



Biodesign[®]
ADVANCED TISSUE REPAIR

2021 Coding and Reimbursement Guide for Rectovaginal Fistula

Disclaimer: The information provided herein reflects Cook's understanding of the procedure(s) and/or device(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 does not, and should not, have access to medical records, and therefore cannot recommend codes for specific cases. When you are making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor, and other health plans to which you submit claims. Cook does not promote the off-label use of its devices.

The reimbursement rates provided are national Medicare averages published by CMS at the time this guide was created. Reimbursement rates may change due to addendum updates Medicare publishes throughout the year and may not be reflected on the guide.

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If you have any questions, please contact our reimbursement team at
800.468.1379

or

by e-mail at:

reimbursement@cookmedical.com

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Introduction

This guide is for those involved with the coding and reporting of provider services. Two letters are provided at the end of this guide (**Sample Letters 1 & 2**) that may be customized for your practice and submitted to your patients' health plans. **Sample Letter 1** is to request preauthorization (non-Medicare payers) and may also be submitted with your claim and operative note to support reimbursement. **Sample Letter 2** may be used to contest noncoverage.

The FDA clearance of the Biodesign Fistula Plug enables physicians to use a minimally invasive procedure for treating rectovaginal fistulas.¹ However, as with many new procedures in medicine, adequate reimbursement sometimes lags medical innovation, and the Biodesign Fistula Plug is no exception. The cost of the device may not be adequately recognized yet in all facility payment systems and rates, but progress continues to be made to rectify this. Until then, Cook Medical has produced this guide to assist in obtaining adequate reimbursement for this beneficial procedure. However, as with all coverage, coding, and payment related issues, we encourage you to contact your patients' insurance plans for guidance.

Physician Coding and Reimbursement

Questions have arisen regarding the correct CPT (Current Procedural Terminology) code to use in reporting rectovaginal fistula repair using the Biodesign 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."² As of 2020, a CPT code that accurately describes the use of the Biodesign Fistula Plug in treating rectovaginal fistulas as described by the Instructions for Use (IFU) does not exist. We suggest you consider using an unlisted code, such as 58999, "Unlisted procedure, female genital system (nonobstetrical)," or 45999, "Unlisted procedure, rectum."

¹ 510(k) K170016 Biodesign Fistula Plug. June 21, 2017.

² American Medical Association. Instructions for use of the CPT codebook. In: CPT 2020 Professional Edition. Chicago, IL: American Medical Association; 2020: xiii. Current Procedural Terminology © 2020 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

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Physician Coding and Reimbursement (Cont.)

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 that contains 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 clinical benefits (**see Sample Letter 1**). Unlisted codes are not universally accepted by all insurance carriers. To avoid unnecessary claim denials, we encourage you to contact the payer for their coding recommendations prior to claim submission.

Establishing a Value for an Unlisted Service

Common questions physicians ask when starting to perform a new service are: "How much do I charge for the procedure?" and "How much should I expect to be reimbursed for the procedure?" Obviously, setting fees is a business decision that must be addressed by the physician and/or designated personnel. However, Medicare law requires that payments under the Medicare fee schedule be based on national, uniform relative value units (RVUs) determined by the resources used in furnishing a service.³ Centers for Medicare and Medicaid Services' (CMS) reasoning behind the law is that the relative value of the work in a physician's service exists only in comparison with the physician's work in another service; therefore, CMS established a set of reference services. The criteria for the reference services were that they must be commonly performed with established work RVUs and be well understood outside of their own specialty.⁴ The work RVUs assigned to the reference services represent benchmarks for comparison with the work represented by other codes.

To help the reader make a value determination, several reference service CPT codes are provided in **Table A**. When establishing the value for treatment of rectovaginal fistulas with the Biodesign Fistula Plug, consider the amount of time, skill, risk and intensity of work. Referencing the information in the table below may aid your decision making and provide a defensible rationale for your value determination.

Table A – Assorted Reference Service CPT Codes CY 2021

CPT Code	Procedure Description	2021 Work RVUs	Global RVUs ⁵	Global Period (Days)
46255	Hemorrhoidectomy, internal and external, single column/group	4.96	10.63	90
46600	Anoscopy; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	0.55	1.19	0
57300	Closure of rectovaginal fistula; vaginal or transanal approach	8.71	18.09	90
57520	Conization of cervix, with or without fulguration, with or without dilation and curettage, with or without repair; cold knife or laser	4.11	8.85	90

³ Section 1848 of the Social Security Act, "Payment for Physicians' Services."

⁴ Fed Regist. 1999;64(211):59428.

⁵ 2021 Medicare Physician Fee Schedule facility global RVU.

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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). If the denial indicates the procedure is not medically necessary or is considered “experimental,” see **Sample Letter 2** for a sample document that can be sent to the payer along with the notification of FDA clearance.

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:

<http://www.cms.hhs.gov/apps/contacts>

Private payer coverage determinations are usually made by the payer’s technology or medical device group. You may need to modify the included letter slightly (**Sample Letter 2**) if you are asking for overall approval of the Biodesign Fistula Plug rather than reconsideration on a specific case. However, the supporting information included in the request should be the same as, or similar to, what is outlined.

As noted in the introduction, two letters are included that can be customized to your practice and may be helpful with payer correspondence. **Sample Letter 1** may be submitted to request preauthorization (non-Medicare payers) or submitted along with your claim and operative note to support reimbursement. **Sample Letter 2** may be submitted to health plans to contest noncoverage.

For electronic copies (Word documents) of either of these letters please contact the Cook Medical Reimbursement team at 800.468.1379 or at reimbursement@cookmedical.com.

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Facility Coding and Reimbursement

The use of Biodesign Fistula Plug to treat rectovaginal fistulas is a minimally invasive procedure. Based on feedback from physicians performing the procedure, it will most often be performed in hospital outpatient surgery departments or free-standing ambulatory surgery centers.

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 vs. hospital inpatient); and **b)** the payer (Medicare, commercial insurance plans, Medicaid, etc.). Following is a brief discussion of the current (2021) facility reimbursement environment for the Biodesign 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. The national average Medicare payments for 58999 and 45999 are listed in **Table B** below.

Table B – APC Levels and Medicare National Average Amounts CY 2021

CPT Code	Procedure Description	APC	Outpatient Hospital Facility Payment ⁶
58999	Unlisted procedure, female genital system (nonobstetrical)	Level 1 Gynecologic Procedures	\$170.32
45999	Unlisted procedure, rectum	Level 1 Lower GI Procedures	\$793.65

⁶ Medicare Program; Hospital Outpatient Prospective Payment System and CY 2021 Payment Rates.

If applicable, Medicare requires hospitals to report device(s) by using the Level II Healthcare Common Procedure Coding System (HCPCS), or “C-code.” The American Hospital Association Central Office on HCPCS suggests using C1763, “Connective tissue, nonhuman,” to describe the Biodesign Fistula Plug to treat rectovaginal fistulas.

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.”⁷

⁷ Medicare Program; Changes to the OPPS and Calendar Year 2006 Rates. Fed Regist. 2005; 70(223).

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Hospital Outpatient Department (cont.)

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

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's not possible for Cook Medical to offer guidance to hospitals regarding an 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 rectovaginal fistulas using the Biodesign fistula plug.

When submitting claims, it may be helpful to provide the documents listed under **Item 1** at the end of this guide.

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. We encourage you to contact your local Medicare carrier to discuss how they want these claims submitted.

When you submit claims, it may be helpful to provide the documents listed under **Item 1** at the end of this guide.

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's not possible for Cook Medical to offer guidance to ASCs regarding an 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 ASC can be effective in obtaining appropriate reimbursement for innovative procedures, such as the treatment of rectovaginal fistulas using the Biodesign fistula plug.

When you submit claims, it may be helpful to provide the documents listed under **Item 1** at the end of this guide.

Item 1:

- (1) The patient's medical record documenting the need for this procedure;
- (2) the operative note describing the procedure; and
- (3) an invoice documenting the cost of the Biodesign Fistula Plug

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Sample Letter 1 (Physician Letterhead)

<<Date>>
<<Name Payer/Person Contacting>>
<<Business Name>>
<<Address>>
<<City, State, Zip>>

RE: Insertion of the Biodesign® (Surgisis®) Fistula Plug for rectovaginal fistula treatment

Dear <<Health Plan/Medical Director>>:

On <<date>> I performed the procedure described on the attached operative note. This is a surgical procedure that uses an FDA-cleared device (Biodesign Fistula Plug)* for the repair of rectovaginal fistulas. The device offers a minimally invasive treatment option and appears to be well tolerated by patients.

<<Optional insertion: Each case has unique circumstances. However, it is generally beneficial to add something about the medical necessity, the clinical benefits, and the patient selection to explain why it's desirable to use the new technology rather than an existing technology or procedure. At your discretion, use any information in this guide that is pertinent to your case in order to strengthen your argument.>>

CPT® code <<suggest inserting 58999, "Unlisted procedure, female genital system (nonobstetrical)," or 45999, "Unlisted procedure, rectum,">> is the correct code to report this service, but as an unlisted CPT code, it has not been assigned a value for payment. Outlined in the table below are general reference procedures, along with their relative value units (RVUs). <<Note: These are merely suggestions.>> In regard to the time, effort, and skills needed to perform this procedure, I suggest that rectovaginal fistula repair using the Biodesign Fistula Plug most closely compares to CPT code <<insert CPT code, descriptor, and total RVU or payments amount the physician feels most closely represents the rectovaginal fistula procedure>>.

CPT Code	Procedure Description	Global RVUs [‡]
46255	Hemorrhoidectomy, internal and external, single column/group	10.63
46600	Anoscopy; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	1.19
57300	Closure of rectovaginal fistula; vaginal or transanal approach	18.09
57520	Conization of cervix, with or without fulguration, with or without dilation and curettage, with or without repair; cold knife or laser	8.85

If you have any questions about this procedure or its application to this particular patient, please contact me.

Sincerely,

<<Insert physician's name>>
<<Physician contact information>>

*510(k) K170016 Biodesign Fistula Plug. June 21, 2017.

[‡]2021 Medicare Physician Fee Schedule facility global RVU.

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Sample Letter 2 (Physician Letterhead)

<<Date>>
<<Name Payer/Person Contacting>>
<<Business Name>>
<<Address>>
<<City, State, Zip>>

RE: Insertion of the Biodesign® (Surgisis®) Fistula Plug for rectovaginal fistula treatment

Dear <<title>> <<name>>:

The insertion of the Biodesign Fistula Plug was recently denied for <<insert patient name and identifying information for the carrier>> for treatment of a rectovaginal fistula. The procedure was denied on the basis of <<insert denial reason>>.

I am writing to you with additional information supporting the treatment of rectovaginal fistulas with the Biodesign Fistula Plug. The plug has received FDA clearance for the repair of rectovaginal fistulas; its 510(k) clearance number is K170016. The device is supplied sterile and is intended for one-time use.

<<Insert patient's name>> was a candidate for this type of rectovaginal fistula repair as opposed to another type of rectovaginal fistula repair for the following reasons: <<outline patient condition and medical reasons for using the Biodesign Fistula Plug as opposed to other existing procedures>>.

Please reconsider your coverage policy and/or denial of this procedure, taking into account the information provided in this letter.

Sincerely,

<<Insert physician's name>>
<<Physician contact information>>