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Dear DME MAC Medical Directors:

On behalf of United Spinal Association's Access and Care Coalition (ACC)¹, I would like to draw your attention to the critical issue of Medicare beneficiary access to ostomy supplies. Ostomy surgery is a life-saving procedure that allows bodily waste to pass through a surgically created stoma on the abdomen into a prosthetic known as a 'pouch' on the outside of the body. Ostomy supplies include ostomy pouches, skin barriers, adhesives, ostomy pastes, deodorizers and moisture barriers.

United Spinal Association, founded by paralyzed veterans in 1946, is dedicated to enhancing the quality of life of all people living with spinal cord injuries and disorders (SCI/D), paralysis, neurological conditions and other mobility disabilities, including veterans, and providing support and information to loved ones, care providers and professionals. United Spinal represents 5.5 million wheelchair users across the country, has over 61,000 members, 45 chapters, 100 support groups and 121 rehabilitation hospitals and therapeutic partners nationwide. We also work collaboratively with Spinal Cord Injury Model (SCI) System Centers and the Model Systems Knowledge Translation Center that provide innovative research and support in the field of SCI. United Spinal Association is also a VA-accredited veterans service organization (VSO). The mission of the Access and Care Coalition's (ACC) is to counter restricted access to medical supplies under Medicare, Medicaid and private insurance for suppliers, manufacturers, clinicians and consumer and disability advocates. ACC members include companies and organizations such as United Spinal Association, United Ostomy Associations of America, Inc., Wound Ostomy & Continence Nurses Society, the Wound Ostomy Continence Certification Board, Association of Rehabilitation Nurses, Spina Bifida Association, Coloplast, Hollister, Wellspect and many others. See full list on page 3 and at the link below.

Individuals who undergo ostomy surgery are often evaluated pre- and post-operatively by a clinician who as expertise in ostomy care such as a Wound Ostomy Continence Nurse (WOCN). 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). During this review process it could be determined that a patient would need ostomy supplies in excess of the Medicare usual maximum amount. Medicare does allow for

¹ Access and Care Coalition, <https://unitedspinal.org/access-care-coalition/>

quantities of supplies that exceed the usual maximum amount, if proper documentation is made in the medical record that explains the need for the increased amount. Despite this process allowing for the approval of supplies that exceed the usual maximum amount, Centers for Medicare and Medicaid Services (CMS) billing contractors, under the Medicare Durable Medical Equipment, Prosthetic, Orthotics and Supplies (DMEPOS) benefit, very rarely approve claims for over the maximum allowable limits. As a result, DME providers very rarely submit claims for over the allowable limit and submit claims for only the allowable quantity regardless of what the clinician has prescribed. Individuals who use ostomy supplies (ostomates) are facing access barriers to medically prescribed care for their ostomy supplies which are covered under the prosthetic device benefit:

Devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ ...

Medicare Benefits Policy Manual, IOM 100-2, 13.120

Replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices ...

Social Security Act § 1861 (s)(8)

Durable Medical Equipment (DME) suppliers usually do not pursue the lengthy and cumbersome appeals process nor does the beneficiary have a denied claim for the overage to appeal. Patients face the financial burden of paying for all supplies over out-of-pocket limits. Worse still are the patients who face negative medical consequences when they cannot afford to pay out of pocket. One patient reported:

"When I have to use regular baggies from the supermarket held onto my body with duct tape, my skin is ripped open."

There is precedence within Medicare that would ease the process to allow for medically necessary treatments above the capped amount. The Bipartisan Budget Act of 2018 (BBA of 2018) (Public Law 115-123) included two provisions related to Medicare payment for outpatient therapy services including physical therapy (PT), speech-language pathology (SLP), and occupational therapy (OT) services.² In short, the law preserves the therapy cap amounts as thresholds but does allow claims to be submitted above the cap but they must include the KX modifier as a confirmation that services are medically necessary as justified by appropriate documentation in the medical record. We would propose that CMS and CMS contractors move forward with implementation of a similar modifier system for ostomy supplies which would greatly reduce claims denials.³

Access barriers to ostomy supplies makes living with an ostomy unmanageable. It results in numerous negative consequences. Clinicians have witnessed ostomates experiencing chronic skin breakdown, pain, appliance leakage, emotional stress and anxiety. Ostomates are hospitalized and sent to the ER for healthcare and some ostomates have resorted to using improper supplies given to them by someone else who no longer uses them.

ACC recommends formal review of the current ostomy HCPCS codes and allowable quantities to increase/adjust as necessary. Quantities have not been changed since 2000. CMS should consider establishing a flag in the system by adding a modifier, for example, for those requiring greater quantities in their medical records, based on medical necessity. The appeal process can take up to 60 days to get a response for a 1st level "redetermination" appeal (one ostomate was still waiting after 6 months) to obtain a greater quantity, at which point an ostomate's

² Section 50202 of the BBA of 2018 repeals application of the Medicare outpatient therapy caps and its exceptions process while adding limitations to ensure payment for appropriate therapy services.

³ CMS Medical Review and Education. <https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/medical-review-and-education>

monthly supply amount will have run out. ACC recommends that CMS establish, at minimum, a weekday 72-hour appeal process.

ACC, specifically, ACC members United Spinal Association, United Ostomy Associations of America and the Wound, Ostomy and Continence Nurses Society would like to work with you to achieve a resolution to this medically dangerous problem. We look forward to hearing from you. Please do not hesitate to contact me at abennewith@unitedspinal.org or (800) 404-2898.

Sincerely,

Alexandra Bennewith

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Access and Care Coalition Membership:

ABC Medical
American Association for Homecare
AppleWest: Home Medical Supply
American Association on Health & Disability
American Urological Association
The Arc
Association of Rehabilitation Nurses
Bladder Cancer Advocacy Network
CHC Solutions
Christopher & Dana Reeve Foundation
Coloplast
Convatec
Crohn's & Colitis
Cure Medical
Har-Kel Inc., Medical Specialties
Hollister
J&R Medical
Lupus Foundation of America
Muscular Dystrophy Association
McKesson
Multiple Sclerosis Society
Paralyzed Veterans of America
The Simon Foundation for Continence
Spina Bifida Association
Teleflex
United Ostomy Associations of America
United Spinal Association
Wellspect
Wound, Ostomy and Continence Nurses Society
Wound Ostomy Continence Certification Board