THE WOUND, OSTOMY, AND CONTINENCE NURSES SOCIETY™ (WOCN®) SUPPORT OF MEDICARE COVERAGE FOR ENTEROCUTANEOUS FISTULAS
Introduction

An enterocutaneous fistula (also known as a gastrointestinal fistula) is an abnormal opening between the stomach, small or large intestine, and the skin; this opening allows contents from the gastrointestinal tract to flow out onto the skin.1 Fistulas are serious complications associated with high morbidity (87.6%) and a 1-year mortality rate of 15%.2 Fistulas develop either after surgery or spontaneously.3,4 Fistulas form as the result of multiple factors including surgical technique and coexisting conditions of patients (e.g., pathology or injury).1 Most fistulas (75% to 85%) are due to previous surgery.1,4 However, 15% to 25% of fistulas occur spontaneously in patients who have not had surgery, but are due to trauma, radiation, diverticular disease, cancer, or inflammatory bowel disease (i.e., ulcerative colitis; Crohn’s disease).1 The most common type of postoperative fistula occurs between the small intestine and skin.4

Fistulas are unintended, unpredictable, and unwanted leading to distress for patients and their caregivers.1 Fistulas have been described as “dreadful problems for patients to endure,” and they are extremely challenging to manage.2 Patients with a fistula face serious and debilitating complications including sepsis, malnutrition, fluid and electrolyte imbalance, hemorrhage, erosion of the skin from the enzymes in the effluent (i.e., drainage from the fistula), impaired mobility, extreme pain, and death.3-5 Fistulas may be classified as simple or complex, according to location and structures involved, and by volume of output1,6:

• A simple fistula is short with a direct tract, is free of an abscess, and does not connect with other organs; a complex fistula has an abscess, involves other organs, and/or may open into the base of a wound.
• Location and structure identifies whether the fistula is internal or external and specifies the site/structure of the origin and termination of the fistula.
• Volume can be identified as high-output (> 500 mL per 24 hours) or low-output (< 200 mL per 24 hours).

Treatment of fistulas can be surgical or medical. In some cases such as with underlying Crohn’s disease, surgery may not benefit the patient due to recurrence of the fistula.4 Delaying corrective surgery for at least 3 to 4 months (ideally reoperation is within 6 to 12 months) allows time to correct the metabolic and nutritional deficiencies and for softening of the dense adhesions (for surgically related fistulas) to reduce the incidence of additional complications.2,4,6 Patients can develop more than one fistula and a complex fistula within a wound further complicates the care of the patient. Approximately 19% to 40% of fistulas close spontaneously if sepsis is controlled and nutrition and fluid/electrolyte balance are adequate; 80% to 90% of fistulas that close, do so within 5 weeks.6 Simple fistulas are more likely than complex fistulas to heal spontaneously.4,6

Unless urgent surgery is warranted (i.e., sepsis, hemorrhage, bowel necrosis, evisceration), fistulas are managed initially with medical treatments in an effort to stabilize the patient and optimize the potential for closure (i.e., control sepsis, correct fluid/electrolyte imbalance and malnutrition, and contain output to prevent skin damage).4 Surgical closure of a fistula may be an option if medical treatment fails. Unfortunately, surgical closure is successful only 75% to 85% of the time.2 In some cases, patients are not good surgical candidates due to comorbid conditions and/or complex fistulas, and the only option for treatment may be containment of the effluent (i.e., drainage from the fistula).

A key problem in managing patients with a fistula is maintaining the integrity of the perifistula skin because the skin can become eroded within 3 to 4 hours of exposure to the enzymatic effluent.7 Skin and wound care are essential to contain the highly corrosive effluent, protect the patient’s skin, control odor, decrease pain, promote the patient’s overall comfort and well-being, and enhance mobility allowing the patient to be more independent. In some cases, a low-output fistula can be managed with a skin barrier and dressings (e.g., gauze, foam, alginate, hydrofiber). However, a pouching system should be used if dressings require changes more often than every 4 hours, if odor is problematic, or the output is greater than 100 mL per 24 hours.1,6 In cases where the fistula is
located high in the intestinal tract, the volume of drainage can be overwhelming with as much as 10 L of fluid per day. An effective pouching system contains drainage, controls odor, promotes comfort and decreases pain due to less frequent changes, protects the skin from caustic drainage, allows for accurate measurement of the output, allows the patient to become more active and mobile, and preserves the patient's dignity and quality of life.

Problem
The current Medicare policy for reimbursement of the supplies necessary for treatment of fistulas is woefully inadequate. Despite available products, Medicare/Medicaid home care and/or long-term care coverage for fistulas is limited to only fistulas that are caused or treated by a surgical procedure. Products for spontaneous fistulas are not covered, thereby denying coverage to many who need effective products for treatment. Furthermore, the current policy for surgically produced fistulas covers only one type product (i.e., wound pouch, A6154), which is insufficient because fistulas vary greatly in size, location, output, and complexity. One type of pouch does not fit all. Consequently, many patients with Medicare/Medicaid must pay out-of-pocket for dressing supplies or pouches to meet their specific needs even if coverage is available. Often these same patients are indigent or of limited economic means and unable to pay for supplies. Many patients, unable to afford the out-of-pocket costs for treatments and supplies, remain hospitalized for several months for management of the fistula until either spontaneous closure occurs or surgical closure can be performed, which results in increased costs.

Solution
A redesign of the coverage policy for fistulas is warranted to provide adequate coverage for fistula pouching systems across all settings. The WOCN Society believes that with adequate coverage, many patients could be treated at home or in long-term care facilities, rather than the hospital setting, thus resulting in increased cost savings. A fistula should be conceptualized as an unplanned ostomy with reimbursement of products analogous to ostomy prosthetic devices.

Action
The WOCN Society recommends that the Centers for Medicare & Medicaid Services revise existing ostomy policy codes to include coverage for fistula pouches and reimburse them similarly to ostomy pouches. This could be accomplished by adding an additional ICD-9 code for fistulas; by amending the existing code (596.60; colostomy and enterostomy complications unspecified); or by expanding the product description for existing durable medical equipment codes to include products for fistulas.

References
8. Local coverage determination (LCD) for surgical dressings (L11460).

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