COALITION OF

Wound Care Manufacturers

March 9, 2017

FCSO
Medical Policy
532 Riverside Ave
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Jacksonville, FL 32202

Submitted Electronically to Medical.Policy@fcso.com

RE: Draft LCD – Wound Care (DL37166)

Dear Dr. Corcoran,

The Coalition of Wound Care Manufacturers ("Coalition") is submitting the following comments in response to First Coast Service Option (FCSO) draft LCD on Wound Care. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to provisions contained in this draft policy. As such, we have a particular interest in this draft document.

The Coalition has the following significant concerns with this draft LCD:

1. The lack of coverage for Disposable Negative Pressure Wound Therapy (dNPWT)
2. The arbitrary utilization parameters for Negative Pressure Wound Therapy (NPWT)
3. Lack of transparency for the changes made in the draft LCD
4. Referenced evidence provided to support changes in the draft LCD

LACK OF COVERAGE FOR DISPOSABLE NEGATIVE PRESSURE WOUND THERAPY (DNPWT)

In this draft LCD, FCSO has stated, **"***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".*

We have two concerns regarding this statement:

1. The CPT coding descriptors that are referenced are inaccurate. There is no mention of the power source in the coding descriptor in the official CPT language which states: "NPWT (e.g. vacuum assisted drainage collection) utilizing disposable, non-durable medical equipment ….)" Therefore, we request that FCSO use the correct language of the CPT

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coding descriptors in the final LCD as stated below:

97607: Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s) wound assessment, and instructions for ongoing care, per session, total wound(s) surface area less than or equal to 50 square centimeters.

97608: Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s) wound assessment, and instructions for ongoing care, per session, total wound(s) surface area greater than 50 square centimeters.

2. We have concerns that FCSO has stated that this dNPWT is not reasonable and necessary.

   We submit that FCSO should delete this statement and cover dNPWT for the following reasons:

   - There is no evidence cited in the bibliography that would indicate that FCSO should come to such a decision. While FCSO does reference older coverage policies with outdated information (such as CGS), the FCSO draft LCD does not include any published studies on dNPWT that provide evidence of non-efficacy. Therefore, we question what evidence was used by FCSO to come to this non-coverage decision and request that the contractor provide this information publicly.

   - Scientifically, negative pressure is negative pressure. NPWT can be delivered either with a traditional or disposable system. Both deliver the same clinical benefits. For example, Armstrong's study listed below addressed this for the dNPWT system while Huddleston 2013, Hyldig et al. 2016, De Vries et al. 2016 stated this more recently for traditional NPWT. Although each of these sources of negative pressure look very different, fundamentally each has the same mechanisms of action. The pressure that is utilized in both a disposable device as well as traditional negative pressure wound therapy meet the same criteria used within the 510K review process in order to provide negative pressure. However, the disposable device is smaller and has more portability which allows the patient to discretely carry the device on them as they work through their activities of daily living. The technology for NPWT devices is evolving which allows physicians more choices in selecting the appropriate device (dNPWT or traditional) based on the physician's assessment of the wound and plan of care. dNPWT devices aid in patient compliance through portability, discreetness and simplicity of use.

   - Congress also recognized the value of dNPWT when it passed legislation 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; They 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 – one which supports the use of dNPWT.

- In addition to being a tool in the arsenal for physicians and clinicians to treat patients with wounds due to its portability and being simpler to use, dNPWT saves money as demonstrated 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.

Finally, the draft LCD states that "*Medicare payment for professional wound care procedures requires that **all applicable adjunctive measures are also employed** as part of comprehensive wound management. Wound care in the absence of such measures, when they are indicated, is not considered to be medically reasonable and necessary*." DNPWT IS an applicable adjunctive therapy that is currently being used to treat patients with wounds and therefore this statement directly conflicts with the non-coverage of dNPWT

In summary, clinical studies listed below by Armstrong, Hurd and Marston demonstrate that there is non-inferiority between dNPWT from NPWT. Disposable negative pressure wound therapy is an alternative for traditional negative pressure wound therapy. As Congress has already identified, it does not matter whether NPWT is disposable or durable as long as the device meets the appropriate FDA approval and requirements.

Therefore, the Coalition is concerned about the lack of coverage of dNPWT in this policy and the lack of transparency by which this decision was made. dNPWT IS an effective treatment option for clinicians to use when treating patients with wounds. As such, **we request that FCSO cover dNPWT as a reasonable and necessary device/therapy** based on the clinical evidence provided as well as Congressional language and the CBO cost saving information. We also **request that FCSO provide analysis and evidence of their review for disposable negative pressure wound therapy**. Disposable negative pressure wound therapy is a valuable effective tool for clinicians to use, helps to increase the quality of life for the patients that receive it.

Clinical Studies

Studies comparing traditional NPWT with DNPWT.

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 Downloaded, with free registration to OWM http://www.o-wm.com/article/use-portable-single-use-negative-pressure-wound-therapy-device-home-care-patients-low-modera
Reference: PCCE-43-0414-NAE

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 Clinical 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.
- Awad T, Butcher M. Managing diabetic foot ulceration with a new, highly portable NPWT device. *Wounds International* 2012;3:40-44.
- 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.
- 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
- Dorafshar, Amir H., Mieczyslawa Franczyk, Lawrence J. Gottlieb, Kristen E. Wroblewski, and Robert F. Lohman. 2012. "A Prospective Randomized Trial Comparing Subatmospheric Wound Therapy with a Sealed Gauze Dressing and the Standard Vacuum-Assisted Closure Device." *Annals of plastic surgery* 69(1):79–84.
- Fong KD, Marston WA. SNaP Wound Care System: Ultraportable Mechanically Powered Negative Pressure Wound Therapy. *Adv Wound Care* 2012;1:41-43.
- 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.
- 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.
- Hutton DW, Sheehan P. Comparative effectiveness of the SNaP wound care system. *Int Wound J* 2011;8:196-205.
- Hyldig, N. et al. 2016. "Meta-Analysis of Negative-Pressure Wound Therapy for Closed Surgical Incisions." *The British journal of surgery* 103(5):477–86.
- 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.

- 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.
- 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.
- 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.
- Malmsjö, Malin, Elizabeth Huddleston, and Robin Martin. 2014. “Biological Effects of a Disposable, Canisterless Negative Pressure Wound Therapy System.” *Eplasty* 14:e15.
- Nair, Sunitha. 2016. “PICO in Chronic Wounds.” in *Smith & Nephew NPWT Experts meeting Challenging wounds. Copenhagen*.
- Nair, Sunithat. 2017. "Disposable Negative Pressure Wound Therapy: A solution for significantly reducing the cost" *presentation pending WOCN Annual Conference*
- Rahmanian-Schwarz, Afshin, Lina-Marie Willkomm, Philipp Gonser, Bernhard Hirt, and Hans-Eberhard Schaller. 2012. “A Novel Option in Negative Pressure Wound Therapy (NPWT) for Chronic and Acute Wound Care.” *Burns : journal of the International Society for Burn Injuries* 38(4):573–77.
- Robson MC, Hill DP, Woodske ME, Steed DL. Wound healing trajectories as predictors of effectiveness of therapeutic agents. *Arch Surg* 2000;135:773-777.
- 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.
- 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.
- 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.
- De Vries, Fleur E. E. et al. 2016. “A Systematic Review and Meta-Analysis Including GRADE Qualification of the Risk of Surgical Site Infections after Prophylactic Negative Pressure Wound Therapy Compared with Conventional Dressings in Clean
- 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.

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

UTILIZATION PARAMETERS FOR NPWT SERVICES

The Coalition is equally concerned about the arbitrary utilization parameters identified in this draft policy in which FCSO states, "*No more than 6 NPWT (CPT codes 97605-97606) services in a four month period will be considered reasonable and necessary*."

The Coalition is concerned that FCSO has set arbitrary utilization parameters without providing any clinical evidence or clinical practice guidelines to substantiate the changes made. In fact, the utilization parameters suggested by FCSO are not substantiated in any of the bibliography's clinical evidence. FCSO is required to be transparent when creating medical policies. The evidence utilized in making any changes to the medical policy must be provided in the bibliography so stakeholders can review the literature reviewed. However, FCSO has not been transparent and did not provide this information in the bibliography.

We also have concerns that FCSO may have used proprietary claims data to determine the utilization parameters in this draft LCD. Not only is this not transparent, it does not meet the criteria established by CMS in the Program Integrity Manual which states that the evidence supporting an LCD "shall be based on the strongest evidence available". We submit that claims data is not the strongest evidence available since it can be flawed and manipulated. Instead, FCSO should be using clinical practice guidelines and clinical evidence as the basis for any utilization parameters in its draft LCD.

Since we could not find any scientific evidence in the "*Sources of Information and Basis for Decision",* in the draft FCSO draft LCD, we are providing you below information which addresses dressing changes when using NPWT.

- Since NPWT has been commercially available for 20 years, some 3500 peer review articles have been published covering a wide range of wound types and clinical settings (Martin 2016).

- Argenta and Morykwas in 1997 wrote a landmark article which stated that the interval after which NPWT dressings should be changed has been set at around 48 hours or more practically 3 times per week. These intervals are important to ensure wound bed granulation tissue does not grow into the foam dressings, causing pain and bleeding on removal and to ensure there is no buildup of slough and debris in the foam and on the wound bed (Argenta and Morykwas 1997)(Birke-Sorensen et al. 2011).

- NPWT dressings should be changed based upon the condition of the wound and according to wound type. Typically, the longer a wound is unhealed, the longer it will take to bring about

its closure. Thus, more acute wounds are typically closed sooner than chronic wounds (Krug et al. 2011) Vig et al. 2011)(Birke-Sorensen et al. 2011). In a large retrospective series of more than 1000 wounds, the median time to the point at which the wounds were ready for a change in therapy, either surgical closure or continuation with conventional dressings was 8 weeks (Hurd et al. 2017). Such patients will have received on average 24 encounters with clinicians to change the NPWT dressings and monitor for wound progress. (Hurd et al. 2017).

- We are concerned that the draft policy conflicts with existing coverage parameters set forth for by the DMEMACs in their NPWT LCDs as well as in other payer medical policies. In their policies the DMEMAC have provided the following parameters:

Utilization Parameters for Traditional NPWT Service; DMEMAC NPWT Local Coverage Determination (LCD), Noridian Healthcare Solutions

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HCPCS Code	Description	Coverage
E2402	Negative pressure wound therapy electrical pump, stationary or portable	Maximum of four months; 30 day progress notes are required
A6550	Wound care set, for NPWT electrical pump, includes all supplies and accessories	Coverage is provided up to a **maximum of 15 dressings *per wound per month***
A7000	Canister, disposable, used with suction pump, each	Coverage is provided up to a maximum of 10 canister sets per month unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day).

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- Furthermore, we are concerned that FCSO has not been clear on ---whether the limitation is per wound per patient or is the limitation based on the patient regardless of the number of wounds the patient may have? This is problematic as it appears that FCSO is providing a limitation based on the patient and not the number of wounds per patient. This will cause serious health implication to the patients that are being treated

Based on the statements above, review of current clinical literature and current practice guidelines, the Coalition does not agree with the utilization parameters set forth in the draft policy. The proposed utilization parameters are completely arbitrary and would be an unwarranted obstruction in clinicians' ongoing wound assessment of their patients. This obstruction can result in increased risk of infection and worsen patient outcomes and are without merit.

Recommendation – The Coalition recommends that FCSO eliminate the utilization parameters set forth in this draft policy for NPWT. There is no basis in the clinical evidence to support setting these parameters and the limitation conflicts with existing Medicare coverage policies.

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.

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

LACK OF TRANSPARENCY FOR THE CHANGES MADE IN THE DRAFT LCD

Finally, over the years, the Coalition has had concerns in the manner in which the MACs have developed new draft LCDs or revised existing ones. The process of developing a draft LCD should be transparent and information forthcoming to any stakeholder interested in the policy. This allows for meaningful comments on the policy being drafted. The information that a MAC utilizes in creating or revising an LCD should all be contained in the *Sources of Information and*

Basis for Decision bibliography in order for stakeholders to review that information to better understand how the MAC substantiated the language placed in the LCD created or revised. The information should be transparent and accessible. If in fact FCSO consulted additional resources, those resources should have been identified in the released draft policy.

The public has a right to review the resources and without access to that information, a draft policy is incomplete. We address our concerns regarding that the articles in the bibliography do not for the most part correspond to the changes made in the draft LCD. In summary, FCSO has not been transparent in their policy making efforts and we request that FCSO provide all the evidence used to impact the policy language contained in this draft LCD.

REFERENCED EVIDENCE PROVIDED TO SUPPORT CHANGES IN THE DRAFT LCD

FCSO states in its draft LCD, "*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"*

The Coalition is concerned by this statement and does not understand what FCSO deems as valid scientific literature and what "methods" are considered investigational. When reviewing the bibliography, it is unclear what criteria is universally being applied to determine whether a product/service is reasonable and necessary. For example, maggot therapy has multiple studies being cited in the bibliography and this therapy is being allowed in this draft policy. Yet none of these studies are RCTs. So we question the criteria by which FCSO is basing its decision to state dNPWT is not reasonable and necessary when there is ample evidence to the contrary? All of the "methods" described in this draft LCD do have scientific literature to support their efficacy and effectiveness much of which we have cited and believe that clinical organizations will provide to you as well.

FCSO cannot pick and choose which studies it believes are appropriate to make its case when other evidence is available which is contrary to the FCSO position. All literature needs to be reviewed. It is therefore unclear whether FCSO is only seeking out RCTs with dNPWT in which FCSO deems to not have any bias. If this is the case, those studies will be limited. RCTs in wound care are very difficult in that 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 eliminated, through 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.

Furthermore, the source of investment for a clinical study is not an automatic cause of bias or concern for the integrity of data generated. The Coalition agrees with CMS staff who have stated publically that there is no bias to a study funded by a manufacturer as long as the investigators have no financial conflict of interest with the manufacturer. One must also question -where will

the studies come from if they are not financed by the manufacturer?

Similarly, as federal and state governments are limited in the funds that they can provide to conduct randomized controlled trials and academic institutions are limited in the funds that they receive from government entities and non-for-profit organizations for conducting randomized controlled trials, it is often device manufacturers that have to fund these studies in order to obtain the clinical evidence that is needed to obtain approval/clearance to market the devices. All of these studies have to be reviewed by institutional review boards at each clinical study site and are subject to scrutiny by the FDA.

As a result, the Coalition questions why FCSO would utilize the multitude of non-RCT maggot therapy studies when there are significantly more studies available for debridement, NPWT as well as dNPWT which were not cited? This goes to the lack of transparency that was discussed above. FCSO should review ALL of the evidence which exists for the products and procedures that are being discussed in this draft - many of which are retrospective studies and case studies that are published in peer reviewed journals. This evidence is based on real world data and should be considered.

Conclusion

The Coalition of Wound Care Manufacturers is a non-voting member of the Alliance of Wound Care Stakeholders. The Alliance submitted more detailed clinical comments which we support. We would like to recommend that FCSO review the Alliance comments and adopt their recommendations. The Coalition appreciates the opportunity to provide you with our comments and look forward to a continuing dialogue with you as you address our comments and our concerns. If you have any questions, please do not hesitate to contact me.

Sincerely,

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Coalition of Wound Care Manufacturers
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