BOWEL MANAGEMENT PRODUCTS ARE NOT COVERED BY MEDICARE

BACKGROUND

Medicare does not cover Transanal Irrigation (TAI) equipment and supplies, exposing beneficiaries with neurogenic bowel dysfunction (NBD) to complications (constipation, fecal incontinence, urinary tract infections, urinary incontinence, hemorrhoids, skin breakdown, and pressure injuries), frequent emergency department visits and, in some cases, bowel surgery (i.e., colostomies or ileostomies). Non-invasive treatment for NBD only includes changes in diet, physical activity levels, and laxative medication. These treatments are ineffective for nearly all individuals with NBD. Individuals may 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). TAI is a minimally-invasive treatment option for individuals with NBD that is supported in treatment guidelines and clinical protocols for individuals with NBD in the United States.

The symptoms of NBD are chronic constipation and/or fecal incontinence. 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 multiple sclerosis, spina bifida and spinal cord injury (SCI) often have NBD. NBD is 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. Individuals with SCI have reported bowel dysfunction as being more problematic than bladder dysfunction, sexual dysfunction, pain, fatigue, and perception of body image.

In a Duke University survey of individuals with NBD in the United States, 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 a quarter make additional physician visits and almost 1 in 5 are treated in the emergency room for bowel-related complications.

- TAI is recognized as medically reasonable and necessary for treating NBD by over half the State Medicaid programs, the Department of Veterans Affairs’ Veterans Health Administration, the Department of Defense’s TriCare program and 120 private sector health plans, including some of the largest plans participating in the Federal Employees Health Benefits Program (FEHBP). Providing coverage for urinary catheters to empty the bladder for individuals with NBD but not providing coverage for TAI which performs an equivalent function regarding bowel emptying is inconsistent Medicare policy. This has a huge negative impact from a health equity perspective on underserved and underrepresented populations across the U.S.
- Studies show that TAI reduces constipation and fecal incontinence and can prevent or delay the need for more invasive interventions including surgical interventions. Large and diverse populations have used TAI with a low incidence of adverse events. Healthcare professionals prescribing TAI are trained on appropriate TAI candidate selection and device use.

Individuals with NBD receive thorough instruction and supervision from healthcare professionals during their first use of TAI.

The population of Medicare beneficiaries with NBD (children and adults with disabilities, dually-eligible for Medicare and Medicaid) likely to use TAI is very small. 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. Medicare coverage of TAI devices would eliminate additional expenses from the Medicare program and from individuals living with NBD. The U.S. Food and Drug Administration approves TAI equipment and supplies, which have been studied extensively in peer-reviewed literature documenting their safety and effectiveness in treating NBD, specifically in reducing constipation, fecal incontinence, bowel complications, and surgery.

REQUEST TO POLICYMAKERS

For children and adults living with NBD, significant bowel management issues or chronic constipation and/or fecal incontinence, we ask that you support the inclusion of TAI devices for the treatment of NBD under the Medicare program and direct the Centers for Medicare and Medicaid Services to update the Social Security Act and categorize TAI devices as prosthetic devices.

5. Over 35 peer-reviewed studies on TAI in human subjects have been published in the past 5 years alone. In the last decade, more than 75 clinical papers, including 4 randomized control trials (RCTs) have documented the benefits of TAI in individuals with bowel dysfunction, including those living with NBD.
6. Ibid.
7. Social Security Act § 1861(s)(8): “prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices...”