WOCN® Wound, Ostomy, and Continence Nurses Society®

THE WOC COMMUNITY OF OPPORTUNITY™

wocn.org

WOCN® National Office
1120 Route 73, Suite 200
Mount Laurel, NJ 08054

P (888) 224.WOCN
F (856) 439.0525
E info@wocn.org

June 27, 2022

Robert M. Califf, M.D.
Commissioner
U.S. Food & Drug Administration
Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Docket No. FDA-2021-N-1212 for "Wound Healing Scientific Workshop."

Dear Commissioner Califf:

On behalf of the Wound Ostomy and Continence Nurses Society™ (WOCN®), I thank you for holding the recent Wound Healing Scientific Workshop and allowing for the opportunity to provide additional comments following the workshop. Founded in 1968, The Wound, Ostomy and Continence Nurses Society™ (WOCN®) is a clinician-based, professional organization of 5,000 members, who treat individuals with wounds, ostomies and incontinence, and are committed to cost-effective and outcome-based health. As such, please find the following comments to the questions posed by the FDA regarding non-healing chronic wounds. The answers to the FDA queries are gleaned from experts within the membership who focus on delivering care in the outpatient and homecare settings, as well as from acute care based practice settings who noted the issues encountered post discharge.

1. Wound types: What subtypes of nonhealing chronic wounds do you treat in your practice? (e.g. diabetic foot wounds, pressure wounds, arterial wounds, venous wounds.

    - Diabetic neuropathic foot wounds, Pressure Injuries, Arterial wounds, Venous wounds, Wounds due to Lymphedema and Mixed disease, Nonhealing surgical wounds, Malignant fungating wounds, Wounds due to trauma (accidents, gunshot wounds, falls, skin tears), Fistulas, Wounds due to drug use, Burns, Atypical wounds due to autoimmune disorders, drug reactions, or severe allergies.

2. Challenges: What have been your challenges to providing care to patients with nonhealing chronic wounds?

    - PCPs sending patients with wounds too late in the game especially foot ulcers.

- Strict surgical dressing rules, not all wounds are full thickness yet need proper dressing products. Partial thickness wounds can be very exudative yet per guidelines hydrofiber or foams are not covered. Most venous ulcers are partial thickness wounds. Not all skin tears are highly exudative or full thickness yet a silicone foam 1 or 2 x week would offer the best healing outcome, ease of use, no pain or further trauma but the patient often has to pay out of pocket. So other products are used that have to be changed daily which does not offer the quickest healing time nor comfort.

- Compression wraps and unna boot applications are limited. Some venous ulcers are so exudative that require 3 times a week changes upon initial therapy or during exacerbations therefore referrals are generated to home health for care.

- Lack of payment for compression until the patient has an ulcer. Costs in coming to wound center far outweigh the cost of compression socks. Many patients are on fixed income (especially in light of our economy) so cost of compression garments does not outweigh the need for food/medications.

- Complexity in obtaining compression pumps for patients with chronic venous disease who then develop go on to develop phlebolymphedema and longstanding venous ulcers; it takes months to qualify for quality lymphedema pumps that encompass LE and core compression.

    - Lee B. B. (2020). Phlebolymphedema: Neglected Outcome of Combined Venous and Lymphatic Insufficiency. *Vascular specialist international*, *36*(1), 1–3 https://doi.org/10.5758/vsi.2020.36.1.1

- Off loading products such as w/c cushions. Medicare will not pay for any seating cushion if they have not been issued a w/c. Complete out of pocket cost. Not all patients who are immobile/activity limitations have a w/c. Many borrow someone's w/c since their reduced mobility maybe limited but still at risk or have a pressure injury have to wait till they develop a stage 3 or 4 pressure injury on the trunk of the body before Medicare will pay for group 2 support surface or failed group 1.... too late, now you have a full thickness wound. Some patients have so many co-morbidies and immobility/impaired sensation that they need a group 2 surface to provide proper pressure redistribution bed or chair prior to developing a dangerous full thickness wound.

- Off loading shoes/inserts or other offloading devices are only covered for those with diabetes. Not all lower extremity neuropathic disease is from diabetes. Many other causes of for a neuropathic foot therefore these patients must pay out of their own pocket (some can't or will not) for proper offloading shoes/inserts once we get their foot ulcers healed.

- Great delay in obtaining proper offloading shoes/inserts b/c PCP has to order. Wound care specialists are not able to write the Rx. Many NPs are the PCP but they cannot write a Rx for footwear. Another visit (again more delays until the patient can be seen by their PCP and if the PCP remembers to write the RX for them to obtain custom inserts/foot wear. Delays means increase risk for re-ulceration and ultimately limb loss!

- Many of the patients are unhoused and have severe psychological issues which make it very difficult to access care and resources. Some insurances that they qualify for will not pay for wound care supplies and they do not have financial resources to pay for supplies.

- Challenges with patient adherence to plan of care due to mental or medical health co-morbidiites, poor understanding of the plan of care relationship to outcomes, financial barriers, nutritional gaps, poor control of underlying disease and transportation barriers to get proper follow up in outpt setting.

- Communication effectiveness between multiple providers including primary care, wound clinics and specialists, home care agencies, that create ineffective treatment plans with poor efficiency with delivery of optimal evidence based care.

- The significant impact of the nursing shortage in some areas are influencing the delivery of home health care to discharged acute care patients or patients who need more care then what can be provided in an outpatient setting.

3. Standard of Care: Do you utilize a standard of care protocol for your nonhealing chronic wound patients? If so describe what standard of care protocol you utilize (specific by wound etiology).

- Protocols are adjusted to meet individual patient focused needs. Some agencies have protocols based on outcomes, some are etiology specific.

- Guidelines used include but are not limited to WOCN Guidelines for care (Lower extremity arterial. Disease, Pressure injuries, Lower extremity wounds due to diabetes mellitus or neuropathic disease, Lower extremity venous disease) and WOCN Best Practice guidelines for care of Moisture associated skin damage and National pressure injury guidelines from NPIAP., International working group on the diabetic foot (IWDGF) ECRI guidelines.

4. Products: What new products (eg. drugs, devices, biologics, combination products) would you find helpful in treating nonhealing chronic wounds?

- Many products are currently available; however access to utilize them with patients is challenged by reimbursement, setting and cost. Some product costs influence usability across care settings based on reimbursement guidelines.

Specific examples

- Utilization of any skin substitutes are solely based upon insurance coverage therefore many patients i.e. with foot ulcers will not receive these products that potentially could expedite or even heal the foot ulcer.
    - should be based upon need in the refractory wound that meets the guideline recommendations vs based on insurance carrier.
- Offloading products are a must for neuropathic foot ulcers but many patients are not eligible. Not all patients can be placed in a Total contact cast due to environmental, psychological or comorbidities.
- Use of advance cynanoacrylate products. These can reduce care giver time and healing especially in patients with MARSI, MASD, Ostomy patients. Not covered in outpatient setting
- Concentrated Surfactant Dressings to address biofilms; limited in outpatient setting use can make all the difference in refractory wounds moving them healing trajectory
- Cadoxmer iodine limited outpt payment
- Honey; Many patients have to pay out of their pocket for this as well

The following would be items that may exist but are not portable or affordable across all settings

- Devices: that measure wounds and organizes wound photos for EMR;
- Thermoscans to detect temperature changes
- Scans that determine microbial impact in the wound,
- Scans that determine microvasularization of wound and surrounding area

5. Reimbursement: How does reimbursement affect your ability to provide care? As noted above as well as the following.

- Many patients are a limited in the number and types of supplies they may provide based on insurance requirements. Individuals without insurance have little if any resources available for wound care supplies. Newer wound products (e.g., drugs, devices, biologics, and combination products) are helpful but getting insurance reimbursement is time consuming for the provider and often the individual will be denied or the cost will be prohibitive.

- Wound care supplies bundled in home health thus many agencies are not utilizing available optimal wound products due to cost especially those who do not have certified WOC nurses on staff.

- In home health there are challenges to delivering optimal care with products/ visit frequency due to reimbursement framework. This coupled with the forementioned challenges provides many missed opportunities for quality outcomes.

- Cumbersome reimbursement for NPWT in post-acute care settings

Not sure how to integrate this, I believe Joanne used the Medicare guideline for surgical dressings. Surgical dressings have deemed that certain products are not recognized as effective i.e. sliver, cadomer iodine, Concentrated Surfactant dressings, chemical enzymes.

- Wound cleansing agents are not covered such as hypoclorous acid, commercial cleanswers, even N.S.

.

"Dressing With Materials Not Recognized As Effective I

Medicare recognizes the surgical dressing materials described by the product types listed above to be effective. They are considered reasonable and necessary when used as described by this policy. Medicare limits reimbursement to items that have sufficient clinical evidence to demonstrate that use of the item is safe and effective (see Medicare Program Integrity Manual, Chapter 13). Materials that lack sufficient clinical evidence are not recognized as effective and are not considered reasonable and necessary. The safety and effectiveness of the following materials have not been established:

- Balsam of Peru in castor oil
- Iodine – other than iodoform gauze packing
- Carbon Fiber
- Charcoal
- Copper
- Honey
- Silver"

We look forward to working with the FDA 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,

Dea J Kent

Dea J. Kent DNP, RN, NP-C, CWOCN
President