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 Wound, Ostomy and Continence Nurses Society, I thank you for the opportunity to provide comments in response to your proposed/draft LCD on Wound Care (ID: DL37166). Founded in 1968, The Wound, Ostomy and Continence Nurses Society™ (WOCN®) is a clinician-based, professional organization of over 5,000 members, who treat individuals with wounds, ostomies and incontinence, and are committed to cost-effective and outcome-based healthcare.

WOCN would like to express our serious concerns with the draft LCD and would encourage your group to scrap this draft in its entirety and work with stakeholders to achieve guidance that are based on clinical evidence and best practices. We note a widespread lack of relevant literature citations for your findings and would encourage you to re-examine the current literature to achieve a more comprehensive understand of current practices.

Outside of our overriding concern regarding the lack of relevant literature, we have specific concerns we would like to point out. First, we have major concerns regarding FCSO’s findings on Disposable Negative Pressure Wound Therapy (dNPWT). Your draft LCD states that dNPWT “is considered not medically reasonable and necessary,” we would again ask that you provide relevant findings in the literature to support this claim. In our experience, coupled with a review of the current literature, dNPWT meet the same clinical and treatment criteria when compared to traditional negative pressure treatment options. We believe your findings regarding dNPWT are inconsistent with current clinical findings. Furthermore, we believe your statements on dNPWT are inconsistency with current law.
On Dec. 18, 2015 President Obama signed into law the Consolidated Appropriations Act of 2016. Included in this legislation was a provision to allow for payment of disposable negative pressure wound therapy devices in the home health setting. The law states a "disposable device" is defined as: a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; and (B) 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 clearly expresses the intent of Congress that dNPWT is a substitute for traditionally NPWT and should be covered accordingly. We request FCSO cover dNPWT as reasonable and necessary based on the afore-mentioned principles.

Another area of concern to WOCN is your proposed language with regard to utilization parameters for debridements and NPWT. Specifically, your language on page 11 reads “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.” WOCN is strongly opposing setting arbitrary limits on the number of treatments for wound care as outlined in your proposed language. The only important factor when treating wounds is providing the appropriate number of treatments as necessary for increasing the chances that a patient’s wound will heal properly. This assertion is support by the current evidence regarding debridement which suggests that frequent debridement increases the chances for wound closure and we are certain that assigning an arbitrary number of debridements to every patient will only result in fewer wound closures and increased costs.

Furthermore, the LCD states “No more than 6 NPWT (CPT codes 97605-97606) services in a four month period will be considered reasonable and necessary. NPWT services exceeding this frequency may be covered upon redetermination only when medical necessity continues to be met as previously outlined and there is documented evidence of clear benefit from the NPWT treatment already provided.” WOCN reasserts its objections to setting arbitrary limitations on our ability to treat our patients. We repeat, the only important factor when treating wounds is providing the appropriate number of treatments as necessary for increasing the chances that a patient’s wound will heal properly.

Concern is also noted regarding your proposed limitation on providing wound care to patients undergoing palliative treatment. Within the limitations section, #5, you have suggested that “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.” In September 2014, the Institute of Medicine (IOM) released a report entitled Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life, this important report highlighted the importance of palliative care for those near the end of life. Specifically, the report notes that “Palliative care is associated with a higher quality of life, including better understanding and communication, access to home care, emotional and spiritual support, well-being and dignity, care at time of death, and lighter symptom burden. Some evidence suggests that, on average, palliative care and hospice patients may live longer than similarly ill patients who do not receive such care.” It further notes that “Palliative care services, including hospice, improve patient outcomes and may reduce health care costs by lessening use of acute care services. Changes are needed throughout the health care system to incentivize provision of comprehensive palliative care.” We would also point you to the Agency for
Healthcare Research and Quality’s findings on Palliative Wound Care at the End of Life\(^1\). This article specifically addresses wound care in palliative patients stating:

> Providing wound care, although it is often curative, is also palliative. It may seem contradictory, but patients nearing the end of their lives may benefit from the curative aspects of wound care. Wound care may lead to wound healing, even among the dying. Physiologically, prior to a patient's death, body systems begin to shut down usually over a period of 10 to 14 days or within 24 hours (Weissman, 2000) and blood circulation slows down. In some instances, the wound will heal in the weeks or days preceding death. Although wound healing may be thwarted by the physiology of the terminally ill, poor wound care and management of symptoms can be responsible for patient discomfort and can have a devastating effect on patients' quality of dying (Mallett, et al., 1999).

> When patients enter the last months, weeks, and days of their lives, the quality of their lives needs to be understood from the patient's subjective perspective in the context of the broader elements of their physical, functional, emotional, and social situations (Cella, 1994). Dying patients are generally weak and dependent on the care from others, often finding their ability to perform everyday functions impaired. Patients can often feel split between who they are and their illness. When possible, promoting self-care rather than having others perform all dressing changes or having others perform all essential activities of daily living can improve a patient’s sense of dignity and wholeness (Dirkson, 1995; Grey, 1994) and quality of life while dying.

We encourage you to revisit your findings on palliative wound care so they reflect both the current state of clinical practice and the findings of IOM and AHRQ.

Additional concern is noted by WOCN with regard to your proposed language on advanced dressings. As stated on page 4 the language reads: “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.” We are again concerned with the overall lack of understanding of wound care shown by FCSO as films, hydrocolloids, hydrogels are not considered advanced dressings.

Please allow us the opportunity to provide you our expertise in treating the patient population impacted by this LCD so together we can create a policy that balances the needs to reduce costs, combat waste and abuse, and improve patient care. We look forward to working with you on this important project. If we can be of assistance to you in any way, please contact Chris Rorick of the Society’s staff at chris.rorick@bryancave.com.

Sincerely,

Carolyn Watts, MSN, RN, CWON
President
Wound, Ostomy and Continence Nurses Society

\(^1\) AHRQ “Palliative Wound Care at the End of Time.”