United Spinal Association's Access&Care COALITION

Via Electronic Mail

Marge Watchorn
Deputy Director, Division of Coding and DRGs
Center for Medicare,
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard,
Baltimore, MD 21244

Dear Ms. Watchorn,

On behalf of United Spinal Association's Access and Care Coalition[1], I am requesting that the Centers for Medicare and Medicaid Services support establishing new Healthcare Common Procedure Coding System (HCPCS) codes for intermittent urinary catheters. The hundreds of thousands of individuals living with neurogenic bladder whose medical conditions require long-term use of intermittent urinary catheters know too well the challenges they face and the key risk factors associated with urinary tract infections (UTIs).[2] [3]

The mission of the Access and Care Coalition[4] (ACC) is to support increased consumer access to medical supplies under Medicare, Medicaid and private insurance. The ACC consists of urological and ostomy medical technology suppliers and manufacturers, as well as clinician, physician, and consumer and disability advocates. Founded by paralyzed veterans in 1946, United Spinal Association has been dedicated to advancing the independence and quality of life of over three million wheelchair users across the country living with neurological and paralyzing conditions such as spinal cord injury, multiple sclerosis, amyotrophic lateral sclerosis (ALS), muscular dystrophy and spina bifida. United Spinal Association is also a VA-recognized veterans service organization (VSO) serving veterans with disabilities of all kinds.

We believe that coding distinctions between catheter differences, including surface material (e.g. hydrophilic technology) and features that aid with clean insertion of the catheter are necessary to ensure patients receive a catheter that fits their individual needs. Intermittent urinary catheters are currently grouped into one of three HCPCS codes; straight tip, coude (curved tip), or sterile kit with insertion supplies included. The current code set does not distinguish between hydrophilic coating, no touch functionality, protective features or any other advanced functions that are necessary for successful catheterization which, along with increased patient adherence, can lead to improved bladder health overall and the decrease of secondary complications.

Patients living with Neurogenic Lower Urinary Tract Dysfunction (impaired bladder function) are often dependent on managing their bladder with clean intermittent catheterization (CIC), done every 4-6 hours every day. Even with careful technique, CIC can lead to false passage, bladder infections and pain with catheterization especially with uncoated catheters. Advancements in hydrophilic (coated/lubricated) catheter technology can

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[1] https://unitedspinal.org/access-care-coalition/

[2] Matthias, W. et al., Journal of Neurotrauma, April 2018 DOI: 10.1089/neu.2017.5413 *Intermittent Catheterization: The Devil Is in the Details*; Kennelly, M. et al., Advances in Urology, 2019: *Adult Neurogenic Lower Urinary Tract Dysfunction and Intermittent Catheterisation in a Community Setting: Risk Factors Model for Urinary Tract Infections*; Matthias, W., Krassioukov, A., European Urology, *Single Use Vs Multi-Use Catheters: Pro Single-Use Catheters*

[3] https://my.clevelandclinic.org/health/diseases/15133-neurogenic-bladder

make catheterization easier, but more importantly, safer, by reducing trauma to the urethra and allowing patients to catheterize with less pain and discomfort increasing patient adherence to follow their catheterization schedule. Decreased friction leads to less damage to the urethra over time. Ready-to-use hydrophilic catheters are often medically necessary for patients with limited functional capabilities, specifically for individuals with limited to no hand function and/or anatomical considerations.

In the recently published guideline on adult Neurogenic Lower Urinary Tract Dysfunction (NLUTD) the American Urological Association along with Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction stated the following:

> "*The clinician treating patients with NLUTD needs to balance a variety of factors when making treatment decisions. In addition to the patient's urologic symptoms and urodynamic findings, other issues that may influence management options of the lower urinary tract include, cognition, hand function, type of neurologic disease, mobility, bowel function/management, and social and caregiver support"*[4]

An HCPCS code reform allows for a level of thorough decision-making when it comes to choosing a catheter that aligns with patient needs. We want to reduce the chances for life-threatening UTIs and other genitourinary complications, not increase them. We want to facilitate every effort to keep UTIs and other complications down to a minimum. The current coding system definitely costs Medicare more money with increased doctor visits, possible hospitalization and potential home health episodes, all because of unnecessary and possibly avoidable UTIs, resulting in an economic burden of at least $2.8 billion (2011 US dollars)[5]. A problematic UTI can hospitalize a beneficiary and if the infection becomes septic, can lead to death. UTIs are serious and can be dangerous to anyone – they are even more dangerous to individuals who are already immunocompromised and vulnerable to infections and secondary complications and comorbidities.

Any medical professional who understands permanent urinary retention in the thousands of individuals living with neurogenic dysfunction (bladder impairment) (including individuals with spinal cord injury, spina bifida, multiple sclerosis, muscular dystrophy) knows how important it is to avoid UTIs and any other infections and complications. Per the current local coverage determination (L33803):

The beneficiary has had distinct, recurrent urinary tract infections, while on a program of sterile intermittent catheterization with A4351/A4352 and sterile lubricant A4332, twice within the 12-month prior to the initiation of sterile intermittent catheter kits.[6]

UTIs and other infections increase the chances of serious illness or death which equates to increased medical costs for Medicare. Infections increase antibiotic use which contributes to antimicrobial resistance (AMR), a WHO Top 10 global health threat.[7] CMS should recognize the importance of decision-making in accordance with an individual's functional capabilities and risk factors for complications such as urinary tract infections.[8] [9] **Physicians should have a way to distinguish between catheter functionalities necessary for successful self-catheterization – which maintains bladder health and kidney function – and insurers need a way to process**

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[4] Ginsberg, D. et al. Journal of Urology, 2021, *The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Treatment and follow up*

[5] Simmering JE, Tang F, Cavanaugh JE, Polgreen LA, Polgreen PM. *The Increase in Hospitalizations for Urinary Tract Infections and the Associated Costs in the United States, 1998-2011*. Open Forum Infect Dis. 2017 Feb 24;4(1):ofw281.

[6] Medicare Local Coverage Determination, L33803, Urological Supplies

[7] The Lancet, November 2021, *Antimicrobial resistance: a top ten global public health threat*, https://doi.org/10.1016/j.eclinm.2021.101221

[8] Flores-Mireles AL, Walker JN, Caparon M, Hultgren SJ. *Urinary tract infections: epidemiology, mechanisms of infection and treatment options.* Nat Rev Microbiol. 2015;13(5):269-284. doi:10.1038/nrmicro3432

[9] The National Spinal Cord Injury Statistics Center, *Annual Report*, 2018, p.32, https://www.nscisc.uab.edu/Public/2018%20Annual%20Report%20-%20Complete%20Public%20Version.pdf

such orders. More detailed code description will support shared decision-making between physician and patient and improve adherence to physician recommendations and patient needs. We therefore support CMS creating new codes in the LCD for A4351, A4352, A4353 to enable more equitable access across all populations living with neurogenic bladder. Please see 'Coding Recommendations' attachment. Thank you for your consideration. If you have any questions, please do not hesitate to contact me at abennewith@unitedspinal.org or 800.404.2898.

Sincerely,

Alexandra Bennewith

Alexandra Bennewith, MPA
Vice President, Government Relations

ACCESS AND CARE COALITION SIGNATORIES
Coloplast
Wellspect
Hollister
Muscular Dystrophy Association
Spina Bifida Association
United Spinal Association
Wound Ostomy & Continence Nurses Society

UNITED SPINAL ASSOCIATION'S ACCESS AND CARE COALITION FULL MEMBERSHIP LIST:
https://unitedspinal.org/access-care-coalition/

CC: Meena Seshamani, M.D., PhD, Deputy Administrator and Director, Center for Medicare
Liz Richter, Deputy Director, Center for Medicare

Encl.: Coding Reform Recommendations, UTI Burden of Illness