WOCN® Wound, Ostomy, and Continence Nurses Society®

POSITION STATEMENT: COMPETITIVE BIDDING AND OSTOMY SUPPLIES

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The Wound, Ostomy, and Continence Nurses Society™ (WOCN®) suggests the following format for bibliographic citations:

Wound, Ostomy, and Continence Nurses Society. (2018). *Position Statement: Competitive Bidding and Ostomy Supplies*. Mt. Laurel, NJ: Author.

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Supplies Originated By:
Wound, Ostomy, and Continence Nurses Society's (WOCN®) Competitive Bidding Task Force

Contributing Authors:

Task Force Chair
Kelly Jaszarowski, MSN, RN, CNS, ANP, CWOCN

Task Force Members:
Christine Berke, MSN, APRN-NP, CWOCN-AP AGPCNP-BC

Barbara Rozenboom, BSN, RN, CWON

Heather Trumm, BSN, RN, CWON

Date Submitted:
April 2018

Date Approved by the WOCN Board of Directors:
May 8, 2018

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Statement of Position

The Wound, Ostomy and Continence Nurses Society (WOCN) does not support the inclusion of ostomy devices (appliances, equipment, and accessories) in the Center for Medicaid and Medicare Services competitive bidding program. The inclusion of such will negatively impact the quality of life of an individual with an ostomy. These individuals frequently require custom fitting of the appliance and/or accessories to meet their individual medical and lifestyle needs.

Purpose

The primary purpose of this position statement is to recognize and to promote the importance of allowing persons with an ostomy the necessity and the freedom to access a variety of brands and types of quality ostomy supplies, accessories, and equipment. This allows individuals with an ostomy to be fit with a customized appliance to maintain their peristomal skin integrity, to limit stomal complications and to help promote their quality of life.

Definitions

1. **Stoma.** Surgically created opening in the urinary system or gastrointestinal tract.

2. **Peristomal skin.** The skin around the stoma.

3. **Irritant dermatitis.** Maceration or erosion of the skin due to chronic exposure to corrosive output from the stoma.

4. **Allergic dermatitis.** Reaction to skin care products applied with or composing the stoma pouching system adhesive; manifests as erythema, pruritis (itching), vesicles, papules, bullae, skin induration and erosions.

History

Competitive bidding is a competition among suppliers who provide specified medical equipment and supplies. Bids are evaluated based on supplier eligibility, financial stability and bid price. Contracts are awarded to the Medicare suppliers who offer the best price and who meet applicable quality and financial standards. Contract suppliers must agree to accept Medicare assignment on all claims for bid items and will be paid the bid price amount.

The fiscal year 2017 budget included a provision to expand Medicare's competitive bidding program to new product categories, including ostomy supplies. The Social Security Act defines ostomy devices as prosthetics: devices required to restore lost functionality after surgery. Individuals undergoing ostomy surgery have lost regular functionality of their bowel or bladder and require an ostomy appliance to be worn on the outside of their body to collect bodily waste.

Under competitive bidding, beneficiary access to high quality, brand name, customizable appliances and accessories will be limited. While the WOCN Society and its members recognize the importance of cost effectiveness, with lowered prices, suppliers may not be able to provide

diverse, high quality products and customized patient services. Suppliers may substitute less expensive, non-customizable ostomy supplies. Product selection will be based on price and not on individual need. Individuals will be faced with a “one size fits all” ostomy product selection which could lead to potential ostomy device-related complications.

Potential subsequent cost increases if an individual is forced to use a “one size fits all” device include: increased hospitalizations and emergency room visits, increased peristomal skin complications, impaired chronic disease management, unsuccessful or prolonged rehabilitation and an increased delay in an individual’s return to work. Furthermore, these customizable devices require the expertise of a certified ostomy specialty nurse for the selection of properly fitted devices. All of the afore-mentioned statements are supported by a consensus document entitled *Ostomy Guiding Principles for Sustainable Access to Ostomy Services, Technologies and Innovation* (WOCN, 2014) which is supported by the following organizations:

- American Academy of Nurse Practitioners
- American Association for Homecare
- Bladder Cancer Advocacy Network
- Crohn’s and Colitis Foundation of America
- ConvaTec, Inc.
- Gerontilogical Advanced Practice Nurses Association
- Great Comebacks
- Hollister, Inc.
- Nu-Hope Laboratories, Inc.
- Society for Urologic Nurses and Associates
- Society of Gastroenterology Nurses and Associates, Inc.
- Society of Pediatric Nurses
- United Ostomy Associations of America
- Wound, Ostomy and Continence Nurses Society
- Youth Rally Committee, Inc.

In September 2017, the Centers for Medicare and Medicaid Services (CMS) decided to temporarily delay moving forward with the next steps of the competitive bidding program to allow the new administration further opportunity to review the program (WOCN, 2016).

Supportive Statements

A literature search conducted using key words including, but not limited to, quality of life with an ostomy, ostomy pouch, peristomal skin and peristomal complications yielded 800 articles. This search was further refined and 201 articles of interest were identified. Of the 201 articles, thirty publications addressed ostomy device fitting and quality of life. Additionally, two resolutions were noted which addressed ostomy devices and access to care: House Resolution 152 and Senate Resolution 95.

Following ostomy surgery, individuals need specially selected medical prosthetics to manage (temporarily or permanently) intestinal or urinary system function, re-establish activities of daily living, and improve quality of life. Ostomy products are customized to the clinical needs of the individual and are not the same as other easily interchangeable medical supplies such as gauze. These individuals, then, require access to uniquely skilled ostomy specialty nurses who recommend and customize ostomy products. In 2011, a bill was brought forth in both the US House and Senate recognizing the life-saving role of ostomy specialty nurses and prosthetics in the daily lives of hundreds of thousands of people with an ostomy in the United States. Congress

has recognized the physical, psychological, and emotional importance of restoring function and improving the quality of life through supporting access to and coverage of prostheses. Currently, ostomy products are prescribed by health care providers and meet the definition of prosthetics under the Medicare program. Ongoing advances and innovation in ostomy prosthetics technology can dramatically improve the lives of those who undergo ostomy surgery by helping to normalize their intestinal or urinary system function and by improving physical well-being. (H. Res. 152, 2011; S. Res. 95, 2011). These individuals will need access to both customizable prosthetics as well as specialty educated ostomy nurses.

Individuals who undergo ostomy surgery are often evaluated pre- and post-operatively by a clinician who is specially educated in the care of individuals with an ostomy. Ostomy supplies are generally clinically selected, adjusted and fitted by a specially educated provider and are based on an individual's ostomy needs. Assessment and pouch refitting by an ostomy expert is recommended periodically throughout the individual's life (Maydick-Youngberg, 2017). Ostomy nurses are familiar with a wide variety of ostomy products and can apply their expertise to recommend appropriate and secure pouching systems. The assessment includes skin type, stoma output and frequency of changing a skin barrier. Once a thorough assessment has been conducted, a plan for an appropriate pouching system is developed. The Association of Stoma Care Nursing (ASCN, 2013) stipulates that choosing an appropriate appliance to suit the individual's needs is a standard of care expected from stoma care nurses.

A study by Gemmill et al. (2010) involving individuals with a urinary diversion revealed that the inability to manage ostomy complications related to daily care and an inability to obtain needed supplies can hinder adjustment to living with an ostomy.

Wound, ostomy and continence (WOC) nurses are familiar with reimbursement issues and the impact on management as well as the supplies required for individuals with complex care needs. The goal is to find the least expensive management system that offers the best skin protection and containment (Wagner, 1998). Most individuals with an ostomy will experience some long-term and, perhaps, lifelong needs after discharge from healthcare services. These needs include concerns or issues relating to ostomy appliances. Ostomy specialists, such as WOC nurses, are essential for individuals with an ostomy to have access to long-term in order to address these needs (Sun et al., 2013). The American Society of Colon and Rectal Surgeons published ostomy guidelines indicating individuals living with an ostomy should have access to an ostomy nurse for follow-up care, as needed and whenever possible (Hendren et al., 2015).

WOC nurses are specialty nurses who are recognized by the American Nurses Association (ANA). WOC nurses have completed additional education focused on ostomy care and many have achieved certification formally validating their knowledge and ability to meet the needs of individuals with an ostomy. ANA's recognition of the WOC nursing specialty is an indication WOC nurses adhere to the standards of practice cultivated by ANA. The WOCN Society has published scope and standards of practice. Within this publication, three focus areas are identified: Scope of Nursing Practice, Standards of Nursing Practice, and criteria for designation of Specialty Practice (WOCN, 2017b).

Pouching a stoma is truly an art. There are a wide variety of ostomy appliance styles to choose from including: one and two-piece systems, clear and opaque pouches, closed and drainable pouches, and flat and convex skin barriers. Additionally, accessory items may be required to obtain a proper fit. The expertise of an educated ostomy nurse, such as the WOC nurse, is invaluable in selecting the proper system for a given individual. The key to preventing and/or alleviating peristomal skin breakdown is finding and carefully fitting an appropriate

pouch (Rothstein, 1994). Ill-fitting ostomy appliances places individuals at risk for skin complications, infections, increased physician office visits, increased emergency room visits, and hospitalizations (WOCN, 2014).

Quality of Life (QOL) studies demonstrate the surgery to create a stoma itself impacts QOL. Many individuals in this population experience either stomal or peristomal complications. Most studies conclude that peristomal skin complications create ostomy self-management issues that affect individuals emotionally, psychologically and financially (Maydick-Youngberg, 2017).

High incidence of peristomal skin disorders eventually affects one's QOL and can result in a higher cost of care due to misuse of medical resources when an individual's discomfort will lead to more frequent changes in ostomy equipment in effort to create a better seal (Agarwal & Erlich, 2010). Prevention of skin problems and good management of the stoma and surrounding skin are critical components of ostomy care with regards to QOL (Hoeflok, Guy, Allen, & St-Cyr, 2009). Adverse events of peristomal skin complications have the potential to increase hospitalizations, increase morbidity, impair QOL and wellbeing, and can lead to social isolation (Cutting &White, 2002; Pittman, Kozell, & Gray, 2009). Prieto, Thorsen, and Juul (2005) reported issues related to the use of an ostomy pouch relating to QOL; including interruption of sleep, peristomal skin disorders, and worries about pouch leakage, smell and odor.

Nichols and Riemer (2011) reported that peristomal skin is vulnerable to stool and urine both of which can be harmful and cause skin breakdown. An improper fit of an ostomy appliance can result in leakage of stool and urine on the peristomal skin. The resulting physical and psychological distress impacts QOL. Frequent appliance changes can cause peristomal skin damage and affect individual's perception of "normal management". In a study by Park, DelPino, and Orsay (1999), skin irritation was the most common early ostomy complication and was attributed or secondary to stoma neglect, leakage, improper fit or frequent change of pouching system.

A study by Lyon, Smith, Griffiths, and Beck (2000) reported the majority (87 of 174) of individuals with an ostomy in the study were diagnosed with irritant dermatitis. Approximately two thirds of these individuals responded to changes in ostomy equipment. According to the *WOCN Clinical Guidelines for the Management of the Adult Patient with a Fecal or Urinary Ostomy* (QOCN, 2017a), it is important to establish a pouching system that maintains a seal for a predictable amount of time without leakage and that protects the peristomal skin. The individual should be advised, therefore, to seek assistance from a WOC nurse or nurse skilled in ostomy care to assist in the selection of an effective pouching system.

Allergic dermatitis should be suspected when the lesions correspond exactly to an area covered by a specific product or component of the pouching system (tape border or skin barrier). The sensitizing product needs to be identified and removed from the ostomy care protocol (Szymanski, St-Cyr, Alam, and Kassouf, 2010). Once the sensitivity develops, it may last a life time (Ratliff & Donovan, 2001). A study by Maydick-Youngberg (2017) showed approximately one third of the participants experienced allergic contact dermatitis and subsequently reported significantly lower QOL scores than those without this complication. Nyback and Jemec's (2008) study reported the majority of persons who experienced peristomal skin problems had allergic contact dermatitis with particular concerns because skin barriers in pouching systems are supposed to protect peristomal skin. Allergic contact dermatitis can be attributed to an individual's sensitivity to the components of the equipment (pouches or accessories). A study by Stevenson (1975) showed dermatitis cleared after the problematic product was removed.

Treatment of allergic contact dermatitis often necessitates a change in appliance brand.

Competitive bidding would potentially limit access to alternative brands of ostomy devices for these individuals.

Periodic weight gain, weight loss or pregnancy will affect the shape of the abdomen and, therefore, the fitting of the ostomy pouch. Many individuals have their appliances customized by their suppliers (Chandler, 2015). The appliance should be carefully measured and may need to be refitted from time to time as the stoma shrinks after surgery or as the individual's weight or abdominal contour changes (Rothstein, 1994). Stomas are not always located in an ideal position or have a perfect spout which impacts the ability to achieve a good seal and prevent leakage. (White, 2014).

Parastomal hernia is a frequent complication after stoma formation. A parastomal hernia is a type of incisional hernia that allows protrusion of abdominal contents through the abdominal wall defect created during ostomy formation. Corwin and Redmond's (2010) study shows just under a third (31%) of individuals surveyed reported they had changed the type of appliance they had used following the appearance of a parastomal hernia. Thinning skin over a herniated bulge has implications for changing an appliance prescription.

A peristomal pressure injury develops when pressure from a rigid skin barrier on the peristomal skin or when increased pressure from the use of an ostomy belt creates mechanical skin damage. Peristomal pressure injury management requires physical exam, resizing and refitting of the pouching system that may be too convex or too firm (Szymanski et al., 2010). *WOCN Clinical Guidelines for the Management of the Adult Patient with a Fecal or Urinary Ostomy* (2017a) recommends identifying and removing the source of pressure causing the injury and providing an alternative pouching system. Competitive bidding would potentially limit the choice of alternative pouching systems available to the individual in need.

Medical Adhesive Related Skin Injury (MARSI) is damage caused by trauma to the skin from the adhesive component of an ostomy appliance. Removing skin barriers will pull off layers of skin cells so a proper choice of appliance is paramount (Thompson, North, Davenport, & Williams, 2011). An individual's preexisting skin problem needs to be considered when selecting an appropriate appliance. Treatment of skin conditions may affect the range of choices of ostomy appliances.

Any disease process that affects the dexterity of an individual's hands will indirectly challenge a person's ability for self-care and to be independent with an ostomy. When advising individuals with an ostomy, the range of movements required for appropriate care of a stoma must be considered. Older people tend to have a reduced grip and sensation, hand and finger strength, speed of hand movement and fine manual dexterity (Carmali, Patison, & Coleman, 2003). Williams (2014) suggested an assessment and choosing the correct appliance based on this assessment is an integral part of ostomy nursing care. Specific issues with manual and visual dexterity make a pouch change more complex.

Conclusion

Ostomy devices are prosthetics required to restore lost functionality of the bowel and bladder after surgery and require customized fitting to meet the individual needs of those with an ostomy. Certified WOC nurses are specialty educated nurses who have received additional education and, as a result, are knowledgeable in ostomy appliance fitting and management. Ostomy appliances and accessories, therefore, should not be included in the competitive bidding process as they are prosthetic equipment. Individuals with an ostomy should have access to specially educated nurses for fitting of these prosthetics.

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