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SUBMITTED ELECTRONICALLY (URORECON@NORIDIAN.COM)

Smitha M. Ballyamanda, MD, CAQSM
Medical Director
DME MAC, Jurisdiction A
Noridian, LLC
PO Box 6742
Fargo, ND | 58108

Sunil V. Lalla, MD, FACS, CPC
Chief Medical Officer
DME MAC, Jurisdiction B
CGS Administrators
26 Century Blvd., Ste. ST610
Nashville, TN | 37214

Robert D. Hoover, MD, MPH, FACP
Chief Medical Officer
DME MAC, Jurisdiction C
CGS Administrators
26 Century Blvd., Ste. ST610
Nashville, TN | 37214

Angela S. Jenny, DO
Medical Director
DME MAC, Jurisdiction D
Noridian, LLC
PO Box 6742
Fargo, ND | 58108

RE: ITEM Coalition's Public Comments for Proposed LCD - Urological Supplies (DL33803)

Dear Drs. Ballyamanda, Lalla, Hoover and Jenny:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition strongly support the expansion of Medicare coverage of sterile intermittent catheter kits for individuals with a spinal cord injury ("SCI") regardless of the level of injury. While we support the proposed changes to the Local Coverage Determination ("LCD," specifically, DL33803), we respectfully urge the Durable Medical Equipment Medicare Administrative Contractors ("DME MACs") to go further in the final LCD or in future LCDs to consider evidence demonstrating that coverage should be expanded to all individuals with neurogenic bladder regardless of etiology, including congenital conditions.

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including spinal cord injury, spina bifida, multiple sclerosis, stroke, paralysis, brain injury, limb loss and limb difference, cerebral palsy, hearing, speech, and visual impairments, myositis, and other life-altering conditions.

Bladder management for individuals with SCI is routinely identified by this population as one of the most vexing challenges in maintaining a high quality of life and functioning independently.

We applaud the DME MACs for proposing to expand Medicare coverage of sterile intermittent catheter kits. The existing coverage criteria set forth in the LCD on Urological Supplies is not evidence based and is unnecessarily restrictive, creating confusion among suppliers and preventing certain patients with an SCI from accessing sterile catheter kits. Access to sterile intermittent catheter kits is essential for beneficiaries with certain conditions such as SCI, as they significantly reduce the risk of urinary tract infections ("UTIs"). Without access to sterile intermittent catheter kits, patients are placed at heightened risk of serious complications, while the Medicare program incurs greater costs associated with preventable infections and emergency interventions.

Accordingly, we greatly appreciate the DME MACs' efforts to expand coverage of sterile urinary catheter kits to include immunosuppressed beneficiaries with an SCI at any level. This represents a critically important step toward aligning policy with both clinical evidence and patient need. The clinical literature clearly demonstrates that sustaining an SCI inherently results in immunosuppression. We believe this should be the standard for coverage, i.e., that every beneficiary with SCI should be considered immunosuppressed and eligible for sterile catheter kits.

If the DME MACs require additional documentation to demonstrate immunosuppression in the SCI patient population, we urge the DME MAC Medical Directors to provide explicit clarification regarding the documentation required to meet this coverage standard. We are concerned that, absent such clarification, the proposed LCD may create confusion among claim reviewers, prescribers, and suppliers regarding the necessary documentation. To be clear, the ITEM Coalition believes that coverage should be granted if the medical record reflects that the patient has incurred an SCI, without requiring additional verbiage or separate documentation to establish immunosuppression.

We note that both congenital and non-congenital conditions may cause neurogenic bladder and carry the same risks of recurrent UTIs, renal deterioration, and life-threatening complications. Individuals with these conditions require sterile catheter kits for safe bladder management. Expanding coverage to neurogenic bladder due to congenital and non-congenital etiologies ensures equitable access to care and reduces preventable costs for the Medicare program.

In addition, the ITEM Coalition respectfully urges the DME MACs to review the clinical literature demonstrating that all individuals with neurogenic bladder, regardless of etiology, would benefit from access to sterile catheter kits. Expanding coverage on this basis would promote equitable access to essential urological care, reduce preventable complications, and ensure that patients receive treatment consistent with current clinical standards of practice.

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Thank you for your consideration of our comments and for your leadership in expanding access to urological supplies for people with disabilities. Should you have any further questions, please contact Peter Thomas, Leela Baggett, or Michael Barnett—ITEM Coalition co-coordinators—at Peter.Thomas@PowersLaw.com, Leela.Baggett@PowersLaw.com or Michael.Barnett@PowersLaw.com.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.
ACCSES
AG Bell Association for the Deaf and Hard of Hearing
All Wheels Up
ALS Association*
American Association for Homecare
American Association on Health and Disability
American Congress of Rehabilitation Medicine
Association of Rehabilitation Nurses
Autistic Women & Nonbinary Network
Center on Aging and DIS-Ability Policy
Christopher & Dana Reeve Foundation*
Clinician Task Force
CureLGMD2i Foundation
Institute for Matching Person and Technology
International Registry of Rehabilitation Technology Suppliers (iNRRTS)
Lakeshore Foundation
Long Island Center for Independent Living (LICIL)
National Association for the Advancement of Orthotics and Prosthetics
National Disability Rights Network
National Multiple Sclerosis Society
NCART
RESNA
Spina Bifida Association*
United Cerebral Palsy
United Ostomy Associations of America
United Spinal Association*

****Member of the ITEM Coalition Steering Committee***