ALLIANCE OF
Wound
Care
Stakeholders

February 24, 2010

Paul Deutsch, MD
Contractor Medical Director
National Government Services, Inc.
P.O. Box 4767
Syracuse, New York 13221-4767

Sent Via Email to lmrpcomment@empireblue.com

RE: DL27373 – Debridement Services

Dear Dr. Deutsch:

I am the Executive Director of the Alliance of Wound Care Stakeholders ("Alliance"), a multidisciplinary consortium of over 15 physician, clinical, provider, manufacturer and patient organizations whose mission it is to promote quality care and patient access to wound care products and services.

On behalf of the Alliance, I am pleased to submit the following comments in response to the National Government Services (NGS) draft local coverage determination (LCD) for Debridement Services – DL27373. This LCD will have a major impact on our Alliance organizations and as such appreciate the opportunity to offer our comments. Furthermore, as NGS finalizes its LCD on debridement services, we would like to offer the Alliance as a resource to you and your staff due to our expertise in this subject. We have provided our comments below.

GENERAL COMMENTS

It appears that NGS has not included any physical therapy related codes in this policy. Given that there are several CPT codes related to debridement in the outpatient physical therapy and occupational therapy services of the code, – 97597, 97598, 97602 – and we question why NGS would leave these codes out of the policy. It appears that this LCD provides the coverage criteria for surgical debridement, and as such the Alliance requests that NGS include language that refers to providers, including physical therapists, who perform non-surgical debridement, such as selective and non-selective debridement as part of wound care management, to the Outpatient Physical and Occupational Therapy Services LCD.

RECOMMENDATIONS: The Alliance recommends that NGS address other providers who perform non surgical debridements. Specifically, we recommend that NGS insert

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the following language into the policy prior to becoming final: "This LCD does not apply to debridement of burned surfaces. For debridement of burned surfaces CPT codes 16000-16036 apply. Regulations concerning the use of these codes are not addressed in this LCD. This LCD does not apply to debridement of nails and the provider is referred to NGS LCD Routine Foot Care and Debridement of Nails (L26426). This LCD does not apply to debridement performed by physical or occupational therapists. For debridement performed by physical or occupational therapists, please use CPT codes 97597, 97598, and 97602. Providers should refer to NGS LCD for Outpatient Physical and Occupational Services (L26884). "

SPECIFIC COMMENTS

INDICATIONS

Under the indications section, the draft policy states, "*Debridements of the wound(s), if indicated, must be performed judiciously and at appropriate intervals. It is expected that, with appropriate care, wound volume or surface dimension should decrease by at least 10 percent per month or wounds will demonstrate margin advancement of no less than 1 mm/week. It is also expected the wound care treatment plan is modified in the event that appropriate healing is not achieved."*

COMMENT: The Alliance has significant concerns with the wording in this section. There is no specific set standard of care that supports either the statement – "that the wound should decrease by at least 10 per cent per month", OR "that wounds will demonstrate a margin of advancement of no less than 1 mm/week" due to the following rationale:

Wounds will not heal 1mm/wk in the initial 30 day time frame. The wound is within the inflammatory and early proliferative phase of healing at this time frame and much of the improvement is at the biochemical and cellular level and not measurable at the macroscopic level. Margin migration will not occur until a wound is fully granulated (depth fully eliminated) and epithelial migration can proceed. Surface area can reduce at this early time frame but it is secondary to contraction which can be asymmetrical and difficult to measure as described in the policy. Furthermore, the 1 mm/wk does not take into account the initial size of the wound, nor its anatomical or physiological location.

As providers, clinicians and researchers, we are not aware of any evidence that would support either the statement "with appropriate care, wound volume or surface dimension will demonstrate advancement of no less than 1mm/week" or that "with appropriate care, wound volume or surface dimension should decrease by at least 10 per cent per month" and do not believe that it is appropriate for a value to be arbitrarily established absent scientific evidence to support it.

There are a variety of factors that determine the rate of closure for patients. These factors vary based on, but not limited to, the type, size and location of the wound and presence of co-morbidities. As such, the Alliance believes that while there are specific measureable

changes that can be utilized for wound healing, specific values should not be utilized – especially when they are arbitrarily established.

RECOMMENDATIONS: The Alliance would like to reiterate our objections to the use of value to determine wound healing. As such, the Alliance recommends that NGS remove any references to value within the indications portion of the policy. 1 mm/wk and 10 per cent per month should be deleted.

The Alliance recommends that the sentence be modified to read, "Debridements of the wound(s) if indicated must be performed judiciously and at appropriate intervals. It is expected that, with appropriate care, and no extenuating medical or surgical complications or setbacks, wound volume or surface dimension should decrease overtime. It is also expected the wound care treatment plan is modified in the event that appropriate healing is not achieved".

If NGS should decide to include a value, then the Alliance would like to recommend the following language, "It is expected that, with the appropriate care, and no extenuating medical or surgical complications or setbacks, wound volume or surface dimension should generally decrease by 10 percent per month". If NGS decides to include this language, the Alliance would like to request that NGS provide the standards of care and the studies that were utilized for the basis of this arbitrary value.

LIMITATIONS

The draft policy states, "skin breakdown under a dorsal corn is not considered an ulcer and generally does not require debridement. These lesions typically heal without significant surgical interventions beyond removal of the corn and shoe modification".

COMMENTS: The Alliance disagrees with the statement made above. Specifically, having a dorsal "corn" in and of itself would not require debridement. However, once, as the policy states, there is "skin breakdown under a dorsal corn" – it is no longer just a "corn". Once there is skin breakdown, it becomes an ulcer. Many patients have an abscess which require debridement, local lavage and systemic and/or topical antibiotics and wound care. Many patients' ulcers begin as hyperkeratosis and eventually cause deep tissue necrosis resulting in wounds where the apoeneurosis are exposed. As such, the Alliance believes that the statement made in the policy is inaccurate and should be removed.

RECOMMENDATION: The Alliance recommends that this language be deleted from the policy as once there is skin breakdown, a dorsal corn is considered an ulcer and may require debridement.

OTHER COMMENTS

The Alliance would like to clarify language placed in this policy. Specifically, the NGS draft policy states, *"bill type codes only apply to providers who bill these services to the*

fiscal intermediary or Part A MAC. Bill type codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier or Part B MAC".

For clarification purposes, we ask if the policy was referring to codes 97597, 97598 and 97602? If so, then the Alliance would like to recommend that the policy be modified so as the sentence would be read as follows: " bill type codes (97597, 97598 and 976092) only apply to providers who bill these services to the fiscal intermediaries or Part A MAC."

BILL TYPE CODES

Under the Bill Type Codes section, the Alliance would like to point out that two provider types are missing from the list of Bill Types identified by NGS. Specifically, 75x – Clinic – CORF and 83x – Special facility or ASC surgery – ambulatory surgical center. RECOMMENDATION: The Alliance would recommend that provider types 75x and 83x be added to the list as debridement services do occur in these facilities.

CPT CODES

The Alliance would like to point out that CPT codes 97597 and 97598 were left out of your debridement policy. As such, CPT code 97597 and 97598 are used to report selective debridement and should be included in your policy for wound debridement. The CPT code definition for CPT 97597 is: Removal of devitalized tissue from wound(s), selective debridement, without anesthesia (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel, and forceps), with or without topical application(s), wound assessment, and instruction(s) for ongoing care, may include use of a whirlpool, per session; total wound(s) surface area <20 cm2. The definition for 97598 is: Removal of devitalized tissue from wound(s), selective debridement, without anesthesia (e.g., high pressure waterjet with/without suction, sharp selective debridement, with scissors, scalpel and forceps), with or without topical application(s), wound assessment, and instruction(s) for ongoing care, may include use of a whirlpool, per session; total wound(s) surface area >20 cm2.

RECOMMENDATION: The Alliance recommends that NGS insert CPT codes 97597 and 97598 into the debridement policy before it becomes final.

ICD-9 CODES

The Alliance would like to point out that a few appropriate ICD-9 codes were left out of the draft policy. Specifically, 680.0 -680.9, 682.0 – 682.9, 686.8, 729.6, 729.90 – 729.99 and 996.52

RECOMMENDATION: The Alliance recommends that you modify your list of ICD-9 codes so that 680.0 -680.9, 682.0 – 682.9, 686.8, 729.6, 729.90 – 729.99 and 996.52 are added to your policy prior to it becoming final.

DOCUMENTATION

The Alliance has concerns with the sentences, *"photographic documentation of wounds immediately before and after debridement is recommended for prolonged or repetitive debridement services (especially those that exceed five debridements per wound). Photographic documentation is required for payment of more than five extensive debridement (beyond skin and subcutaneous tissue) (CPT code 11043 and/or 11044) per wound"*.

COMMENT: The Alliance has several concerns with the wording in this section. First of all, the sentences seem to be conflicting. In one sentence, NGS is recommending photographic documentation, and then in the next proceeds to require it for payment. This is contradictory. The Alliance believes that you should recommend photographic documentation but not require it. It is too costly for providers to take photographs on wound both before and after debridement. Unless Medicare is willing to increase the RVU amount, this should not be a requirement. Providers already are documenting medical necessity as a requirement for payment. Requiring photographs is too extreme and costly. Additionally, the Alliance believes that recommending photographs immediately before and after the debridement is excessive - one or the other should suffice. Finally, the policy fails to acknowledge other clinically accepted methods for measuring wounds.

RECOMMENDATIONS: The Alliance recommends that the sentence be modified to read, "Photographic documentation of wounds either immediately before or immediately after debridement is recommended for prolonged or repetitive debridement services (especially those that exceed 5 debridements per wound).

UTILIZATION

Under the Utilization Guidelines, NGS draft language states, *"Coverage will be extended for up to five surgical debridements, CPT code 11043 and/or 11044, per patient, per year. Services which exceed the fifth surgical debridement, CPT code 11043 and/or 11044, per patient, per year, will be payable only upon medical review of records that demonstrates the reasonableness and medical necessity."*

COMMENT: While the Alliance understands the need for NGS to put utilization guidelines in place, we do not agree that the five surgical debridements should be limited to "five surgical debridements per patient, per year". Many patients have multiple wounds and therefore the limitation stated is not acceptable unless the wording can be modified to state, "per patient, per year, per wound". Should this modification be made, the Alliance agrees with the language provided above as it applies to a patient with a chronic wound being treated in an outpatient setting.

The Alliance would also like to point out that in most local coverage policies, the contractor language suggests that when services exceed the fifth surgical debridement,

medical records may be requested to ensure medical necessity. It is unusual to mandate medical review once a limitation has been reached, barring abuse. It seems excessive – and expensive – to review every case of surgical debridement after the fifth surgical debridement – especially when medical necessity and general documentation is kept in the patient files.

RECOMMENDATION: The Alliance recommends that the language above be modified to read, " For patients with chronic wounds being treated in an outpatient setting, services beyond the fifth surgical debridement, CPT Code 11043 and/or 11044, per patient, per year, per wound may require a medical review of records demonstrating the medical reasonableness and necessity".

CONCLUSION

The Alliance appreciates the opportunity to provide NGS with our comments on the draft LCD for debridement services. As stated earlier in our comments, due to the diversity of organizations with wound care knowledge and experience who comprise the Alliance, we would be pleased to serve as a resource to you now or in the future. We look forward to working with you as you finalize this policy. If you have any questions, or would like further additional information, please feel free to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director