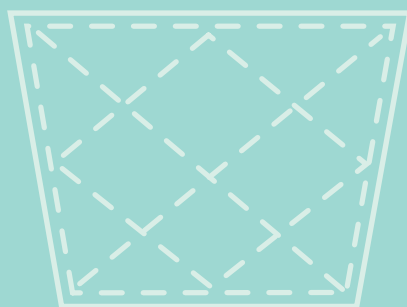
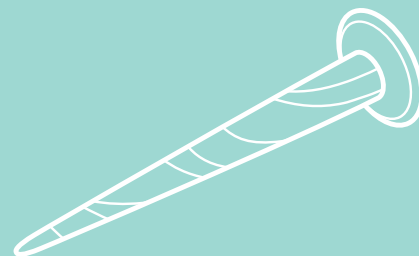
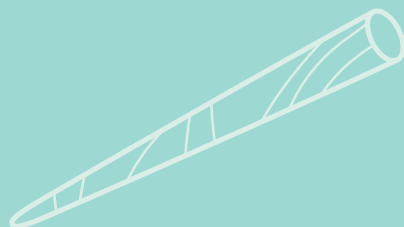




Biodesign[®]
SURGISIS[®] FISTULA PLUG



Rectovaginal Fistula

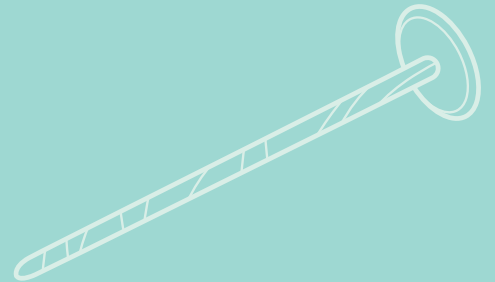
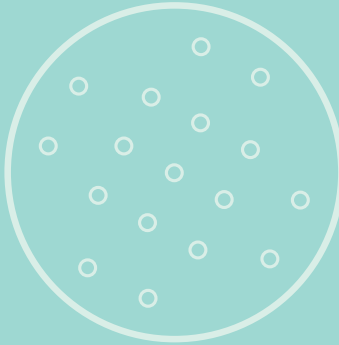
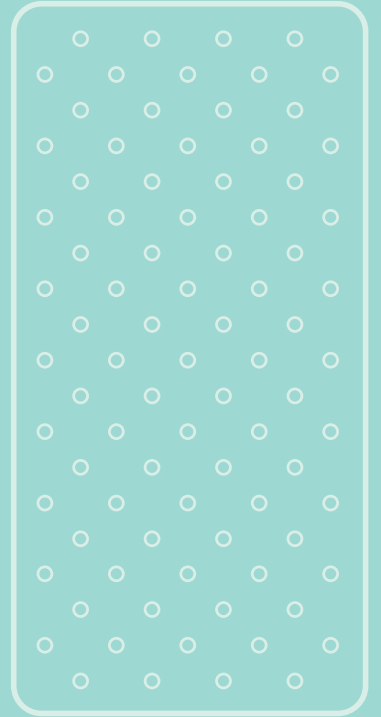
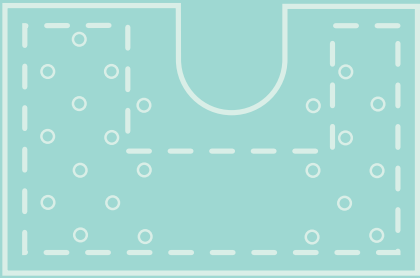
2010 Coding and Reimbursement Guide

Effective January 1, 2010 - February 28, 2010

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Coding and Reimbursement Guide

2010

The information provided herein reflects Cook Medical's understanding of rectovaginal fistula repairs using the Biodesign® Fistula Plug; the CPT®, ICD-9 and MS-DRG coding systems; 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 other 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 making coding decisions, we encourage you to seek input from the AMA, AHA, 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.

If you have any questions, please contact our reimbursement team at 812.339.2235 or via 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 new 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 new 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 "[s]elect 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 procedure or service exists, then report the service using the appropriate unlisted procedure or service code."² As of 2010, a CPT code does not exist that accurately describes the use of the Biodesign Fistula Plug in treating rectovaginal fistulas as described by the Instructions for Use (IFU). Efforts are ongoing to have a CPT code created. In the meantime, we suggest you consider using an unlisted code, such as 58999, "unlisted procedure, female genital system (nonobstetrical)" or 45999, "unlisted procedure, rectum."

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.

¹510(k) K062729 SIS Rectovaginal Fistula Plug. October 10, 2006.

²American Medical Association. Instructions for use of the CPT codebook. In: CPT 2010 Professional Edition. Chicago, IL: American Medical Association; 2009:xiv.

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 fairly 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 aid the reader with 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 2010

CPT	Description	2010 Work RVU	Global RVUs ⁵	Global Period Days
46255	Hemorrhoidectomy, internal and external, single column/group;	4.96	8.94	90
46600	Anoscopy; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)	0.55	1.01	0
57300	Closure of rectovaginal fistula; vaginal or transanal approach	8.71	14.63	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	7.32	90

³Section 1848 of the Social Security Act, “Payment for Physicians’ Services.”

⁴Federal Register Vol. 64, No. 211, November 2, 1999, p. 59428.

⁵2010 Medicare physician fee schedule out-of-office, i.e., facility global RVU, Federal Register Vol. 74, No. 226, November 25, 2009, Addendum B.

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 812.339.2235 or reimbursement@cookmedical.com.

Facility Coding and Reimbursement

The use of the 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 (2010) facility reimbursement environment for the Biodesign Fistula Plug.

Hospital Outpatient Department

Medicare

Medicare pays hospital outpatient facilities 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.

Presently (2010), CPT code 58999, “unlisted procedure, female genital system (nonobstetrical)” is assigned to APC 0191, “**Level I Female Reproductive Procedures,**” and the current (2010) national average Medicare payment to hospital facilities for this APC is \$8.90. CPT code 45999, “unlisted procedure, rectum” is assigned to APC 0148, “**Level I Anal/Rectal Procedures,**” and the current (2010) national average Medicare payment to hospital facilities for this APC is \$361.63. (The actual fee schedule amounts vary from hospital to hospital, based on local wage indices, geographic location, etc.)

Medicare also requires that pass-through or C-code devices used in the hospital outpatient setting be included on the claim. Currently there is no specific HCPCS C-code assignment for the Biodesign Fistula Plug.

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 ratesetting and encourage them to include all appropriate charges on their Medicare claims.”⁶

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 facilities. Unlisted codes do not appear on the ASC approved list. We encourage you to contact your local Medicare carrier to discuss how they want these claims submitted.

When submitting 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 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 ASC can be effective in obtaining appropriate reimbursement for innovative procedures, such as rectovaginal fistula repair 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.

Hospital Inpatient

Medicare

Medicare pays for inpatient hospital services based on the MS-DRG (Medicare Severity - Diagnosis Related Group) system. Within this system, Medicare assigns patients to a MS-DRG based primarily on their diagnosis (coded with ICD-9 diagnosis codes) and any procedures (coded with ICD-9 procedure codes) performed during their hospital stay. Medicare has established hospital-specific MS-DRG fee schedules that determine how much the hospital will get paid for a given admission.⁷ These amounts vary from hospital to hospital based on the hospital's location, whether it is a teaching hospital and whether it sees a disproportionate share of low-income patients.

The ICD-9 diagnosis code for rectovaginal fistula is:	619.1 Digestive-genital tract fistula, female
Fistula:	<ul style="list-style-type: none"> intestinouterine intestinovaginal rectovaginal rectovulval sigmoidovaginal uterorectal
The ICD-9 procedure code for rectovaginal fistula repair using the Biodesign Fistula Plug is:	70.73 Repair of rectovaginal fistula

Patients admitted with 619.1 as their primary diagnosis and who receive 70.73 as their primary procedure will typically fall into one of the MS-DRGs listed below:

MS-DRG 329	Major Small and Large Bowel Procedures with Major Complications and Comorbidities
MS-DRG 330	Major Small and Large Bowel Procedures with Complications and Comorbidities
MS-DRG 331	Major Small and Large Bowel Procedures without Complications and Comorbidities or Major Complications and Comorbidities

The actual MS-DRG assignment is dependent on the presence or absence of certain comorbid or complicating diagnoses documented in the patient's medical record and captured on the claim form submitted to Medicare.

The current (2010) average Medicare hospital reimbursement rates for these MS-DRGs are:⁷

MS-DRG 329	\$26,844.85
MS-DRG 330	\$13,047.93
MS-DRG 331	\$8,331.95

Actual hospital payment rates will vary based on, among other things, the hospital's geographic location, its status as a teaching hospital and whether it sees a disproportionate share of low-income patients.

Note: As mentioned under the hospital outpatient section, charges play an important role in future CMS rate-setting; therefore, it is important to capture all appropriate service charges.

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 any individual plan. We encourage you to work closely with your local hospital management and insurance plans to understand the contracted payment arrangements between them. A coordinated effort between the physician and hospital can be effective in obtaining appropriate reimbursement for innovative procedures, such as rectovaginal fistula repair using the Biodesign Fistula Plug.

When submitting claims it may be helpful to provide the documents listed under **Item 1** below.

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.

⁷Hart A, ed. Appendix E. In: *DRG Expert: A Comprehensive Guidebook to the DRG Classification System*. 25th ed. Eden Prairie, MN: Ingenix; 2009.

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 utilizing an FDA-cleared device (Biodesign Fistula Plug)* that is proving effective in treating rectovaginal fistulas. The device offers a minimally invasive treatment option and appears to be well tolerated by patients.

<<Optional insertion: it is generally beneficial to add in something as to the medical necessity and the clinical benefits and patient selection regarding use of the new technology rather than an existing technology/procedure.>>

<<Consider comments made in body of guide.>>

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 time, effort and skills needed to perform this procedure, I suggest rectovaginal fistula repair using the Biodesign Fistula Plug most closely compares to CPT code <<insert CPT code, descriptor and total RVU or payment amount the physician feels most closely represents the rectovaginal fistula procedure>>.

CPT	Description	Global RVU
46255	Hemorrhoidectomy, internal and external, single column/group;	8.94
46600	Anoscopy; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)	1.01
57300	Closure of rectovaginal fistula; vaginal or transanal approach	14.63
57520	Conization of cervix, with or without fulguration, with or without dilation and curettage, with or without repair; cold knife or laser	7.32

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) K062729 SIS Rectovaginal Fistula Plug. October 10, 2006.

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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 provide you with further information supporting the safe and effective 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 K062729. The device is supplied sterile and is intended for one-time use.

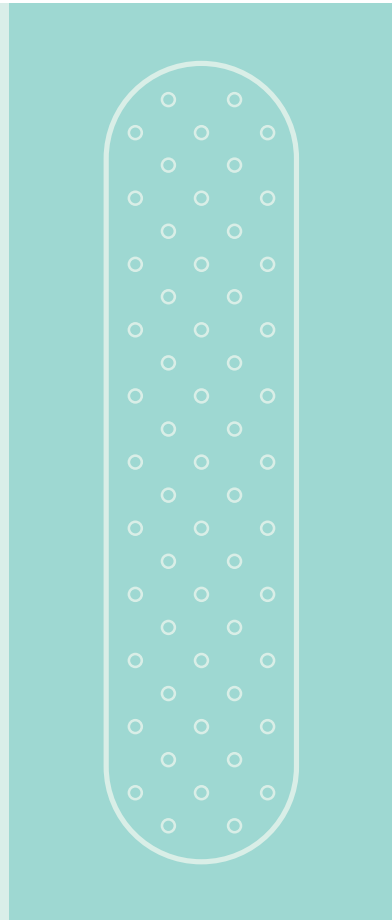
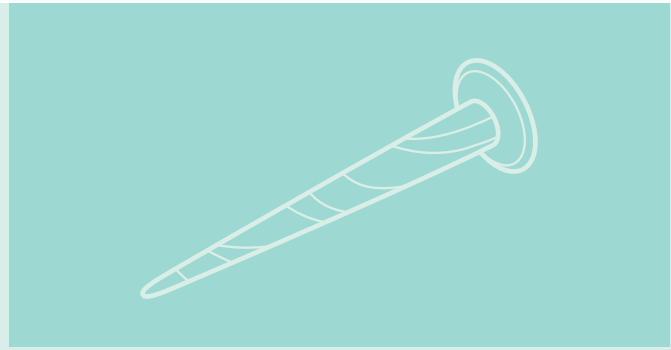
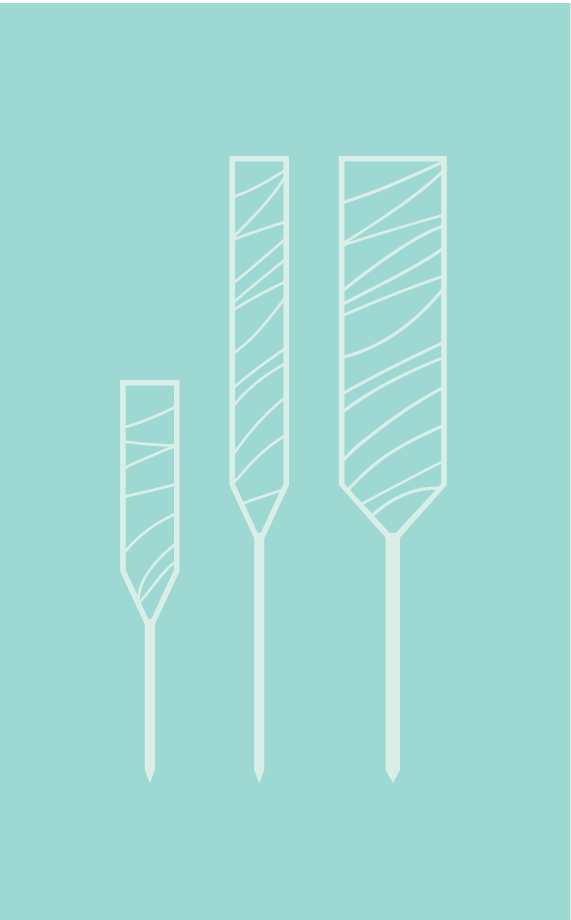
<<insert patient's name>> was a candidate for this type of rectovaginal fistula repair as opposed to another type of rectovaginal fistula repair for the following reasons: <<outline patient condition and medical reasons for using the Biodesign Fistula Plug as opposed to other existing procedures>>

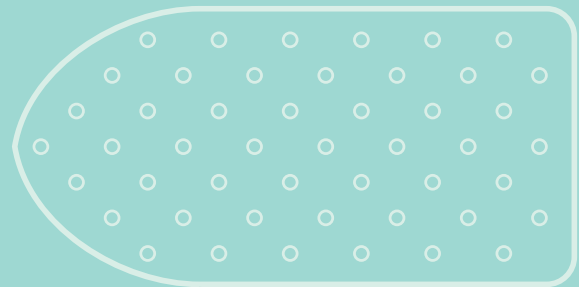
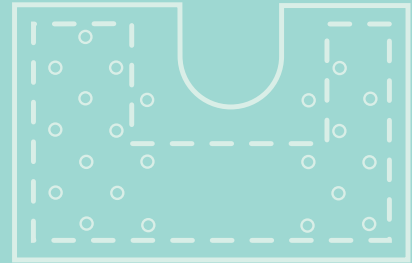
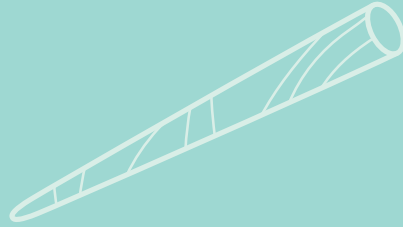
Please reconsider your coverage policy and/or denial of this procedure, taking into account the information provided in this letter.

Sincerely,

<<insert physician's name>>

<<physician contact information>>





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