

## **Bowel Management Devices (BMD) – Response to Comment Summary**

October 2015

The public comment period for the draft local coverage determination for Bowel Management Devices (BMD) closed on August 31, 2015. A public meeting was held on August 26, 2015.

### **Comments – Renew<sup>®</sup> Anal Insert**

1. The draft LCD did not take into account the latest published, peer-reviewed literature on the safety and efficacy of the device (Lukacz, et.al. *Dis Rectum Colon* 2015;58:892-898).

Response: There are only two articles published in the peer-reviewed literature evaluating the safety and efficacy of the Renew<sup>®</sup> Anal Insert device. The Lukacz article cited by the commenter has several shortcomings as pointed out by the authors:

- Use of a nonvalidated assessment scale
- Non-randomized
- No control comparison group
- Non-blinded

In addition to the above points, the Medical Directors also note the following issues:

- Short treatment time (12 weeks)
- “Satisfaction” with device only assessed and reported in those completing 12 week trial thus introducing bias by not counting those that dropped out due to dissatisfaction with the device
- 25% withdrawal rate from study
- Dropout rate higher for Medicare-age population
  - Average age of those withdrawing – 74.3 (range 55.2 – 85.2)
  - Average age of those completing – 67.2 (range 33.9 – 88.9)
- 49% self-reported effectiveness rate
- Study development, implementation, data collection and data analysis funded by manufacturer
- All authors of the study were paid consultants to manufacturer

At this time, based on the paucity of literature demonstrating the effectiveness of the Renew<sup>®</sup> Anal Insert device, the Medical Directors will maintain the current not reasonable and necessary coverage statement.

2. Rectal inserts are not investigational or experimental.

Response: The Medical Directors agree; however, as noted above, the strength of the peer-reviewed literature does not support Medicare coverage at this time.

3. CMS acknowledges the similarity between urethral inserts and rectal inserts and should afford similar coverage.

Response: Coverage of one type of device by Medicare does not confer automatic coverage of another device. The strength of the peer-reviewed literature does not support Medicare coverage of the Renew<sup>®</sup> Anal Insert device at this time.

### **Comments – Peristeen<sup>®</sup> Transanal Irrigation (TAI) System**

1. The proposed draft uses an incorrect and incomplete definition of “prosthetic device” as applied to the Peristeen<sup>®</sup> Transanal Irrigation (TAI) System. The Peristeen<sup>®</sup> Transanal Irrigation (TAI) System should be afforded coverage under the Prosthetic Devices benefit category.

Response: The Medical Directors disagree. The Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Workgroup has determined that the Peristeen<sup>®</sup> Transanal Irrigation (TAI) System is not a prosthetic device. Moreover, as noted in the related Policy Article for the draft LCD, it does not meet the definition of durable medical equipment.

The CMS HCPCS Workgroup held a public meeting on May 28, 2014 to hear comments on the applications for new 2015 HCPCS codes. The CMS HCPCS Workgroup is comprised of members from commercial insurance plans, the Veteran’s Administration, CMS and state Medicaid agencies. A summary of the meeting preliminary decisions is available on the CMS.gov website at:

<http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2014-05-28-Supply-Summary.pdf>

The CMS HCPCS Workgroup determined that the preliminary coding determination associated with this request indicated that existing code A4458 ‘Enema bag with tubing, reusable’ adequately describes the product, and the preliminary payment determination associated with this request indicated that the payment rules associated with the existing code apply to this product. Pricing = 00.

In fecal incontinence, there is a malfunction of the anal sphincter. Based on a review of the Peristeen<sup>®</sup> product, we do not believe that it replaces the function or structure of the anal sphincter. Similar to other enema systems, it helps with defecation by increasing the fluid in the bowel. The Medical Directors therefore believe that the HCPCS Workgroup determination of benefit category and the pricing indicator of 00 for code A4459 is correct.