



June 21, 2024

SUBMITTED ELECTRONICALLY

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: ITEM Coalition Request for Medicare Coverage of Medically-Prescribed Bowel Management Products

Dear Administrator Brooks-LaSure:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition write to share our significant concern regarding the lack of Medicare coverage for bowel management products—devices for Transanal Irrigation (“TAI”)—that are particularly important for people with spinal cord injury and other types of paralysis.

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, brain injury, stroke, paralysis, cerebral palsy, spina bifida, multiple sclerosis, limb loss and limb difference, hearing, speech, and visual impairments, myositis, and other life-altering conditions.

Access to TAI is critical for the multiple impacted populations living with neurogenic bowel dysfunction (“NBD”), including individuals living with congenital disorders such as Hirschsprung disease and anorectal malformations as well as those with post-surgical low anterior resection syndrome (which can occur due to a low anterior resection for bowel cancer), as well as colorectal cancer.

TAI works by replacing the function necessary to support bowel emptying for individuals with bowel dysfunction similar to how urinary catheters support the function of voiding urine for individuals with bladder dysfunction.¹ TAI is not an enema, which is a non-covered Medicare benefit. TAI is a non-surgical treatment option for individuals with NBD who are not responsive to basic NBD treatment and who might otherwise be considered candidates for surgery. Children and adults with NBD experience chronic constipation and/or fecal incontinence resulting from central nervous system disease or injury and many are unable to manage their own

¹ Rodriguez et al. J Clin Med. Mar 7 2024;13(6).

bowels. Neurologic injury or disease impairs the brain and the bowels from functioning together, resulting in the inability of the bowel to function in a typical fashion.

Individuals with spinal cord injury (“SCI”) and other forms of paralysis often have NBD, which is both physically and socially debilitating. Individuals with fecal incontinence have increased rates of depression and bullying as well as decreased rates of school attendance in childhood, lower overall educational attainment and lower employment rates.² In fact, individuals with SCI have reported bowel dysfunction as being more problematic than bladder dysfunction, sexual dysfunction, pain, fatigue, and perception of body image.³ In addition to paralysis, common causes of NBD include amyotrophic lateral sclerosis, spina bifida, multiple sclerosis, Parkinson’s disease, stroke, diabetes mellitus, and cerebral palsy.

Currently, Medicare does not cover TAI equipment and supplies, exposing beneficiaries with NBD to complications such as frequent constipation, fecal incontinence, urinary tract infections, urinary incontinence, hemorrhoids, skin breakdown, pressure injuries [ulcers/wounds]), frequent emergency department visits and, in some cases, bowel surgery (i.e., colostomies or ileostomies). Non-invasive treatment for NBD is currently limited to changes in diet, physical activity levels, and laxative medication. Unfortunately, these treatments are ineffective for nearly all individuals with NBD⁴ and, as a result, individuals typically have to progress to more invasive treatments such as colostomy or appendicostomy (creating a channel between the abdomen and colon using a portion of the appendix). In contrast, TAI is a minimally-invasive treatment option for individuals living with NBD that is supported in treatment guidelines and clinical protocols for impacted individuals in the United States.

For instance, new data from a recent survey conducted by Duke University of individuals with NBD in the United States supports the request to include coverage of TAI devices as a treatment for NBD under the Medicare program.⁵ In that survey, over two-thirds of children and adults—primarily individuals with spina bifida and SCI—experience fecal incontinence, almost half live with bowel pain or pressure, nearly one quarter make additional physician visits due to this condition, and almost 1 in 5 are treated in the emergency room for bowel-related complications.

The Duke University survey data supports the request to include TAI devices as a treatment for NBD under the Medicare program. Current Medicare policy provides coverage for urinary catheters as prosthetic devices that empty the bladder for individuals with NBD, but the program currently does not cover TAI products, which perform an equivalent emptying function for the bowel. Medicare coverage for TAI devices may avoid additional expenses both for the Medicare program and for individuals living with NBD. The U.S. Food and Drug Administration (“FDA”) has approved TAI equipment and supplies, which have been studied extensively in peer-

² Kelly MS, et al. Release and highlights of the *Lifespan Bowel Management Protocol* produced for clinicians who manage neurogenic bowel dysfunction in individuals with spina bifida. *J Pediatr Rehabil Med.* 2023; 16(4): 675–677.

³ Management of Neurogenic Bowel Dysfunction in Adults after Spinal Cord Injury: Consortium for Spinal Cord Medicine Clinical Practice Guidelines, p. 44.

⁴ Kelly MS, Wiener JS, Liu T, et al. Neurogenic bowel treatments and continence outcomes in children and adults with myelomeningocele. *J Pediatr Rehabil Med.* 2020;13(4):685-693.

⁵ Duke University: “A Study to Determine Barriers of Using Transanal Irrigation (TAI) Systems: A Survey Conducted among People with Neurogenic Bowel, and/or Bowel Incontinence/Constipation, *IRB Pro00113381*

reviewed literature documenting their safety and effectiveness in treating NBD for eligible candidates, specifically in reducing constipation, fecal incontinence, bowel complications, and surgery.

For these reasons, the ITEM Coalition urges the Centers for Medicare and Medicaid Services (“CMS”) to determine that TAI devices should be assigned the benefit category of prosthetic devices because they “replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices...”⁶

To render this determination, CMS will have to revisit its decision in 2015 involving TAI devices. At that time, CMS announced that it would not cover TAI devices used with rectal balloon catheters because CMS did not believe these items fit a defined benefit category. TAI devices with rectal balloon catheters are different from enemas based on their design, instructions for use and mechanism of action. TAI with rectal balloon catheters replaces the function of a malfunctioning anal sphincter and malfunctioning colon in individuals with NBD. A sister coalition to the ITEM Coalition will soon submit an application to the Healthcare Common Procedure Coding System (HCPCS) Work Group requesting CMS to establish a positive “benefit category determination” (“BCD”) for TAI devices used with rectal balloon catheters. TAI device manufacturers are also submitting formal HCPCS coding applications to establish billing codes that appropriately describe these items. The evidence base is stronger than it was ten years ago and ITEM Coalition supports CMS freshly examining this important BCD and coding issue.

Thank you for your consideration of our request. We look forward to working with CMS to help ensure that patients and individuals with NBD have access to the medically necessary devices that meet their unique medical needs. If you have any questions regarding this matter, please contact the ITEM Coalition Co-Coordination, Peter.Thomas@PowersLaw.com and Michael.Barnett@PowersLaw.com, by email or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.

ACCSES

All Wheels Up

American Association for Homecare

Association of Rehabilitation Nurses

American Association on Health and Disability

American Congress of Rehabilitation Medicine

Autistic Women & Nonbinary Network

Center for Medicare Advocacy

Lakeshore Foundation

Long Island Center for Independent Living

National Association for the Advancement of Orthotics and Prosthetics

⁶ Social Security Act § 1861 (s)(8).

National Association of Councils on Developmental Disabilities

Spina Bifida Association*

Team Gleason*

The Buoniconti Fund to Cure Paralysis

The Miami Project to Cure Paralysis

United Spinal Association*

****ITEM Coalition Steering Committee Member***

CC:

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Chairwoman
House Energy & Commerce Committee
2322A Rayburn House Office Building
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The Honorable Jason Smith
Chairman
House Ways & Means Committee
1129 Longworth House Office Building
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The Honorable Ron Wyden
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