

## The Critical Need to Provide Intermittent Catheter Urological Supplies Specific to Patient Need to Improve Health Outcomes

### **EXECUTIVE SUMMARY/PURPOSE**

Individuals with urinary retention may require assistance draining their bladder via catheters inserted into the urethra. Home medical equipment (HME) providers work closely with the end user and clinical community to provide urological supplies and services to those requiring catheterization in a home-based setting. While there are many different types of catheters to meet individual's needs, this paper will primarily focus on intermittent catheterization.

Depending on one's clinical needs, a variety of urological supplies are available to help manage one's medical condition, increase adherence, and prevent negative health outcomes such as catheter-associated urinary tract infections (CAUTIs) which can exacerbate co-morbidities and increase costs of care. Intermittent catheters, which are used to drain the bladder at certain intervals throughout the day, do not remain inserted into the bladder. They are the preferred method of bladder management among individuals with urinary retention and are clinically shown to have a lower risk of CAUTI. In addition to providing supplies, HME providers and their manufacturer partners provide extensive education and support for those using urological supplies to maximize outcomes and empower the end user to self-catheterize safely and effectively.

Recent payer trends in the Medicaid, private insurance, and Managed Care Organizations (MCO) markets have made it more challenging for the HME provider community to provide the urological supplies and services that meet clinical and personal needs of individuals. Current Medicare codes for intermittent catheters are fairly generic and do not distinguish the wide range of products with differing features classified within a single Healthcare Common Procedure Coding System (HCPCS) code. Unsustainable reimbursement rate reductions limit both the services provided and the types and brands of urological supplies offered. This can lead to avoidable restriction of end users' choice, product access, and access to care, as well as hospital readmissions ultimately increasing the total cost of caring for individuals requiring catheterization.

This paper is the third of a white paper series to address the type of products and HME provider services needed to manage an individual's bowel and bladder needs. The series also highlights how ensuring adequate reimbursement for these supplies is an indispensable part of payers achieving the Triple Aim of health care, as stated by the Institute of Healthcare Improvement as improving the patient experience and health outcomes while reducing costs. To ensure end users receive the appropriate products and to promote the most positive outcomes, payers need to ensure rates for these services are no less than the current corresponding 2021 fee-for-service Medicare rates for these same products.

### **UROLOGICALS OVERVIEW**

Catheters are used to drain the bladder when an individual cannot control the process of urination or is unable to empty their bladder. A catheter is a thin, hollow tube inserted into the urethra or inserted into surgically created stomas/Mitrofanoff valve to drain the bladder into a drainage bag or toilet. There are many varieties of catheters available depending on an individual's unique medical needs.

#### **Population**

Urinary retention, characterized by incomplete bladder emptying or an inability to adequately empty the bladder, which is a manifestation of several conditions affecting both children and adults. Prevalence and

incidence information is not readily available on all populations; therefore, the data cannot be seen in its entirety.

41.3% of patients with neurogenic lower urinary tract dysfunction (NLUTD) perform intermittent self-catheterization (ISC), making it the most common method of bladder drainage. Eleven percent of patients with multiple sclerosis (MS) perform ISC. ISC is performed by males and females; however, males are more likely to perform ISC than females.<sup>1</sup>

## **End User Medical Conditions**

### *Co-Morbidities*

Urinary retention and incontinence issues may develop as result of conditions such as spinal cord injury, spina bifida, multiple sclerosis, Parkinson's disease, late-stage diabetes, stroke, cancer, enlarged prostate, and pelvic floor dysfunction or prolapse. Although there are many conditions, the population requiring catheterization is relatively small but clinically diverse.

Catherization is a method employed to empty the bladder when normal function of the urinary system is impaired due to neurological impairments (damage to nerves involved with bladder emptying), obstruction (such as due to an enlarged prostate), or pelvic floor dysfunction and prolapse. These issues can result in urinary retention or an inability to empty the bladder. Various issues which inhibit genitourinary (GU) tract function that IC users may experience include:

- Urinary retention known as neurogenic lower urinary tract dysfunction (NLUTD)
- Incomplete bladder emptying resulting in high post-void residual urine volume
- Urethral stenosis/stricture disease
- Urinary retention:
  - Without bladder outlet obstruction if the bladder can be emptied by a maximum frequency of every four hours
  - With bladder outlet obstruction due to non-traumatic, non-infectious diagnosis
  - Chronic urinary retention with or without bladder outlet obstruction<sup>1</sup>

### *UTI Prevalence/Risk*

Complications and risk of urinary tract infection can arise at any time a device is inserted into the urethral tract as a method to drain the bladder. This creates a portal of entry for potential infection, and duplication of bacteria in the bladder can occur.

When it comes to UTI rates of IC versus indwelling the literature is varied but the Centers for Disease Control and Prevention (CDC) (and many other global guidelines) recommend IC over indwelling for bladder management in the home setting.<sup>2,3,4,5,6,7</sup> According to the CDC, "each day the indwelling urinary catheter remains, a patient has a 3%-7% increased risk of acquiring a CAUTI".<sup>8</sup>

Urethral trauma, UTIs, pain and discomfort are the main adverse events reported for urethral catheterization in general.<sup>9</sup> The incidence of UTI for spinal cord injured individuals, a population who may require IC, is in the region of 2.5 per person per year,<sup>10,11</sup> with over 80% of people experiencing at least one UTI over a 5-year period.<sup>12</sup>

Within the first 30 days after starting intermittent catheterization, studies report that 16% of patients utilize the emergency department and 10% of patients require an overnight hospital readmission.<sup>13</sup> This can be very expensive, especially in older patients with multiple comorbidities. UTIs are common causes of healthcare visits. Using clinically appropriate catheters can reduce some risk factors for UTIs, such as urethral and bladder trauma from catheters and post void residual urine. These risk factors can be reduced by product design features such as no touch grippers, protective sleeves, ready-to-use uniform hydrophilic coating, polished eyelets (drain holes) and catheter length.<sup>14,15</sup> The method and type of catheterization must be matched to the

patient's functional abilities and secondary conditions, (bladder and hand dexterity, spasticity, contractures), preferences, and the ability to prevent contamination.<sup>16</sup>

## **PRODUCT TYPES OVERVIEW**

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.

### **Intermittent Catheter Options**

Intermittent catheters (IC) are used to drain the bladder at certain intervals throughout the day; they do not remain inserted in the bladder. Intermittent catheterization involves the temporary insertion of a catheter via the urethra into the bladder to achieve bladder emptying or via a surgically created stoma and is the preferred method of bladder management among individuals with urinary retention.<sup>17,18</sup> The Society of Urological Nurses and Associates (SUNA) recommends intermittent self-catheterization be performed at regular intervals through the day, every 4-6 hours (4-6 times per day) to keep the amount of urine in the bladder less than 400-500mL.<sup>19</sup>

Intermittent catheterization has been identified as an alternative to indwelling catheterization by the Infectious Diseases Society of America (IDSA)<sup>20</sup> and preferable to indwelling catheterization for bladder management by the Healthcare Infection Control Practices Advisory Committee (HICPAC).<sup>21</sup>

Clinicians and patients together determine the most medically appropriate catheter for the individual based on that person's co-morbidities, underlying conditions, and risk factors.

### **Other Types of Catheters**

Catheters that are left in the bladder are known as indwelling urinary catheters (IUCs), and some individuals use this method of bladder emptying throughout their lifetime. External urinary catheters are urine collection devices with tubing that use either gravity or suction to drain urine away from the urethral opening. External catheters are not inserted into the body and are contraindicated for those with urinary retention. These catheters will be discussed in greater detail in a separate paper.

## **UROLOGICALS EXPENSE**

### **Quality Products to Optimize Health Care Outcomes/Expenses**

Medicare, and other payers, need to ensure that individuals have access to the catheters prescribed for their use to avoid life-threatening infection and other complications that result in increased health care costs. These medical products are clinically prescribed, and finding the right product is necessary to address specific clinical needs.

A 2016 study that reviewed lifetime use of ICs found that hydrophilic-coated ICs are more cost effective than uncoated ICs over the course of lifetime use.<sup>24</sup> Advancements in technology have made a broad range of features possible:

- Hydrophilic coatings offer an instantly available uniform lubricious (lubricant coating) layer minimizing the risk of UTIs,
- New soft and flexible catheter tip design for easier insertion, reduced risk of perforations, false passages, and urethral damage in the case of twisted and narrow urethras,
- Ways to cut eyelets to reduce friction and urethral damage,
- New materials providing varying levels of firmness allowing options to accommodate various dexterity and anatomical challenges,
- New insertion tips and protective coverings/sleeves to minimize microbial entry,

- Innovative grippers/packaging/design configurations to expand usability for varying dexterity levels to reduce the risk of catheter contamination.

All these advances have led to increased satisfaction with end-users and the ability for more people to lead independent and healthy lives.<sup>25</sup> Today, a higher number of individuals and prescribers choose hydrophilic coated catheters; these types of catheters help protect the urinary tract, reduce pain during catheterization, and increase treatment compliance which leads to fewer UTIs overall.<sup>25</sup>

**Limited Intermittent Catheter Codes for Variety of Products**

HCPCS codes for ICs are fairly generic; there are a wide range of products with differing features that fit within a single HCPCS code. There are approximately 1,300 products in the IC space with varying characteristics and construction materials to address safety features, infection control, dexterity issues, and patient medical needs, but there are currently only three HCPCS codes to describe them. According to CMS, “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>26</sup>

Wound, Ostomy, and Continence Nurses Society (WOCN) is concerned that a lack of appropriate classification limits patient access to appropriate products which impacts patient outcomes due to poor patient compliance, increased complications including resource heavy UTI, and long-term complications due to inadequate bladder emptying.

**PAYER/HEALTH SYSTEM CONSIDERATIONS**

**Cost of Supplies vs Unintended Health Outcomes**

Selecting the most appropriate urinary catheter and drainage system is an important factor affecting patient health, outcomes, and comfort. 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. Inappropriate selection may introduce an array of unnecessary catheter-associated health problems for the patient such as:<sup>27</sup>

Catheter Associated Urinary Tract Infections (CAUTI)	Hematuria	Bladder Stones
Urethral Trauma	Epididymitis	Pain/Discomfort

UTIs are the most common type of healthcare-associated infection reported to the National Healthcare Safety Network (NHSN).<sup>28</sup> UTIs may require extensive antibiotic use and additional resource utilization to accommodate appointments with a healthcare professional for diagnoses, tests, and prescriptions.<sup>29</sup>

With the introduction of new data on Catheter-Associated UTI (CAUTI) frequency, admission trends, and costs, Hollenbeak et al. estimated the economic burden to be \$1.7 billion annually in the US (2016 USD).

Key considerations for managing and preventing CAUTIs:

- **Single use ICs lower the risk of CAUTIs**– A recent literature review showed that existing evidence supports the use of sterile, single-use catheters for IC, as they are associated with a lower risk of UTI compared with catheters that are reused despite being single use devices.<sup>30, 31</sup>
- **CAUTIs may require extensive antibiotic therapy; drug resistance increases CAUTI costs of care** – Multi-drug resistant organisms also affect CAUTIs’ costs of care through increased days of antibiotic therapy to administer appropriate treatments and extended hospital length of stay.<sup>32</sup> Additionally, the increase of multi-drug resistant strains of E. coli, P. aeruginosa, Enterobacter spp. Klebsiella, and E. faecalis, may also affect the future of CAUTI costs of care.<sup>32</sup>

- **CAUTIs can exacerbate the symptoms of various disease states** – As example, among those with MS, UTIs may trigger a relapse; these relapses may require additional costs for the treatment of MS symptoms subsequent to the cost of treating UTIs.<sup>33</sup>
- **CAUTIs can lead to significant expenses via medical complications and admissions to skilled nursing facilities.** The 2021 MedPAC report to Congress noted that UTIs were one of the top five reasons for referral to a facility.<sup>34</sup> Without treatment, CAUTIs can lead to sepsis and death.<sup>35</sup>

### **Patient Choice Improves Adherence, More Cost Effective**

According to research by Hakansson, individuals should be allowed to choose their type of intermittent catheter, even when a more expensive option is preferred [and/or medically necessary], as this approach is expected to improve adherence to the recommended catheterization procedure, and therefore, prove to be cost-effective in the long-term.<sup>30</sup>

When the HME provider is limited by reimbursement, it may become cost-prohibitive to continue providing clinically appropriate urological supplies to those who need them and/or force the HME provider to seek out less costly alternatives which may not be the ideal fit for the end user. This can result in additional costs, including hospital readmissions, and reduce or eliminate any savings expected from the limited reimbursement. Further, it may increase end user out of pocket expenses as they bypass their covered benefit to get the specific products they need.

### **Intermittent Catheterization Reuse Increases Risk of Infection**

In 2007, a policy reconsideration was submitted asking CMS to remove the requirement for patients to reuse catheters which are labeled as single use devices. The reconsideration was accompanied by letters from the CDC, the Food and Drug Administration (FDA), and the Infectious Diseases Society of America which all supported the policy of single sterile intermittent catheterization due to the increased possibility of infections (namely UTIs). In April of 2008, CMS made the policy change to cover “up to 200” catheters per month.<sup>36</sup>

### **Medicare Competitive Bidding Demonstration Project Finds Little Savings, Negative Outcomes**

The federal government previously attempted to reduce spending by including urological supplies in its Polk County Competitive Bidding Demonstration Projects in 1999 and 2001. The pilot failed to achieve savings and negatively impacted quality, patient access, and support; as a result, CMS advised against including urological supplies in Competitive Bidding.

CMS stated that “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>37</sup> The Agency acknowledged that “within a single HCPCS, some products may better match a patient’s needs than another”,<sup>26</sup> however “it was evident that the reimbursement for certain HCPCS codes does not adequately cover the cost of some products within that HCPCS code”.<sup>26</sup> CMS opined price suppression could cause suppliers to limit product lines or provide lower quality products, noting “quality problems are most likely to occur in the urological supplies product category.”<sup>26</sup>

CMS concluded some product categories like urological supplies are “not well suited for Competitive Bidding...”<sup>37</sup>

## **ROLE OF HME PROVIDER**

### **Required Supplier Standards**

All suppliers serving Medicare beneficiaries must meet the following CMS requirements:

CMS approved suppliers must complete a comprehensive application and maintain all criteria set forth in Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Supplier

Standards to be able to bill for urological supplies. Suppliers who have successfully passed a survey by a recognized independent accreditation organization approved by CMS in accordance with the requirements may operate as accredited providers. Suppliers must either fill product orders from their supply stock or contract with approved manufacturers. The supplier is responsible for product delivery and instructing end-users on the safe and effective use of the product supplied. The supplier must answer questions, respond to customer complaints, and maintain documentation of the interaction as well as the resolution. The supplier must provide the end-user a copy of the DMEPOS standards. Each supplier is responsible for providing additional information and/or documentation of medical necessity for CMS audit requests.<sup>38</sup>

### **Coordination with Clinical Community**

All urological products used must be properly evaluated by an appropriately trained medical professional to ensure they align with the patient's unique anatomy and overall physical health.

Clinicians and beneficiaries together determine the most medically appropriate catheter for the individual. Clinicians work with the beneficiaries and HME provider to ensure the proper catheter is prescribed depending on clinical complications such as UTIs, hematuria, sepsis/bacteremia. HME providers work closely with the end user and the clinical team to coordinate urological supplies and management in a homecare setting.

### **Product Selection, Fulfillment, & Billing**

Suppliers must maintain a large variety of products in their inventory to be able to provide urological supplies to their diverse group of patients, which greatly increases the inventory management costs. Prosthetic supplies need to be selected and fitted for individuals by specially trained health care professionals based on the unique medical and physical needs of each person.<sup>39</sup> The WOCN recognizes that health care providers choose catheter type, length, materials, and frequency of catheterization based upon the unique needs of each patient. There is no "one size fits all" when it comes to catheters.

HME providers go through an extensive process to provide the appropriate products for the end user, including:

- Working in coordination with clinical staff to make recommendations on potential product(s) to achieve the best possible outcome for the patient
- Obtaining prescription, patient demographics, chart notes, and other required documentation from prescriber to support the clinician's medical necessity determination
- Verifying insurance and providing prior authorization (PA) information as needed
- Processing the order and submitting claims for insurance after verifying confirmation of receipt of supplies
- Ensuring the patient does not have any issues with the product and coordinating with clinical staff to select a suitable alternative product as necessary
- Following up monthly with the patient for health assessment, billing updates, and product fulfillment

See Appendix A for details.

### **Patient Use Education**

Case management of patients and education are significant costs incurred by the suppliers and manufacturers when providing intermittent catheters, yet there is no separate billing code or reimbursement for education provided.

#### *Supplier Educational Efforts*

In addition to the standard customer service, suppliers have established case management programs that include welcome calls, lifestyle education materials, and check-in calls every 30-60 days to encourage access to educational materials at critical times. New patients often need to utilize different types of catheters before

they find the right product that meets their needs. This selection process redirects resources and is time consuming for suppliers. Additional reimbursement is not available when multiple products are provided to the end user.

#### *Manufacturer Educational Efforts*

Some catheter manufacturers have recognized the need to complement supplier support programs and created more comprehensive, individualized patient and caregiver support programs that include:

- Nurse-validated product and lifestyle education resources
- Troubleshooting challenges with product and catheterization technique
- Self-assessment tools critical for patient adherence to self-care routines
- Information on how to use the catheters, different product attributes and options, availability, and how to develop self-support habits

Many manufacturer patient support programs are free of charge, and some are open to all catheter users regardless of the product brand. There has been a significant reduction in readmissions and emergency department visits recently reported due to patient support programs for intermittent catheterization.<sup>13</sup>

### **VALUE OF MANAGING UROLOGICAL NEEDS WITH SUSTAINABLE REIMBURSEMENT**

As the continuum of care continues to shift from the hospital to the home, sustainable reimbursement will be required to successfully manage patients requiring catheterization.

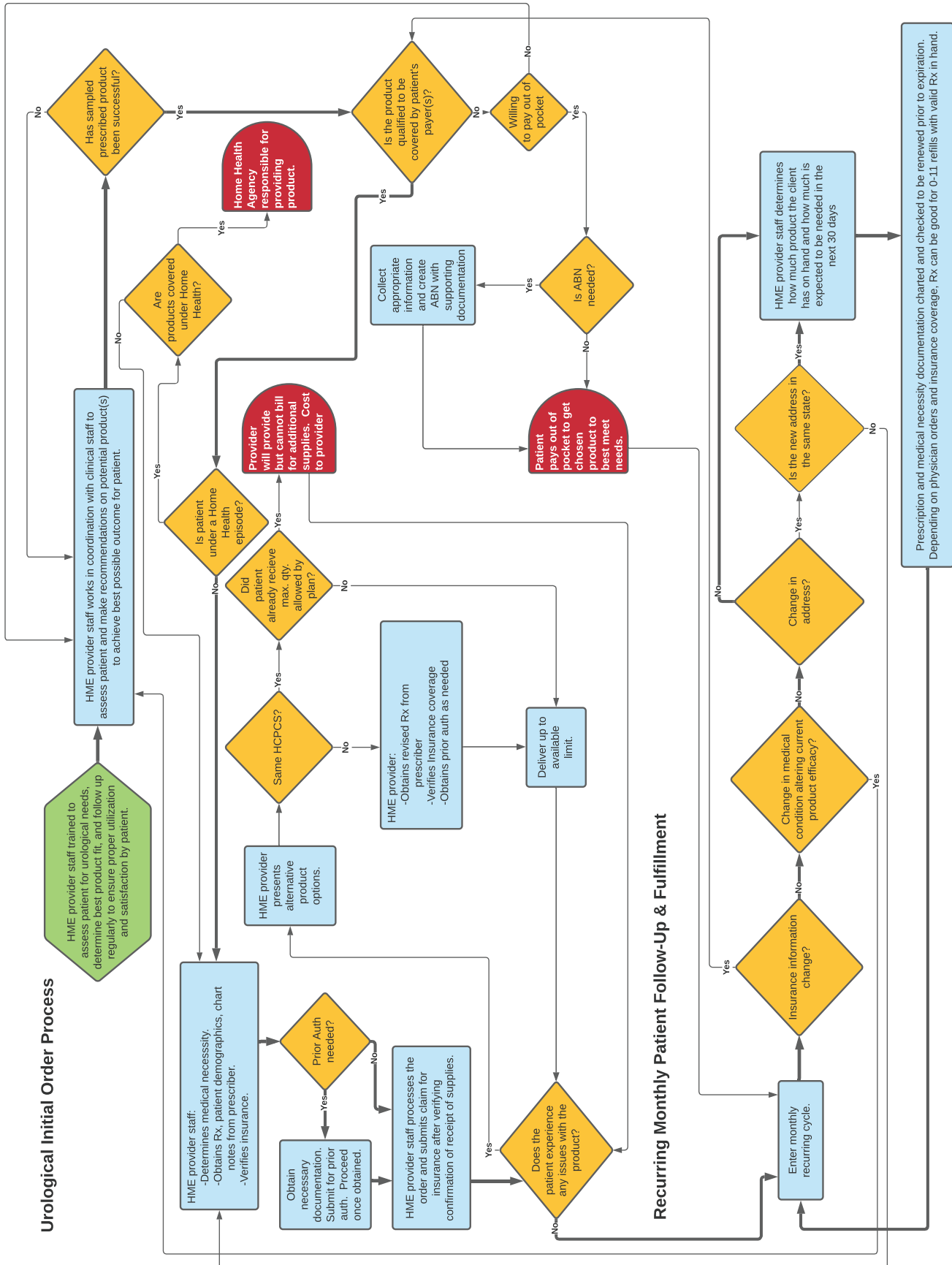
Payers can benefit from the positive long-term impact achieved by setting rates that ensure patient choice and access to the most medically appropriate urological supplies and services. This will prevent avoidable expenses and unintended consequences stemming from a lack of access to products that best meet individuals' needs such as life-threatening infections and other health issues that can lead to hospitalization and other costs.

By investing in a cost-effective, home-based solution to manage individuals requiring urological supplies under a stable reimbursement environment, payers can achieve the Triple Aim of better medical outcomes, patient experience of care, and reduction in overall per-capita costs. Stability in reimbursement also can help foster medical innovation and technology from manufacturers, which drive advancements for better care at a reduced overall cost and higher patient satisfaction.

### **THE ASK**

The clinical community, HME Industry, advocacy groups, end users, and their caregivers are asking payers to re-evaluate their fee schedule for urological products. Many HME providers already struggle with low margins; as the provider network continues contracting, it is difficult for end users using urological supplies to find HME providers that offer specific urological products they may need. Reduced fee schedules have resulted in HME providers being forced to either stop taking individuals requiring urological supplies or offer lower quality products. The short-term savings for a health plan specific to the DME fee schedule may result in significant increases of utilization and negative health outcomes which have resulted in higher health care costs. **To ensure end users using urological supplies receive the appropriate product to promote positive outcomes, payers need to ensure rates for these products and services are no less than the current corresponding 2021 fee-for-service Medicare rates for these same products.**

# APPENDIX A





## Resources

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