ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

March 9, 2017

FCSO
Medical Policy
532 Riverside Ave
ROC 19T
Jacksonville, FL 32202

Submitted Electronically to Medical.Policy@fcso.com

RE: Draft LCD – Wound Care (DL37166)

Dear Dr. Corcoran,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to First Coast Service Option Solutions ("FCSO") draft LCD on "Wound Care." 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 practice of wound care is not limited to one particular medical specialty---instead, many different specialists treat patients with chronic wounds. These practitioners include but are not limited to the following: surgeons (e.g. vascular surgeons, plastic surgeons, and foot and ankle surgeons), vascular medicine physicians, podiatrists, phlebologists, nurse practitioners, physical therapists, nurses, registered dietician nutritionists, and primary care physicians who are in the full time practice of managing patients with wounds.

Our comments were written with the advice of Alliance physician medical specialty societies and clinical specialty societies whose members include wound care physicians and clinicians who possess expert knowledge in complex chronic wounds and in wound care research. A list of our members can be found in Appendix A and on our website: www.woundcarestakeholders.org.

GENERAL COMMENTS

The Alliance has grave concerns regarding this FCSO draft LCD on wound care. We believe that these changes if enacted have the potential of serious public health consequences for the wound care patients our members treat. Our comments include both general and specific concerns. Our overarching issues include the following major points:

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- Changes in the draft LCD seem to have no foundation in medical evidence or clinical practice guidelines and are not supported by citations in the bibliography especially in regards to:
  - The change in utilization parameters for both debridement and NPWT;
  - The change in coverage for disposable NPWT (dNPWT);

  Instead, it is our understanding that in some cases FCSO is potentially using proprietary claims data as rationale for new draft utilization parameters which is problematic.
- Information contained within the draft LCD is inaccurate.
- There is confusing and at times conflicting language throughout this draft policy.

We have such serious concerns with the draft LCD that we are respectfully requesting that FCSO **withdraw** this policy and work with the Alliance physician specialty societies and clinical organizations and other stakeholders to establish an accurate well-balanced policy that is in line with clinical evidence and will not adversely impact patient care.

We elaborate below on these important topics:

Changes in the draft LCD seem to have no foundation in medical evidence or clinical practice guidelines and are not supported by citations in the bibliography

- *The Alliance is concerned that FCSO created a draft policy in which the evidence used to support the many changes throughout this draft is not substantiated in the draft LCD.*

  First of all, it is our understanding that changes in a draft LCD should be based on the most relevant scientific evidence and clinical practice guidelines. In this FCSO draft LCD, we do not find evidence cited in the bibliography ("Sources of Information and Basis for Decision") which supports recommendations that the contractor proposes and thus we submit that these proposed changes have no foundation in medical evidence and should be deleted.

  According to the Program Integrity Manual (PIM) 13.7.1, the evidence supporting an LCD "shall be based on the strongest evidence available". The extent and quality of supporting evidence is key to defending challenges to LCDs. **The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question.**

  Secondly, we have concerns that for the most part, much of the clinical evidence that is stated in the reference section of the bibliography is not topical or relevant to many of changes that are in this draft LCD (i.e., changes in debridement change in utilization parameters for both debridement and NPWT; and the change in coverage for disposable NPWT)

Thirdly, it is difficult for those reading the LCD to understand which references validate the statements made in the draft LCD since there is no cross reference of the clinical references in the bibliography to the supporting statements.

Finally, it is problematic that FCSO released this draft LCD without either conducting a thorough review of the published scientific evidence and the clinical practice guidelines so as to include it in this draft LCD or the contractor conducted the review and chose to ignore this critically important information.

Therefore, FCSO not only did not gather all the evidence that exists when developing this draft LCD, it uses data that is not clinically sound or comports to the standards of practice based on clinical practice guidelines. The Alliance believes that the changes that have been made in this draft LCD challenge the current standards of practice and FCSO does not provide the necessary evidence to support the multiple changes made including but not limited to: the utilization parameters for debridement and NPWT and the statement that dNPWT is not medically reasonable or necessary. In fact, FCSO does not adhere to the above PIM guidelines for making such changes.

- *The Alliance has concerns regarding the basis for which utilization parameters were established in that they do not adhere to current clinical practice guidelines and appear to be arbitrary.*

  It is our understanding that FCSO is basing the utilization parameters identified in the draft LCD on claims data. We have serious concerns regarding this since claims data can be both flawed and manipulated. It is also the interpretation of the claims data which could make for inappropriate utilization parameters. For instance, hospital or physician's paid claims data may not provide the actual number of debridements performed per wound since it would only show actual debridements CPT codes billed which may not be the same as total number of wounds debrided.

  The following scenario illustrates our concern: A patient has three (3) chronic wounds that were all debrided into down to and including subcutaneous tissue with measurements of:

  - Ulcer #1 – 2cm X 3cm (6 sq. cm.)
  - Ulcer #2 - 1 X 2 (2 sq. cm.) and
  - Ulcer #3 - 2 X 4 (8 sq. cm), respectively – for a total of 16 square centimeters

  These three (3) wounds would be billed using the following CPT guidance – "in multiple wounds, sum the surface area of those wounds that are at the same depth, but do not combine sums from different depths". Therefore, in this scenario, one (1) unit of CPT code 11042 (Debridement subcutaneous tissue – first 20 sq. cm or less) would be billed even though 3 wounds were debrided by the practitioner. This would also be the same scenario if the practitioner was performing a selective debridement using CPT code 97597.

  Claims data would <u>not show</u> that 3 wounds were debrided. The Medicare beneficiary's medical record would need to be requested and reviewed to obtain this information.

We submit that any changes in medical coverage policy should be based on clinical evidence and not claims data, which is difficult for not only the MAC but for stakeholders to verify. In addition, it is not transparent as well not clinically relevant.

In addition, the PIM further states, "LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage". It is incumbent on FCSO to provide the evidence that it used to base its decision not to cover dNPWT and for the changes in utilization for debridement and NWPT. We submit that claims data is not sufficient to make these changes, an incomplete and not current bibliography is not sufficient to validate these changes, nor is the lack of review of current clinical practice guidelines.

- *Since FCSO did not include the most relevant and recent scientific evidence and clinical practice guidelines on these topics, we have included them in our comments.* The Alliance would be pleased to discuss this evidence with the medical directors when we have the opportunity to work with FCSO to establish its next version of this draft LCD. In reviewing the evidence for wound care, we wanted to make FCSO aware of the following:

  - The evidence for wound care does exist; it is substantive and is representative of "real world" patients—the ones that our Alliance members treat on a daily basis. Patients with chronic wounds have multiple and serious co-morbidities that are not always represented in wound care RCT studies and data. These "real-world" patients are often not included due to strict exclusion criteria in RCT studies, as are patients with chronic renal disease, morbid obesity and auto-immune disease. These factors can increase the duration and cost of wound care and may impact the effectiveness of advanced therapeutics in ways that cannot be ascertained by RCTs. [Fife, C. E., & Carter, M. J. (2012). *Wound care outcomes and associated cost among patients treated in U.S. outpatient wound centers: data from the US wound registry.* Wounds: a compendium of clinical research and practice, 24(1), 10-17).]

    The US Wound Registry (USWR), a Qualified Clinical Data Registry (QCDR), evaluated the exclusion criteria of all major randomized controlled trials (RCTs) performed in wound care over a decade (1998-2008). It compared those exclusion criteria with the co-morbid conditions, wound characteristics and medications documented among 3,201 patients in 18 hospital-based outpatient wound centers. The data showed that **approximately 75% of 'real world' patients would have been excluded from every major wound healing RCT that brought new products to market over that decade at the "first pass" before study related laboratories or tests would have been performed**.

    The USWR data confirms what the Alliance has been stating in our comments to regulatory agencies and Medicare Administrative Contractors (MACs); ***"RCTs are not able to evaluate the effectiveness of a wound care product or intervention, when more than half of patients are excluded from participation, greatly diminishing the applicability of RCT results to real world populations and evidence based medicine."***

The Alliance believes that evidence can be established for coverage not only through RCTs but also through registry data, retrospective clinical studies (includes populations of patients with multiple co-morbid conditions that are commonly eliminated in most RCTs), scientific evidence and expert knowledge. Even if the studies are small, this approach is consistent with the widely accepted definition of evidence-based medicine and also adopted by the important organization Patient Centered Outcomes Research Institute (PCORI). While we have heard that wound care evidence is not of "good" quality – the evidence that is being reviewed is often RCTs and not the type of real world evidence identified above such as retrospective studies.

There is inaccurate information as well as confusing and at times conflicting language throughout this draft LCD

In our specific comments, we have included examples of where there was inaccurate information in the draft LCD. This includes incorrect examples of types of debridement as well as addressing inaccurate terms and definitions. We are happy to work with FCSO to create accurate terms and definitions. There are many wound care books and clinical practice guidelines that contain appropriate terms and definitions which FCSO staff can use; for instance, WOCN Clinical Practice Guidelines which contain glossaries or AAWC website (https://aawconline.org/wp-content/uploads/2015/10/AAWC-Quality-of-Care-with-I-CVIswebsite-v3.pdf) which FCSO could use as a starting point. Again, we would be pleased to work with you on this important issue.

Finally, the policy has inconsistent, conflicting and at times confusing language throughout the policy. This language should be resolved prior to finalizing this policy.

The Alliance has separated our specific comments into two distinct sections. The first addresses our 6 most significant specific concerns with this draft policy. The second section addresses additional concerns we have with language identified throughout the policy which will be presented in the order those provisions appear in the draft LCD rather than in order of importance.

Our specific comments follow.

SPECIFIC COMMENTS

Section 1 - Six Significant Specific Concerns

1. DISPOSABLE NEGATIVE PRESSURE WOUND THERAPY (DNPWT)

Language in Policy – (p. 8) *Disposable non-powered mechanical or single use non-electrically powered NPWT (CPT codes 97607, 97608) for any indication is considered not medically reasonable and necessary*

Concerns:

1. The CPT coding descriptors terminology are inaccurate in that for both CPT code 97607 and 97608 there is no mention of the power source of the device. Instead, the correct language should be: NPWT (e.g. vacuum assisted drainage collection) utilizing disposable, non-durable medical equipment ….) FCSO should be consistent with the CPT code descriptor language when referring to these technologies to ensure accuracy and not add additional language to what has already been officially created for this procedure**.** We have provided current CPT codes that are used with traditional NPWT in the table below.

Current Procedural Terminology (CPT) Codes used with Traditional NPWT

CPT	Description
97605	Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical applications(s), wound assessment, and instruction(s) for ongoing care per session; total wound(s) surface area less than or equal to 50 square centimeters
97606	Total wound(s) surface area greater than 50 square centimeters

2. Most importantly, the Alliance is extremely concerned that the draft LCD states with respect to dNPWT that "it is considered not medically reasonable and necessary". We question this decision not to cover this technology for the following reasons:

    a. Disposable negative pressure wound therapy is the next generation of traditional negative pressure wound therapy technology – of which FCSO is currently providing coverage. The

negative pressure provided by both a disposable device and a negative pressure durable medical equipment device meet the same criteria under the FDA's 510K pre market approval process in order to provide negative pressure. But, the disposable devices are smaller and portable which enables discreetness and simplicity of use – leading to greater patient compliance. While dNPWT may look different than NPWT, its mechanism of action is fundamentally the same.

In fact, legislation was passed by Congress in late 2015 to allow for payment of disposable negative pressure wound therapy devices in the home health setting. Congress defined a "disposable device" as: a disposable negative pressure wound therapy device that is an integrated system comprised of a receptacle for collecting exudate, and dressings for the purposes of wound therapy; It further stated that "**disposable negative pressure wound therapy is a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy".** This is an important point.

As Congress has already identified, it does not matter whether NPWT is disposable or durable medical equipment as long as the device meets FDA approval and requirements to provide NPWT. Equivalent Negative pressure is negative pressure. The FDA would not have cleared disposable negative pressure devices into the marketplace through the 510K approval process if they did not meet the negative pressure requirements nor would the PDAC have issued the appropriate HCPCS codes through the coding verification request process.

Since dNPWT provides the same negative pressure as NPWT, it is an effective tool in the arsenal for clinicians to treat patients with wounds. It is portable and simpler to use and it saves money as shown by the Congressional Budget Office (CBO). The provision (Section 504 of the Consolidated Appropriations Act, 2016) establishing the disposable NPWT benefit is estimated by the CBO to reduce Medicare spending by $88M over ten years.

b. We request the evidence that FCSO reviewed to make the decision to not cover this revolutionary technology in the draft LCD. While FCSO does reference older coverage policies with outdated information (such as CGS), FCSO policy does not include any published studies on dNPWT that provide evidence of non-efficacy. While they are not represented in the bibliography at the end of the policy, there are clinical studies which demonstrate the equivalence between dNPWT and NPWT. Disposable negative pressure wound therapy is an alternative for traditional negative pressure wound therapy. The studies we have cited below by Armstrong, Hurd and Marston show that there is non-inferiority between dNPWT from NPWT.

Recommendation: The Alliance is concerned about the lack of coverage of dNPWT in this policy and the lack of transparency by which the non-coverage decision was made. As such, we request based on the clinical evidence we have provided below as well as Congressional language and the CBO cost saving information that FCSO cover dNPWT as a reasonable and necessary device/therapy. We also request that FCSO provide the analysis and clinical evidence used as the basis for the decision to not cover dNPWT in its draft LCD. dNPWT is a valuable effective tool for clinicians to use and helps to increase the quality of life and decreased time to heal for the patients that receive it.

Clinical Studies

Armstrong DG, Marston WA, Reyzelman AM, Kirsner RS. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: A multicenter randomized controlled trial. *Wound Repair Regen* 2012;20:332-341.

Hurd et al, Use of a Portable, Single use Negative Pressure Wound Therapy Device in Home Care patients with Low to Moderately Exudating Wounds: A case series; Ostomy Wound Management (2014) 60(3): 30:36
http://www.o-wm.com/article/use-portable-single-use-negative-pressure-wound-therapy-device-home-care-patients-low-modera

Marston WA, Armstrong DG, Reyzelman AM, Kirsner RS. A multicenter randomized controlled trial comparing treatment of venous leg ulcers using mechanically versus electrically powered negative pressure wound therapy. *Adv Wound Care* 2015; 4:75-82

Additional Studies

- Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. *Ann Plast Surg* 1997; 38:563-576.
- Fong KD, Marston WA. SNaP Wound Care System: Ultraportable Mechanically Powered Negative Pressure Wound Therapy. *Adv Wound Care* 2012; 1:41-43.
- Lerman B, Oldenbrook L, Ryu J, Fong KD, Schubart PJ. The SNaP wound care system: A case series using a novel ultraportable negative pressure wound therapy device for the treatment of diabetic lower extremity wounds. *Journal of Diabetes Science and Technology* 2010; 4:825-830.
- Fong KD, Hu D, Eichstadt S et al. The SNaP system: biomechanical and animal model testing of a novel ultraportable negative-pressure wound therapy system. *Plast Reconstr Surg* 2010; 125:1362-1371.
- Isago T, Nozaki M, Kikuchi Y, Honda T, Nakazawa H. Effects of different negative pressures on reduction of wounds in negative pressure dressings. *J Dermatol* 2003; 30:596-601.
- Robson MC, Hill DP, Woodske ME, Steed DL. Wound healing trajectories as predictors of effectiveness of therapeutic agents. *Arch Surg* 2000; 135:773-777.
- Steed DL, Hill DP, Woodske ME, Payne WG, Robson MC. Wound-healing trajectories as outcome measures of venous stasis ulcer treatment. *Int Wound J* 2006; 3:40-47.

- Sheehan P, Jones P, Caselli A, Giurini JM, Veves A. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. *Diabetes Care* 2003; 26:1879-1882.
- Warriner RA, Snyder RJ, Cardinal MH. Differentiating diabetic foot ulcers that are unlikely to heal by 12 weeks following achieving 50% percent area reduction at 4 weeks. *Int Wound J* 2011; 8:632-637.
- Lerman B, Oldenbrook L, Eichstadt SL, Ryu J, Fong KD, Schubart PJ. Evaluation of Chronic Wound Treatment with the SNaP Wound Care System versus Modern Dressing Protocols. *Plast Reconstr Surg*2010; 126:1253-1261.
- Bradbury S, Walkley N, Ivins N, Harding K. Clinical Evaluation of a Novel Topical Negative Pressure Device in Promoting Healing in Chronic Wounds. *Adv Wound Care* 2015; 4:346-357.
- Fong KD, Hu D, Eichstadt SL et al. Initial clinical experience using a novel ultraportable negative pressure wound therapy device. *Wounds* 2010; 22:230-236.
- Awad T, Butcher M. Managing diabetic foot ulceration with a new, highly portable NPWT device. *Wounds International* 2012; 3:40-44.
- Hutton DW, Sheehan P. Comparative effectiveness of the SNaP wound care system. *Int Wound J* 2011; 8:196-205.

ADDITIONAL REFERENCES

- November 13, 2014 79 Federal Register 67670
- Congressional Language - PUBLIC LAW 114–113 Section 504 DEC. 18, 2015
- HHAPPS final rule –cite FR
- CBO Study - https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr2029amendment1divisionsa.pdf

2. UTILIZATION PARAMETERS- DEBRIDEMENTS

Language in Policy – (p. 11) *Debridements will be limited to eight total services per year for any of the debridement codes listed in this LCD (CPT codes 11000,11004-11006,11010-11044, 97597 and 97598). Of the eight debridements, no more than five debridements involving removal of muscle and/or bone (CPT codes 11043, 11044) per year will be considered reasonable and necessary. Services beyond these limits may be considered through the redetermination process when supported in the medical record*

Concern: The Alliance is concerned that FCSO is setting an arbitrary number of debridements which will be permissible under this coverage policy. Not only does setting a specific number contradict the earlier statement in this policy which reads**, "**The appropriate interval and frequency of debridement depends on the individual clinical characteristics of patients and the extent of the wound" but there is no published clinical evidence that supports limiting the number of debridements. Actually, the literature supports the notion that wounds that undergo frequent debridement close more rapidly. No utilization parameters in terms of the maximum number of debridements was identified by this data. Consensus

guidelines, including those by the Wound Healing Society, the Society for Vascular Surgery, and the United Kingdom's National Institute of Clinical Excellence (NICE), also recommend debridement as often as necessary as best practice for wound care, without limiting the number. Furthermore, the current evidence-based guidelines from multiple interdisciplinary societies support debridement of ulcers whenever possible to remove debris and necrotic tissue from the wound surface to promote healing. None of the guidelines limit the number of debridements. These guidelines can be obtained from www.guidelines.gov.

The Alliance questions the evidence that FCSO has reviewed which suggests limiting the number of debridements to 8 and the evidence regarding the frequency of debridements. The studies in the draft LCD bibliography did not define any frequency of debridement that would have formed the basis for a number in this draft LCD. Furthermore, there is no language contained in this policy recognizing that patients may have multiple independent wounds requiring debridement, and that the debridement limitations imposed are for each separate wound, and not the total for the aggregate wound total. Also, the policy does not recognize that patients who may have multiple wounds be permitted to more debridements in any given year. This too is problematic.

Recommendation: The Alliance recommends that FCSO eliminate language that provides a certain number of debridement services permitted in a year. Rather, the policy notes that debridement services are based on documented medical necessity supported by the standard of care. The clinical evidence and consensus documents that exist suggest that there is no standard limiting wound debridements that can be applied universally to any set patient population.

Clinical Studies

Wilcox JR, Carter MJ, Covington S. Frequency of Debridements and Time to Heal; A Retrospective Cohort Study of 312 744 Wounds. *JAMA Dermatol.* 2013; 149(9):1050-1058. **http://jamanetwork.com/journals/jamadermatology/fullarticle/1720508**

Steed DL, Donohoe D, Webster MW, Lindsley L. Effect of extensive debridement and treatment on the healing of diabetic foot ulcers. Diabetic Ulcer Study Group. *J Am Coll Surg* 1996; 183(1): 61-64. **https://www.ncbi.nlm.nih.gov/pubmed/8673309**

Warriner, Robert A. III MD, ABPM/UHM, FACA, FCCP, FCCWS; Wilcox, James R. BSN; Carter, Marissa J. PhD, MA; Stewart, Deborah G. MD. More Frequent Visits to Wound Care Clinics Result in Faster Times to Close Diabetic Foot and Venous Leg Ulcers. *Advances in Skin & Wound Care:* November 2012:25(11): 494-501.

Cardinal M, Eisenbud DE, Armstrong DG, et al. Serial surgical debridement: a retrospective study on clinical outcomes in chronic lower extremity wounds. *Wound Repair Regen*. 2009; 17(3):306-311.

Consensus Guidance Documents

Lavery LA, et al. WHS guidelines update: Diabetic foot ulcer treatment guidelines. *Wound Repair Regen 2016;* 24:112-26

Hingorani A, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *J Vasc Surg* 2016; 63:3S-21S.

National Institute of Clinical Excellence. Diabetic foot problems: Prevention and management. Updated January 2016. https://www.nice.org.uk/guidance/ng19/chapter/Patientcentred-care

Many consensus guidelines, including those by the Wound Healing Society, the Society for Vascular Surgery, and the United Kingdom's National Institute of Clinical Excellence (NICE), recommend debridement as often as necessary as best practice for wound care, without limitation of the number.

3. Utilization Parameters- NPWT Services

Language in Policy – (p. 11) *No more than 6 NPWT (CPT codes 97605-97606) services in a four month period will be considered reasonable and necessary*.

Concern – As previously stated, the Alliance is concerned that FCSO has set arbitrary utilization parameters without providing any supportive clinical evidence or standard clinical practice guidelines to substantiate the changes made. In fact, the utilization parameters suggested by FCSO are specifically not substantiated in their evidence. FCSO is required to be transparent when creating medical policies. The evidence utilized in making any changes to medical policy must be provided in the bibliography so stakeholders can review the literature reviewed. However, FCSO has not been transparent and has not provided such evidence in the bibliography**.**

If FCSO is setting utilization parameters based on claims data, not only is this not transparent, but it does not meet the criteria established by the Program Integrity Manual (PIM). Additionally, there is a question as to whether **parameters even need to be set**. We agree with the FCSO policy which states that "wound care must be performed in accordance with accepted standards for medical and surgical treatment of wounds." FCSO policy further states, "The appropriate interval and frequency of debridement depends on the individual clinical characteristics of patients and the extent of the wound". While this statement refers to debridement it is appropriate for any type of wound care service and/or procedure. NPWT dressings should be changed (CPT 97605-97606) based upon the condition of the wound as well as the manufacturers' recommendation in their instructions for use.

In summary, the Alliance does not agree with the utilization parameters established in this policy. The evidence cited in the bibliography (which is not current) does not substantiate the utilization parameters provided in this policy. The proposed utilization parameters are completely arbitrary and can result in increased risk of infection for patients and worsen outcomes.

Recommendation – The Alliance recommends that FCSO eliminate the references to utilization parameters for NPWT.

Clinical Studies

Argenta, L. C. and M. J. Morykwas. 1997. "Vacuum-Assisted Closure: A New Method for Wound Control and Treatment: Clinical Experience." *Annals of Plastic Surgery* 38(6):563–76; discussion 577.

Birke-Sorensen, H. et al. 2011. "Evidence-Based Recommendations for Negative Pressure Wound Therapy: Treatment Variables (Pressure Levels, Wound Filler and Contact Layer) - Steps towards an International Consensus." *Journal of Plastic, Reconstructive & Aesthetic Surgery : JPRAS* 64 Suppl:S1–16.

Hurd, Theresa, Alan Rossington, Paul Trueman, and Jennifer Smith. 2017. "A Retrospective Comparison of the Performance of Two Negative Pressure Wound Therapy Systems in the Management of Wounds of Mixed Etiology." *Advances in Wound Care* 6(1):33–37.

Krug, E. et al. 2011. "Evidence-Based Recommendations for the Use of Negative Pressure Wound Therapy in Traumatic Wounds and Reconstructive Surgery: Steps towards an International Consensus." *Injury* 42 Suppl 1:S1-12.

Martin, R. 2016. "PubMed Search 16th September 2106 Negative Pressure Wound Therapy." *PubMed*.

Vig, S. et al. 2011. "Evidence-Based Recommendations for the Use of Negative Pressure Wound Therapy in Chronic Wounds: Steps towards an International Consensus." *Journal of Tissue Viability* 20 Suppl 1:S1-18.

Clinical Practice Guidelines

* World Union of Wound Healing Society (WUWHS), Principles of best practice: Vacuum assisted closure: recommendations for use. A Consensus Document. 2008
* Guidelines of Managing Pressure Ulcers with Negative Pressure Wound Therapy, Adv Skin Wound Care, 2004
* **http://www.usaisr.amedd.army.mil/cpgs/CCATCPGNegativePressureWoundTherapyDec2013.pdf**

4. Rate of Closure

Language in the policy*: Medicare expects that with appropriate care:*
Wound volume or surface dimension should decrease by at least 10 percent per month or
Wounds will demonstrate granulation tissue advancement of no less than 1 mm/week

Concerns: The Alliance has significant issues 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".
First of all, wounds will not heal 1mm/week in the initial 30 day time frame. The wound is in 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/week does not take into account the initial size of the wound or any co-morbidities or individual patient medical circumstances presented.

As providers, clinicians and researchers, our members 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. The medical literature does not provide a rate of 10% per month or 1mm/week and no reference was provided by FCSO to substantiate this requirement.

The Alliance believes that while there are specific measureable changes that can be utilized for establishing the status of a wound that is healing, setting specific values should not be utilized – especially when they are arbitrarily established.

Recommendations: Since the Alliance objects to the use of values to determine wound healing, we recommend that:

- FCSO remove any references to value within the indications portion of the policy. "1 mm/week and 10 per cent per month" should be deleted.

- FCSO should provide the citations used to set the healing values presented in the draft LCD, including references for the studies that were utilized to develop this policy.

5. PHOTOGRAPH

Language in Policy – *Identification of the wound location, size, depth and stage by description and may be supported by a drawing or photograph. 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 debridements (beyond skin and subcutaneous tissue) per wound*

Concerns: First of all, there is conflicting language. In one sentence, FCSO is recommending photographic documentation, and then in the next, proceeds to require it for payment. The Alliance believes that FCSO should recommend photographic documentation but not require it. It is too costly for providers to take photographs on a 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.

Recommendation*:* 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).

6. PALLIATIVE CARE

Language in the Policy:

Under the section labeled *History and Background*, it states:

"Medicare coverage for wound care on a continuing basis for a given wound in a given patient is contingent upon evidence documented in the patient's record that the wound is improving in response to the wound care being provided."

AND

"*In rare instances, due to severe underlying debility or other factors such as operability, the goal of wound care provided in outpatient settings may be only to prevent progression of the wound"*

Under the section *Limitations* (specifically number 5), it states:

"Since the goal of care is healing and not palliation, it is neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement as outlined in the LCD cannot be shown."

Concerns: The Alliance agrees that there are times when the goal of wound care may be only to prevent the progression of the wound as stated above. However, this language does contradict the other two statements in the draft LCD which state "*that these services are non covered for palliative care" and "wound care coverage is contingent on evidence that the wound is improving"*. While healing is the objective in most cases, it is not the singular goal of good wound care. In patients at end of life or in complex cases where wound healing is not possible, good wound care may have any of the following alternative goals: prevent infection (local and systemic), prevent amputation, manage exudate, reduce odor, prevent the wound from worsening, and provide for comfort. These alternative goals help to

reduce mental anxiety and social embarrassment and are cost effective since poor wound care can lead to infection and hospitalizations.

Many wounds will never heal. There is a need for palliative care coverage as FCSO has recognized in part of this policy. Yet the draft LCD contradicts itself when it states, "the overall goal of care is healing and not palliation, it is neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement as outlined in this LCD cannot be shown". Defining wound healing as the only acceptable goal of wound care implies (1) that physicians are always able to determine in advance that wounds are "healable" and (2) that healing is the only justifiable reason for chronic wound care services when in some cases reasonable goals for care determined by the patient's values and clinical status are limited to: reduction in pain and debility, prevention of recurrent hospitalization, or control of infection or secondary complications. Some patients require palliative wound care which may require physician oversight and periodic intervention but with goals that are distinct from the "typical" chronic wound patient.

It must also be recognized that a patient may be in palliative care due to life-limiting processes, but not be in palliative wound care. Conversely, the fact that the patient is in palliative wound care does not imply that they are terminally ill. Furthermore, we recognize that patient status may change, thus allowing wounds which were previously considered unhealable to re-enter active therapy.

We have defined palliative wound care as "the care of wounds that are not expected to close (heal)". The Alliance is concerned about the conflicting language in this policy and that FCSO does not believe that palliative care is reasonable and necessary for the vast population that currently receive this type of care.

Recommendation: The Alliance recommends that FCSO acknowledge that complete wound healing is not the goal in all patients and that palliative care is reasonable and necessary and will be covered if supported by the medical documentation. To that end, we recommend that FCSO edit the statement above which states, "*In rare instances, due to severe underlying debility or other factors such as operability, the goal of wound care provided in outpatient settings may be only to prevent progression of the wound"* by adding the following language, "*If it is determined that the goal of care is not wound closure, the patient should be managed following appropriate covered palliative care standards as described in the Palliative Care LCD."*

The Alliance has attached a proposed draft of a Palliative Care LCD for your consideration (Appendix 2). *We request that FCSO adopt this Palliative Care LCD.* The Alliance crafted this Palliative Care LCD in response to another MAC LCD

Furthermore the Alliance recommends that FCSO delete the following language from this LCD: *Since the goal of care is healing and not palliation, it is neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement as outlined in the LCD cannot be shown.*

CLINICAL STUDIES/EVIDENCE

Langemo DK, Black J, and the National Pressure Ulcer Advisory Panel. Pressure ulcers in individuals receiving palliative care: A National Pressure Ulcer Advisory Panel White Paper. *Adv Skin Wound Care* 2010; 23:59-72

Hughes RG, et al. Palliative wound care at the end of life. Agency for Healthcare Research and Quality. https://archive.ahrq.gov/professionals/systems/long-term-care/resources/coordination/wound/

Section 2 – Additional Specific Problematic Language in the Draft LCD

In this section of our comments we have identified other areas in the policy in which the Alliance has specific concerns. These comments have been provided in the order the specific provision/language shows up in the policy.

CMS National Coverage Policy

Language in the policy: (p. 2) *Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice*.

> **Clarification Request:** We are seeking clarification to ensure that FCSO believes that based on this language any state's scope of practice supersedes the payment policy rules.

History/Background/General Information

Language in the Policy: (p. 3) *Various methods to promote wound healing have been devised over time. Physicians and health care providers must understand that many of these methods are expensive and unproven by valid scientific literature, and would be considered investigational.*

> **Concern**: FCSO has erroneously stated that these methods are unproven by valid scientific literature, yet do not identify any recent literature on these methods. There is evidence that is not cited in this document that does exist including clinical practice guidelines. The Alliance is concerned that FCSO has not done a thorough literature review and has made arbitrary decisions which are not based on scientific literature or clinical practice guidelines. Furthermore, the Alliance is concerned that FCSO has made a sweeping statement "many of these methods are expensive and unproven by valid scientific literature, and would be considered investigational". With all due respect, if a valid current literature review is not conducted, it is difficult to ascertain that these methods are unproven by valid scientific literature. Finally, FCSO does not identify which method(s) is/are considered investigational.

Recommendation: The Alliance recommends and requests that FCSO provide the basis for these statements above and provide examples.

Language in the Policy: (p. 3) *Wound care must be performed in accordance with accepted standards for medical and surgical treatment of wounds*.

Concerns: The Alliance supports this statement but we are concerned that it is being undermined in this policy as FCSO contains language throughout this draft policy which does not adhere to this statement. FCSO has prescribed arbitrary utilization parameters that we have heard is being based on claims data but yet do not align with clinical practice guidelines or current scientific literature. There are other areas in this LCD in which the Alliance has provided comments below that also do not adhere to current standards of practice.

Recommendation: The Alliance recommends that FCSO review current literature as well as clinical practice guidelines. The clinical organizations that comprise the Alliance have provided recommendations below which do reflect current clinical practice and accepted standards of care. They are experts in their fields. As such, if it is FCSO's intention to create a policy in which wound care is performed in accordance with accepted standards for medical and surgical treatment of wounds, we recommend that it adopt the recommendations that have been provided in this comment letter.

Language in the Policy: (p. 3) *With appropriate management, it is expected that, in most cases, a wound will reach a state at which its care should be performed primarily by the patient and/or the patient's caregiver with periodic physician assessment and supervision. Wound care that can be performed by the patient or the patient's caregiver will be considered to be maintenance care*.

Concerns: The language contained in the policy needs some clarification. What is FCSO's definition of a caregiver? It is our opinion that when a patient is being seen by a clinician, the clinician is considered a caregiver, yet we do not believe that this is what FCSO intended. We would also like clarification regarding what is meant by periodic – what is the timeframe that is deemed reasonable for a physician assessment and supervision?

Recommendation: The Alliance recommends that FCSO clarify the definition of a caregiver as well as periodic assessment. This language should be provided prior to this policy being finalized.

Language in the Policy: (p. 3) *treatment plan for a patient who requires frequent repeated debridement be reevaluated to ensure that pressure reduction and infection control have been adequately addressed*.

Concern: Pressure reduction and infection control are not the only two issues that require repeated debridements. We request clarification in whether FCSO believes that infection control and pressure reduction are the only areas which require reevaluation?

Recommendation – The Alliance requests clarification when a patient requires frequent repeated debridement and are required to reevaluate – is the required only to determine whether pressure reduction and infection control are adequately addressed?

Definitions of Terms for this Policy

The Alliance is appalled that FCSO has put forward a policy in which even the definitions provided are not correct. We have identified over 10 inaccuracies in this section where it is apparent that FCSO did not reach out to appropriate clinical associations or clinical literature to guide them in crafting the correct language to define the terms used in this policy. We have provided just two examples but frankly, there are too many to identify in our comments.

As stated on page 5 in our general comments, we would be pleased to work with FCSO to create accurate terms and definitions. There are many wound care books and clinical practice guidelines that contain appropriate terms and definitions which FCSO staff can use; for instance, WOCN Clinical Practice Guidelines which contain glossaries or AAWC website (https://aawconline.org/wp-content/uploads/2015/10/AAWC-Quality-of-Care-with-I-CVIswebsite-v3.pdf) which FCSO could use as a starting point.

Language in Policy: (P. 4) *Advanced dressings: Used with increasing frequency to provide gentle debridement in the treatment of acute wounds, chronic venous, diabetic and pressure ulcers. A variety of dressings are available including transparent films, foams, hydrocolloids, and hydrogels*

Concern: As already stated, the Alliance continues to be concerned about FCSO's understanding of debridement. Films, hydrocolloids, hydrogels are not considered advanced dressings.

Recommendation: As stated above, the Alliance would appreciate the opportunity to work with FCSO to create accurate terms and definitions. The WOCN, AAWC and other professional societies/organizations have guidelines and glossaries that could be helpful here. We recommend that FCSO review those guidelines to assist them in providing accurate definitions for this policy.

Language in Policy: (p. 4) *Dressing changes (removal and subsequent reapplication) alone do not require the skills of physicians, podiatrists, physical therapists, occupational therapists or wound care nurses and in fact are usually performed by non-physician providers*.

Concerns: The Alliance has concerns with the language contained here. It appears that FCSO believes that dressing changes (removal and subsequent reapplication) a) do not require skills at

the level of a physician, NPP, PT or wound care nurse – which we completely disagree with and b). FCSO is assuming that when a dressing change is being done – nothing more is happening than just changing the dressing. The act of a dressing change is only part of "wound care" which includes: the entire assessment of the wound status, healing trajectory, patient tolerance to topical care and pain control. This part of the assessment is included in the act of removal or application of the dressing and is critical for all members of the provider team to influence the best outcomes possible in healing.

The wording is confusing and needs to be clarified since it appears that all the providers listed are NOT non physicians which is incorrect. The Alliance is also concerned that the way this language is drafted should one of the providers listed do the dressing changes they will not be reimbursed for their services. Finally, this sentence lists podiatrists separately from that of physicians. It appears that FCSO does not believe podiatrists are physicians which is not correct. Podiatrists are physicians and should not be singled out as different providers than physicians. Additionally – due to the language contained above, the Alliance would like for FCSO to spell out who they believe are considered NPPs.

Recommendation: The Alliance recommends that FCSO eliminate the language contained here. It is not only confusing it does not accurately reflect the scope of practice of the individual clinicians and does not take into consideration skills that are required when performing a dressing change.

Covered Indications

Language in Policy: (p. 4) 2. *Active Wound Care Management: Debridement is indicated whenever necrotic tissue is present on an open wound*.

Concern: There are times when there is cellular debris on the wound bed and also requires debridement for removal. If cellular debris is left in the wound bed it has the potential to become infected and/or necrotic and will then require a debridement. Removal of cellular debris maintains the wound bed in an active phase of healing and helps to promote faster healing. Therefore we do not agree with the language that is contained in the policy.

Recommendation: The Alliance recommends that FCSO edit the language above to read as follows, "Debridement is indicated whenever necrotic tissue as well as protenatious debris is present on an open wound in order to keep the wound in an active state of healing".

Language in Policy Active Wound Care Management: *Blunt Debridement (p. 5)*

Concern: The Alliance is confused by the terminology used in this section and would like to obtain clarification regarding what FCSO defines as "blunt debridement." Is FCSO calling this blunt debridement when it should be called mechanical debridement?

Recommendation – The Alliance requests that FCSO define what is meant by "blunt debridement." It is our opinion that the term "blunt debridement" should not be used but rather FCSO should utilize the term "mechanical debridement."

Language in Policy Active Wound Care Management: (p. 5) *Mechanical Debridement: Wet-to-dry or dry-to-dry dressings may be used with wounds that have a high percentage of necrotic tissue. Wet-to-dry dressings should be used cautiously as maceration of surrounding tissue may hinder healing.*

Concerns: The purpose of a wet-to-dry or wet-to-moist dressing is to provide non-selective debridement of the wound bed that has greater than 50% non-viable tissue. This technique of debridement promotes an inflammatory wound bed, does not allow for the optimal temperature for wound healing to be reached in the wound bed, removes healthy tissue that should remain, creates an environment for bacterial overgrowth, and is excessively painful to the patient. More modern dressings, such as alginates, foams, enzymatic debriding agents, and autolytic debriding agents, have superseded the need for wet-to-dry dressings as they allow for selective debridement, while promoting a hospitable environment for wound healing, greatly reducing the pain associated with the wet-to-dry technique and are more cost-effective. Prevalence studies have shown that wet-to-dry dressings are the most frequently misprescribed dressing. This is attributed to lack of modern wound care education amongst physicians, particularly general surgeons. Neither wet or dry dressings provide gentle debridement as described in your definitions section and both are substandard care as identified in the clinical literature.

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Recommendation: - The Alliance recommends that this section needs to be rewritten so that it is in compliance with current standards of care in conjunction with clinical stakeholders who are wound care practitioners. The Alliance would be happy to serve as a resource.

CLINICAL STUDIES/EVIDENCE

Sharon Baranoski, Elizabeth Ayello, Wound Dressings: An Evolving Art and Science*; Advances in Skin and Wound Care* 2012; 25: 87-92.

Marissa J. Carter, Evidence Based Medicine: AN Overview of Key Concepts, *Ostomy Wound Management;* 2010; 56(4): 68-85.

Renee Cordrey, Gauze, Impregnated Gauzes and contact layers; Advances in Wound Care Vol 1 120-125. DOI 10.1089/awc/2009.0155

Linda J. Cowan. Prevalance of Wet to Dry Dressings in Wound Care, Advances in Skin and Wound Care 2009; 22: 567-73

Cynthia Fleck. Newer Debridement Methods for Wound Bed Preparation, Advances in Skin and Wound Care July 2010; 23(7): 313-315.

Johan P.E. Junker, Rami A. Kamel, E.J. Caterson, and Elof Eriksson. *Advances in Wound Care.* September 2013, 2(7): 348-356. doi:10.1089/wound.2012.0412.

Clinical Practice Guidelines

AAWC Clinical Practice Guidelines – Pressure Ulcers. These state the following:

> "Mechanical debridement using wet-to-dry gauze is considered substandard practice."
>
> Recommendations section for appropriate pressure ulcer (PU) dressings states… "Avoid gauze use as a primary PU dressing. It delays healing, increases pain, infection rates, and dressing change frequency, and is not cost effective."
>
> Citations for wet/dry dressings. See AAWC clinical practice guidelines re wet dressings not being standard or care. Citations below are also provided for covered indications: active wound management section below on mechanical debridement:

WOCN guidelines

Language in the Policy Active Wound Care Management: (p. 5) *Jet Hydrotherapy and Wound Irrigation: types of mechanical debridement used to remove necrotic tissue. Jet Hydrotherapy and Wound Irrigation should be used cautiously as maceration of surrounding tissue may hinder healing*.

> **Concern:** It appears from the language in this policy that FCSO believes that jet hydrotherapy is still considered standard of care. The Alliance would like to point out that this type of therapy is no longer considered standard of care.
>
> **Recommendation:** The Alliance recommends that FCSO remove this language out in the policy. It is no longer considered the standard of care

Language in Policy (p. 5) *Wound Care Surgical Debridements - Conditions that may require surgical debridement of large amounts of skin include: rapidly spreading necrotizing process (sometimes seen with aggressive streptococcal infections), severe eczema, bullous skin diseases, extensive skin trauma (including large abraded areas with ground-in dirt), or autoimmune skin diseases (such as pemphigus).*

> **Concern** All diagnoses are not related to chronic or acute wounds that are subject to this policy. All of these conditions are dermatologic conditions and other than the necrotizing processes (and traumatic wound), none require debridement.

Recommendation: The Alliance recommends eliminating this language as it does not have anything to do with the debridement of wounds**.**

Language in Policy (p. 5) *Wound Care Surgical Debridements - Surgical debridement occurs only if material has been excised and is typically reported for the treatment of a wound to clear and maintain the site free of devitalized tissue including but not limited to necrosis, eschar, slough, infected tissue, abnormal granulation tissue, etc., and should be accomplished to the margins of viable tissue. Surgical excision includes going slightly beyond the point of visible necrotic tissue until viable bleeding tissue is encountered in some cases*.

Concern Presence of absence of bleeding was not considered important to make a distinction as to the level of debridement. We question why it is included since it is not clinically important. Furthermore, when the AMA revised these CPT codes they did not address bleeding but rather the level of tissue removed.

Recommendations: The Alliance recommends that FCSO delete the following language, "Surgical excision includes going slightly beyond the point of visible necrotic tissue until viable bleeding tissue is encountered in some cases"

Language in Policy – (p. 5) *Negative Pressure Wound Care (NPWT), electrically powered (CPT codes 97605, 97606)*

Concern: The Alliance is concerned that FCSO has strayed from current CPT code descriptors. Electrically powered is not in the CPT code descriptor.

Recommendation: We recommend that FCSO adhere to the actual CPT code book definitions for any of the codes being utilized in this draft policy including NPWT. Please see page 6 in our comments for the accurate CPT coding descriptors. As such, in this case, we recommend that FCSO eliminate the term "electrically powered" from the description of NPWT as it does not appear in the CPT code descriptor and use the correct CPT code descriptors.

Language in Policy (p. 6) *Negative Pressure Wound Care (NPWT), There is a chronic, nonhealing ulcer with lack of improvement for at least the previous 30 days despite standard wound therapy, including the application of moist topical dressings, debridement of necrotic tissue (if present), maintenance of an adequate nutritional status, and weekly evaluations with documentation of wound measurements (i.e., length, width, and depth) in ONE of the following clinical situations:*

- *Chronic Stage III or Stage IV pressure ulcer*
- *Chronic diabetic neuropathic ulcer*
- *Chronic venous ulcer*

Concerns: There are other examples than those provided above in which NPWT would be appropriate. We are concerned that FCSO is limiting NPWT for only the three types of ulcers above. Examples of appropriate wound types include:

• Chronic
• Acute
• Traumatic
• Subacute and dehisced wounds
• Partial-thickness burns
• Ulcers (such as diabetic or pressure)
• Flaps and grafts
• Closed surgical incisions

Recommendations: The Alliance recommends that FCSO edit the language for the types of wounds in which NPWT is appropriate to include the following:
Chronic
• Acute
• Traumatic
• Subacute and dehisced wounds
• Partial-thickness burns
• Ulcers (such as diabetic or pressure)
• Flaps and grafts
• Closed surgical incisions

All of the wounds identified are included in the WOCN Clinical Practice Guidelines which the Alliance recommends that FCSO review.

Language in Policy: (P. 7) Application of Paste Boot (Unna Boot) or Application of Multi-layer compression (MLC) *Unna boot is a type of compression dressing used to promote return of blood from the peripheral veins back into the central circulation. When both a debridement is done and an Unna boot is applied only the debridement will be reimbursed. If only an Unna boot is applied and the wound is not debrided, then only the Unna boot application may be eligible for reimbursement*

Concern – The Alliance is very concerned about the language within this policy as it relates to applying an Unna Boot or ML Compression and performing a debridement. The MLC, Unna Boot and debridement all have their own procedure codes and should be able to be performed on the same day. One is not dependent on the other. MLC and/or Unna Boots are designed to treat the circulatory system while debridement deals with the wound itself – it takes care of bacteria and debris. Compression is not managing the wound --it is managing the underlying circulatory disease. Furthermore, the policy states that compression is a dressing. In fact, it is not a compression dressing-- it is compression therapy. Applying compression systems alone - whether an Unna boot or multilayer compression - is not sufficient alone to heal the ulcer.

Recommendation: The Alliance recommends that FCSO remove this statement from the policy. Unna Boot and MLC can be used when a debridement is performed. The NCCI edits allow for modifiers to be used regarding these services to be performed on the same day since they both have their own procedure codes, are distinct services and address different things – both of which

are necessary to help heal the wound. Therefore, this is an inaccurate statement and needs to be removed**.**

Limitations Section

Language in Policy- (p. 7) *It would not be expected that an individual wound would be repeatedly debrided of skin and subcutaneous tissue because these tissues typically do not regrow very quickly. Coverage for prolonged, repetitive debridement services will be considered through the redetermination process.*

Concern: First, FCSO does not define what is considered repeated debridement. More importantly**,** we are unable to locate the literature reference in the draft LCD bibliography that would support this statement. Furthermore, best practices for debridement include other indications such as: removal of sentient cells, biofilms, removal of hyper-proliferation, non-migratory tissue, elimination of rolled edges and matrix metalloproteinases.

Recommendation: Delete the following statement: "It would not be expected that an individual wound would be repeatedly debrided of skin and subcutaneous tissue because these tissues typically do not regrow very quickly".

Language in Policy – (p. 7) *The use of a sharp instrument does not necessarily substantiate the performance of surgical excisional debridement.*

Concerns: Term excisional is inappropriate as it is not part of the definition for each of the debridement codes:
11042-Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq. cm or less
11043-Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 sq. cm or less: 11044-Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq. cm or less.

Moreover, there is inconsistent conflicting language in the policy. FCSO also states that the use of curette or scalpel is ok to meet the criteria for debridement.

Recommendation: We request that the term and definition be deleted from the policy due to inaccuracy.

Language in Policy – (p. 7) *Wound debridement utilizing experimental or investigational methods is considered not reasonable and necessary. Therefore, it would not be reasonable and necessary to report these services with any CPT code*

Concern – FCSO makes a broad generalization that **"**Wound debridement utilizing experimental or investigational methods is considered not reasonable and necessary". However, nowhere in this policy does FCSO identify experimental methods or what are considered investigational methods.

Recommendation: The Alliance recommends that FCSO eliminate these statements unless FCSO can support it with literature and examples. FCSO needs to provide examples and then provide the clinical evidence to support their statement that those methods are experimental or investigational.

Language in Policy – (p. 7) *A wound that shows no improvement after 30 days requires a new approach, which may include a physician reassessment of underlying infection, metabolic, nutritional, or vascular problems inhibiting wound healing, or a new treatment approach.*

Concerns: First, we believe that there are other qualified providers that can and do reassess non-healing wounds. Second, we are concerned about the 30 day requirement as written. If a patient (and therefore the wound) suffers a setback, for example, a severe heart attack, the 30 day clock should reset. FCSO has not made any provisions in this draft policy for the 30 day clock to restart should there be a setback or a stall in healing. The Alliance believes that the resetting of the 30 days is very important as different interventions will be taken to treat the patient depending on their status. We would also like to have FCSO clarify when the actual 30 day requirement would begin.

Recommendation: The Alliance believes the sentence needs to be modified to read as follows: "A wound that shows no improvement after 30 days requires a new approach, which may include a reassessment by a qualified provider of underlying infection, metabolic, nutritional or vascular problems inhibiting wound healing or a new treatment approach. If a patient suffers a medical or surgical condition that negatively impacts wound healing progression –whether a stall or a setback in healing -then the 30 day requirement would reset."

Language in Policy (p. 8) *The following procedures are considered part of an E/M service or wound care management services, and are not separately covered: removal of necrotic tissue by cleansing and dressing, including wet or dry-to-dry dressing changes*

Concern: This language contradicts what was placed in this policy previously which states: *Mechanical Debridement: Wet-to-dry or dry-to-dry dressings may be used with wounds that have a high percentage of necrotic tissue. Wet-to-dry dressings should be used cautiously as maceration of surrounding tissue may hinder healing*.

Recommendation – The Alliance recommends removing this language from this policy as it contradicts previous language in the policy.

Language in Policy – (p. 8) *When both an Unna boot is applied and a wound debridement is performed, the debridement will be reimbursed, if the medical record supports that the service is reasonable and necessary as outlined in this LCD, the Unna boot application will be denied*.

Concern – We question the rationale for the lack of reimbursement when an Unna boot is applied the same day a debridement is performed since we believe it is without basis. They are not dependent on one another and each has its own procedure code. Application of compression addresses the underlying vascular/circulatory etiology while debridement of the wound addresses a different set of issues related to wound healing (biofilm/bioburden, non-viable tissue, cellular senescence, etc.)

Recommendation –We recommend that this provision needs to be deleted as it is not accurate

Language in Policy – (p. 8) *The following services are considered to be not reasonable and necessary wound debridement services: Removal of necrotic tissue by cleansing, scraping (other than by a scalpel or a curette), chemical application, or dry-to-dry or wet-to-dry dressing*

Concern –The only service listed that is not considered a debridement and therefore accurate to be listed here is cleansing**.** The other services listed addressed in this policy when discussing debridement. Therefore, placement in this section contradicts what was contained in the policy previously**.**

Recommendation – The Alliance recommends that this language be eliminated as it is inaccurate and contradicts what is previously contained in the policy

Language in Policy – (p. 8) *Paring or cutting of corns or non-plantar calluses. Skin breakdown under a dorsal corn that begins to heal when the corn is removed and shoe pressure eliminated is not considered an ulcer and does not require debridement unless there is extension into the subcutaneous tissue*.

Concern -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 it is inaccurate. Once there is skin breakdown, a dorsal corn is considered an ulcer and may require debridement.

Language in Policy – (p. 8) Incision *and drainage of abscess including paronychia, trimming or debridement of mycotic nails, avulsion of nail plates, acne surgery, or destruction of warts. 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*.

Concerns – First**,** the first sentence has nothing to do with wound care. Most of what is contained in this section are dermatologic conditions and need to be removed as they do not apply to wound care. Second, the Alliance would like more information as to what FCSO means by a). Non tissue integrated fibrin, and b). Crusts,– (is it necrotic tissue at the edge of the wound eschar?). Third, with respect to Biofilm – bacteria is secreted and encased in polysaccharide which embeds into the bed of the wound. It adheres and integrates into the wound. If an antiseptic solution is used, it cannot penetrate polysaccharide. Biofilm is important as it can't be rinsed away; it has to be surgically removed as it adheres to the tissue underneath, otherwise bacteria will form. When biofilm is removed, tissue is automatically being removed as it anatomically adheres to the wound. So the language contained here either is not applicable, or it is inaccurate.

Recommendation: As stated above, language contained in this section is inaccurate and needs to be removed.

Documentation Requirements

Language in Policy – (p. 10) *A pathology report substantiating depth of debridement shall be submitted when billing for the debridement procedure described by CPT code 11044*.

Concern – The Alliance is concerned about the need for all to go to pathology. It should be sent to pathology during the first debridement but not for subsequent debridement of the same area. Thus, it should only require one pathology report per episode of care and that should be sufficient.

Recommendation: The Alliance recommends that when this procedure is done for the first time it should be sent to pathology. It is appropriate in order to determine if there is cancer or osteomyelitis. However, should subsequent procedures be required, it is a waste of money for pathology to be done for every procedure after the first one has been conducted. As such, the Alliance recommends that the language be modified to read as follows**, "**A pathology report substantiating depth of debridement shall be submitted when billing for the initial debridement procedure described by CPT code 11044."

Language in Policy – (p. 10) *The status of the wound is such that the treatment is expected to make a significant practical improvement in the wound in a reasonable and generally predictable period of time*

Concern. This statement is a broad generalization and thus problematic. We question what it means and is it even possible to have significant practical improvement OR can the timeframe

even be predictable? What does FCSO determine is a predictable period of time? It appears that FCSO believes that physicians can predict the amount of time it will take to heal a wound.

Recommendation: The Alliance recommends that FCSO eliminate reference to the predictability of improvement. Furthermore, the Alliance recommends that FCSO provide clarification regarding that it means by the following language contained in the draft LCD "significant practical improvement".

Language in Policy – (P. 10) *A wound that shows no improvement after 30 days requires a new approach. Documentation of such cases may include a physician reassessment of underlying infection, metabolic, nutritional, or vascular problems inhibiting wound healing, or a new treatment approach*.

Concerns: First, we believe that there are other qualified providers that can and do reassess non-healing wounds. Second, we are concerned about the 30 day requirement as written. If a patient (and therefore the wound) suffers a setback, for example a severe heart attack, the 30 day clock should reset. FCSO has not made any provision in this draft policy for the 30 day clock to restart should there be a setback or a stall in healing. The Alliance believes that the resetting of the 30 days is very important as different interventions will be taken to treat the patient depending on their status. We would also like to have FCSO clarify when the actual 30 day requirement would begin.

Recommendation: The Alliance believes the sentence needs to be modified to read as follows "A wound that shows no improvement after 30 days requires a new approach, which may include a reassessment by a qualified provider of underlying infection, metabolic, nutritional or vascular problems inhibiting wound healing or a new treatment approach. If a patient suffers a medical or surgical condition that negatively impacts wound healing progression –whether a stall or a setback in healing -then the 30 day requirement would reset."

CONCLUSION

The Alliance appreciates the opportunity to provide you with our comments. As stated in our general comments, we do have so many serious concerns with this draft LCD that we are respectfully requesting that FCSO **withdraw** this policy and work with the Alliance physician specialty societies and clinical organizations and other stakeholders (whose names are listed in Appendix 1 below) to establish an accurate well-balanced policy that is in line with clinical evidence and will not adversely impact patient care.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

Appendix 1- List of Alliance of Wound Care Stakeholders Physician Medical Specialty Societies and Clinical Association Members:

- Academy of Nutrition and Dietetics
- American Association of Nurse Practitioners
- American College of Foot & Ankle Surgeons
- American College of Hyperbaric Medicine
- American College of Phlebology
- American College of Wound Healing and Tissue Repair
- American Diabetes Association® Interest Group on Foot Care
- American Physical Therapy Association
- American Podiatric Medical Association
- American Professional Wound Care Association
- American Venous Forum
- Association for the Advancement of Wound Care
- National Lymphedema Network
- Society for Vascular Medicine
- Society for Vascular Surgery
- Undersea & Hyperbaric Medical Society
- Visiting Nurse Associations of America
- Wound, Ostomy and Continence Nurses Society (WOCN©)

Appendix 2- Proposed Palliative Wound Care LCD

Indications and Limitations of Coverage and/or Medical Necessity

For the purposes of this policy, palliative wound care is defined as care of wounds that are not expected to close (heal). No one specific diagnostic test can currently reliably determine healing potential, and wounds exist in the context of patients who may themselves be highly compromised. Since there are currently no specific guidelines to quantify when a wound is "un-healable," the point at which a patient enters "palliative wound care" is a clinical decision based on the patient's underlying serious medical condition(s), an unacceptable risk-benefit ratio for aggressive interventions aimed at healing, or be made after the failure of some reasonable period of aggressive wound care. It must also be recognized that a patient may be in palliative care due to life-limiting processes, but not be in palliative wound care. Conversely, the fact that the patient is in palliative wound care does not imply that they are terminally ill. Furthermore, we recognize that patient status may change, thus allowing wounds which were previously considered un-healable to re-enter active therapy.

While the goal of palliative wound care may not be wound closure, there are several legitimate goals which will likely improve patient quality of life with a reasonable expenditure of healthcare resources. The primary endpoints of palliative wound care include:

- odor control
- pain management
- quality of life improvements (overall QOL)
- local wound bed stabilization
- control of bioburden
- control of exudate
- limiting infectious complications

In addition to improving quality of life, one other potential beneficial outcome might be that with appropriate palliative care, the need for hospitalization, intravenous antibiotics, and other expensive interventions will be reduced. Furthermore, appropriate palliative care should require a limited number of clinic/physician visits to maintain the wound status. Devices, drugs, advanced wound care technologies, and certain bioactive dressings designed to stimulate wound closure may not be appropriate for wounds in palliative care although secondary benefits of advanced technologies may in some cases justify their use. Dressings and other interventions focused on reduction of infection risk may be appropriate. Dressing regimens for pallia chosen if possible to limit the work of care givers. Simplification of dressing regimens will allow, whenever possible, the burden of care to be shifted to the least skilled but competent care-giver available, preferably, a family member.

Debridement may still be required to achieve the goals outlined above by reducing the burden of devitalized tissue which can serve as a harbor for bacteria. In fact, non-healing wounds may continue to undergo necrosis and thus require periodic debridement to maintain a clean environment.

A palliative care plan should still employ modalities to control pain, unrelieved pressure, infection, uncontrolled metabolic derangement, and/or nutritional deficiency to prevent deterioration of the wound, development of

new wounds, or deterioration in overall patient status. These interventions require regular, if infrequent clinic visits. It is anticipated that, in the absence of visits needed to address specific problems, palliative wound care can be accomplished with visits no more frequent than every 30 days.

Documentation Requirements

•Documentation supporting the medical necessity should be legible, maintained in the patient's medical record and made available to Medicare upon request.
•There must be a documented plan of care with documented palliative care goals and documented physician follow-up present in the patient's medical record.
•The patient's medical record must contain clearly documented evidence as to whether the palliative care goals are being met. This documentation at a minimum must include current wound size, wound depth, presence and extent of or absence of obvious signs of infection, presence and extent of or absence of necrotic, and devitalized or non-viable tissue.
•Appropriate evaluation and management of contributory medical conditions or other factors affecting the course of wound management (such as nutritional status or other pre-disposing conditions) should be addressed in the record at intervals consistent with the nature of the condition or factor.

Utilization Guidelines

•If measurable signs of healing (e.g., decrease in wound size/surface or volume, decrease in amount of exudates and decrease in amount of necrotic tissue) have not been demonstrated within any 180-day period, the patient should be considered for palliative care.
•Palliative wound care is not expected to include advanced wound care technologies such as semi-synthetic human skin, growth factors, or other modalities directed at wound closure, but may include such technologies when secondary benefits of their application are consistent with the goals established for a specific palliative wound care patient.
•The frequency of visits for patients in a palliative care mode is anticipated to be no more often than every 30 days