

02-45000-02

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Reviewed: 01/24/19

Revised: 02/15/19

Subject: Plugs for Fistula Repair

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

An anal fistula is an abnormal communication between the interior of the anal canal or rectum and the skin surface. Rarer forms may communicate with the vagina or other pelvic structures, including the bowel. Most fistulas begin as anorectal abscesses, which are thought to arise from infection in the glands around the anal canal. When the abscess opens spontaneously in the anal canal (or has been opened surgically), a fistula may occur.

Fistula plugs are designed to provide a structure that acts as a scaffold for new tissue growth. The scaffold, which can be derived from animal (eg, porcine) tissue or a synthetic copolymer fiber, is degraded by hydrolytic or enzymatic pathways as healing progresses. The plug is pulled through the fistula tract and secured at the fistula's proximal opening; the fistula tract is left open at the distal opening to allow drainage. Several fistula plugs have been cleared for marketing by the U.S. Food and Drug Administration (FDA).

POSITION STATEMENT:

Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material, are considered **experimental or investigational** for the repair of anal fistulas. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding

46707	Repair of anorectal fistula with plug (e.g., porcine small intestine submucosa [SIS]) (investigational)
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REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Noncovered Services (L33777) located at fcso.com.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

REFERENCES:

1. Blue Cross Blue Shield Association Medical Policy Reference Manual, 7.01.123 Plugs for Anal Fistula Repair, 11/18.
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3. ClinicalTrials.gov, A Randomized, Prospective, Multi-Centered Study Comparing Clinical Outcomes of the Ligation of Intersphincteric Fistula Tract (LIFT) Procedure Versus Use of Anal Fistula Plug (AFP) in the Surgical Repair of Trans-Sphincteric Anal Fistulae of Cryptoglandular Origin, sponsored by Colon and Rectal Surgery Associates, Ltd.; accessed 12/13/18
4. ClinicalTrials.gov, A Retrospective Review of the Use of the Cook Biodesign® Fistula Plug (C-FPS-0.2, C-FPS-0.4, and C-FPS-0.7) to Treat Anorectal Fistulas, sponsored by Cook Group Incorporated; accessed 12/13/18.
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13. Steele SR, Kumar R, et al. Practice parameters for the management of perianal abscess and fistula-in-ano. *Dis Colon Rectum*. 2011 Dec;54(12):1465-74.
14. Stewart DB, Sr., Gaertner W, Glasgow S, et al. Clinical Practice Guideline for the management of anal fissures. *Dis Colon Rectum*. Jan 2017;60(1):7-14.
15. U.S. Food and Drug Administration (FDA); accessed at fda.gov.
16. Vogel JD, Johnson EK, Morris AM, et al. Clinical practice guideline for the management of anorectal abscess, fistula-in-ano, and rectovaginal fistula. *Dis Colon Rectum*. Dec 2016;59(12):1117-1133; accessed at fascrs.org.
17. Wang et al. Treatment of transsphincteric anal fistulas:are fistula plugs an acceptable alternative? *Dis Colon Rectum*. 2009 Apr;52(4):692-7.
18. Whiteford MH, Kilkenny J 3rd, Hyman N, Buie WD, Cohen J, Orsay C, Dunn G, Perry WB, Ellis CN, Rakinic J, Gregorcyk S, Shellito P, Nelson R, Tjandra JJ, Newstead G. Practice parameters for the treatment of perianal abscess and fistula-in-ano (revised). *Dis Colon Rectum* 2005 Jul;48(7):1337-42.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 01/24/19.

GUIDELINE UPDATE INFORMATION:

07/15/10	New Medical Coverage Guideline.
07/15/12	Scheduled review; position statement unchanged; coding and references updated.
07/15/13	Scheduled review; position statement unchanged; Program Exceptions section updated; references updated.
07/15/14	Scheduled review; position statement unchanged; references updated.
11/01/15	Revision: ICD-9 Codes deleted.
03/15/18	Review; investigational position maintained; description, position statement, and references updated.
02/15/18	Review; investigational position maintained; title, position statement, and references updated.