The Critical Need to Provide Ostomy Supplies Specific to Patient Need to Improve Health Outcomes

EXECUTIVE SUMMARY

An estimated 725,000-1,000,000 individuals in the United States are currently living with an ostomy.[1] An ostomy is a surgical advancement that has enhanced the ability to treat disease or repair and minimize the effects of trauma.[2] Ostomy surgery involves creating a stoma (opening) in the gastrointestinal tract or within the urinary system to divert stool or urine. Each body and ostomy type is unique, and a customized approach is required in order to determine the combination of products and brands that best meet a person's clinical and personal needs. Ostomy supplies and services such as education and delivery are provided by Home Medical Equipment (HME) providers to help individuals manage their ostomy needs in the home setting.

Life-sustaining ostomy surgeries have a significant impact on mortality, health outcomes, quality of life, and end users' ability to continue contributing to the economy. HME providers play a key role in creating successful outcomes for end users with ostomies, allowing them to regain many aspects of their pre-surgery life. These providers/suppliers are an essential part of the continuum of care and work closely with the clinical community to deliver appropriate supplies to people living with an ostomy that is affordable to the insurance provider and patient.

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 ostomy supplies and services that meet clinical and personal needs of individuals. Unsustainable reimbursement rate reductions limit both the services provided and the types and brands of ostomy supplies offered. This can lead to avoidable hospital readmissions, restriction of end users' choice, product access, and access to care. HCPCS (Healthcare Common Procedure Coding System) reimbursement for ostomy appliances has been trending downward against research and development costs, causing increased associated costs for the end user. Collectively, these restrictions ultimately add risk for adverse health outcomes that affect the total cost of care and cause inequity in access to care.

This paper is the second 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 and 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 Medicare fee for service rates for these products.

ABOUT OSTOMY

Ostomy Overview

People living with an ostomy have had surgery that requires removal of their bladder and/or removal or bypass surgery in areas within the gastrointestinal tract, which impairs their ability to store and eliminate bodily waste. They have a surgically-created stoma (opening) for diversion of the gastrointestinal or urinary tract for elimination of waste. Ostomy supplies are defined as prosthetic devices under the Social Security Act; they replace the lost function of waste, storage, and elimination.[3]

The ostomy pouching system is self-applied or applied by a caregiver, worn continuously, emptied of waste as needed, and changed as needed. Ostomy prosthetic devices are unique to each individual's body profile

and medical needs. People living with an ostomy require a pouching system to be worn 24 hours a day and often for the rest of their lives.

Some ostomies are created as a temporary diversion after surgery ranging from six weeks to six months. Temporary stomas may be used in life-saving situations or when the bowel needs to rest and heal. Many times, however, a stoma is permanent (lifelong) as when normal intestinal or bladder function is compromised due to disease or trauma.

Ostomy surgery may be necessary for the following conditions (not all-inclusive list):

- Bladder Cancer
- Crohn's Disease
- Colorectal Cancer
- Congenital Abnormalities
- Diverticulitis
- Familial Adenomatous Polyposis
- Perforated Colon
- Trauma
- Ulcerative Colitis
- Neurogenic Bladder Dysfunction and/or Neurogenic Bowel Dysfunction

The most common types of ostomies are described below.

- **Colostomy:** a surgically created opening of the colon (large intestine). A colostomy is created when a portion of the colon or the rectum is removed, and the remaining colon is brought to the abdominal wall.[4] Typical discharge is stool, gas, and mucus.
- **Ileostomy:** a surgically created opening from the ileum, the lowest part of the small intestine. Typical discharge is liquid stool containing digestive enzymes.
- **Urostomy:** a surgically created opening to divert the urinary tract. This is a general term for a surgical procedure which diverts urine away from a diseased or defective bladder. Discharge of a urostomy is urine and mucus.

There are estimated to be 725,000 to one million people living with an ostomy in the United States, with approximately 100,000 ostomy surgeries performed each year in the U.S.[1] Roughly half of all individuals living with a stoma are under the age of 64, and approximately half of those under the age of 64 are split evenly amongst males and females.

The key parts of a pouching system are the skin barrier and the pouch. The skin barrier is the interface between the pouch and the skin; it provides the seal and adhesion to protect the peristomal skin (skin around the stoma opening) from urine and feces. Each ostomy supply manufacturer offers different skin barrier materials that support the unique needs of individual skin types and body contours. The pouch is designed to collect the waste and keep it away from the skin. There are closed and drainable pouches all designed to accommodate the type of ostomy and waste. A pouching system is available in a 1-piece (the barrier and pouch are one unit) or a 2 -piece option (the barrier and pouch snap or lock together or are an adhesive coupling system).

An important requirement for the successful management of an ostomy is a properly fitted pouching system because it minimizes the risk of leakage and skin complications. This has lent itself to the development of several features incorporated into barriers and accessory products to help improve the fit. Although labeled as "accessories" by the Centers for Medicare and Medicaid Services (CMS), items like skin barrier rings/strips, paste, and belts may be necessary to achieve a proper fit for prosthetic functionality and to prevent peristomal breakdown and leakage of intestinal waste or urine from the stoma onto the skin. Peristomal skin is the area around the stoma that provides a surface for the pouching system to adhere to. If compromised, the result is a decreased pouch adherence which could result in further damage to the skin area and may become infected.

It's crucial for the end-user to be made aware that they have many product choices. They are not limited to what they receive in the hospital nor should they be restricted by what the agency may provide in the

formulary. Oftentimes, end users must use products from multiple manufacturers in order to devise a pouching system that will provide a well-sealed fit to collect bodily waste. The end user should have access to the pouching system that was recommended and prescribed by their medical professional. Often, product substitutions are ill-suited for individuals and can cause leakage and skin damage that can lead to increased expense for the consumer who may have to pay out-of-pocket for additional supplies and on the health care system when additional clinical resources (clinic, emergency department, or readmission) are utilized to correct the fit of the pouching system.

Ostomy Expense

Risks of Improper Management: Peristomal Skin Complications and Costs

Increased ostomy surgeries in recent years are driven in part by the rapidly aging population and increase in the number of operative procedures involving creation of intestinal stoma.

Caring for a stoma is extremely important given the high risk and financial burden of complications following ostomy surgery. A study published in 2011 designed to measure the rate of, cost, and risk factors for hospital readmission after colorectal surgery found individuals with an ostomy were nearly three times more likely to be readmitted in 30 days than those without an ostomy.[5]

Multiple independent studies have concluded that timely intervention of securely fitting ostomy products reduce the total number of peristomal skin complications (PSCs).[6, 7, 8, 9, 10] In addition, Neil et al. noted that "Each PSC event avoided yielded, on average, 8 additional quality-adjusted life days over 1 year".[9]

The involvement of a certified wound, ostomy, and continence (WOC) nurse and/or an ostomy-trained specialist can positively influence the quality of life and facilitate better overall outcomes for these individuals while reducing costs to the healthcare system. Current literature supports this assertion by showing that a WOCNCB board certified ostomy nurse or WOC specialist can positively influence the quality of life and facilitate better overall health outcomes for these individuals and reduced costs to the health care system.[11,12] Additional educational programs (whether administered by the healthcare system, the HME provider or the manufacturer of ostomy products) can lead to a more educated user and offer better outcomes overall.

Payer/Health System:

When the end-user is deficient of proper training or an appropriate appliance, overall healthcare costs rise. According to a study from The Journal of Wound, Ostomy, and Continence Nursing, approximately one-third of ostomy end users developed peristomal skin complications within 90 days of their surgery. These complications are associated with higher overall healthcare costs and a greater likelihood of hospital readmission.[8] In 2012, Meisner published a study looking at the cost of peristomal skin complications and found that a severe skin complication can be up to six times more expensive than a mild PSC and four times more expensive than a moderate PSC to treat due to the need for additional clinical support, accessory items, and increased pouch use.[13]

Correctly managing peristomal skin complications not only reduces the overall spend for ostomy care but leads to a higher health-related quality of life for the user. Skin complications and leaks can lead to lower social connectivity and isolation.[6] Additionally, out-of-pocket financial costs for ostomy care can negatively impact quality of life (QOL) for individuals with ostomies.

Quality Products to Optimize Health Care Outcomes/Expenses

Limiting reimbursement not only prohibits product selection for the end user but also decreases manufacturer involvement in further medical advancements. When reimbursement rates are not sustainable, providers may resort to substituting another less costly product that may not provide equivalent prosthetic function for end users and may cause avoidable negative health outcomes. In a study completed in Sweden, it was proven in both one- and two-piece systems, a group of ostomy end users using products

from companies with high patent activity (PA) [that is, companies with more product designs and more research and development efforts] had significantly lower ostomy-related expenditures than the low PA group of companies. Fewer pouch and skin wafer purchases per month were an important driver of cost differences.[14] While the industry is able to develop products that can produce better outcomes – such as ostomy pouches manufactured from hydrocolloids and polymers for better stretchability and pouches that fit individual body contour and adapt to body movements – manufacturers are still constrained by reimbursement.

PATIENT CARE COORDINATION

Transition of Care from Post-Surgery to Home

While an elective ostomy surgery may allow for pre-surgical education, many of these surgeries are conducted as emergency procedures. According to HCUP data, the average length of stay for a person undergoing ostomy surgery is approximately 12 days.[15] That includes pre- and post-surgery; thus the emphasis on ostomy training is limited and knowledge retention low. After the acute stay, many individuals with ostomies move to a Home Health Care environment. The hospital may rely on the Home Health Agency nurse to continue the necessary training;[16] unfortunately, many home health care agencies do not have any or enough ostomy specialists on staff. Additionally, Medicare provides a fixed bundled payment to reimburse a Home Health Agency. Limitations to formulary brand(s) and reduced utilization are common procedures to manage ostomy supply costs and maintain profitability. However, this payment method may limit an agency's access to beneficial, brand specific ostomy pouching systems and accessories prescribed in the acute setting.

Suppliers and manufacturers currently engaged in providing products to individuals living with an ostomy understand the complex needs of this population and have invested significant resources in order to meet these needs. They can assist in finding the right product for the individual customer as their needs change post-surgery, by offering various pouching systems and helping to match those to the individual's personal needs. Both suppliers and manufacturers also continue with needed education and assist not only the end-users, but the home care nurses as well.

Once the individual is released from Home Health, the HME provider helps navigate challenges by assuming responsibility for providing supplies and continued education. The certified ostomy nurse, WOC specialist, and/or ostomy specialist in an outpatient setting may also be able to assist with ongoing education/refitting.

When the HME provider is limited by reimbursement, they are forced to either stop accepting that insurance coverage or seek out less costly alternatives, which may not be the ideal fit for the end user and may increase the occurrence of peristomal skin complications, leakage, and end user frustration. These alterations in the continuum of care can result in the additional costs referenced above, including hospital readmissions, and reducing any savings expected from the limited reimbursement.

SELECTION OF PRODUCT

Selecting the Appropriate Ostomy Products

End users along with their medical team often go through a lengthy process of trial and error to find a pouching system that meets each person's clinical needs. Ostomy supplies are highly customizable with a diverse range of options required to address these unique needs. Ostomy supplies:

- Are prescribed by medical professionals to address the individual's tailored medical needs. They are not a one-size-fits-all or over-the-counter products.
- Are not easily interchangeable. Every individual has unique requirements due to body contours, skin type, type of waste, the level of which the intestine extends through the ostomy site (which determines how well the waste will drain into the pouch), and even environmental concerns. It is essential that each person have access to compatible products to avoid medical consequences.

- Require a health care professional's (such as a WOC nurse or Ostomy Management Specialist) ongoing services for selection, fitting, training, and adjustments that may be necessary. Reassessment of ostomy status may be needed as new health conditions arise.

The stoma size and shape change over time. Immediately after surgery, the stoma is quite different and may require the individual to change his/her ostomy pouching system 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.

There are many factors considered by medical professionals when prescribing an ostomy pouching system that will work best for the end user. Location and protrusion of the stoma, unique body contours, scars, folds, and barrier adhesion are just some of the challenges that must be considered. Some manufacturers have custom-made products to fit unusual situations.

See Appendix A for Flow Chart of Ostomy Order Process and Monthly Fulfillment.

VALUE OF MANAGING OSTOMY WITH SUSTAINABLE REIMBURSEMENT

Ostomy surgery is a life-changing event. After surgery, the most cost-effective care environment for a person with an ostomy is at home. Not only is this better for the emotional health of the person, it also substantially reduces the costs of care. This home-based care for individuals with ostomies requires collaboration between clinicians, HME providers, and manufacturers. Coordinated care can reduce the cost of overall care while improving one's quality of life and overall outcomes.

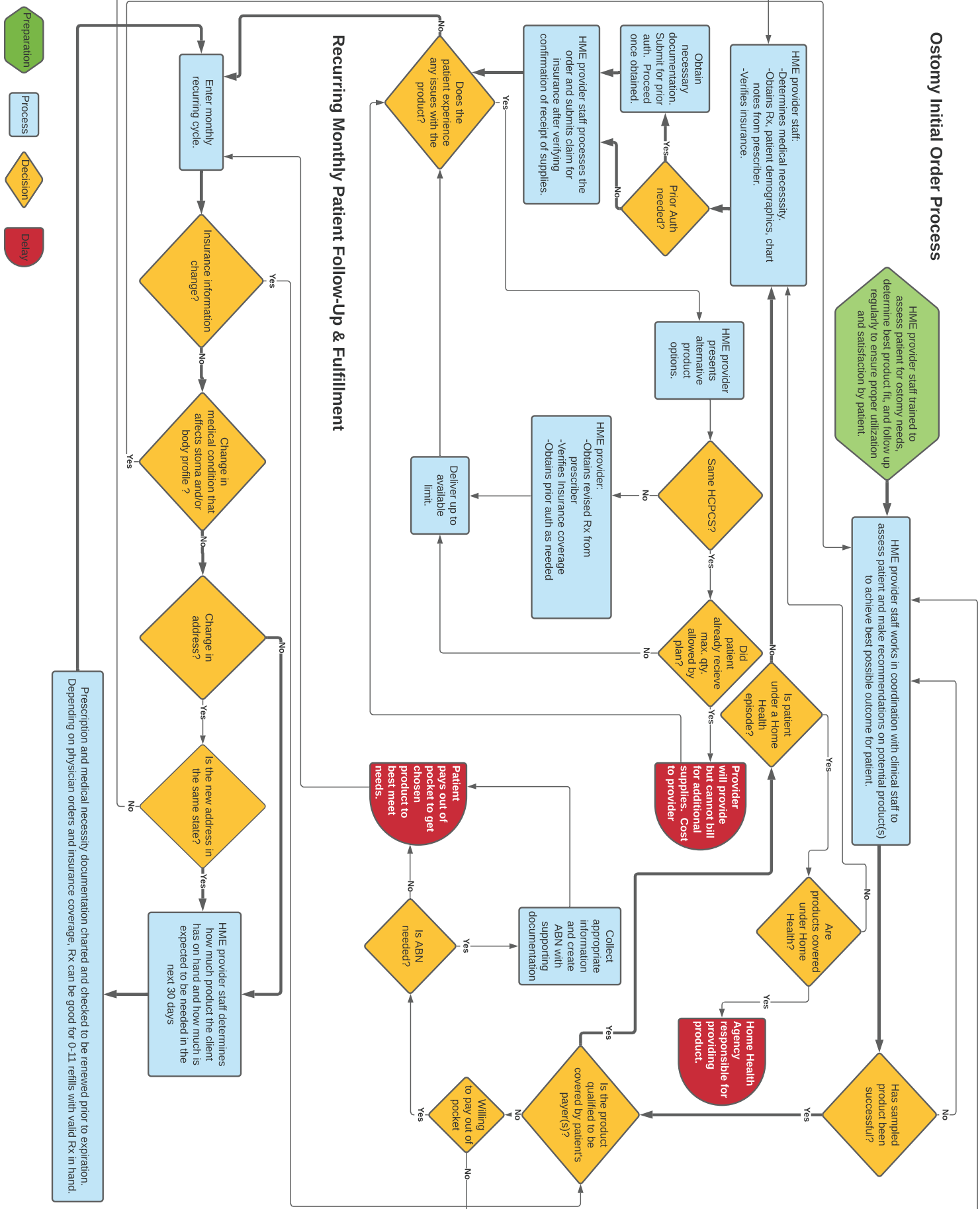
Continued fee erosion of reimbursements result in less training being allocated, deviation away from clinically prescribed ostomy prosthetic devices, and limits manufacturing advancements thus contradicting the Institute of Healthcare Improvement's concept of the Triple Aim. Resulting outcomes may include a decline in the end user's quality of life with potential increases in pain and depression and a possible hospital readmission which leads to increased costs to care.

A fee schedule floor will prevent Medicaid, private insurance, and Managed Care Organizations from paying fees lower than Medicare established reimbursement rates. This minimum would protect the end user by allowing HME providers to work with the prescriber and end user to supply the most appropriate product and continue to provide ongoing education as the end user transitions into the community. A fee schedule floor would also encourage manufacturers to continue to develop new products and support tools that address the unique challenges faced by those living with an ostomy.

THE ASK

The clinical community, HME Industry, individuals with ostomies, and their caregivers are asking payers to re-evaluate their fee schedule for ostomy products. Many HME providers already struggle with low margins; as the provider network continues contracting, it is difficult for ostomy end users to find HME providers that offer specific ostomy products they may need. Reduced fee schedules have resulted in HME providers being forced to either stop taking individuals with an ostomy 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 skin damage to the surrounding stoma which have resulted in higher health care costs.[14] **To ensure end users with an ostomy 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 Medicare fee for service rates for these products.**

Appendix A



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