

United Ostomy Associations of America (UOAA) Opposes “Non-Medical Switching” of Ostomy Prosthetic Supplies

Background

UOAA is a 501c(3) non-profit organization advocating for the 725,000 to 1,000,000 people living with an ostomy or continent diversion in the United States as well as the approximate 100,000 new patients facing ostomy surgery annually¹. People living with an ostomy have undergone surgery to remove their bladder or part of their bowel due to a disease process or trauma. This impairs their ability to store and eliminate bodily waste. They have a surgically-created opening (stoma) on their abdomen for the elimination of waste and a ‘pouching prosthetic system’ is continuously worn over the stoma to contain the waste.

Ostomy products:

- are defined as *prosthetic devices* under the Social Security Act since they replace the lost functions of waste storage and elimination².
- are prescribed by medical professionals to address ostomates’ tailored medical needs. They are not a one-size-fits-all, off-the-shelf, or over-the-counter generic product. Additionally, items in the same category of function vary in composition among manufacturers so that one manufacturer’s product may not perform in the same manner as another manufacturer’s product.
- are not easily interchangeable. It is essential that each person have access to the products that are compatible to them. Every person has a unique abdominal contour, skin characteristic and stoma output.
- require a health care professional’s ongoing services for selection, fitting, training on use, and assessment of physical and emotional adjustment. Also important is reassessment of ostomy status as needed and as new health care conditions arise.

Issue

Patients along with their medical team often go through a lengthy process of trial and error to find a pouching system that meets these goals: 1) the system is appropriate for their stoma and body habitus; 2) it maintains a predictable 2-5 day leak-proof wear time; and 3) is suitable for the performance of their occupational and personal activities.

Unfortunately, patients have reported a practice by some third party payers of refusing to cover the products that are components of these carefully designed pouching systems in favor of different products that are oftentimes less expensive. In some cases, patients have been limited to formularies that do not include the products used by the patient. Some distributors have also been found to substitute products that differ from the products prescribed. This practice, “non-medical switching”, removes the collaborative process between the medical professional and patient substituting a cost cutting strategy by non medical staff. This often results in increased MD visits, ER visits and possible rehospitalization and surgery. The consequence of this practice is that many ostomates are unable to obtain their prescribed prosthetic devices and are no longer able to effectively manage their ostomy. This negates the purpose of a prosthetic device and jeopardizes their health and well being.

There are a number of different approaches to switching for non-medical reasons that an ostomate may encounter including:

- Insurers stop covering the particular medical device (in this case components of the ostomy pouching application system) or remove it from their formulary, forcing patients to pay out-of-pocket for the device that is already working well for them.
- Insurers may restrict consumers to specific brands or specific suppliers, which limits patient access to the products they need, as patients often must use products from multiple manufacturers.
- Some suppliers “switch out” what was prescribed and substitute generic, poorer quality, or less expensive brands without consultation with the patient or the prescribing medical professional.
- Health care facilities such as hospitals (including LTAC, and rehabilitation hospitals), and skilled nursing facilities as well as home health agencies switch what a person uses for their in-house formulary brand.

Impact on Patients

Changes to an individual's prescribed pouching system for *non-medical reasons* could result in their unique combination of ostomy products not achieving the prosthetic's desired function for them. This may lead to medical consequences such as peristomal skin damage from a pouching system that does not fit the patient resulting in leakage of effluent onto the skin. Severe skin damage can result in hospitalization and increased health care costs.

If a patient refuses the "switched" product, they must shoulder the cost of the treatment on their own, increasing their financial burden of care. The patients are then forced to appeal a *non-medical decision* when they have collaborated with their physician and determined which products function successfully for them. If they can not afford to purchase the effective products, they are forced to utilize ineffective products.

Additionally, "non-consented switching" means that patients do not receive any instruction from their medical provider about how to use the new product. In the case of ostomy supplies, this may result in a lack of understanding in the technique of pouch application resulting in a poor fit and seal.

Although there are no studies currently, specific to the practice of the switching of ostomy products, a study was completed with asthma patients whose inhaler products were switched, and the patients experienced negative outcomes³. With ostomy patients the clinical experience is clear and patients are found to experience peristomal skin complications following the non-medical substitution of products.

Further, research has also shown that non-consented switching and switching for non-medical reasons is associated with direct negative effects on many important outcomes including disease control and results in increased healthcare costs^{4,5}.

From the patient perspective:

"I am a veteran and cancer survivor. I worked with my ostomy specialist to find and decide on what products would be best and work for my ostomy. My ostomy specialist put in the prescription order with the VA (Veterans Affairs) Pharmacy in MN for "Brand X" products. I received 4 of the 5 components I needed for my ostomy but they were all Brand Y products, then a day later by USPS I received the Brand Y pouches. Although they are an equivalent product and the right size, I don't understand why if myself and my medical professional requested Brand X, which is what is effective for me, why I got Brand Y. If the VA won't help me resolve this substitution, I need to "go into my pocket" to pay for the products that I need." - Jim W.

"It took approximately 18 months to find a pouching system that did not leak (I can tell you real horror stories about leakage) and did not cause skin problems. Only one company's products satisfied my needs. Other company products simply do not fit my needs. Skin problems are a major concern for an ostomate and when you find a system that works, you simply can't change. An ostomate's quality of life depends on their pouching system. If you take that away from them, their quality of life simply does not exist. It's hard to explain to a person that does not have an ostomy but a proper pouch (which is from a specific company) is needed to have any quality of life." - Denny H.

"Over the years, I've tried almost every pouching system out there and again last year tried many different products to find a combination of items from different companies that work together with my new stoma site. It took several weeks and a lot of trial and error before I settled on a combination that worked for two days consistently. It's like a recipe - leave one item out and it ruins the whole pie - even though it may look like a good pie, it stinks. The multitude of surgery outcomes, body shapes and individual differences is no more similar than our eyes need for corrective vision. One tiny difference can necessitate the use of an entirely different pouch, perhaps custom made by a relatively obscure supplier." - David D.

"I am a professional and need a very reliable and secure appliance. Ostomy supplies are not one size fits all. Every ostomy appliance available is good for someone, but not every appliance is good for every person with any ostomy. Don't think of ostomy supplies as you would for an oxygen tank or a crutch. It is not a one size fits all. Ostomy appliances are critical to a person living a normal life but the appliance has to work for each person's body chemistry, shape, size and lifestyle. The availability of a wide range of choices and manufactures of products has been the greatest single advance for those with ostomies in the last fifty years." - Gary S.

“If I am forced to wear any ostomy bag other than the one I am currently wearing, I will not be able to return to work. I will be a prisoner in my home, oozing stool on myself... Additionally, ostomy appliances that do not fit correctly have to be changed far more often (resulting in use of more supplies), as well as the fact that poor fitting ostomy appliances are directly linked to skin breakdown and wound formation. My insurer will have to pay for wound dressings and appointments with wound specialists instead.” - Heather B.

CALL TO ACTION

United Ostomy Associations of America, Inc. (UOAA) recommends that the practice of non-medical switching, especially for economic reasons, be abandoned to prevent further cost-shifting aimed at patients with chronic health needs as well as to prevent physical harm to those living with an ostomy. Treatment to manage ostomies and ostomy pouching prosthetic devices should be recommended and prescribed by medical professionals in collaboration with the ostomy patient. UOAA is of the opinion that switching products disrupts quality of life and the goals of care an ostomate has achieved for prosthetic function to maintain health and wellness physically, emotionally and financially.

¹Ostomy 101 - Provided by United Ostomy Associations of America. (2017). Retrieved August 17, 2020, from https://www.ostomy.org/wp-content/uploads/2019/03/ostomy_infographic_20170812.pdf

²Title XVIII, §1861 (s)(8) of the Social Security Act defines prosthetics as those, which replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, and replacement of such devices.

³Doyle S, Lloyd A, Williams A, et al. What happens to patients who have their asthma device switched without their consent?. *Prim Care Respir J.* 2010;19(2):131-139. doi:10.4104/pcrj.2010.00009

⁴Nguyen E, Weeda ER, Sobieraj DM, Bookhart BK, Piech CT, Coleman CI. Impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior: a systematic literature review. *Curr Med Res Opin.* 2016;32(7):1281-1290. doi:10.1185/03007995.2016.1170673

⁵Björnsdóttir US, Gizurason S, Sabale U. Potential negative consequences of non-consented switch of inhaled medications and devices in asthma patients. *Int J Clin Pract.* 2013;67(9):904-910. doi:10.1111/ijcp.12202