COOK MEDICAL Biodesign® ADVANCED TISSUE REPAIR

2018 Coding and Reimbursement Guide for Enterocutaneous Fistula

The information provided herein reflects Cook Medical's understanding of the procedure(s) and/or devices(s) from sources that may include, but are not limited to, the CPT® coding system; Medicare payment systems; commercially available coding guides; professional societies; and research conducted by independent coding and reimbursement consultants. This information should not be construed as authoritative. The entity billing Medicare and/or third party payers is solely responsible for the accuracy of the codes assigned to the services and items in the medical record. Cook Medical does not, and should not, have access to medical records, and therefore cannot recommend codes for specific cases. We encourage you, when making coding decisions, to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you may submit claims. Cook Medical does not promote the off-label use of its devices.

If you have any questions, please contact our reimbursement team at
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or
by e-mail at
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Introduction

The FDA clearance of the Biodesign® Enterocutaneous Fistula Plug enables physicians to choose a minimally invasive procedure for treating enterocutaneous fistulas. However, as with many new procedures in medicine, the development of new reimbursement codes lags behind medical innovation. The enterocutaneous fistula plug is no exception, because this device is used in a procedure not currently described by an existing CPT code, and the costs of the new device may not be adequately recognized in current facility payment systems and payment rates. Efforts are ongoing to rectify this situation. In the meantime, Cook Medical has created this guide to assist you in your efforts to obtain adequate reimbursement for this beneficial procedure. However, as with all coverage, coding and payment issues related to services you have provided or are considering providing, we encourage you to contact your patients' insurance plans for specific guidance and direction.

Physician Coding and Reimbursement

Questions have arisen regarding the correct CPT code to use in reporting enterocutaneous fistula repair using the enterocutaneous fistula plug. CPT coding convention requires that you "select the name of the procedure or service that accurately identifies the service performed. Do not select a CPT code that merely approximates the service provided. If no such specific code exists, then report the service using the appropriate unlisted procedure or service code."[1] Currently (2018) a CPT code does not exist that accurately describes the use of the enterocutaneous fistula plug in treating enterocutaneous fistulas as described by the device's Instructions for Use (IFU). The appropriate coding authorities suggest using an unlisted code, such as 44799, "Unlisted procedure, small intestine" or 45399, "Unlisted procedure, colon,".

Submission of a claim with an unlisted code typically requires: (a) a paper claim, (b) the operative note attached to the claim, and (c) a cover letter to the health plan/payer. This cover letter should contain the following information: 1) identification of comparable procedure(s) to assist the insurer in establishing a payment level and (2) an explanation of the procedure, the patient selection, the medical necessity and the clinical benefits. Unlisted codes are not universally accepted by all insurance carriers. To avoid unnecessary claim denials, we encourage you to contact the payer for its coding recommendations prior to claim submission.

1. American Medical Association. Instructions for use of the CPT code book. In: *CPT* 2018 *Professional Edition*. Chicago, IL: American Medical Association; 2017:xii.

Contesting Noncoverage

If the procedure is still denied by Medicare or another payer after following this process, you may need to further educate the payer regarding medical necessity, FDA clearance and/or the efficacy of the procedure. If reimbursement is denied, the reason should be listed under the explanation of benefits (EOB), and we encourage the operating physician to contact the local health plan's medical director(s) to discuss the clinical merits of this procedure.

Influencing Payer Decision Making

If Medicare is a dominant payer and you plan to do the procedure on a regular basis, you may want to go directly to the Carrier Advisory Committee (CAC) member or Carrier Medical Director (CMD) for your state Medicare carrier. The medical director contact directory may be accessed through the following link: www.cms.hhs.gov/apps/contacts

Private payer coverage determinations are usually made by the payer's technology or medical device group. As with Medicare, we encourage you to contact your other local commercial health plans to discuss coverage of this procedure, whether for a specific case or for overall approval of the Biodesign® Enterocutaneous Fistula Plug.

Facility Coding and Reimbursement

The use of the enterocutaneous fistula plug to treat enterocutaneous fistulas is a minimally invasive procedure. It is anticipated that the procedure will be performed in both the inpatient and outpatient settings.

The method and amount of facility reimbursement for medical services is dependent on a number of factors, including: a) the site of service (ambulatory surgery center vs. hospital outpatient department. vs. hospital inpatient), and b) the payer (Medicare, commercial insurance plans, Medicaid, etc.). Following is a brief discussion of the current (2018) facility reimbursement environment for the enterocutaneous fistula plug.

Hospital Outpatient Department

Medicare

Medicare pays hospital outpatient departments under the Hospital Outpatient Prospective Payment System (OPPS). Medicare updates its list of approved procedures annually. Each of these procedures is assigned to an Ambulatory Payment Classification (APC) created by Medicare. Although there are several hundred APCs, a CPT code is assigned to only one APC. The facility is reimbursed the APC amount that the CPT code is assigned to.

CPT code 44799, "Unlisted procedure, small intestine," is currently assigned to APC 5301 "Level 1 Upper GI Procedures," and the current national average Medicare fee schedule amount for this APC is $743.44[2]. CPT code 45399, "Unlisted procedure, colon," is currently assigned to APC 5311 "Level 1 Lower GI Procedures" and the current national average Medicare fee schedule amount for this APC is $709.93[2]. The actual fee schedule amount varies from hospital to hospital, based on local wage indices, geographic location, etc.

If applicable, Medicare requires hospitals to report device(s) by using the Level II Healthcare Common Procedure Coding System (HCPCS) or "C-codes". The American Hospital Association's Central Office on HCPCS suggests using C1763, "Connective tissue, non-human," to describe the Biodesign® Enterocutaneous Fistula Plug. C1894, "Introducer/Sheath," should also be reported to describe the Flexor® sheath.

Please note the importance of submitting appropriate charges for this procedure, as Medicare uses charge data to ensure equitable payment in the future. According to CMS:

> "Our goal is to establish payment rates that provide appropriate relative payment for all services paid under the OPPS without creating payment disincentives that may reduce access to care. As a matter of policy, we do not tell hospitals how to set their charges for their services. However, we will continue to inform hospitals of the importance of their charge data in future rate setting and encourage them to include all appropriate charges on their Medicare claims."[3]

Also note that revenue codes are to be assigned at the provider's discretion.

[2]2018 Medicare Hospital Outpatient Prospective Payment System

[3]Medicare Program; Changes to the OPPS and Calendar Year 2006 Payment Rates; Final Rule. *Fed Regist*. 2005;70(223).

Commercial Insurance

Unlike Medicare, commercial insurers have not established a consistent national payment methodology, so arrangements between insurers and hospitals vary considerably. Because of this, it is not possible for Cook Medical to offer guidance to hospitals regarding any individual plan. We encourage you to work closely with your local hospital management and insurance plans to understand their contracted payment arrangements. A coordinated effort between the physician and hospital can be effective in obtaining appropriate reimbursement for innovative procedures, such as the treatment of enterocutaneous fistulas using the Biodesign® Enterocutaneous Fistula Plug.

When submitting claims, it may be helpful to provide the following documents:

- The patient's medical record documenting the need for this procedure
- The operative note describing the procedure
- An invoice documenting the cost of the enterocutaneous fistula plug

Ambulatory Surgery Center (ASC)

Medicare

Medicare's payment system for ASCs is also based on a list of approved procedures identified by CPT codes, but it is not the same list that is used for hospital outpatient departments. Unlisted codes do not appear on the ASC-approved list. We encourage you to contact your local Medicare carrier to discuss how it wants these claims submitted.

When submitting claims, it may be helpful to provide the following documents:

- The patient's medical record documenting the need for this procedure
- The operative note describing the procedure
- An invoice documenting the cost of the enterocutaneous fistula plug

Commercial Insurance

Unlike Medicare, commercial insurers have not established a consistent national payment methodology, so arrangements between insurers and hospitals vary considerably. Because of this, it is not possible for Cook Medical to offer guidance to ASCs regarding any individual plan. We encourage you to work closely with your local ASC management and insurance plans to understand their contracted payment arrangements. A coordinated effort between the physician and ambulatory surgery center can be effective in obtaining appropriate reimbursement for innovative procedures such as enterocutaneous fistula repair using the Biodesign® Enterocutaneous Fistula Plug.

When submitting claims, it may be helpful to provide the following documents:

- The patient's medical record documenting the need for this procedure
- The operative note describing the procedure
- An invoice documenting the cost of the enterocutaneous fistula plug