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July 14, 2017

**VIA ELECTRONIC MAIL**

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**Re: Coalition of Wound Care Manufacturers Urgent Request to Delay Future Local Coverage Determination (LCD): Surgical Dressings (L33831)**

Dear DME MAC Medical Directors:

On behalf of our client, The Coalition of Wound Care Manufacturers (the "Coalition"), we write to strongly urge CGS Administrators, LLC and Noridian Healthcare Solutions, LLC (collectively, the "DME MACs") to delay implementation of the above-captioned Future Local Coverage Determination (the "LCD") beyond its scheduled effective date of July 24, 2017. This delay is critically necessary to meet the existing regulatory requirements of the LCD development process—particularly in light of the LCD standards Congress enacted into law through the 21st Century Cures Act (the "Cures Law") nearly six months before this LCD was published.[1] The new coverage restrictions adopted in the LCD conflict with the weight of published, peer-reviewed evidence, as well as established standards of care recommended by leading clinical societies in wound care. Moreover, the future LCD adopted changes further restricting coverage for certain clinical scenarios without providing for any notice and comment,

[1] *See* 21st Century Cures Act, Pub. L. No. 114-255, tit. IV, § 4009 (2016).

as required by CMS. While the Cures Law requires greater transparency and consideration of clinical evidence when adopting coverage criteria, this LCD process represents the very opposite approach. The clear examples of improper coverage criteria, described below and in Appendix 1, demonstrate the critical need for the DME MACs and CMS to delay implementation of the LCD until the published evidence can be fully considered, and rationales for coverage can be developed. If not delayed, the impact of these actions by the DME MACs and CMS will be profound and harmful to Medicare beneficiaries.

The Coalition's serious concerns with this LCD relate to the negative impact these new, unsupported coverage restrictions will have on beneficiaries, as well as the DME MACs' lack of consideration of stakeholders' recommendations and offers to work collaboratively with the DME MACs on a revised LCD. Instead of working with leading clinicians or responding to stakeholders' concerns, the DME MACs simply rejected every suggestion for a substantive change to, or clarification of, the LCD's coverage criteria—which are exactly the same in the Future LCD as they were in the Draft LCD. This fact, in and of itself, suggests there was some rush to issue this LCD without the necessary consideration and quite possibly in order to try to avoid complying with the Cures Law.

Assuming the DME MACs appropriately determine to delay implementation, the Coalition respectfully requests a meeting with the DME MAC medical directors to discuss these comments and other concerns to arrive at an appropriate policy. As you know, the Coalition represents leading surgical dressings manufacturers and the manufacturers of other wound care products used by Medicare beneficiaries. Historically, the DME MACs have worked more collaboratively with the Coalition, its members, The Alliance for Wound Care Stakeholders, and others, to develop LCDs that are consistent with published evidence and clinical practice. The Coalition, along with these various stakeholders, remain committed to working with the DME MACs to ensure the LCD is based on current evidence and established standards of clinical practice and will allow beneficiaries access to proven wound treatments.

## I. THE FUTURE LCD CONTAINS FLAWED COVERAGE CRITERIA THAT VIOLATE CURRENT MEDICARE REQUIREMENTS AND FAIL TO COMPLY WITH CONGRESSIONAL INTENT.

Despite the clear intent from Congress through the Cures Law that Medicare contractors rely on evidence to support coverage determinations and provide more detailed explanations of those determinations, the Future LCD deviates significantly from the evidence and provides nearly no explanation of why new coverage restrictions were adopted. Even before the Cures Law went into effect, CMS has required Medicare contractors to: (i) base coverage determinations on the strongest evidence available, (ii) provide an opportunity for stakeholders to comment on draft determinations, and (iii) provide responses to those comments.[2] These standards were adopted to ensure coverage criteria are consistent with relevant published evidence and established clinical practices. The failure to abide by them—as here—results in an LCD that includes unsupported coverage criteria that will harm beneficiaries.

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[2] *See* CMS, Program Integrity Manual (PIM), Ch. 13, Sec. 13.7.

### A. The Future LCD should have met the requirements of the Cures Law, but at minimum was required to meet longstanding Medicare requirements.

There have been serious and longstanding concerns (well-known to CMS and the DME MACs) that the Medicare standards identified above were not being followed consistently. In July 2015, the Committee on Energy and Commerce of the U.S. House of Representatives recognized that improvements were needed to the LCD development process and recommended specific statutory provisions to "increase transparency around the LCD process and begin the process of bringing greater accountability to the actions of those contracting with the Centers for Medicare and Medicaid Services."[3] Five months later, Congress took the extremely unusual step of formalizing the LCD development requirements in statute and adopting additional, critically important procedural protections when it passed Section 4009 of the Cures Law. Section 4009 requires Medicare contractors that develop LCDs to provide to stakeholders certain information, including (i) a response to comments submitted to the contractor; (ii) a summary of evidence that was considered by the contractor during the development of the LCD; and (iii) an explanation of the rationale that supports the coverage determination.[4] This new law should have sent a clear message that, at minimum, Medicare contractors must abide by existing CMS requirements. But beyond that, the contractors should have worked immediately to meet the intent if not the actual requirements of the Cures Law, as it was abundantly clear to Congress and the President that there were serious concerns about the manner in which contractors and CMS had been developing LCDs without regard to existing requirements and evidence.

This LCD development process, however, neither complied with the Cures Law nor existing CMS requirements. The LCD does not meet longstanding Medicare requirements that (i) new LCDs that non-cover established clinical practices be supported with "evidence that convincingly refutes" evidence in support of coverage, or (ii) new coverage restrictions go through the notice and comment process. Nor does the LCD meet the Cures Law requirements of providing (i) a summary of evidence that was considered during the development of the LCD, or (ii) an explanation of the rationale that supports the coverage limitations. It is particularly troubling that this LCD was published just a week before the actual effective date of Section 4009 of the Cures Act, though the DME MACs and CMS were on notice months before of the new requirements. There has always been an expectation that the LCD would meet existing Medicare requirements, if not the Cures Law. To issue this deficient and harmful LCD without regard to any of these requirements flies in the face of the prior Medicare requirements and clearly expressed Congressional intent in the Cures Law—all intended to ensure that Medicare beneficiaries receive the care to which they are entitled.

Although the LCD's new coverage criteria raise a wide range of clinical concerns, the new restrictions on coverage for hydrogel, composite, and collagen dressings most clearly demonstrate that the LCD does not comply with applicable evidentiary requirements. Because the new coverage restrictions would eliminate coverage for dressings used in manners consistent with accepted standards of practice, CMS requires the DME MACs to provide "sufficient

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[3] *See* H.R. REP. NO. 114-190, at 127 (2015).

[4] *See* CMS, Program Integrity Manual (PIM), Ch. 13, Sec. 13.7.

evidence to convincingly refute evidence presented in support of coverage."[5] The responses to stakeholder comments fail to address any of the evidence provided by stakeholder comments—or even recognize that the coverage criteria would change under this Future LCD. As discussed above, it critical for the DME MACs to delay implementation of the LCD until the full spectrum of evidence pertaining to hydrogel, collagen, and composite dressings has been reviewed and the Future LCD has been revised to reflect to reflect this evidence.

### B. The LCD would eliminate coverage for hydrogel dressings to treat stage II ulcers, without any evidence or explanation.

The Future LCD departs from the current Surgical Dressings LCD to impose an absolute prohibition on coverage for hydrogel dressings to treat stage II ulcers (ulcers with partial-thickness skin loss and exposed dermis), but provides no explanation of what—if any—evidence was consulted to make that determination. The current Surgical Dressings LCD states, "hydrogel dressings are not usually medically necessary for stage II ulcers," but also confirms that there are situations in which documentation will substantiate the necessity of a hydrogel dressing for a stage II ulcer, such as an ulcer in the sacro-coccygeal area.[6] In contrast, the Draft LCD and Future LCD state "hydrogel dressings are not reasonable and necessary for stage II ulcers," with no allowance for clinical judgment or documentation to support the necessity for use on a stage II ulcer.[7] In response to commenters' strong opposition to this new restriction, the Comments and Response Summary did not acknowledge that anything had even changed, stating: "Coverage criteria related to wound staging for . . . hydrogel dressings in the draft policy are unchanged from the current long-standing LCD."

As demonstrated above, this response is objectively not true. Moreover, the response did not address commenters' concerns or the evidence that demonstrates hydrogels are reasonable and necessary for the treatment of certain stage II ulcers. For example, in July 2013, the Cochrane Library published a systematic review of hydrogel dressings for the treatment of diabetic ulcers ranging from Wagner grade 1 (partial- or full-thickness) to 4 (partial foot gangrene), which concluded, "[b]ased on a comprehensive review of current evidence, hydrogel dressings may be better than basic contact wound dressings at healing non-complex diabetic foot ulcers."[8] The authors also concluded, "[t]here is some evidence to suggest that hydrogel dressings are more effective in healing (lower grade) diabetic foot ulcers than basic wound contact dressings." This information provides evidence supporting the reasonable and necessary use of hydrogel dressings for the treatment of partial-thickness ulcers, which apparently was not reviewed or considered when the LCD adopted this new coverage determination, as it was not cited among the Future LCD's Sources of Information and Basis for Decision.

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[5] *See id.*, Sec. 13.7.1.

[6] *See* DME MACs, *Local Coverage Determination (LCD): Surgical Dressings (L33831)* (eff. June 1, 2016 to July 23, 2017).

[7] *See* DME MACs, *Surgical Dressings Comments and Response Summary* (June 8, 2017) (emphasis added).

[8] *See* Dumville *et al.*, *Hydrogel dressings for healing diabetic foot ulcers (Review)*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS (July 2013).

This evidence is consistent with the FDA-cleared instructions for use of many hydrogel dressings, which are indicated for "[m]aintenance of a moist environment in stages II-IV pressure ulcers" and other wound types.[9] The Future LCD's noncoverage of stage II ulcers would violate CMS evidentiary requirements for determinations that non-cover previously covered items, and accordingly cannot go into effect without further explanation. Additionally, doing so without clear explanation or rationale facially violates the requirements of the Cures Law.

### C. The LCD would adopt coverage restrictions for collagen dressings that conflict with the standard of care and the weight of the evidence.

The Future LCD fails to recognize the weight of the evidence demonstrating that collagen dressings are reasonable and necessary for the treatment of partial thickness wounds and wounds with heavy exudate. Neither the Future LCD's "Sources of Information and Basis of Decision" nor the Comments and Response Summary clarifies the evidence upon which the DME MACs relied to support these coverage criteria for collagen dressings. The absence of such clarification is concerning, particularly where the noncoverage determination conflicts with an array of published evidence demonstrating that collagen-based wound dressings are highly effective for the treatment of various types of wounds—regardless of thickness or exudate level.

For example, a systematic review of 466 papers, published in the journal *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*, found that collagen dressings are effective for both partial- and full-thickness diabetic ulcers without regard to exudate levels. The systematic review demonstrated the strong, peer-reviewed evidence supporting use of collagen dressings for both partial- and full-thickness wounds, regardless of exudate level, and directly conflicts with the Future LCD's coverage restrictions. This data is also consistent with the FDA-cleared instructions for use of many collagen dressings, which are intended for "the management of full and partial thickness wounds" and for "heavily exudating wounds."[10] Moreover, clinical practice recommendations and guidelines confirm that wounds with minimal to heavy exudate may benefit from collagen dressings..[11]

### D. The Future LCD provides no explanation for the new prohibition on the use of composite dressings to treat lightly exudative wounds, despite such use being the standard of care.

The Future LCD also fails to articulate the evidence that could have justified a new restriction on coverage for composite dressings for lightly exudative wounds, even though this

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[9] *See, e.g.*, hollisterwoundcare, *Hydrogel Impregnated Sponge*, available at http://www.hollisterwoundcare.com/files/pdfs/ifus/RestoreImprgSpongeColorBreak.pdf (last visited July 13, 2017).

[10] *See, e.g.*, smith&nephew, *BIOSTEP Ag, Collagen Matrix Dressing with Silver*, available at https://www.smith-nephew.com/global/assets/pdf/products/wound/biostep_ag_patient_insert_pi_02273-a.pdf (last visited July 13, 2017).

[11] *See, e.g.*, What you need to know about collagen wound dressings, WOUND CARE ADVISOR (2013), available at https://woundcareadvisor.com/what-you-need-to-know-about-collagen-wound-dressings/ (last visited July 13, 2017).

restriction is inconsistent with published clinical studies and the standard of care. The current Surgical Dressings LCD provides coverage for composite dressings regardless of the exudate level of the wound. Where both Medicare policy and clinicians have recognized that composite dressings are reasonable and necessary to treat wounds regardless of exudate levels, composite dressings have become the standard of care for wounds with light, medium, and heavy exudate levels. For example, the Association for the Advancement of Wound Care (AAWC), a non-profit multidisciplinary organization dedicated to the research and clinical application of evidence-based wound care, has published Venous Ulcer Guidelines that specifically recommend clinicians use composite dressings for wounds with excess exudate.[12] Without an explanation of the evidence supporting this new coverage restriction that would overturn the current standard of care, the LCD cannot adopt such a prohibition.

## II. THE FUTURE LCD ADOPTS NEW COVERAGE RESTRICTIONS WITHOUT COMPLYING WITH THE REQUIRED NOTICE AND COMMENT PERIODS.

Beyond the evidentiary concerns summarized above, a procedural discrepancy must delay the implementation of the Future LCD. The CMS Program Integrity Manual requires contractors to provide both a comment period and a notice period to revise LCDs to restrict existing LCDs.[13] Between the publication of the Draft LCD and the Future LCD, the description of wound staging was materially revised in a way that impacts coverage, without any opportunity for stakeholders to review the change and provide comments. The staging descriptions included in the Appendix to the current LCD differs substantially from the Future LCD, particularly in the descriptions of stage II and stage III ulcers. Most relevantly, the current LCD's definitions of "stage II" and "stage III" ulcers consider some ulcers without exposed fat "stage III" ulcers when there is full-thickness tissue loss. The Future LCD, in contrast, would deem all ulcers without exposed fat "stage II" ulcers. This distinction leads to a difference in coverage, since the Future LCD will not cover hydrogel dressings applied to stage II ulcers.

This restriction was not included in the Draft LCD, which contained the same ulcer staging definitions as the current LCD. Obtaining stakeholder input on a change of this magnitude is particularly critical when clinical consensus has not yet been reached on the new staging criteria included in the Future LCD. As such, because the Future LCD includes provisions that restrict coverage compared to an existing LCD, and the provisions were not included in the Draft LCD, the Future LCD must be delayed until the necessary notice and comment has been allowed for this coverage restriction.[14]

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[12] *See* AAWC, *Venous Ulcer Guideline* (Feb. 11, 2014), available at https://aawconline.org/wp-content/uploads/2015/11/AAWC-Venous-Ulcer-Guideline-Update-Algorithm-v28-updated-11Feb2014.pdf (last visited July 13, 2017).

[13] *See* CMS, PIM, Ch. 13, Sec. 13.7.2.

[14] *See id.* (requiring contractors to provide both a comment period and a notice period for revised LCDs that restrict existing LCDs).

## III. CONCLUSION

The Future LCD restricts coverage for surgical dressings in circumstances when the dressings are standard care for certain wound types, yet it fails to provide discussion of the evidence that would convincingly refute evidence that supports coverage in these circumstances. The Future LCD would also impose restrictions on coverage for surgical dressings without providing a notice and comment opportunity to the public. The apparently rushed publication of the Future LCD before the effective date of the 21st Century Cures Act seems to have caused these substantive and procedural deficiencies, which we believe must be resolved before the Future LCD becomes effective. The Coalition is prepared and willing to collaborate with the DME MACs in their evidentiary review and in revising the Future LCD for consistency with the strongest available evidence, but until that occurs, the implementation of the LCD must be delayed.

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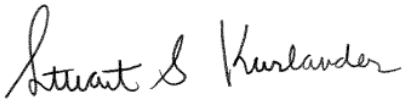
We appreciate your consideration of this very important matter and, for the reasons stated above, urge the DME MACs to delay implementation of the Future LCD. Please do not hesitate to contact us if we can offer any additional information.

Sincerely,



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