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RE: Meeting Request: Coding Review and Exceeding Maximum Amounts - Ostomy Supplies

Dear DME MAC Medical Directors:

Thank you for your quick response to our letter dated April 10, 2024, requesting a review of both the current ostomy Healthcare Common Procedure Coding System (HCPCS) codes and long-term outstanding coverage issues, as well as the processing of Medicare-approved claims that exceed the usual maximum amount. On behalf of the million people living with an ostomy or continent diversion in the United States and approximately 100,000 surgeries performed annually, the Wound Ostomy Continence Nurses Society (WOCN), United Ostomy Associations of America, Inc. (UOAA) and the Access and Care Coalition (ACC) look forward to working with you on these two important issues to help ensure each beneficiary has access to appropriate ostomy supplies. The WOCN Society and UOAA worked with the DME MACs back in October 2000 on the issue of ensuring Medicare beneficiaries have sufficient quantities of ostomy supplies.

The feedback we have gathered from both clinicians and patients suggests that a vast majority of patients are not receiving medically necessary supplies when they exceed the Medicare allowable despite proper documentation in the medical record explaining the need for an increased amount. Secondly, a comprehensive code review of ostomy supplies has not been done in over two decades and current literature supports updates to some of the allowables for products within the ostomy supplies category, as well as providing clarification for certain parts of the ostomy coverage policy.

Beneficiary Access to Supplies Above Maximum Allowable

We believe the most immediate need is an administrative review of the process used by MACs when adjudicating claims for the small percentage of beneficiaries who need ostomy supplies above the maximum allowable amount. Local Coverage Determination (LCD) L33828 states that Medicare will approve the use of a greater quantity of supplies than the amounts listed if adequate documentation is included in the beneficiary's medical record. This statement is also supported in the Ostomy Supplies Policy Article A52487 which provides that *"For quantities of supplies that exceed the usual maximum amount, there must be information in the medical record that explains the need for the increased amount. This information must be available upon request"*. The policy also states that *"There will be variation according to individual beneficiary need and their needs may vary over time...the actual quantity needed for a particular beneficiary may be more or less than the amount listed depending on the factors that affect the frequency of barrier and pouch change."*

While Medicare has clearly stated that it will approve quantities above the maximum allowable, we have found that the process used by MACs to approve these claims is disjointed, ambiguous, and results in a vast majority of claims being outright denied. Furthermore, following a denial we have found that the current appeals process available to beneficiaries is often lengthy and impractical for someone needing monthly supplies.

While many of the current allowable limits are acceptable for a majority of ostomates, each beneficiary has their own clinical needs and a small number of them require additional supplies for clinical indications such as a high output stoma, wound at the stoma site, skin folds and creases, and skin excoriation to name a few). According to the *WOCN Clinical Guidelines for the Management of the Adult Patient with a Fecal or Urinary Ostomy* (QOCN, 2017a), up to 80% of patients experience stomal complications within their lifetime including stomal complications (2%-80%) such as stomal retraction of hernia or peristomal skin complications (29%- 63%) all which influence pouching efficiency. 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. In order to maintain skin integrity and avoid complications it is imperative that providers be able to manage each ostomate as their clinical condition dictates. As noted in the *Ostomy and Continent Diversion Patient Bill of Rights: Research Validation of Standards of Care* in the *Journal of Wound Ostomy & Continence Nursing*, it is crucial that ostomates have access to compatible and securely fitting ostomy products to improve patient outcomes and avoid medical consequences such as [peristomal skin complications] PSCs and hospital readmissions.¹

In proven estimates, 90% of beneficiary appealed claims for supplies above the maximum allowable are denied.² While a small percentage of those denials can be attributed to improper documentation by the provider, in an overwhelming majority of the cases the denial is granted despite proper documentation in the medical record as required by Medicare. We would ask that the DME MACs work with provider and patient advocacy groups to highlight inefficiencies in this process and identify solutions which would result in more beneficiaries receiving the supplies their providers have deemed necessary.

Those who are providing the care for ostomates are dedicated to ensuring their supply needs fit their clinical needs and are willing and able to provide the medical documentation to support claims requiring overages. We believe there is a breakdown in communication between providers and MACs regarding the requirements for medical necessity. Access challenges to medically necessary products include individuals with more than one ostomy; the location of the stoma may cause leakage; a high output stoma; and skin integrity issues around the stoma.³

Ostomy Supplies Coding and Allowable Review

In addition to ensuring access to supplies above the maximum allowable, we believe it is appropriate to undergo a comprehensive review of the ostomy-related HCPCS codes as we have identified several outdated and/or missing codes and associated allowables. We would welcome the opportunity to work with you on updating the ostomy coverage policy and identify the appropriate literature to support those updates. A few examples of necessary updates include the following:

- **Multiple Ostomies:** Individuals with 2 ostomies often do not have access to an adequate number of supplies. The current policy does not specifically include language to address the coverage criteria and quantity limits for multiple stomas which leads to inconsistencies with coverage. **We would request an update to the Local Coverage Determination highlighting this important need.**
- **Irrigation Supplies: A4436 and A4437:** The coding for irrigation supplies was split into 2 codes to distinguish between a disposable and reusable sleeve (A4436 and A4437 replaced A4397). This also included a quantity change from 4 (each) to once a month for a monthly allowable. Even though the code represents a disposable sleeve, the quantity published is 1 and it is a 'monthly supply'. Additionally, the reusable sleeve now shows a quantity of 1 and providers are only distributing 1 sleeve per month rather than the previous monthly quantity of 4. **We would request an update to the Local Coverage Determination clarifying this coverage policy.**
- **Hernia Belt: A4396:** HCPCS A4396 is listed in the ostomy policy, so technically A4396 should be covered for anyone with a surgically created stoma without the need for an additional diagnosis code. However, in the experience of most clinicians, Medicare will not pay for A4396 unless a diagnosis for hernia is present in the

¹ Burgess-Stocks, J.; Gleba, J.; Lawrence, K.; Mueller, S. *J Wound Ostomy Continence Nurs.* 2022;49(3): 258-259. Ostomy and Continent Diversion Patient Bill of Rights: Research Validation Standards of Care.

² United Ostomy Associations of America, Retrospective Quantitative Survey, 2019

³ Ibid.

medical notes (even though a hernia diagnosis code is not in the ostomy policy). **We would request an update to the Local Coverage Determination clarifying this coverage policy.**

Ostomy accessories are products that are used in addition to the typical ostomy system which includes the barrier and a pouch. Accessories include strips, rings, sprays, adhesive remover wipes, paste, powder, cleanser wipes to name a few. The purpose of ostomy accessories is to achieve the best possible fit, seal, and healthy peristomal skin. Often individuals must 'mix and match' supplies and accessories to find the best solution. We see access issues for individuals who require more accessories than the max allowable or who require more than one accessory from the same HCPCS family. **We would request an update to the Local Coverage Determination clarifying this coverage policy.**

As previously noted, the ostomy coverage policy has not had a review in over two decades. Since then, there has been significant progress in ostomy product manufacturing, changes in terminology, and development of new products that necessitate a comprehensive review, in line with the Journal of Wound Ostomy & Continence Nursing's Ostomy and Continent Diversion Patient Bill of Rights: Research Validation of Standards of Care⁴, to ensure the continued needs of individuals with bowel and bladder diversions are met so they can live functional and full lives.

It would be most effective to discuss this with you so both patients and providers can highlight their individual experiences around denials in order to identify areas in need of improvement. We would very much like to schedule a meeting to discuss these access issues with you in more detail. Thank you for your consideration. Should you require any additional information, please do not hesitate to contact me at abennewith@unitedspinal.org or 800-404-2898. We look forward to hearing from you.

Sincerely,

Alexandra Bennewith

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Vice President, Government Relations, United Spinal Association
Co-ordinator, Access and Care Coalition

Cc: Denise Winsock, Senior Provider Relations Analyst, CGS Administrators

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

⁴ Burgess-Stocks, J.; Gleba, J.; Lawrence, K.; Mueller, S. *J Wound Ostomy Continence Nurs.* 2022;49(3):251-260. Ostomy and Continent Diversion Patient Bill of Rights: Research Validation Standards of Care.

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