Open Meeting: Urological Supplies

Meeting Date & Time: October 2, 2025, 10:00 a.m. ET
Location: Virtual Meeting

MICHAEL HANNA (00:00:06): Good morning, everyone. Thank you so much for joining us this morning as we discuss the proposed updates to the Urological Supplies LCD. We have 7 stakeholder, I'm sorry, 6 stakeholders that want to speak this morning. So at that point in time, we'll ask you to unmute your line and then remute after your speaking session. Everyone has up to 10 minutes of time for their commentary, and with that being said, I'll turn it over to Dr. Angela Jenny, Dr. Jenny.

DR. ANGELA JENNY (00:00:37): Good morning, everyone, and welcome to our virtual open meeting. Today we'll be soliciting public comments regarding the proposed urologic supplies local coverage determination. My name is Dr. Angie Jenny, and I'm with Noridian Healthcare Solutions, the Jurisdiction D, DME MAC, also from Noridian is Dr. Smitha Ballyamanda from Jurisdiction A. And representing CGS Administrators are Dr. Sunil Lalla and Dr. Robert Hoover with Jurisdictions B & C, respectively.

We look forward to your comments regarding the proposed urologic supplies LCD updates. Please write these comments and send them to us via email at URORecon@noridian.com. Please remember that we can only respond to written comments. These comments are due by 5:00 p.m. Eastern Time on Saturday, October 11th, 2025, when the comment period closes.

Also we will record the meeting today which will be posted on the DME MAC websites. You are giving your consent to use the use of your recorded voice and comments by signing into this meeting.

Please be careful about sharing any personal health information in your verbal comments.

We only allow registered commenters to speak at today's meeting, but anyone can submit written comments to the e-mail address I mentioned earlier.

For our speakers today, we ask that you introduce yourself, the organization that you represent, and any conflicts of interest that you may have with this topic.

For those who are listening, please mute your phone line and computer if applicable. Speakers should be prepared to begin their comments immediately after being called upon.

Now let us talk a little bit about the proposed LCD. The DME MACs are proposing to include an example in the coverage criteria for sterile intermittent urinary catheter kits and supplies, A4297, A42- 4353 for Medicare beneficiaries with a spinal cord injury at any level. Additionally, the proposed LCD proposes the addition of the new HCPCS codes A4295, A4296, A4297 for hydraulic-hydrophilic catheters. Please note that hydrophilic catheters do not require additional lubricant because they are self-lubricating.

And now I'm going to turn the bike- mic back over to our moderator, Michael Hanna from CGS. Thanks.

MICHAEL HANNA (00:03:08): Thank you, Dr. Jenny. We're now ready for the presentation of oral comments from the individuals that requested to speak this morning. The first individual is Casey Haan. Casey, if you would unmute your line for us, please.

CASEY HAAN (00:03:26): I believe I'm unmuted. Can you hear me OK?

MICHAEL HANNA (00:03:29): Yes, ma'am. Your audio's fine. Go ahead, please.

CASEY HAAN (00:03:32): OK, I was going to share my video, but it doesn't look like I'm able to do that, so I'm ready to speak. Good morning. My name is Casey Haan and I am Senior Director of Market Access and Government Affairs at Hollister Incorporated and I have no restrictions or any conflicts to report today.

First, I want to thank you for the opportunity to speak about an issue that directly impacts the health, dignity and daily lives of Medicare beneficiaries. Today, I'm not only here on behalf of

Hollister, but most importantly on behalf of the Medicare beneficiaries who depend on safe, reliable access to sterile catheter supplies.

On behalf of Hollister and the patients we serve, I want to sincerely thank the DME MACs for your continued engagement and for the thoughtful review of our LCD request for reconsideration.

We are grateful for your careful attention to ensuring appropriate and equitable access to sterile intermittent catheter kits and supplies under HCP- HCPC codes A4297 and A4353. We strongly support the proposed revision to the LCD, affirming that all individuals with spinal cord injuries, regardless of the level of injury, meet the immunosuppressant coverage criterion. This proposed clarification is a critical step forward. It brings coverage policies into closer alignment with contemporary medical standards and with the needs of vulnerable high risk population.

The medical literature is clear. Spinal cord injury impairs neuroendocrine signaling and weakens immune response. This leads to significantly higher risk of infection, most notably urinary tract infections. UTIs are among the most common and costly complications for individuals living with SCI. And importantly, this risk is not confined to high level injuries. It extends across all levels of spinal cord injury.

Sterile catheter kits reduced the incidence of UTIs and by doing so, help reduce hospitalizations, antibiotic use and overall costs. Yet under current policy, many patients, particularly those with lower level injuries, have faced unnecessary barriers and confusion in accessing these kits.

The proposed LCD addresses much of this concern, but to ensure consistent implementation, we respectfully urge the DME MACs to provide explicit documentation guidance. A documented diagnosis of spinal cord injury alone should be sufficient to meet the immunosuppression criterion for coverage of HCPCS codes A4297 and A4353.

This simple clarification would eliminate ambiguity for clinicians and suppliers, reduce unnecessary administrative burden and prevent inappropriate coverage denials ensuring patients receive the supplies they need without delay.

Lastly, while today our focus is on patients with SCI, we hope the DME MACs will continue to evaluate coverage policy as it relates to other high risk patient populations with neurogenic bladder. Those patients, too, often face comparable risks and clinical challenges, as those with an SCI.

In closing, we are deeply grateful for your leadership in modernizing this coverage policy. Your willingness to engage in meaningful dialogue and align coverage with medical evidence will make a lasting difference in the lives of Medicare beneficiaries living with spinal cord injury. Thank you.

MICHAEL HANNA (00:07:16): Thank you very much, appreciate your comments. We are ready to move to our next speaker, Chris Wiesman. Chris, are you on the call today? If I can find your name. If you can unmute your line for us, please.

CHRIS WIESMAN (00:07:47): Yes, I'm here. Can you hear me okay?

MICHAEL HANNA (00:07:51): Yes, Chris, the audio's fine. Go ahead please.

CHRIS WIESMAN (00:07:53): Okay, hi, good morning. This is Chris Wiesman on behalf of HR Healthcare and there are no conflicts of interest with respect to the comments.

And first, you know, to follow on Casey's, you know, comments, I just wanted to thank you for the opportunity to continue to engage in this dialogue and for the work that's being done to, you know, expand these HCPCS- HCPCS codes and the LCD and, you know, our comments are I'd say relatively minor and elaborated in the letter that we submitted and it really can be summarized into two areas, and first one is around the sterile intermittent catheter kits under codes A4353 and A- the new code A4297, and you know, I think Casey did a great job of highlighting, you know, the concerns that a lot of folks have around Medicare beneficiaries with spinal cord injuries, so don't need to elaborate there. But our recommendation, and what we would like to see happen, and what we've flushed out in our comment letter was that, you know, the L- to have the LCD revised to allow those beneficiaries at, you know, Medicare beneficiaries with a documented spinal cord injury at any level to qualify for a sterile intermittent catheter kit without requiring proof of immunosuppression. And, you know, the reason we want to just advocate for this a little bit more is, you know, you know, it- it is, you know, a documented spinal cord injury at any neurological level, you know, it should be in enum- one of the enumerated criteria which would render the beneficiary eligible for that without having to go through the- the hurdle of- of getting documented immunosuppression to be able to qualify for that, just cause it creates an additional hurdle for those beneficiaries to go through to, you know, receive those supplies. And the second area of comment from HR Healthcare was, you know, just, you know, we- it- you know, we thought that the language of the proposed LCD as it relates to the new HCPCS codes was, you know, was,

you know, headed in the right direction and wanted to just, you know, reiterate our support and that, you know, that there should not be a distinction between non-hydrophilic and hydrophilic catheters with respect to the required medical documentation or any other criteria that, you know, would need to be met by a beneficiary before they would be eligible to qualify for a- a hydrophilic catheter. In other words, you know, some type of step up criteria or anything like that, there should be equal access to that just given the- the body of evidence around hydrophilic catheters and, you know, what the benefit to those that type of product delivers to beneficiaries.

So thats wraps up the comments from HR Healthcare. Again, thank you, for the time and the opportunity and the continued dialogue around this key initiative to deliver better outcomes and- better outcomes to beneficiaries.

MICHAEL HANNA (00:12:14): Thank you, Chris, we appreciate you being on the call today. The next speaker is Leela Baggett. Leela, if you would be kind enough to unmute your line for us, please.

LEELA BAGGETT (00:12:29): Good morning. Can you hear me?

MICHAEL HANNA (00:12:30): Yes, ma'am. Your audio's fine. Thank you.

LEELA BAGGETT (00:12:33): Thanks so much. Good morning and thank you for the opportunity to speak today. My name is Leela Baggett. I am a partner at Powers Law firm representing the Independence Through Enhancement of Medicare and Medicaid Coalition, abbreviated ITEM Coalition. The ITEM Coalition is a national consumer and clinician led coalition comprised of a 100 member organizations devoted towards building support for policies that will enhance access to technology for people with disabilities and chronic conditions.

The ITEM Coalition strongly supports the proposed expansion of Medicare coverage for sterile intermittent catheter kits for individuals with spinal cord injury, regardless of their level of inj- ind- sorry- level of injury.

At the same time, we respectfully urge the DME MACs to further evaluate the clinical evidence supporting expanded coverage for all individuals with neurogenic bladder irregardless of etiology, including congenital conditions.

Bladder management remains one of the most persistent and complex challenges faced by individuals with spinal cord injury and neurogenic bladder. It's frequently cited by patients and clinicians as a major barrier to maintaining health, independence, and quality of life.

Now, fortunately sterile intermittent catheter kits are a well-established and effective clinical tool used to reduce the incidence of UTIs (urinary tract infections) - one of the most common and serious complications associated with spinal cord injury as well as neurogenic bladder. Now unfortunately, the existing LCD on urological supplies contains overly restrictive criteria that have caused confusion among suppliers and unintentionally denied access to appropriate supplies for- for beneficiaries with spinal cord injury and without timely access to spiral catheter kits, these patients are placed at a significantly elevated risk of serious complications, including UTI's that may escalate into severe infections, requiring emergency medical intervention or hospitalization.

This is particularly concerning in light of the robust clinical evidence demonstrating that individuals with a spinal cord injury are especially vulnerable to recurrent UTIs, and this elevated risk is directly linked to the immunosuppressive effects inherent in spinal cord injury, which as we know, compromises the body's ability to fight infection.

So access to sterile catheter kits is critical for Medicare beneficiaries living with spinal cord injury, and we commend the DME MACs for acknowledging this clinical reality and for proposing the expanded coverage criteria to include all individuals with spinal cord injury, regardless of the injury level under the immunosuppression criteria.

The ITEM Coalition believes that the policy clarifications is both evidence based and urgently needed, and we respectfully encourage the DME MACs to explicitly state that a documented diagnosis of a spinal cord injury in the medical record by itself is sufficient to establish immunosuppression for coverage purposes under HCPCS codes, A4297 and A4353.

No additional verbiage or separate additional documentation should be required to validate the immunosuppression criterion. In addition, we urge the DME MACs to consider clinical literature supporting the use of sterile catheter kits in all patients with neurogenic bladder irrespective of the underlying cause, and that would include both congenital and acquired conditions.

Expanding coverage would ensure that Medicare beneficiaries with neurogenic bladder receive equitable access to essential urological care while also reducing the preventable complications and aligning Medicare policy with standards of clinical practice.

So thank you for the opportunity to provide input on this critically important issue. We sincerely appreciate your ongoing commitment to evidence based and patient centered policies and your efforts to ensure that Medicare coverage better reflects the reality of patient needs and clinical care. We stand ready to answer any questions you may have. Thanks.

MICHAEL HANNA (00:16:56): Thank you, Leela, Much appreciated. Our next commentary comes from Michael Kennelly. Michael Kennelly, if you would unmute your line for us, please.

MICHAEL KENNELLY (00:17:10): All right, Thank you. And my name is Michael Kennelly, and I'm a professor of urology at Wake Forest School of Medicine. From a conflict standpoint, my disclosure is that I'm a consultant and also a research investigator for Coloplast.

From a background standpoint, not only am I a professor of urology, but also board certified in urology, but also subspecialty certification in female pelvic medicine reconstructive surgery. And I've also had over 30 years in treating patients with neurogenic bladder, specifically spinal cord injury.

In addition, I've had the pleasure of serving as past president of both the American Spinal Injury Association, which is ASIA, and also the Academy of Spinal Cord Injury Professionals (ASCIP), which does give me kind of a broad perspective on the challenges faced by, you know, this patient population.

First of all, I definitely want to express my strong support for this proposed expansion of Medicare coverage. Sterile intermittent catheterization kits for individuals with spinal cord injury has been kind of a long process during my career, is way long overdue, and the clarification definitely aligns the policy with clinical reality.

As you're aware, and you've heard earlier this morning, spinal cord injury does profoundly affect bladder function, it compromises the body's ability to fight infection. And these patients aren't really just at risk, they're uniquely vulnerable to recurring urinary tract infections, in addition to autonomic dysreflexia and other serious complications that lead to hospitalizations including sepsis and kidney problems.

Overall, during my clinical experience, we've seen that sterile capitalization is really not a convenience. I remember the days when we didn't have sterile catheterization, you know, it's critically important and it's an intervention that directly impacts patient safety, definitely the hospitalization rates, and also long term outcomes.

Unfortunately, the current Medicare coverage criteria creates unnecessary barriers. You know, patients with spinal cord injury often struggle to get access to get sterile catheter kits even despite clear medical necessity, you know there's a disconnect between policy and practice, which does lead to preventable infections, avoids hospitalizations, and diminished quality of life.

The proposed clarification that all individuals with spinal cord injury meet the immunosuppression criteria is definitely welcomed and I think it is a necessary first step. You know, it reflects what clinicians are seeing every day in clinical care. You know, we see the spinal cord injury patients regardless of level of completeness compromised, their immune system is definitely compromised, and they are at increased risk and I certainly support this change full heartedly.

You know, that said, I think I would also reiterate what you know, Miss Baggett was saying is that, you know, it's kind of as a clinician you want the DME MACs to even go further. You know, this proposal does address the critical need for the spinal cord community, but it does leave behind other patients with neurogenic bladder, you know conditions such as multiple sclerosis, spina bifida, myelomeningocele cerebral palsy. You know these individuals face the same elevated risk and do deserve the same access to sterile catheterization supplies. Expanding coverage to include all patients under neurogenic bladder, regardless of ideology, would even be a more equitable and clinically sound policy.

You know, however, given that fact, I do applaud, you know the MACs for what they're currently doing. You know, the proposed LCD does move things forward and I do respectfully recommend that CMS provide clear documentation guidelines for practitioners. It's very difficult out there in the community when we are trying to get the best care for patients yet there's confusion on what the- the MACs are supposed to do. So a diagnosis of spinal cord injury alone should be sufficient to establish the eligibility under the immunosuppression criteria. You know, I do encourage that we have straightforward actionable criteria that reduce the administrative burden and ensure timely access to care.

In closing, as I stated before, I do commend CMS and the DMS MACs for taking this important step. I encourage continued refinement of the policy to ensure that all patients with neurogenic bladder receive the supplies they need to maintain their health, dignity, and independence. And I thank you for your time and consideration, open to any questions.

MICHAEL HANNA (00:21:42): Thank you so much. Our next speaker on our agenda is Miss Sara Struwe. Miss Sara, would you unmute your line for us, please?

SARA STRUWE (00:21:54): Thank you. My name is Sara Struwe and I serve as- as the President and CEO of the Spina Bifida Association. I represent nearly 166,000 Americans living with spina bifida. We are fully in support of this expansion, and I have no disclosures for the- at this time.

Spina bifida is the leading cause of neurogenic bladder. It is the most common permanently disabling birth defect in the United States, affecting the- those 166,000 children and adults with spinal bifida, as well as their families.

Nearly all individuals born with spina bifida also live with the neurogenic bladder, meaning they require bladder management from birth, not later in life. And they will require it throughout their entire life.

Nearly all individuals born with spina bifida must use sterile intermittent catheterization as that- that birth- as that bladder management. So, without sterile intermittent catheterization, individuals with spinal bifida face lifelong risk of kidney damage, recurrent UTI infections, and life threatening sepsis.

In your deliberations, we ask that you consider equity in coverage for congenital conditions. While we support this expansion, current coverage proposals office focus- focus on spinal cord injuries while excluding congenital conditions like spina bifida, despite the identical clinical needs.

People with spina bifida would not face- should not face barriers simply because they're bladder dysfunction is present at birth rather than acquired later in life. Expanding Medi- Medicare coverage insures equitable treatment for all individuals with neurogenic bladder regardless of life. We ask you to consider the prevention of serious and costly complications.

Individuals with spinal bifida experience some of the highest rates of recurrent UTIs and kidney complications of any neurogenic bladder population. Sterile catheterization kits are proven to reduce ER visits, hospitalizations, and costly interventions. Expanding access is not only lifesaving, it is also cost saving for Medicare by reducing long term expenditures related to infections and renal failure. Including spina bifida in this discussion, you would be supporting independent living and quality of life not only for those SCI patients, but also for children and adults with spina bifida.

Bladder management is among the greatest daily challenges for people with spina bifida and their caregivers. Reliable access to sterile supplies supports dignity, independence and participation in school, work, and community life. Denying these disproportionately harms this population, which already faces significant daily medical demands.

This expansion aligns with the clinical standards of care. Clinical guidelines, including the umpire protocol and SB's lifespan, bowel and bladder management protocol recognize sterile intermittent catheterization as the gold standard for preventing kidney- for preserving kidney health. Expanding Medicare coverage would not- would bring policy in line with the modern clinical practices and standards followed by leading urologists and multidisciplinary spina bifida clinics.

This expansion also addresses gaps in transition to adulthood. Many individuals with spinal bifida will lose access to needed supplies during transition from pediatric to adult care due to restrictive insurance rules. Medicare expansion would ensure continuity of care across the lifespan, reducing preventable health crises during vulnerable periods.

Expanding Medicare coverage of sterile intermittent catheterization kits, including- to include people with spinal cord injury and if the determination is made to add congenital conditions like spina bifida, is essential to reduce preventable infections and hospitalizations, protect kidney function across the lifespan, promote independence and quality of life, and ensure equity alongside spinal cord injury populations.

People with spinal bifida face the same medical risk as those with spine- spinal cord injuries from birth- but from birth, and they deserve the same access to evidence based lifesaving urological care as someone who acquires a neurogenic bladder by spinal cord injury. Thank you for this opportunity to share our thoughts.

MICHAEL HANNA (00:27:03): Thank you so much, Miss Sarah, appreciate that. Our final speaker on the agenda this morning is Kent Keyser. Kent, if you could unmute your line for us, please.

KENT KEYSER (00:27:22): Thank you. I'm Kent Keyser, a policy fellow with the United Spinal Association. We represent our nation's 5.5 million wheelchair users. Our mission is to empower and advocate for people like me with spinal cord injuries and all wheelchair users to achieve our highest quality of life. Good health is a pillar of our mission.

United Spinal has long objected to the truly barbaric requirement that if you have a spinal cord injury, an SCI, you must have two urinary tract infections within 12 months before a closed system, intermittent catheters will be covered. So on behalf of those with SCI's across America, thank you, thank you very much, for your proposed local coverage determination.

We do ask, please, that in the final LCD you clarify that having an SCI equates to immune- immune- sorry, immunosuppression. That will- that will save America, and countless Americans, a lot of time and money.

Thank you also for considering and acting favorably on the clinical evidence about immunosuppression of those of us with an SCI. But as you've heard, and most respectfully, there is also more you must do. We urge you to please go further in the final LCD to consider clinical evidence demonstrating that coverage should be expanded to all individuals with neurogenic bladder, regardless of cause, including congenital conditions. To force Americans with Disabilities, America's senior, and especially America's children to endure two UTI's, two antibiotic regimes, and through the process increase their antibiotic resistance, sets in motion a lifetime of healthcare cost and tragedies.

By expanding the LDC- LCD to cover all people with a neurogenic bladder, America will truly be healthier again. And here's why, some variables that were left out of your calculations on the SCI population go to the heart of this administration's growing crusade to prev- to preventing health risks. They are quantifiable, measurable variables of everyone's life, and they're fundamental to our physical and mental health. For instance, inevitably, what you're proposing, reducing UTIs, will improve our productivity and increase our quality of life. Both of which also pay higher, healthier dividends. I say this because if you've ever had a urinary tract infection, you know the setbacks you experience, the missed work days, the family obligations, the personal fitness goals all suffer. Now imagine a UTI in a SCI neurogenic bladder, like mine, multiplies the magnitude of a UTI. For a million of us- millions of us with a neurogenic bladder, UTIs are simply debilitating. And all those costs are on top of the national price tag of physician fees, emergency room care, hospitalizations and, yes, even death that UTIs can cause.

All of this is to say, we also thank you for posing to reduce the cost of America's healthcare, both the human and economic cost. But please consider including all these variables in your future decisions. We also want to thank the industry that has continued to innovate for our healthcare needs. United Spinal's president said it took him 20 years to find a catheter that helps reduce UTIs, He struggled with many products until he found a closed hydrophilic coated system that gave him safe independence with cathing. His journey reflects the pathways that I've seen the industry take over the last 20 years to continually innovate safer products. Even more innovations are on the way to reduce UTIs and micro traumas.

In fact, we would not be having this session today were it not for industry, namely the persistent leadership of Hollister Incorporated. And yet the innovations that industry invests in so heavily and that- and are also investments in healthier people and a healthier bottom line for our economy. But these innovations are not recognized soon enough by you. We would welcome the opportunity to work with you on how we can better speed innovation to full coverage, whether or not there's an immediate answer to this through application of an existing model in CMS's Innovation Center or a new model must be constructed, I can't say, but please, let's work together on it- on recognizing and including the value that industries' innovation have in making America's budget and America's lives healthier again.

Thank you very much for considering these comments and I did not see in the meeting requirements if we had to disclose any financial interest, but if we do, let me know and I'll get that for you. Thank you very much for this opportunity.

MICHAEL HANNA (00:33:40): Thank you for your input Kent, much appreciated. That concludes the stakeholder comments portion of this morning's open meeting for urological supplies. At this point, I'll turn it back over to Dr. Angela Jenny with the closing remarks.

DR. ANGELA JENNY (00:33:57): We want to thank you for your thoughtful comments today. Once again, please remember to send your comments in writing to the appropriate email address. As another reminder, the comment period will end on Saturday, October 11th, 2025. Once we have considered and collated all of the comments received during the open comment period, we'll consider any changes necessary as a result of the comments received and then post final LCDs along with a response to the comments document. The final LCDs will take effect a minimum of 45 days following the posting of the final LCDs.

For any updates, please refer to the DME MAC websites. I want to thank everyone for participating today. We will formally adjourn this meeting now.