

## **BOWEL MANAGEMENT PRODUCTS ARE NOT COVERED BY MEDICARE**

### **BACKGROUND**

Medicare does not cover Transanal Irrigation (TAI) equipment and supplies, exposing beneficiaries with bowel dysfunction to complications, frequent emergency department visits and the potential for stoma surgery. Bowel dysfunction, the inability for a person to manage his or her bowels, is characterized by chronic constipation and/or fecal incontinence which can stem from a physical malformation, injury or disease. Individuals with spinal cord injury, spina bifida and multiple sclerosis often have neurogenic bowel dysfunction (NBD) from damage to the nervous system that prevents their brain and bowels from working together in a functional capacity. Conservative treatment for bowel dysfunction can include changes in diet, activity level and fluid intake and prescription or over the counter medication like laxatives. These conservative treatments are not always effective, and individuals with bowel dysfunction often progress to more invasive treatments like stoma surgery.

Bowel dysfunction characterized by chronic constipation and fecal incontinence is physically and socially debilitating. In one study, individuals living with spinal cord injury and NBD reported that, of all their symptoms, bowel dysfunction has the greatest impact on their daily lives, ahead of sexual function, bladder issues, wheelchair use, pain, spasticity, and skin care. Defecation disturbances from bowel dysfunction can be severe enough to increase individuals' risk for repeated emergency care. Due to the anatomical proximity of the bowel and lower urinary tract, complications from inadequate bowel management can also result in an increased risk for urinary tract infections (UTIs).

- TAI is recognized as medically reasonable and necessary for treating bowel dysfunction by over half the State Medicaid programs, the VA, TriCare and 120 private sector health plans, including some of the largest plans that participate in Federal Employees Health Benefit Program (FEHBP). Over 120 peer-reviewed studies on TAI in human subjects have been published in the past 5 years alone. In the last decade, more than 35 clinical papers, including 4 randomized control trials (RCTs) have documented the benefits of TAI in individuals with bowel dysfunction, including those living with NBD.
- Studies show that TAI reduces constipation and fecal incontinence and can prevent or delay the need for more invasive interventions. TAI has been used by large and diverse populations with a low incidence of adverse events. Importantly, TAI devices are not over-the-counter enemas and are prescription use only. All health care professionals who prescribe TAI are trained. They conduct a careful review of the history of individuals with NBD and perform a digital rectal examination before the initial prescription. Individuals with NBD also receive thorough instructions and supervision from trained providers during their first use of TAI.
- The population of Medicare beneficiaries with NBD (people with disabilities, dual-eligible on Medicare and Medicaid, low-income) likely to use TAI is very small. One study estimated that only 1000 beneficiaries would adopt TAI over a ten-year period if TAI were a Medicare benefit. Therefore, the costs to Medicare of adding TAI as a benefit are also likely to be modest.

### **REQUEST TO POLICYMAKERS**

Support the inclusion of TAI devices for the treatment of bowel dysfunction under the Medicare program. TAI is a non-surgical treatment for patients with bowel dysfunction who are unable to use conservative bowel management treatments and who might otherwise be considered candidates for surgery. TAI addresses slow transit of digestive system contents and TAI equipment and supplies are cleared by the U.S. Food and Drug Administration and have been studied extensively in peer-reviewed literature documenting their safety and effectiveness for reducing constipation, fecal incontinence and complications from poorly treated NBD.

- People living with bowel dysfunction lack the ability to adequately manage their bowels and experience chronic constipation and/or fecal incontinence.
- Complications of bowel dysfunction can result in emergency department visits, a high incidence of UTIs and, in severe cases, stoma surgery. Literature broadly supports the use of TAI for treating bowel dysfunction, especially NBD. TAI devices are FDA cleared and regular use of TAI has been shown to reduce constipation, fecal incontinence, complications like UTIs and the need for stoma surgery.
- Excluding TAI equipment and supplies from Medicare exposes chronically ill beneficiaries to medical complications from poorly treated bowel disease which results in additional costs to both Medicare and individuals with bowel dysfunction.

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