocolloid wound covers, and transparent film, when used as secondary dressings, are meant to be changed at frequencies less than daily, appropriate clinical judgment should be used to avoid their use with primary dressings which require more frequent dressing changes. When claims are submitted for these dressings for changes greater than once every other day, the quantity in excess of that amount will be denied as not medically necessary..." (LCD, paragraph 8, pg 3/20) This statement is not consistent with most manufacturer recommendations nor best practice. The basis for this LCD was formulated in 1993 and the field of wound management has not only become more specialized, but evolved exponentially over the past 16 years. This statement may have been adequate 16 years ago when the LCD was

initially drafted, but it is not accurate based upon today's science and clinical understanding of wound management. Further, the combination of a primary and secondary dressing enhances the characteristics of each independent dressing rendering them more effective and better at providing moist wound healing. Primary and secondary dressings should not be considered isolated components, but rather a wound management system. This system is specifically and uniquely designed to accommodate the needs of the wound and that of the resident/patient. This is vital for optimal cellular functioning as well as maintaining normothermia, as chronic wounds are hypothermic. Best practice dictates that secondary dressings should be changed at the same frequency as primary dressings (unless the primary dressing is a contact layer or time dependent antimicrobial dressing). A proper secondary dressing (in combination with an appropriate primary dressing) maintains the proper level of wound moisture for moist wound healing (the standard of care), hastens autolytic debridement, and protects and shields the periwound. The skin is the largest organ of the body and is vital for homeostasis. Dressings assume the role of the skin over an area of altered integrity. Once the dressing has been removed or peeled back, the integrity of the dressing (acting like skin) has been compromised and must be replaced. It is imperative that wounds are evaluated frequently particularly in those individuals who are more compromised. "Evaluation is expected on a more frequent basis (e.g., weekly) in patients in a nursing facility or in patients with heavily draining or infected wounds...This evaluation must include the type of each wound (e.g., surgical wound, pressure ulcer, burn, etc), its location, its size (length x width in cm.) and depth, the amount of drainage, and any other relevant information." (LCD Documentation Requirements Section, paragraph 4, pg 14/20). The elderly, obese, patients with heavily draining wounds or those with critically colonized or infected wounds need more frequent evaluations than once a week. Again, this speaks to the regulations and Guidance for Surveyors (F314 & F309) in long term care. A comprehensive evaluation (as stated above) can occur once a week, but daily assessments of the wound base, wound edge, and periwound must be made to ensure proper healing and to detect subtle changes that could lead to wound deterioration or patient decline. This process involves removing all dressings to adequately view the status of the wound. The need for daily evaluations and dressing changes (with primary and secondary dressing combinations) is also evident when considering the implications of gerontodermatological changes beginning in the 6th decade of life. There are two independent skin aging processes: normal aging which involves the slow irreversible degeneration of tissue, and extrinsic aging which involves photoaging due to exposure from the elements (particularly UV radiation). The combination of normal aging and photo-aging, results in altered wound healing processes due to the progressive loss of skin function, the increased vulnerability to the

external environment, and decreased homeostatic ability of the skin. The physical and histological gerontodermatological changes are termed replicative senescence and involve the following alterations/changes:

- Epithelial and fatty layers become thinner
- Alterations in dermal structures
 - Collagen and elastic fibers shrink 1% per year
 - Elastin in aged dermis presents with disordered morphology
 - Sweat glands decrease in number and size
- Marked reduction in cutaneous blood flow and dermal lymphatic drainage
 - Vessel walls thin
 - Atherosclerotic changes occur in small and large vessels
- Decreased surface contact at basement membrane
- Keratinocytes decrease migration from basal layer by 50%
- Decrease in number and function of antigen-presenting cells

With these changes:

- Oxygen-carbon dioxide exchange decreases
- Cellular turnover slows
- Increase occurrence of ecchymosis
- Inflammatory response decreases
- Tissue regeneration is slower which can delay healing and make tissue more susceptible to infection

(Reddy M. Skin and wound care: Important considerations in the older adult. *Adv Skin Wound Care* 2008;21:424-36.)

The combination of these gerontodermatological changes coupled with compromised skin due to a wound justifies the need for more frequent assessment. Patient/resident's physiologic status, comorbid conditions and immunocompetence must be considered, along with wound status when prescribing dressing change frequencies. . More often than not, a dressing change three times a week is not sufficient, nor is a weekly evaluation. Wound care provided in outpatient clinics cannot be compared to that provided in acute care, long term care or even home health as the needs of the individuals receiving the treatment is too variable. Dressing systems (primary and secondary dressing working together), health status, risk factors, intrinsic and extrinsic factors, nutrition and hydration status, etc., all impact the need for more frequent wound assessment and dressing change frequency. To date, we have a greater understanding of how dressings work and interact with the wound bed, what dressing combinations are most effective, and understand the proper dressing change frequency.

5. “Dressings containing silver are coded based on the other component of the dressings. For example, foam dressings that contain silver are billed using the foam dressing codes. Gauze dressings that contain silver are billed with the non-impregnated gauze dressings codes.” (Policy Article, paragraph 9, pg 5/8). Consider adding a unique modifier for antimicrobial dressings to address or account for each type of antimicrobial agent (e.g. silver, cadexomer iodine, honey, etc.) as this will enable the scientific community to track utilization and begin to provide data on clinical outcomes. Antimicrobial dressings are unique in their characteristics and ability to act on the wound and at the cellular level. It would be prudent to have a unique modifier for this dressing category especially in light of “super bugs” and bacteria of greater virulence. These products are effective at managing bioburden and critical colonization and should be tracked; they should not be “downgraded” to the carrier dressing classification. Having a unique modifier would be invaluable for the scientific and research community in tracking utilization, monitoring outcomes and capturing resistance, toxicity or other unknown long-term effects data.
6. The current version of the LCD does not leave room for the advancement of wound care science. The wound care community has seen a tremendous increase in the variety and variability of dressings well beyond the main dressing categories. Consider adding a section to address unique dressings that do not readily fit into one of the previous general dressing categories. Such dressings could be considered *chimeras* in that they have separate and distinct characteristics rendering them unique; not just the typical dressing categories. This would be particularly advantageous for dressings with multiple components or ingredients. This addresses the following statement: “Products containing multiple materials are categorized according to the clinically predominant component (e.g., alginate, collagen, foam, gauze, hydrocolloid, hydrogel). Other multi-component wound dressings not containing these specified components may be classified as composite or specialty absorptive dressings if the definition of these categories has been met...” (Policy Article, paragraph 8, pg 5/8) For example, some newer dressings have their main component as sterile water yet have very effective active ingredients rendering them more active than a basic hydrogel as the current LCD would have them categorized. These dressings should be based or classified on their clinically predominant active component and not just on the main carrier. These *chimera*-type dressings are being developed and trialed frequently, often with great success in improving healing rates, as well as reducing pain. These type of dressings were not available 16 years ago when the LCD was initially drafted, and they are worthy of individual recognition.
7. When the LCD was first created, skin preps (liquid skin protectant films) were considered incident-to wound management. Over the 16 years, research and anecdotal

evidence has shown their true value beyond "prepping" the skin. Not only do these products protect the skin and assist with its integrity, but skin preps enhance product utilization and performance by enabling adhesive dressings to stay more secure and intact. In clinical practice they have also been found to help preserve fragile skin's integrity and they assist in maintaining stable eschar. Skin preps should be recognized on the LCD as a separate category.

8. With respect to modifiers, A1-A9, a modifier should be added to allow for coding if a primary is actually a pharmaceutical and to designate the cover dressing as a secondary. (Policy Article, paragraph 8, pg 6/8)
9. "Codes for composite dressings without adhesive border (A6200, A6201 and A6202) are invalid for claim submission." (Policy Article, paragraph 5, pg 4/8) This does not make clinical sense in that both bordered and non-bordered composites are widely used and very useful on a variety of wounds and anatomical locations. Having a composite without a border is often warranted especially if the periwound skin is compromised and in certain areas of the body, the borders do not conform adequately to protect the wound base. Eliminating non-bordered composites does not appear to be clinically supported. Multiple manufacturers produce composite dressings in unique shapes tailored for specific anatomical sites. These shapes and the sites to which they are intended do not easily lend themselves to an adhesive border. These require a separate method of affixing the dressing. Eliminating the use of these dressings only because they lack an adhesive border limits the clinician's ability to create an individualized Plan of Care. Non-bordered composites should be included as a tool for the clinician in situations where the patient's overall status, poor skin turgor, skin fragility, pain and wound presentation dictates. This statement should be removed from the LCD Coding Guidelines especially considering that applying this philosophy, all non-bordered dressings would be "at-risk" for invalidation. The wound care community values the atraumatic nature of this dressing category as many factors must be considered when selecting the appropriate dressing for the wound and individual with the wound. The choice between a border or non-border is essential.
10. It is recommended to adopt the updated National Pressure Ulcer Staging Definitions (Feb, 2007) for inclusion within the LCD (Appendices, pg 14/20). In addition, the practice of "reverse staging" or "down staging" a wound should be removed to be consistent with upcoming changes in MDS 3.0 for the long term care arena. Back-staging is neither histologically, nor clinically appropriate. The staging system was created to describe a pressure ulcer based on the anatomy and structures involved. Anatomically and physiologically, an ulcer does not resolve or heal from a Stage IV to Stage III to Stage II to Stage I. The dermis cannot regenerate, therefore in deeper wounds (Stage III, Stage IV and/or full thickness wounds) the defect fills in with scar

tissue. This is not consistent with the original anatomy present; therefore, it is more appropriate to state, “healing Stage IV or resolving Stage IV. Once the area has healed (closed/resurfaced) it is still considered a “closed/resolved/healed Stage IV” or whatever the depth it was determined to be.

The updated pressure ulcer staging definitions are as follows (available at www.npuap.org):

Suspected Deep Tissue Injury:

Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

Stage I:

Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Stage I may be difficult to detect in individuals with dark skin tones. May indicate “at risk” persons (a heralding sign of risk)

Stage II:

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

Presents as a shiny or dry shallow ulcer without slough or bruising.* This stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation.

*Bruising indicates suspected deep tissue injury

Stage III:

Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining or tunneling.

The depth of a stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

Stage IV:

Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.

The depth of a stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and stage III ulcers can be shallow. Stage IV ulcers can extend into muscle and/or supporting structures (e.g. fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.

Unstageable:

Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

Until enough slough or eschar is removed to expose the base of the wound, the true depth, and therefore stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as “the body’s natural (biological) cover” and should not be removed.

Respectfully submitted...

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