

June 24, 2020

To Whom It May Concern:

On behalf of United Ostomy Associations of America, Inc., our organization strongly supports the creation of a new HCPCS code for an ostomy product, specifically disposable irrigation sleeves, under Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS). As the voice and leading organization advocating for people living with an ostomy, we know first-hand how important access to ostomy supplies are for this patient population.

United Ostomy Associations of America, Inc. (UOAA) is a 501(c)(3) nonprofit organization that supports, empowers, and advocates for people who have had or will have ostomy or continent diversion surgery. We have over 300 affiliated support groups across the United States. There are between 725,000 to one million Americans living with an ostomy or continent diversion, and over 100,000 new life-saving ostomy surgeries occur in America yearly.

Ostomy surgery may be needed by people who suffer from inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, birth defects, injury, cancer and other intestinal or urinary or gastroenterology medical conditions. After undergoing surgery, patients rely on pouching systems for the collection of their bodily waste, sometimes for the rest of their life.

Colostomy irrigation is a well-established procedure. It is a procedure in which a patient with a colostomy instills water into the colon, like an enema, using a tube with an attached cone that is lubricated and then inserted into the stoma. This causes the colon to empty and pass stool through the stoma into a transparent sleeve. Irrigation allows for control of bowel function by reducing or eliminating spontaneous episodes of stool and gas through the ostomy. Research has demonstrated improved quality of life outcomes for those who choose to perform irrigation¹.

There are specific ostomy supplies needed for this procedure that include: 1) water bag/regulator and a cone to introduce water into the colostomy, 2) an irrigation sleeve which is placed around the stoma and directs the flow of stool into the toilet, 3) an adjustable belt to attach to the irrigation sleeve, and 4) a tail closure for the end of the irrigation sleeve.

Ostomy supplies are covered under the Prosthetic Device benefit (Social Security Act Section 1861(s)(8)). Currently, there is only one HCPCS code for irrigation sleeves (A4397), which has been in effect since 1/1/1996. CMS established a maximum quantity limit of four (4) per month for this product.

Since its inception of this code, technology has improved and changed; wherein, in addition to reusable irrigation sleeves, disposable sleeves are also now used and available on the market. A reusable sleeve needs to click onto a faceplate with a belt or a 2 piece pouching system and needs to be cleaned, hung dried and reused daily; hence the allotment and reimbursement rate of only 4 sleeves per month. Disposable sleeves can be used with almost any pouching system, are applied directly onto the skin and need to be disposed of after each bowel movement because it cannot re-adhere to the skin's surface. Hence, patients using disposable irrigation sleeves require a 30-day supply allotment.

Current Medicare guidelines with the existing code and 4 sleeve allotment per month, result in restricted access to colostomy irrigation which disproportionately impacts individuals who:

- present with challenging abdominal contours (a common issue, especially among obese individuals), deep creases or folds causes stool/water to seep around traditional rigid reusable irrigation sleeves. On the other hand, the adhesive/flexible backing of disposable sleeve securely fits into creases/folds
- produce thick/pasty stool, which is very difficult to clean from a reusable irrigation sleeve. In addition, thick/pasty stool is an indication in of itself to perform irrigation as it often contributes to leakage in traditional pouching systems
- use a 1-piece pouching system or 2-piece coupling system due to abdominal contours and history of leakage
- present with medical conditions (e.g., having a suprapubic stoma close to a colostomy and being prone to bladder infections) with surgeon recommendations to use new disposable irrigation sleeve daily
- prefer irrigation as a lifestyle choice

In our advocacy efforts for these individuals with restricted access to colostomy irrigation, UOAA submitted an LCD Reconsideration Request with the DME MACS to request an increase to the utilization limit for A4397, irrigation sleeve, each. This request was denied and during our informal interview, a pathway to a new HCPCS code was suggested for disposable sleeves by PDAC and the Medical Directors.

For the reasons above, we assert the necessity of a new HCPCS code for disposable irrigation sleeves for proper monthly allotment and reimbursement. Ultimately, all people have a right to access the appropriate amount of supplies needed to perform colostomy irrigation.

If we can be of assistance to you in any way, please contact Jeanine Gleba, UOAA's Advocacy Manager at advocacy@ostomy.org.

Thank you for recognizing the importance of this issue and considering this application for a new code.

Sincerely,



Susan Burns
UOAA President

1. Grant M, McMullen CK, Altschuler A, et al. Irrigation practices in long-term survivors of colorectal cancer with colostomies. Clin J Oncol Nurs 2012;16(5):514-9 doi: 10.1188/12.CJON.514-519[published Online First: Epub Date]