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February 9, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks-LaSure,

Thank you for your steadfast commitment to the United States' healthcare system as demonstrated by your decades long service. I am writing to clarify some information regarding female external urinary collection devices (EUDs) and its coverage under Medicare and Medicaid.

I am concerned about the potential gender disparities and accessibility in coverage of these devices and request follow-up information. Female EUDs are an alternative to minimize use of indwelling urinary catheters for non-critically ill women, where the latter often lead to high rates of urinary tract infections (UTIs). Research has found that indwelling urinary catheters – for both female and male patients – are placed at a highly unnecessary rate, with half of the five million indwelling catheters placed being deemed as not appropriate.¹ Women are still more likely to develop a catheter-associated urinary tract infection than men.² Female EUDs are an effective alternative to not only decrease infections, but to also allow patients to use these devices at their homes.

However, Medicare and Medicaid only cover female EUDs as an alternative to indwelling catheters for patients who have permanent urinary incontinence.³ Can you please clarify the following:

- What conditions qualify under permanent urinary incontinence for female patients?
- If a female patient does not have a condition qualified as permanent urinary incontinence, what are their options for coverage of female EUDs?
- Outside of hospital settings, up to 50% of females experience urinary leakage or incontinence during their lifetime and up to 10-20% suffer from bothersome leakage, which an external urinary

¹ Prevent Catheter-Associated Urinary Tract Infections. Cambridge, MA: Institute for Healthcare Improvement; 2011. (<https://www.alliance4ptsafety.org/IHAMAPS/media/media/HEN/ihihowtguidepreventcauti.pdf>)

² Letica-Kriegel AS, Salmasian H, Vawdrey DK, et al. Identifying the risk factors for catheter-associated urinary tract infections: a large cross-sectional study of six hospitals. (<https://bmjopen.bmj.com/content/9/2/e022137.citation-tools>)

³<https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ProviderComplianceTipsforUrologicalSupplies-ICN909474Print-Friendly.pdf>

collection device may help alleviate.⁴ This typically comes from weak pelvic floor muscles, commonly due to vaginal childbirth. Has CMS considered covering female EUDs for these conditions?

- There is a significant amount of catheterization methods for the male anatomy and very few in comparison for the female anatomy.⁵ However, several female EUDs have been designed in the past decade and have been found to reduce the use of indwelling catheters.⁶ Has CMS considered using this data to expand its coverage of female EUDs?

I respectfully request answers to these questions in 30 days. I appreciate your diligence and dedication to providing essential services to the American people and I look forward to hearing from you.

Sincerely,



Bonnie Watson Coleman
Member of Congress

⁴ Lukacz, Emily. Patient Education: Urinary incontinence treatments for women (Beyond the Basics). (https://www.uptodate.com/contents/urinary-incontinence-treatments-for-women-beyond-the-basics?topicRef=8403&source=see_link)

⁵ Beeson T, Pittman J, Davis CR. Effectiveness of an External Urinary Device for Female Anatomy and Trends in Catheter-Associated Urinary Tract Infections. *J Wound Ostomy Continence Nurs.* 2023, (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9990593/>)

⁶ Ibid.