ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

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Comments Submitted Electronically to policydmedraft@noridian.com

Re: DMEMAC Draft Surgical Dressings Local Coverage Determination (DL 33831) and Policy Article (A54563)

Dear Dr. Moynihan,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the DMEMAC draft surgical dressing LCD (DL33831) and policy article (A54563). The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of the Alliance member clinical specialty societies and organizations who not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org. Since our members use surgical dressings daily in their practices, we have a vested interest in ensuring that our comments are taken into account by the DMEMAC medical directors as the final coverage determination and policy article are written.

This policy has historical significance for me as the Executive Director of the Alliance since I was fortunate to be asked by Dr. Adrian Oleck, one of the original DMERCs to work with him, IAET (now WOCN) and the NPUAP to help craft the original policy in 1994. We spent a great deal of time to ensure that stakeholders such as clinicians in various sites of service, manufacturers and supplier/distributors were engaged in helping to write the policy so that concerns were addressed and resolved up front before a draft policy was released. The Alliance welcomes a similar opportunity to engage with the DMEMAC medical directors to take advantage of our expertise, which could help resolve some of the concerns we have addressed below.

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GENERAL CONCERNS

The Alliance agrees that after 20 years, it was time for the DMEMAC medical directors to revise the surgical dressing LCD and policy article. With new technologies in the marketplace and clinical practices changing over the years, it is important to recognize these changes and create a policy that reflects them.

However, the Alliance has serious concerns regarding this draft LCD as it is currently written. There are many clinical concerns since it does not conform to current clinical practice, there is a lack of clarity and conflicting language in the policy article and the LCD, leading to confusion of the clinical community. We also believe that the 50% by weight standard for multi-component dressings must be removed from the policy article because it is unsupported by evidence, too complicated to implement, and was inappropriately adopted by a Correct Coding article before this LCD and article were finalized. Finally, as was stated during the public meeting, the bibliography is not complete thus impacting the validity of the draft policy itself.

The Alliance urges the DMEMACs to withdraw the new draft surgical dressing LCD as a result of the issues identified above. We also request to allow us to work with you to craft an alternative LCD based on the current clinical literature and clinical practice.

Our concerns regarding the LCD include but are not limited to:

- Removal of clinical judgment in the LCD language
- New coverage criteria for dressings inappropriately focused on materials not recognized as effective
- New coverage and utilization criteria is ambiguous and inconsistent
- Lack of clarity which leads to confusion
- Lack of a complete bibliography

In addition, we noticed that the utilization parameters included grading scales (i.e. Grade II or IV). Please note that these are related to pressure ulcers. There are various scales/classification systems available to stage pressure, diabetic foot and venous ulcers. However, there is no uniformity amongst providers in ONLY utilizing these systems. One provider may use the University of Texas classification versus the Wagner scale for DFU and another provider in the same practice would use the WiFI scale. We would recommend that these grading scales should be removed as they do not apply to all types of chronic wounds and are not consistently used by all providers. We are happy to discuss this with you at your convenience

Our specific comments follow.

SPECIFIC COMMENTS

REMOVAL OF CLINICAL JUDGMENT IN THE DRAFT LCD LANGUAGE

The Alliance clinical associations believe their first obligation is to their patients and it is important that they have the flexibility to use the wound care products and procedures appropriately to heal their patient's

wound. Typically, their decision to use a product is based on the wound appearance and its characteristics as well as their goals for healing. Clinicians need to have the ability to use their clinical judgment in cases to change the dressing on the wound depending on how it is healing. Therefore, we have concerns that the DMEMACs have substituted the words "may be " with "is" when determining per day dressing changes and eliminated the term "usual" in describing many of the utilization parameters such as in specialty absorptive and transparent film. We request that the term 'usually" be included in the final LCD. Other concerns are noted in the section below on new coverage and utilization criteria.

NEW COVERAGE CRITERIA FOR DRESSINGS IN APPROPRIATELY FOCUSES ON MATERIALS NOT RECOGNIZED AS EFFECTIVE

The Alliance has grave concerns about the language that is used in this section. Our concerns are the following:

1. Clarification of conflicting language in the draft policy and article.

If one compares the language used in both the policy article and the LCD regarding coverage for such ingredients as medical grade honey and silver, it is unclear whether the DMEMACs will cover any dressing which contains them in a multi component dressing if the amount is under 50% by weight.

The language in the LCD states:

> *Dressings containing multiple components are classified based upon the clinically predominant component. Multi-component dressings predominantly comprised of materials not recognized as effective are not considered reasonable and necessary even if there is some minor proportion of effective materials included in the composition of the complete product. Claims for surgical dressings composed predominantly of materials not listed as reimbursable in the policy will be denied as not reasonable and necessary*

Yet the policy article states,

> *Products where a single material comprises greater than 50% (by weight) of a product's composition are coded based upon the applicable specific HCPCS code for that material. If a specific HCPCS code does not exist for the predominant component, HCPCS code A4649 is used*

So, if a multi-component dressing has no component that is greater than 50% by weight, but has an ingredient such as medical-grade honey, silver or other component that is less than 50% but greater than the other components, will these dressings be reimbursed? Furthermore, if a multi-component dressing has an ingredient such as medical grade honey or silver that is less than 50 % by weight, and there is a covered component that is more than 50% by weight, will the dressing be reimbursable? We have had multiple conference calls with our members and other clinicians, and no one has a definitive answer with the language that is used.

2. Draft LCD is putting misplaced emphasis on the safety and effectiveness of the ingredients added to multi-component dressings in an attempt to eliminate existing coverage for these items.

The DMEMAC medical directors' decision to premise its coverage determination on an analysis of the "safety and effectiveness" of the materials that compose a surgical dressing impermissibly shifts the "reasonable and necessary" determination away from the surgical dressing itself—being the covered item, in totality—to ingredients like honey, copper, silver or carbon – the materials that make up some part of the dressing and provide extra benefits beyond the dressing itself. CMS, however, only requires that the surgical dressing, as a completed product, be medically necessary.

The draft LCD's assertion that "materials that lack sufficient clinical evidence are not recognized as effective and are not considered reasonable and necessary," therefore, is statutorily unfounded and immaterial to a coverage determination. No requirement in either the Social Security Act, CMS regulations or the Medicare Policy Manuals states that every material included in an item must be "safe and effective." The focus of Medicare coverage determinations is on the item and not what makes up the item; to evaluate coverage only on the latter, while disregarding the entire product, disregards the very basic simple logic that the whole is greater than the sum of its parts. Indeed, if the DMEMAC medical directors' had examined the surgical dressing in its entirety it would have found that the FDA has already cleared the surgical dressings that contain honey and silver as safe and effective.

CMS has stated that it defers to FDA determinations of safety and effectiveness. However, the DMEMAC medical directors' judged the "safety and effectiveness" of the surgical dressing without ever assessing the dressing as a whole. They have used the materials contained in the surgical dressing as a proxy from which to analyze the surgical dressing itself, concluding that because materials like honey, silver, carbon or copper have not been shown to be safe and effective in their own right, then a surgical dressing containing these materials cannot be safe and effective. The FDA, however, explicitly contradicts the DMEMACs' standard and conclusion, finding that these multi-component surgical dressings, when considered as a whole, are safe and effective for their intended use.

Clinicians choose a surgical dressing based on the function of the whole dressing and how it works together to help in healing a chronic wound. The draft LCD is putting misplaced emphasis on the safety and effectiveness of the ingredients added to multi-component dressings in an attempt to eliminate existing coverage for these items. This shift of focus from an analysis of the item as a whole to independently examining ingredients of a complete and finished item is inconsistent with the scope of CMS's statutory authority as set forth in 42 U.S.C. § 1395y(a)(1)(A). Accordingly, the Alliance submits that the proposed LCD should not and cannot proceed.

3. Both honey impregnated and silver dressings have adequate data to demonstrate clinical evidence to be safe and effective and thus considered as stated in this draft LCD "reasonable and necessary."

As stated above, honey impregnated and silver dressings have been cleared by the FDA as safe and effective. In addition, there is scientific evidence for medical grade honey impregnated dressings that was sent to the PDAC by clinical associations last year which led the PDAC to confirm that the HCPCS codes that these dressings were originally in based on their substrate was correct.

In terms of silver dressings, there have been many published articles, and posters addressing the clinical evidence of these products. These include but are not limited to the following:

- Kotz Paula, Fisher Jane et al, A prospective, multi-center, non-comparative clinical in-market evaluation of adhesive and non-adhesive absorbent 3-layer silver barrier dressings;
- Fife, Caroline, Carter, Marissa et al., A Retrospective Data Analysis of Antimicrobial Dressing Usage in 3084 Patients, *Ostomy Wound Management* 2010; 56(3):28-42
- Jørgensen B, Price P, Andersen KE, et al. The silver-releasing foam dressing, Contreet Foam, promotes faster healing of critically colonised venous leg ulcers: a randomised, controlled trial. *Int Wound J* 2005; 2:64-73.
- Lazareth I, Meaume S, Sigal-Grinberg ML, et al. The role of a silver releasing lipido-colloid contact layer in venous leg ulcers presenting inflammatory signs suggesting a heavy bacteria colonization: results of a randomized controlled study. *Wounds* 2008; 20:158-166.
- Meaume S, Vallet D, Morere MN, Téot L. Evaluation of a silver-releasing hydroalginate dressing in chronic wounds with signs of local infection. *J Wound Care* 2005; 14:411-419.
- Münter KC, Beele H, Russell L, et al. Effect of a sustained silver-releasing dressing on ulcers with delayed healing: the CONTOP study. *J Wound Care* 2006; 15:199-206.
- Jude et al, DFUs, Aquacel vs. Algosteril. Diabet Med 2007;24:280-8.
- Jurczak et al, surgical/traumatic wounds, Aquacel vs povidone-iodine gauze. Int Wound J 2007;4:66-76.
- Wunderlich & Orfanos, VUs, Siax (silver-impregnated activated charcoal) vs. various. Hautarzt 1991; 42:446-50.
- White J et al.The use of a new flexible mesh nanocrystalline silver product over a bilayered tissue-engineered skin substitute. Poster presentation, WOCN, 2012. (n=1)
- Gago, et al.A Comparison of the Effectiveness of Three silver Dressings in the Treatment of Chronic Infected Wounds. Wounds. 2008. Oct., 20(10) 273-283 (n=75)
- Sibbald G, et al.Bacteriology, Inflammation, and Healing: A Study of Nanocrystalline Silver Dressings in Chronic Venous Leg Ulcers. Advances in Skin & Wound Care. 2007. Oct., 549 558. (n=15) Clinical trial
- Sibbald G Screening Evaluation of an Ionized Nanocrystalline Silver Dressing in Chronic Wound Care. OWM.2001;47(10):38-43. (n=29) Case series

4. The 50% by weight standard for multi-component dressings must be removed from the policy article

The Alliance submits that this standard must be removed because it is unsupported by evidence, too complicated to implement, and was inappropriately adopted by a Correct Coding article before this LCD and article were finalized. One of our members, the Coalition of Wound Care Manufacturers, is addressing this issue in detail in its comments and we support their arguments concerning this.

The Alliance clinical association members have used these surgical dressings since they have been on the market and have continued to use them due to the positive results they see in helping to heal their patients' wounds. In fact, as Kara Couch who represented the Alliance at the DMEMAC public meeting stated, " the ability to apply a silver impregnated alginate or honey-impregnated alginate on a wound should be based on

my judgment as a clinician and not dictated by a policy which doesn't allow for appropriate therapy based on some arbitrary designation of components. I don't believe that I have ever given any thought to the "weight" of a product's composition until I read this draft. I have written numerous papers on dressing selection and this is simply not a factor in clinical decision making."

Recommendation: This section should be deleted and the proposed LCD should be rescinded.

NEW COVERAGE AND UTILIZATION CRITERIA IS AMBIGUOUS AND INCONSISTENT

The proposed language is inconsistent in a number of places, leading to restrictive and uncertain guidelines, and possibly prevents any deviation from the LCD even when reasonable and necessary. With the best interest of the patient in mind, there are times that stepping outside of the LCD will lead to the most clinically appropriate avenue of care. The ambiguity and inconsistency with language regarding utilization creates an inability to put the patients' needs first. This limitation will most certainly lead to a marked increase in re-hospitalizations and concerns with care coordination. Specific examples include but are not limited to the following:

ALGINATE OR OTHER FIBER GELLING DRESSING (A6196-A6199):

Language in the Policy: *Alginate or other fiber gelling dressing covers are covered for moderately to highly exudative full thickness wounds (e.g., stage III or IV ulcers); and alginate or other fiber gelling dressing fillers for moderately to highly exudative full thickness wound cavities (e.g., stage III or IV ulcers). They are not necessary on dry wounds or wounds covered with eschar. Dressing change is up to once per day. One wound cover sheet of the approximate size of the wound or up to 2 units of wound filler (1 unit = 6 inches of alginate or other fiber gelling dressing rope) is used at each dressing change*

Issues:

- As a result of the removal of the word 'usual', it appears that there is a limit of dressing changes to one time a day, even with supportive clinical documentation. An example of this clinical support may be copious drainage with 100% strikethrough presented on the dressing, which can create periwound breakdown.

Recommendations:

- Reinstate the word 'usual' so that the policy reads, " Usual dressing change is up to once per day".

COLLAGEN DRESSING OR WOUND FILLER (A6010, A6011, A6021-A6024)

Language in the Policy: ***Collagen Dressing Or Wound Filler (A6010, A6011, A6021-A6024):*** *A collagen-based dressing or wound filler is covered for* ***full thickness*** *wounds (e.g., stage III or IV ulcers) wounds with light to moderate exudate, or wounds that have stalled or have not progressed toward a*

*healing goal. They can **stay in place up to 7 days,** depending on the specific product. Collagen based dressings are not covered for wounds with heavy exudate, third-degree burns, or when an active vasculitis is present*

Issues:

- This is the first time collagen dressings have been described in the surgical dressing LCD.
- This new "category" contains verbiage that is inconsistent from all other primary dressings including language that states, "dressings can stay in place up to 7 days, depending on specific product." The language is unclear from a claim submission standpoint. Does this mean that only 1 collagen dressing can be used in a 7 day period? Our concerns are that there are many manufacturers of collagen dressings and their FDA instructions for use (IFU) range from daily dressing changes to once every 7 days.
- The e.g. stage II or IV ulcers is not complete and provides confusion. There are many wound ulcer classification tools and they are specific to wound ulcer type. For example, Stage III or IV is specific for pressure ulcers and does not classify diabetic foot ulcers which may use a Wagner scale. For a DFU, Wagner 2 is *Ulcers extend into tendon, bone, or capsulea.* When only some of the classification/ staging tools are placed in the policy and are not complete, it causes confusion to the clinical community as well as claims administrators and ALJ when they don't see specific criteria.
- Collagen dressings can be used on all exudate levels, therefore the comment about use on light to moderate exudate levels is not clinically correct.
- There appears to be coverage for this type of dressing only for full thickness wounds when in fact there are other times when these products would be utilized for wounds that are not full thickness wounds and should be covered under these circumstances as well

Recommendations:

- Collagen dressings be covered for both full- and partial-thickness wounds
- Remove the examples for wound stages or place full list of staging options. Please see our general comments regarding staging- There are various scales/classification systems available to stage pressure, diabetic foot and venous ulcers.
- Delete "*They can **stay in place up to 7 days,** depending on the specific product"* and add instead "The frequency of change should be dictated by the condition of the wound and be determined by the physician/health care provider treating the wounds as wound change over the course of time as they go through the healing process. We would like also to discuss with you the possibility of including the term "usual" and perhaps including an utilization parameter for this category.
- Remove the light to moderate exudate comments, or add heavy exudate to the list. Alliance- do you agree?

COMPOSITE DRESSING (A6203-A6205)

Language in the Policy: Composite Dressing (A6203-A6205): *Composite dressings are covered for* ***moderately to highly exudative*** *wounds. Composite dressing change is up to 3 times per week, one wound cover per dressing change.*

Issues:

- The DMEMACs removed the word "usual" and now there are limits with utilization for greater than three times per week, even with supportive clinical documentation.
- There is a new requirement that the wound must present with moderate to high exudate in order to be covered. Often wounds present with minimal drainage and composite dressings are an ideal dressing to use. *Wound Source* states in that the manufacturers' indications for use are: "Composite dressings are indicated for use as either a primary or secondary dressing in the treatment of minimally to heavily draining partial- and full-thickness wounds such as stage I-IV pressure ulcers, dermal ulcers, and surgical incisions
- Composite dressings are covered for moderately to highly exudative wounds, however, the dressing change frequency is up to three times per week. This is contradictory when you are treating a highly exudative wound that typically requires daily dressing changes.

Recommendations:

- Change language to state that composite dressings can be used on wounds with all levels of exudate
- Coverage should be for both full- and partial-thickness wounds
- Keep "usual" with required supplemental documentation

CONTACT LAYER (A6206-A6208)

Language in the Policy: Contact Layer (A6206-A6208): *Contact layer dressings are used to line the entire wound to prevent adhesion of the overlying dressing to the wound. They are* ***not*** *reasonable and necessary* ***when used with any dressing that has a non-adherent or semi-adherent layer as part of the dressing****. They are not intended to be changed with each dressing change. Dressing change is up to once per week.*

Recommendations:

- The definition reads in part that "It has a nonadherent property over the wound site" We seek clarity on what this means—does it mean that there is a nonadherent layer?

FOAM DRESSING OR WOUND FILLER (A6209-A6215)

Language in the Policy: *Foam dressings are covered when used on full thickness wounds (e.g., stage III or IV ulcers) with moderate to heavy exudate. Dressing change for a foam wound cover used as a primary dressing is up to 3 times per week. When a foam wound cover is used as a secondary dressing for wounds*

with very heavy exudate, dressing change is up to 3 times per week. Dressing change for foam wound fillers is up to once per day.

Issues:

- In regards to the sentence, *"When a foam wound cover is used as a secondary dressing for wounds with very heavy exudate, dressing change is up to 3 times per week* - the removal of "may be" and addition of "is" limits the ability to change the foam dressing greater than three times per week. This leads to unclear and ambiguous direction when reasonable and necessary medical needs prove treating a wound with more than a 3 times a week dressing change is needed.

Recommendations

- Add/adapt the language to state that dressing changes may be necessary with required supportive documentation showing medically reasonable and necessary.
- Insert "usual" for a foam wound cover and for a foam wound filler in the sentences above.

GAUZE, IMPREGNATED, WITH OTHER THAN WATER, NORMAL SALINE, HYDROGEL, OR ZINC PASTE (A6222-A6224, A6266)

Language in the Policy: Coverage is based upon the characteristics of the underlying material(s). Dressing change for gauze dressings impregnated with other than water, normal saline, hydrogel or zinc paste is up to once per day.

Issues:

- This wording of "Coverage is based upon the characteristics of the underlying material(s)" could lead to limitations to manufacturers with the creation of dressings and further growth and enhancement to the wound care preventative and healing measures of the future.

Recommendations:

- Although reimbursement categories are based on the materials of the dressing, further clarification of this specific new wording is requested.

HYDROCOLLOID DRESSING (A6234-A6241)

Language in the Policy: *Hydrocolloid dressings are covered for use on wounds with light to moderate exudate. Dressing change for hydrocolloid wound covers or hydrocolloid wound fillers is up to 3 times per week.*

Issues:

- Removal of the word "usual" limits ability beyond 3 times a week. When clinical presentation justifies a need for further use, concerns with substandard care practice is raised.

Recommendations:

- Change the language in the policy from "Dressing change for hydrocolloid wound covers or hydrocolloid wound fillers is up to 3 times per week" to Dressing change for hydrocolloid wound covers or hydrocolloid wound fillers is usually up to 3 times per week.

HYDROGEL DRESSING (A6231-A6233, A6242-A6248)

Language in the Policy: Hydrogel dressings are covered when used on full thickness wounds with minimal or no exudate (e.g., stage III or IV ulcers). Hydrogel dressings are not reasonable and necessary for stage II ulcers. Dressing-change for hydrogel wound covers without adhesive border or hydrogel wound fillers is up to once per day. Dressing change for hydrogel wound covers with adhesive border is up to 3 times per week

Issues:

- By removing of the words "usually medically" and added "reasonable and" for stage II, the new sentence reads that hydrogels are NOT reasonable and necessary for Stage II Ulcers". This raises issues with the inability to provide hydrogels for Partial Thickness (PT)/Stage II wounds. The NPUAP Clinical Guidelines provide contradicting practice guidance.
- PT/Stage II wounds need a moist environment in order to create ideal healing and re-epithelialization, a hydrogel provides this ideal environment. NPUAP Clinical Guidelines in the Wound Dressing for Treatment of Pressure Ulcers suggest "selecting a wound dressing based on ability to keep the wound bed moist."

Recommendations:

- In the sentence, "*Hydrogel dressings are not reasonable and necessary for stage II ulcers",* remove the word "not" to allow hydrogels to be used on all wounds with minimal drainage.

HYDROGEL FILLER

Language in the Policy: *The quantity of hydrogel filler used for each wound must not exceed the amount needed to line the surface of the wound. Additional amounts used to fill a cavity are not reasonable and necessary. Maximum utilization of code A6248 is 3 units (fluid ounces) per wound in 30 days.*

Use of more than one type of hydrogel dressing (filler, cover, or impregnated gauze) on the same wound at the same time is not medically necessary.

Issues:

- This section defines the maximum utilization, providing guidance to clinical teams when determining proper utilization of this product. This is the only product section in which the "maximum" is defined throughout the proposed LCD.
- We question why a maximum is being set for only this surgical dressing category rather than being consistent with the other dressing categories?

- The addition of "is not reasonable" provides a barrier to provide more than 3 ounces when clinical presentation shows this is medically necessary.

Recommendation:

- In the sentence, "Additional amounts used to fill a cavity are not reasonable and necessary", remove "are not reasonable". Thus, the sentence should read as follows: Additional amounts used to fill a cavity can be reasonable and necessary when supportive documentation is provided to justify utilization in excess of 3 units…."

SPECIALTY ABSORPTIVE DRESSING (A6251-A6256)

Language in the Policy: Specialty Absorptive Dressing (A6251-A6256): *Specialty absorptive dressings are covered when used for moderately or highly exudative* ***full thickness wounds*** *(e.g., stage III or IV ulcers). Specialty absorptive dressing change is up to once per day for a dressing without an adhesive border and up to every other day for a dressing with a border*

Issues:

- The removal of "usual" to limit coverage to up to once per day
- Addition of "Full Thickness" excludes utilization for these dressings on partial thickness wounds. There are situations when specialty absorptive dressings are clinically justified for a partial thickness wound. An example of this may be a wound with a diagnosis of a venous etiology with moderate-heavy exudate.

Recommendation:

- The sentence, "*Specialty absorptive dressing change is up to once per day for a dressing without an adhesive border and up to every other day for a dressing with a border"* should be changed to read, "Usually, specialty absorptive dressing change is up to once per day for a dressing without an adhesive border and up to every other day for a dressing with a border
- Since there are clinically justified reasons to use specialty absorptive dressings on partial thickness wounds, recommend deleting full thickness from the sentence "Specialty absorptive dressings are covered when used for moderately or highly exudative full thickness wounds" to read as follows, Specialty absorptive dressings are covered when used for moderately or highly exudative wounds.

TRANSPARENT FILM (A6257-A6259)

Language in the Policy: *Transparent film dressings are covered when used on open partial thickness wounds with minimal exudate or closed wounds. Dressing change is up to 3 times per week*

Issues: The removal of "usual" causes a limitation to provide greater than 3 times a week. This could be a concern if a dressing change of more than 3 times a week is reasonable and necessary.

Recommendations: Usual should be added to the following sentence "*Dressing change is up to 3 times per week"* so it reads, "Usual dressing change is up to 3 times per week"

WOUND FILLER NOT OTHERWISE CLASSIFIED A6261-A6262

Language in the Policy: Coverage is based upon the characteristics of the underlying material(s). Dressing change is up to once per day

Issues:

- This wording could lead to limitations to manufacturers with the creation dressings and further growth and enhancement to the wound care preventative and healing measures of the future.

Recommendation:

- Provide a definition of what is meant by characteristics of the underlying material

ZINC PASTE IMPREGNATED BANDAGE (A6456)

Language in the Policy: *A zinc paste impregnated bandage in covered for the treatment of venous leg ulcers that meet the statutory requirements for a qualifying wound (surgically created or modified, or debrided). Dressing change frequency for A6456 is weekly.*

Claims for A6456 used for treatment of venous insufficiency without a qualifying wound or when used for other non-qualifying conditions will be denied as statutorily non-covered, no benefit. Refer to the related Policy Article Non-Medical Necessity Coverage and Payment Rule for information about the statutory benefit requirements.

Issues:

- The policy limits utilization to one per week

Recommendations:

- Replace the following sentence "*Dressing change frequency for A6456 is weekly"* with the following sentence "Dressing change frequency for A6456 is up to 3 times per week with clinically supportive documentation."

LIGHT COMPRESSION BANDAGE (A6448-A6450), MODERATE/HIGH COMPRESION BANDAGE (A6451, A6452), SELF-ADHERENT BANDAGE (A6453-A6455), CONFORMING BANDAGE (A6442-A6447), PADDING BANDAGE (A6441)

Language in the Policy: *Compression bandages and multi-layer systems are only covered when they are used as a primary or secondary dressing over wound that meet the statutory requirements for a qualifying wound (surgically created or modified, or debrided).*
Claims for compression bandages and multi-layered systems used without a qualifying wound or when used for other non-qualifying conditions will be denied as statutorily non covered, non benefit. Refer to the related Policy Article Non Medical Necessity Coverage and Payment Rules for information about the statutory benefit requirements.

Most compression bandages are reusable. Frequency of replacement would be no more than one per week unless they are part of a multi-layer compression bandage system.

Conforming bandage dressing change is determined by the frequency of change of the selected underlying dressing.

Issues:

- Elasticized bandages included as part of the sustained, graduated compression therapy system are **not reusable**
- For those Medicare beneficiaries who have venous stasis ulcers, even once the wound is healed, compression is still a cornerstone of treatment. So to combat reoccurrence, clinicians still must apply these sustained, graduated compression therapy systems to their patients.
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Recommendation:

- Delete the sentence "most compression bandages are reusable".
- Add "Compression bandages and multi-layered systems are covered for up to 4 weeks after the wound is healed to combat reoccurrence of the wound. Our rationale for this recommendation is that the skin of a newly healed wound is only at 3% of the strength of the surrounding, non-wounded skin. At 3 weeks after closure, the skin is now 30% of its normal strength. Venous ulcers in particular need extra protection of the fragile skin to prevent immediate recurrence of the ulcer. Similarly, plantar diabetic foot ulcers need protection for several weeks after healing. Coverage of multi-layered systems should be covered for up to 4 weeks after the ulcer is healed to prevent recurrence.

DRESSING WITH MATERIALS NOT RECOGNIZED AS EFFECTIVE

The Alliance has grave concerns about the language that is used in this section. Our concerns are expressed in pages 3-5 of this comment letter.

MISCELLANEOUS

Recommendations:

- Within the drafted Miscellaneous section, the proposed LCD states "use of more than one type of wound filler…" removing the verbiage "rarely medically necessary" this results in the inability to provide 2 primaries if clinically justified.
- Recommend keeping "rarely medically necessary" with supportive documentation
- Third paragraph of Miscellaneous section--- the proposed LCD states that the use of more than one type of wound filler or more than one type of wound cover in a single wound is not reasonable and necessary. Further, the stated exceptions to this rule are 2 specific primary dressings (alginates and hydrogels). The inclusion of alginates and hydrogels as primaries. Collagen should be added to the list as an exception. Wound Source's Indications for Collagen state: "Collagen dressings are indicated for use as a primary dressing in the treatment of partial- and full-thickness wounds such as skin grafts,

donor sites, surgical wounds, tunneling wounds, infected and non-infected wounds and wounds with minimal to heavy exudate (depending on the form of the dressing)."

MISCELLANEOUS- "the frequency of recommended dressing changes…"

Language in Policy: *The frequency of recommended dressing changes depends on the type and use of the surgical dressing. 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.*** *For example, it is not reasonable and necessary to use a secondary dressing with a weekly change frequency over a primary dressing with a daily change interval. Such claims will be denied as not reasonable and necessary.*

Issues:

- The frequency of dressing changes does NOT depend on the type and use of the surgical dressing but rather on the wound itself and how it is presented (i.e. – how big is the wound and where is it located, is it a heavy exudating wound etc.).
- This eliminates all options of secondary dressing OTHER THAN GAUZE, based on the other changes proposed in the LCD and gauze is not considered the standard of care

Recommendations:

- Delete the paragraph and add: "Should the frequency of dressing change of the primary dressing be greater than that typically allowed for the secondary dressing, then supportive documentation is required to justify clinical rationale for utilization."

MISSING SITUATION, COMMONLY SEEN:

The LCD provides NO coverage for secondary dressings for minimally draining wounds other than gauze and thin films. Clinically this does not follow the standard of care which is addressed in the NPUAP Practice Guidelines, Gary Sibbald R., et al, Wound Bed Preparation 2012, J.Cutan Med Surg 2013 Oct;17 Suppl 1:S12-22 and Liza Ovington, "Hanging Wet to Dry Out to Dry.

OTHER ISSUE- "Gradient Compression Stockings"

Gradient compression stockings (A6530, A6533-A6544, A6549) --These items have been non-covered under the Medicare program—

Recommendations:

- The use of lower pressure compression stockings to sustain the tissue integrity and vascular flow for patients with venous insufficiency post healing of a venous ulcer to prevent recurrence should be permitted

- These compression stockings need to be covered as an option for clinical treatment of venous wounds.

The Alliance further recognizes that non-clinical aspects of the proposed LCD and Associated Policy Article effect whether or not the DME MACs will deem claims for surgical dressings reasonable and necessary. Many of these non-clinical aspects surround documentation requirements such as, but not limited to, the Detailed Written Order, Policy Specific Documentation Requirements, Refill Requirements, Proof of Delivery, Prescription Requirements, Medical Record Information and Dressing Guidelines. We believe that vague, contradictory, and inconsistent language within the aforementioned sections of the Proposed Draft and Associated Policy Article create confusion for providers and suppliers which will ultimately lead to the submission of deficient claims resulting in delays or elimination of service to Medicare Beneficiaries.

We include specific comments below:

REFILL REQUIREMENTS

The drafted language in the LCD states that billing must be based on prospective, not retrospective use with further instruction for supplies to monitor and adjust based on potentially weekly changes. This creates confusion and questions surrounding how billing should occur prospectively only once per month, but still follow the directives in the LCD.

DOCUMENTATION REQUIRMENTS

Paragraph "Clinical information which….."

- Adds "This information MUST be updated by the treating physician (or the designee) on a monthly basis

  Who qualifies as a designee?-LCD does not define - this is problematic because many facilities do not have a physician documenting on the wounds on a monthly basis. This monthly documentation will be expected with any and all appeals. Facilities will have to change their clinical practices OR the LCD needs to better define who can be 'designated' to perform the monthly evaluations. We would also suggest that instead of physician, the language should be changed to provider so as to include LPN, RN, NP/PA

  "Weekly evaluations are EXPECTED" in nursing facilities. This is problematic because the majority of long term care facilities only document on pressure ulcers. Rarely do they provide supportive documentation or weekly evaluations on non-pressure wounds (such as venous, arterial, and neuropathic ulcers).

BIBLIOGRAPHY

Finally, the Alliance members have reviewed the bibliography and question how the articles support the language in the LCD. In fact, the Alliance suggests that the language in the articles listed in the bibliography is contrary to the position taken by the DMEMAC in this draft. Furthermore, we were surprised to hear at the public meeting that the bibliography was not complete—so we question, how can we legitimately comment on the draft LCD when it is not complete and what is contained in the bibliography is contrary to your position? Again, the incomplete and contradictory bibliography substantiates our request for withdrawal of this draft LCD and our request to work with the Alliance and other stakeholders to craft a more clinically appropriate policy.

CONCLUSION

We therefore respectfully request that implementation of the new LCD be withdrawn pending the opportunity for all stakeholders to provide clinical evidence and expert input. The Alliance stands ready to work with you to craft an LCD that provides needed clarity around criteria and meets the clinical needs of this deserving Medicare population.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director