



## Ostomy and Urological Supply Categories are Not Well Suited for the Medicare Competitive Bidding Program

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## EXECUTIVE SUMMARY

Prescribed ostomy and urological products are used to manage medical conditions that interfere with or do not allow for normal bowel and/or bladder function. These product categories are broad and extremely complex. The complexity of product is needed to meet the distinct and highly variable needs of patients to appropriately manage biological waste.

Medicare completed a Competitive Bidding Demonstration project (2004) that included urological supplies and concluded they are “not well suited” for competitive bidding.<sup>1</sup> In this report, Medicare concluded that ostomy and urological supplies present little competitive potential and limited savings potential on a small dollar base on Medicare expenditures.

Medicare should not expand the Competitive Bidding program to include these products in exchange for the potential of immaterial savings and the likelihood of adverse impact on patient health.

## INTRODUCTION

Ostomy and urological supplies are medically necessary for 750,000-1 million Americans who have compromised bowel and/or bladder functions.<sup>2</sup> These products are highly customizable in nature, and a diverse range of options is required in order to best meet each patient’s clinical needs.

Suppliers and manufacturers currently engaged in providing ostomy and urological products understand the complex needs of this population and have invested significant resources in order to meet these needs. A survey of eight leading Medicare suppliers and three national manufacturers was conducted in August 2017; the findings illustrate the broad array of products required by users of ostomy and urological supplies. Collectively, survey supplier and manufacturer participants have more than 2,200 items made by more than 100 manufacturers on hand ready to provide to Medicare beneficiaries in need of ostomy or urological supplies.

Within the past 2 years, there have been references to expanding the controversial Medicare Competitive Bidding Program for Durable Medical Equipment (DME) to other product categories, including ostomy and urology supplies, in either the President’s Budget or MedPAC recommendations. Such action would significantly diminish the number of unique products available to meet beneficiaries’ needs and would compromise patient health while failing to achieve cost-savings goals. The Competitive Bidding Program puts ostomy and urology supplies at risk for commoditization, that is the loss of differentiation in function or functionality. As explained below, ostomy and urology products are unique to each person’s clinical needs and are not commodity products.

The American Association for Homecare is not alone in this concern. Others, such as the Wound Ostomy and Continence Nurses Society, have identified access to wound, ostomy, and incontinence supplies as a “public policy and advocacy priority with a goal to protect and enhance patients’ access to wound, ostomy, and continence supplies.”<sup>3</sup> Their concern is that the lack of new categories “do not recognize the prosthetic, life-restoring nature of these devices. This lack of appropriate classification limits an individual’s access to proper products, creates safety issues, and inhibits innovation in new ostomy technology”.

Other organizations such as the United Spinal Association have stated their opposition to the President’s Budget, voicing concern that the decision will “limit access to prosthetic supplies which need to be clinically prescribed, selected, and/or adjusted and fitted for individuals by specially trained health care professionals based on the unique medical and physical needs of each person.”<sup>4</sup> They go on to state that “Medicare, and other payers, need to ensure that individuals have access to the catheters and

ostomy supplies prescribed for their use to avoid life-threatening infection [and complications] and increased health care costs". The United Spinal Association noted that such medical products are clinically prescribed and finding the right product to address specific clinical needs requires continual adjustment for the appropriate fit due to physical changes across the lifespan.

United Ostomy Associations of America (UOAA) is also concerned, as ostomy and urological prosthetics are not one-size-fits-all, or over-the-counter generic products, and are not easily interchangeable. Since every individual's skin and stomal output are different, it is essential each person has access to products that are compatible with their body. UOAA also noted that improper pouching systems can result in leakages and odor, which may have an emotional impact on a person, leading to depression and social isolation.<sup>9</sup>

Numerous reports by CMS point to the limited potential for program savings found through the DMEPOS Competitive Bidding Demonstration Projects that included urologicals, concluding that these products are "not well suited" for Competitive Bidding.<sup>1,7</sup> The Competitive Bidding Demonstration Project pointed to the limited savings potential and "deleterious effect on product selection"<sup>5</sup> that the Competitive Bidding program could have in spite of some products being better suited for individuals than others within a single HCPCS code.<sup>5</sup>

If product variation decreases as anticipated by the US Department of Health and Human Services, (now CMS), many individuals' health will be compromised. Ill-fitting or inappropriately sized products can result in consequences such as severe skin damage, life-threatening infections, and other health issues that can lead to hospitalizations and other increased costs related to use of products not aligned with the individual patient's physiology. This is not good policy or sound program management.

## PRODUCT BACKGROUND

There are a wide variety of products necessary to effectively manage ostomy and urinary incontinence or retention. In order to fully comprehend why product differentiation is required, it is important to understand what ostomy and urological products are and how they are used.

### Ostomy

An ostomy is a surgically created opening (stoma) in the body by which fecal matter and urine are emptied into a collection pouch. The emptying or voiding of the waste is an involuntary action. Ostomy pouches are adhered to the skin by an adhesive barrier (wafer), collecting urine or fecal matter. There are several types described below.

- Colostomy: A surgical procedure in which an opening (stoma) is formed by attaching the colon (large intestine) to the abdominal wall. It is often used for individuals who have diverticulitis, colon cancer, bowel obstruction, paralysis, trauma and/or injury or congenital birth defects.
- Ileostomy: A surgical procedure in which an opening (stoma) is formed by attaching the ileum (small intestine) to the abdominal wall. It is commonly used in individuals with ulcerative colitis, Crohn's disease, Familial Polyposis (FAP), and colon cancer.
- Urostomy: A surgical procedure in which an opening (stoma) is formed for the urinary system. This is done to divert the normal flow of urine from the kidneys and ureters to the stoma. A urostomy is a permanent solution. A urostomy is most often needed due to bladder cancer but also inflammation of the bladder or congenital birth defects.

## **Incontinence and Urinary Retention**

Urinary retention is the inability to voluntarily void urine. This condition can be acute or chronic.

Urinary incontinence is the involuntary leakage of urine; in simple terms, it means a person urinates when they do not want to. Control over the urinary sphincter is either lost or weakened.

Causes of urinary retention and incontinence are numerous. Individuals with conditions such as spinal cord injury, Parkinson's disease, stroke, brain injury, enlarged prostate, multiple sclerosis, cerebral palsy, spina bifida, and cancers often may be living with urinary retention and incontinence issues. For some conditions, the communication between the brain and bladder is altered resulting in problems with bladder storage and bladder emptying. Bladder may empty too frequently, not frequently enough, or in an uncoordinated way.

Urological supplies include catheters which are inserted into the urethra to drain the bladder, either on an intermittent basis or left inserted into the bladder for a week or longer. Catheters that are left in the bladder are known as indwelling catheters, and some individuals use this method of bladder emptying throughout their lifetime. Catheters left in place in the bladder and those that are applied externally also require urine collection devices such as night drainage bags and leg bags.

## **Selecting the Appropriate Ostomy Products**

There are many factors considered by medical professionals when prescribing an ostomy pouching system that will work best for the patient. The length of the stoma, type of barrier adhesion, abdominal firmness and shape, the location of the stoma, scars and folds near the stoma, physical demands, and height and weight all must be considered. Special changes may have to be made for stomas near the hipbone, waistline, groin, or scars. Some manufacturers have custom-made products to fit unusual situations. These products also require a healthcare professional's (such as a certified ostomy nurse or ostomy management specialist) ongoing services for selection, fitting, training on use, adjustment, and to address health care conditions and clinical complexities that arise.

The stoma size and shape change over time. Immediately after surgery, the stoma is quite different and may require the patient to change his/her ostomy systems more often. The need for barriers, pouches, and accessories will vary over time. Further, varying climate conditions (such as high humidity) play a role, affecting the frequency in which the pouching system must be reapplied.

A good pouching system should be:

1. Secure, with a good leak-proof seal to prevent incontinence and skin breakdown
2. Odor-resistant
3. Protective of the skin around the stoma
4. Nearly invisible under clothing
5. Easy to take off and apply

## **Selecting the Appropriate Urological Products**

Selecting the most appropriate urinary catheter and drainage system is an important factor affecting patient health, outcomes and comfort. Inappropriate selection may introduce an array of unnecessary catheter-associated health problems for the patient, such as urinary tract infections<sup>8</sup>, bleeding, and urethral strictures (scarring). There is a vast selection of catheters, materials used, and drainage systems available. Some of the materials used are vinyl, rubber, and silicone. Use of the appropriate material, type, and size of catheter is critical to the patient's health. Catheters should also be selected by a healthcare professional based on a person's functional capacity and medical history.

All ostomy and urological products used must be properly evaluated by an appropriately trained medical professional, such as a Wound Ostomy Continence Nurse, to ensure they align with the patient's unique anatomy and overall physical health.

## BACKGROUND FOR BIDDING ON UROLOGICALS

### The Challenge

Product selection in a competitive bid environment will likely be lessened as anticipated by the Health and Human Services Department in the 2004 Final Report to Congress on a Competitive Bidding Demonstration project that included urological supplies.

### Demonstration Projects History

The only times that the Competitive Bidding Program included urological supplies were in the 1999 and 2001 Competitive Bidding Demonstrations in Polk County. The resulting analysis from government agencies concluded that "We believe that the product category of urological supplies is not as well suited for Competitive Bidding... Urological supplies has much lower allowed charges than [other] product categories, so it offers relatively little potential for program savings." <sup>7</sup>

### Specifically, CMS reports state:

#### ***Negative Impact on Quality, Access, and Support***

- "Some product categories, especially smaller ones such as urological supplies, may be vulnerable to a lessening of product selection under reduced prices. Some urological supplies are associated with strong patient preferences, and therefore may be particularly vulnerable to supplier market strategies that narrow patient choice." <sup>1</sup>
- "Beneficiary complaints in the early months of the hotline centered around beneficiaries' dissatisfaction with switching suppliers and/or having to switch name brands (especially for urological supplies.)" <sup>5</sup>
- "In a product with relatively few suppliers, quality may suffer if several of the winning suppliers are inexperienced, perceived access may fall if patients prefer local suppliers and several of the winning suppliers are located outside the area, and product selection could be reduced if several winning suppliers adopt more limited product lines." <sup>7</sup>
- "For urological supplies, it became apparent that suppliers need to be knowledgeable about this product and that beneficiaries would benefit from a wide selection of products to accommodate different needs." <sup>7</sup>
- "Quality problems are most likely to occur in the urological supplies product category." <sup>5</sup>

#### ***HCPCS Variety vs Reimbursement***

- "There is a wide variety of products available for some urological codes. Because the reimbursement level applies to a broad category of products regardless of material used or quality of item, the incentive is for the supplier to find the least expensive item in the category that would still provide the beneficiary with an acceptable level of quality." <sup>5</sup>
  - "However, because urological supplies are very personal items, the patient often has brand and product preferences. Moreover, even within a single HCPCS codes, some products may better match a patient's needs than another." <sup>5</sup>
  - "However, lower reimbursement levels in the demonstration may have strengthened this incentive so that suppliers were willing to provide products of lower quality than they did in the past." <sup>6,7</sup>
- "During interviews with urological suppliers, it was evident that the reimbursement for certain HCPCS codes does not adequately cover the cost of some products within that HCPCS code." <sup>5</sup>

### ***Inappropriateness of Urologicals for Competitive Bidding***

- “The evaluators judged that several [products] were ‘not as well suited’ for competitive bidding (surgical dressings, general orthotics, urological supplies, and enteral nutrition). [They] tended to have relatively low allowed charges and low numbers of suppliers. Both characteristics may not indicate sufficient potential for total savings and competition that would lead to significant price reductions.”<sup>1</sup>
- “Small-volume DMEPOS categories may represent lower-priority areas for conducting competitive bidding, not only in terms of the limited savings potential on a small dollar base but also in terms of a category’s competitive potential.”<sup>1</sup>

### **Key Role of Experienced, Local Supplier & Wide Product Offerings**

Among changes between the two rounds of bidding in Polk Co, CMS noted that the Demonstration Ombudsman attributed an improvement to some of the urological supplies issues to a local, experienced supplier participating who “offered several brands of supplies, allowing [patients] to satisfy individual preferences and/or offer alternate products if one brand was not working properly”. The report continued that “should the experienced supplier leave the market or if the demonstration were extended to an area without such an experienced supplier, the practice of using only one brand to obtain a more competitive price for the supplier could have a deleterious effect on product selection”.<sup>7</sup>

## **SOLUTION**

**CMS should work with provider and patient groups to determine if there are cost reducing mechanisms that can be employed to achieve program savings in ways that do not adversely affect beneficiaries that require Ostomy and Urological supplies. CMS and Congress should ensure beneficiaries continue to have access to the broad array of supplies to meet their unique medical needs.**

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Other: American Cancer Society ostomy product recommendations