June 5, 2018

Dr. Robert Kettler
Medical Director
WPSIC
1717 W. Broadway
Madison, WI 53701-1787

Re: Clarification on WPS Wound Care LCD

Dear Dr. Kettler:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am submitting this letter to obtain clarification on various issues that are included in the WPS Wound Care LCD that was effective on April 16, 2018. 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 chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) through effective advocacy and educational outreach in the regulatory, legislative, and public arenas.

The Alliance submitted comments to WPS on the proposed Wound Care Policy on June 22, 2017. While we appreciate that WPS did adopt several of our recommendations, the Alliance still has significant concerns with some of the language contained in the final LCD – including clinically incorrect statements. Those issues will be addressed separately. For the purposes of this letter, we are reaching out to WPS in order to obtain clarification on the following items included in the WPS Wound Care LCD (effective on 4/16/2018):

1. WPS has removed debridement coverage for chronic non pressure ulcers when the severity is classified as "limited to breakdown of skin". The CPT® manual describes 97597 as the appropriate code to utilize when only epidermis and/or dermis are debrided. This WPS change is contradictory to the definition and goals of debridement included in the Coverage Indication, Limitations and/or Medical Necessity section of the Wound Care LCD which states:

> *"Debridement is defined as the removal of foreign material and/or devitalized or contaminated tissue from or adjacent to a traumatic or infected wound until surrounding healthy tissue is exposed. This LCD applies to debridement of localized areas such as wounds and ulcers."*

Since the LCD states that a debridement is proper for "the removal of foreign material and/or devitalized or contaminated tissue from or adjacent to a traumatic or infected wound until surrounding healthy tissue is exposed", CPT code 97597 and 97598 would be used to remove devitalized tissue from the dermis or epidermis level. However, WPS is instructing that providers bill an E/M code when the severity is classified "as limited to breakdown of skin". We are seeking clarification as to why WPS would go against common coding and billing practice. It is our understanding that physicians and hospitals should code procedures to the most specific

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codes which in this case would be 97597 and 97598, if the ulcers are greater than 20 sq.cm. While the Alliance requests that WPS allow debridement coverage (CPT code 97597/97598) for chronic non pressure ulcers with a tissue severity of limited to breakdown of skin (this coverage is consistent with all other Medicare Administrative Contractors (MACs) and other 3rd party payers (commercial insurance companies), we are also seeking clarification. If a physician removed the necrotic tissue – they can no longer bill an open wound (97597 /97598) debridement. So is it is permissible for the provider and the hospital to bill the appropriate level of E/M (per their documentation) so they can receive reimbursement for the services rendered during the patient encounter? Or will WPS modify the policy to be consistent with the other MACs and commercial insurance companies by allowing debridement coverage for chronic non pressure ulcers with a tissue severity of limited to breakdown of skin and permitting physicians and hospitals to bill CPT 97597/98?

2. WPS identifies conditions which must be present and documented in order for a debridement to be covered. The policy states:

"At least ONE of the following conditions must be present and documented:

- Pressure ulcers, Stage III or IV,
- Venous or arterial insufficiency ulcers,
- Dehiscenced wounds,
- Wounds with exposed hardware or bone,
- Neuropathic ulcers,
- Neuroischaemic ulcers,
- Complications of surgically created or traumatic wound where accelerated granulation

The Alliance is seeking clarification as to whether diabetic ulcers are in fact covered under this policy as one of the conditions that must be present for a debridement to be performed. The list identified includes neuropathic and neuroischemic ulcers, but does not identify diabetic ulcers. Yet, in WPS's LCD response to comments, its comment #16 states that the inclusion of neuropathic and neuroischemic ulcer includes the category of diabetic ulcer. This is causing confusion as the actual LCD does not include diabetic ulcers as a condition which is present in order to have a debridement performed, yet the response to comments does include diabetic ulcers. Also, neuropathic and/or neuroischemic ulcers do not capture all types of diabetic ulcers (e.g. an infected diabetic ulcer without neuropathy or ischemia). **Diabetics are the great masqueraders of infection and many times do not elicit systemic signs or symptoms. Many times it is an elevated blood sugar that herald a limb or life threatening infection and timely debridement is mandatory. Debridement may not be a single event in the diabetic but to limit or not stress the importance of early and aggressive diabetic debridement of any problematic wound carries serious risk including death for diabetic patients.** (References to support this statement have been provided below). The Alliance maintains that the policy should list diabetic ulcers as one of the covered diagnosis for a debridement as they are the most prevalent diagnosis and especially since it appears that WPS intends to cover them based on the response provided. Thus, the Alliance is seeking clarification as to whether diabetic ulcers are covered under this LCD as one of the conditions that must be present for a debridement to be performed.

Furthermore, as we stated in our comments, there are 1,747 distinct ICD-10 diagnosis codes of wounds and ulcers that require debridement. To limit the conditions that must be present in order for a clinician to be permitted to perform a debridement is clinically unsound and unreasonable. A patient who requires a

debridement of a wound does not always have one of the conditions present that WPS has identified in this LCD. There are many other conditions that should be included in this list including but not limited to the following:

- Necrotizing Fasciitis
- Osteomyelitis
- Pyoderma Gangrenosum
- Ischemic ulcers secondary to Sickle Cell Anemia
- Burns
- Vasculitic ulcers
- Deep Tissue Injury
- Diabetic Foot Ulcers

We request that WPS clarifies why these have been left off the list of conditions which must be met. In addition, we request whether it would be permissible for the provider and the hospital to bill the appropriate level of E/M (per their documentation) so they can receive reimbursement for the services rendered during the patient encounter should a debridement be performed on a condition not included on this list?

Finally, we recommend that WPS provide guidance that is consistent with Novitas JL and JH and the FCSO Wound Care LCDs which state the following: "It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted. No procedure code to diagnosis code limitations are being established at this time."

3. The LCD states: "Removal of fibrinous material from the margin of an ulcer." The Alliance could not find a clear and concise definition for the terms "fibrinous material". As such, we would like to request that WPS provide their definition of "fibrinous material." Furthermore, the Alliance is also seeking guidance on what happens if fibrinous material is removed from the wound bed? The LCD does not list that as an exception and as such, we assume that it is covered as a debridement. It appears that the WPS policy is limiting non-coverage to the margin only. The Alliance would like to seek not only clarification on this issue but WPS rationale for that limitation.

4. We are very concerned about the provisions related to Negative Pressure Wound Therapy – and are seeking clarification on a number of issues within this section of the policy.

First, WPS states that "the coverage of traditional Negative Pressure Wound Therapy (NPWT) device/unit/type, or supplies is covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)), and providers should consult their DME LCD for specific coverage, parameters, and guidelines". However, in the utilization parameters, WPS goes on to limit the utilization of NPWT. Specifically, the language in the policy reads, "Negative pressure wound therapy services should not exceed a 120 day period. There should be no more than 4 dressing changes per wound per month for the majority of wounds." So, should the provider look to the DMEMAC LCD or the WPS LCD for the coverage and utilization parameters? This is confusing and contradictory. The Alliance would request clarification on this issue.

Furthermore, the Alliance is seeking clarification as to how WPS arrived at the utilization parameters for dressing changes and whether the parameters identified are for traditional versus disposable NPWT. It is not

clear from the policy or the response provided as to why WPS limited the dressing change to 4 dressing changes per wound per month when clearly in the response to comments WPS lists A6550 – 15 dressing changes per wound per month (which is appropriate). We are very concerned about the utilization limitation as it appears that the statement in the WPS policy is:

- Contrary to the FDA label guidelines for NPWT,
- Confusing as to whether the DMEMAC or WPS policy should be adhered to
- Contradicts the WPS response to comments, and
- Contrary to best practices.

5. The Alliance is seeking clarification as to whether it was intended that the following list of ICD-10 codes were missing from the list of codes identified in the LCD that support medical necessity for Postthrombotic syndrome with ulcer and inflammation and chronic venous hypertension:

I87.031 Postthrombotic syndrome with ulcer and inflammation of right lower extremity
I87.032 Postthrombotic syndrome with ulcer and inflammation of left lower extremity
I87.033 Postthrombotic syndrome with ulcer and inflammation of bilateral lower extremity
I87.311 Chronic venous hypertension (idiopathic) with ulcer of right lower extremity
I87.312 Chronic venous hypertension (idiopathic) with ulcer of left lower extremity
I87.313 Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity
I87.331 Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity
I87.332 Chronic venous hypertension (idiopathic) with ulcer and inflammation of left lower extremity
I87.333 Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity

These codes are necessary since Medicare beneficiaries with these conditions may require debridements. These ICD-10 codes are included in the Noridian and CGS Debridement/Wound Care LCDs. NGS, Novitas and FCSO Wound Care LCDs do not provide a list of ICD-10 codes that support medical necessity and ICD-10 code limitations. Novitas and FCSO state the following in their LCD: "It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted. No procedure code to diagnosis code limitations are being established at this time."

If WPS did not intend for the codes to be left off, then the Alliance requests that WPS place those codes in the policy. If it was intended, the Alliance would like to know the rationale for leaving them off the list.

6. The LCD states the following:

The following services may be done during wound care services and can be medically necessary, but they are not considered wound debridement services and wound debridement CPT codes should not be used.

- *Removal of necrotic tissue by cleansing, scraping (other than by a scalpel or a curette), chemical application, or wet to dry or dry to dry dressing. Generally, dressing changes are not considered a*

skilled service. The prior dressings are different and distinct from wet to moist dressings that are used for removal of devitalized tissue from wound(s) for non-selective debridement

- *Removal of non-tissue integrated fibrin exudates, crusts, biofilms or other materials from a wound without removal of tissue does not meet the definition of any debridement code and may not be reported as such*

The Alliance is concerned that WPS has stated that certain things are not considered wound debridement services and therefore wound debridement CPT codes should not be used when the CPT descriptor clearly lists those items. Therefore we are seeking clarity on the following:

CPT 97597 states, *"Debridement (e.g. high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel, and forceps), open wound (e.g. fibrin, devitalized epidermis and/or dermis exudate, debris, biofilm) including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq. cm or less."*

WPS states that fibrin is not covered for a debridement when it is clearly listed in the code descriptor. We request clarification if leaving fibrin out of the policy was intended? If it was not intended that fibrin was left out, the Alliance requests that WPS place fibrin back in the policy so to adhere to the CPT code descriptor. If it was intended to leave fibrin out, again, the Alliance would like to know the rationale for WPS not adhering to the CPT code descriptor language.

Similarly, 97597 clearly lists scissors and forceps when selective debridement is performed, yet WPS limits the removal of necrotic tissue to a scalpel or curette. Again, we would request that WPS clarify if it was intended to leave these out of the policy. If not intended that scissors and forceps were left out, the Alliance requests that WPS place scissors and forceps back in the policy so the language reads, "*Removal of necrotic tissue by cleansing, scraping (other than by a scalpel, a curette or scissors or forceps)."* If it was intended, the Alliance requests the rationale for leaving them off the list.

The Alliance recommends that WPS revise this policy so that it is consistent with the CPT code descriptors so as to not cause confusion in the clinical community.

We would appreciate a response from WPS so that we can provide clarity to our members. We would be pleased to speak with you about this if we can answer any questions.

Thank you so much.

Sincerely,

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Alliance of Wound Care Stakeholders
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Diabetic Foot Ulcer References

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