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SUBMITTED VIA ELECTRONIC MAIL

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Re: LCD Reconsideration Request - L33803: Urological Supplies

Dear Drs. Ballyamanda, Lalla, Hoover, and Jenny:

On behalf of Hollister Incorporated and the Medicare beneficiaries it serves,¹ we write to continue the dialogue with the Durable Medical Equipment Medicare Administrative Contractor (“DME MAC”) Medical Directors concerning the coverage restrictions set forth in Local Coverage Determination (“LCD”) L33803: Urological Supplies with respect to sterile catheter kits described by Healthcare Common Procedure Coding System (“HCPCS”) code A4353 (intermittent urinary catheter, with insertion supplies).² We appreciate your time and thoughtful feedback on this LCD when we spoke virtually this year.

¹ Hollister Incorporated is an independent, employee-owned company that manufactures intermittent catheters, including sterile catheter kits.

² DME MACs, *Local Coverage Determination (LCD) L33803: Urological Supplies*, <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33803&ver=47&keyword=urological%20supplies&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>.

We continue to believe that the coverage criteria for these sterile catheter kits, as it currently exists, results in confusion among healthcare prescribers and suppliers and is having the effect of inappropriately barring certain patients with a spinal cord injury from accessing sterile catheter kits. As discussed in detail below, the evidence base demonstrates that all patients with a spinal cord injury are likely to have neurogenic bladder and autonomic dysreflexia, are highly susceptible to urinary tract infections (“UTIs”), and are at risk for frequent UTI-related hospitalizations. Because sterile catheter kits reduce the incidence of UTIs, all individuals covered by Medicare who have a spinal cord injury should have access to these kits if their physician prescribes them.

Therefore, we respectfully request that the DME MAC Medical Directors ensure that all individuals with a spinal cord injury have access to sterile catheter kits by either:

- (1) Revising LCD L33803 to explicitly state that Medicare covers HCPCS code A4353 for all Medicare beneficiaries with a spinal cord injury (regardless of pregnancy status), or
- (2) Clarifying that the immunosuppression criterion for HCPCS code A4353 encompasses all individuals with a spinal cord injury regardless of the level of injury.

The latter approach could be accomplished by amending the LCD or simply revising the DME MACs’ websites that elaborate on this coverage requirement. An LCD change would be more enduring, but a change to the DME MAC websites could be employed as a more immediate, transitional step forward.

We understand that the DME MACs may be in the process of amending the LCD in light of the recent, final coding decision to separately identify hydrophilic catheters. Accordingly, we believe the DME Medicare Directors should take advantage of the opening of the LCD (L33803) to clarify this coverage matter. However, if the DME MACs proceed with the latter approach we suggest above (i.e., option 2), we urge the DME MACs to clarify exactly how practitioners must demonstrate that an individual with a spinal cord injury is immunocompromised. We believe it should be sufficient to simply state in the medical record that the patient has a spinal cord injury. This clarification would help ensure appropriate access to care for this vulnerable Medicare population.

Narrow Interpretation of LCD L33803: Urological Supplies

Under the current LCD, Medicare will cover sterile catheter kits “when the beneficiary requires catheterization and the beneficiary meets one of the following criteria (1-5):”

1. The beneficiary resides in a nursing facility,
2. The beneficiary is immunosuppressed, for example (not all-inclusive):
 - on a regimen of immunosuppressive drugs post-transplant,
 - on cancer chemotherapy,
 - has AIDS,
 - has a drug-induced state such as chronic oral corticosteroid use.
3. The beneficiary has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization,

4. The beneficiary is a spinal cord injured female with neurogenic bladder who is pregnant (for duration of pregnancy only),
5. 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.³

On November 1, 2023, Noridian Healthcare Solutions published an article clarifying that the aforementioned immunosuppression criteria for the A4353 includes, but is not limited to, the following:

- “High-level spinal cord injury patients (T3 and higher) will be considered for coverage when conducting medical reviews.”⁴

We maintain that the language in LCD L33803, as clarified by Noridian Healthcare Solutions’ article, is being narrowly interpreted by the catheter community, leading to gaps in access for patients with a spinal cord injury who have not had two UTIs in the past 12 months, who are not pregnant, female spinal cord injured patients, and have an injury at T4 or below. We are aware of patients who fall in this category who have not been able to obtain sterile catheter kits due to the restrictive interpretation of LCD L33803. Attached is an affidavit from a Medicare beneficiary with a spinal cord injury describing her inability to access sterile catheter kits due to the DME MACs’ coverage criteria. (See Appendix A).

Medicare Should Cover Sterile Catheter Kits for All Individuals with a Spinal Cord Injury

The spinal cord regulates immunological and visceral functions,⁵ and proper function of the bladder and urethral sphincter requires coordination between the central and the peripheral nervous systems.⁶ Injury to the spinal cord dysregulates those functions, compromising the ability of the individual to fight infections.⁷ One of the leading causes of both morbidity and mortality in those with a spinal cord injury is a lack of ability to control microbial infections.⁸ Individuals with a spinal cord injury are more likely than those without one to die from a preventable infection.⁹

³ DME MACs, *Local Coverage Determination (LCD) L33803: Urological Supplies*, <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33803&ver=47&keyword=urological%20supplies&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>.

⁴ Noridian Healthcare Solutions, *Coverage Criteria for Intermittent Urinary Catheters A4353 - Immunosuppressed Beneficiaries Meeting Criteria 2*, <https://med.noridianmedicare.com/web/jadme/article-detail/-/view/6547796/coverage-criteria-for-intermittent-urinary-catheters-a4353-immunosuppressed-beneficiaries-meeting-criteria-2-1> (last updated Nov. 1, 2023).

⁵ DiSabato et al., System Failure: Systemic Inflammation Following Spinal Cord Injury, 54 *Eur. J. Immunology* (Oct. 2023).

⁶ McKibben et al., Urinary Tract Infection and Neurogenic Bladder, 42 *Urologic Clinics of North America* 527 (Nov. 2015).

⁷ DiSabato et al., *supra* note 5; Yang et al., Dominant Mechanism in Spinal Cord Injury-Induced Immunodeficiency Syndrome (SCI-IDS): Sympathetic Hyperreflexia, 35 *Revs. Neuroscience* (Oct. 2023).

⁸ Yang et al., *supra* note 7, at 1.

⁹ DiSabato et al., *supra* note 5, at 2.

Individuals with a spinal cord injury at any level of injury (including T4 and below) experience neuro-endocrine changes and inflammatory responses that render them more susceptible to infections. Any injury to the spinal cord causes impaired neuro-endocrine signaling, which disrupts the body's control of immune cells, increasing the risk of infection.¹⁰ Moreover, literature suggests using neurological level of injury is not a good indicator for an individual's risk of autonomic dysreflexia. For instance, individuals with a spinal cord injury at neurological level of injury T6 or above are more likely to experience autonomic dysreflexia, however, individuals with injury T7 or lower can also experience autonomic dysreflexia.¹¹

In addition to their compromised immune function, as part of the neurogenic bladder population, those with a spinal cord injury face more complex and recurrent UTIs. “[V]irtually all SCI will lead to bladder dysfunction.”¹² Disruption caused by impaired nervous system coordination “can lead to neurogenic bladder with abnormal bladder storage and emptying.”¹³ Those with neurogenic bladder are predisposed to both renal failure and recurring UTIs.¹⁴ This predisposition is attributable to “urinary stasis from elevated residual urine volumes.”¹⁵ Patients with neurogenic bladder are much more likely to have polymicrobial infections. For patients without neurogenic bladder, the most common type of bacteria found in UTIs is negative gram rods. However, those with neurogenic bladder experience higher rates of infection with other microbes, including “Pseudomonas (15 %), Acinetobacter (15 %), Enterococcus (6 %) and multi-organismic infections (26 %).”¹⁶ Studies of patients with neurogenic bladder have found a correlation between abnormal “urodynamic” (bladder pressure and flow) parameters and higher risk of developing a UTI.¹⁷

UTIs are one of the most prevalent complications for individuals that have experienced a spinal cord injury.¹⁸ A large study that analyzed the claims data of individuals with neurogenic bladder and spinal cord injury found that 31 percent of patients with a spinal cord injury experienced a UTI within the first year of diagnosis and 21 percent had to be hospitalized for the infection.¹⁹ Due to these recurring and severe infections, patients with a spinal cord injury and neurogenic bladders experience higher rates of morbidity and mortality than the general population.²⁰

Patients with a spinal cord injury are at high risk to develop recurrent UTIs that are drug resistant.²¹ Approximately 50-75 percent of patients with a spinal cord injury have had urine cultures positive for

¹⁰ Kyleigh A. Rodgers et al., Immune Dysfunction After Spinal Cord Injury – A Review of Autonomic and Neuroendocrine Mechanisms, 64 *Current Opinion in Pharmacology* 102230 (2022), <https://doi.org/10.1016/j.coph.2022.102230>.

¹¹ *Id.*

¹² DiSabato et al., *supra* note 5, at 4.

¹³ McKibben et al., *supra* note 6, at 527.

¹⁴ Balsara et al., Enhanced Susceptibility to Urinary Tract Infection in the Spinal Cord-Injured Host with Neurogenic Bladder, 81 *Infection and Immunity* 3018 (Aug. 2013).

¹⁵ *Id.*

¹⁶ Jahromi et al., UTIs in Patients with Neurogenic Bladder, 15 *Current Urology Rep.* 433 (Aug. 2014).

¹⁷ McKibben et al., *supra* note 6, at 528.

¹⁸ DiSabato et al., *supra* note 5, at 3.

¹⁹ Jahromi et al., *supra* note 17, at 433.

²⁰ *Id.*

²¹ Samal et al., The Prevalence of Antibiotic-Resistant and Multidrug-Resistant Bacteria in Urine Cultures from Inpatients With Spinal Cord Injuries and Disorders: An 8-Year, Single-Center Study 22 *BMC Infectious Diseases* 1 (March 2022).

infection.²² High levels of bacteria are particularly prevalent for patients that use permanent or intermittent catheters.²³ This is due to impaired voiding, which in turn causes impaired elimination of bacteria, and increased introduction of bacteria during catheter use.²⁴

Multiple factors contribute to a “permanently high” risk of UTI following a spinal cord injury.²⁵ Extended use of catheters increases the risk that bacteria will be introduced into the urinary tract, which also increases the risk of infection.²⁶ Additionally, “incomplete voiding” increases the risk of infection and serious complications.²⁷ Dysregulated neurogenic control disrupts the normal function of the lining and tissues of the urinary tract, which makes it easier for bacteria to bind to the bladder wall and increases white blood cell counts.²⁸ The presence of white blood cells leads to an inflammatory response by the body, which in turn exacerbates the disruption of bladder tissue.²⁹ Studies have shown that rats with a spinal cord injury have been found to have a muted inflammatory response to UTIs.³⁰ For humans, this could explain the higher risk for recurrent UTIs for individuals with a spinal cord injury.³¹ Other risk factors that have been cited as a reason for high UTI susceptibility in the spinal cord injury population include “urinary stasis due to elevated postvoid residual volumes, bladder overdistention, high-pressure voiding, vesicoureteral reflux, nephrolithiasis, and the use of chronic indwelling catheters.”³²

Most spinal cord injury patients with neurogenic bladder deficiencies depend on catheters to drain their bladder, and sterile catheter kits are the primary recommendation to offer the highest degree of infection prevention with features that help avoid potential contamination vectors. Sterile catheter kits are utilized to reduce the incidence of UTIs and, by definition, reduce the costs and medical risks associated with treatment of UTIs, including pharmacological interventions and, if necessary, hospitalization. Separately provided components do not provide the equivalent degree of sterility achieved with sterile catheter kits, especially for spinal cord injury patients with dexterity issues associated with their neurological injury.

Conclusion

For the reasons set forth above, we respectfully request that the DME MACs ensure that all individuals with a spinal cord injury have access to sterile catheter kits by either (1) revising the LCD to explicitly state that sterile catheter kits are covered when the beneficiary has a spinal cord injury, or (2) clarifying that the immunosuppression criterion in LCD L33803 encompasses all individuals with a spinal cord injury. While our preference would be to have the DME MAC Medical Directors amend the LCD accordingly, the DME MACs could expeditiously clarify its guidance on this matter

²² *Id.*

²³ Slim et al., Nosocomial Transmission of Highly Resistant Microorganisms on a Spinal Cord Rehabilitation Ward, 32 J. Spinal Cord Med. 422 (Aug. 2009).

²⁴ *Id.*

²⁵ DiSabato et al., *supra* note 5, at 4.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.* at 4-5.

³⁰ *Id.* at 5.

³¹ *Id.*

³² Balsara et al., *supra* note 15, at 3018.

on their respective websites as a transitional step forward. If the DME MACs proceed with option (2) above, we urge the DME MACs to clarify that the mere diagnosis of a spinal cord injury in the medical record is sufficient proof, given the research provided in this letter, that these individuals are immunosuppressed.

We welcome the opportunity to continue discussing this issue with you further. If you are amenable to another meeting to discuss our request in more depth, we would be more than happy to help arrange a meeting at a time that is convenient for you. Thank you for your consideration of our request and the enclosed evidence. (See Appendix B).

Sincerely,

Casey Haan

Casey Haan
Senior Director, Market Access & Government Affairs
Hollister Incorporated