

02-45000-02

Original Effective Date: 07/15/10

Reviewed: 02/26/26

Revised: 03/15/26

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. Studies have reported that 26% to 37% of cases of perianal abscesses eventually form anal fistulas. Anal fistula plugs (AFPs) are biosynthetic devices used to promote healing and prevent the recurrence of anal fistulas. They are proposed as an alternative to procedures including fistulotomy, endorectal advancement flaps, seton drain placement, and use of fibrin glue in the treatment of anal fistulas.

Summary and Analysis of Evidence: The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anorectal Abscess, Fistula-in-Ano, and Rectovaginal Fistula (Gaertner 2022) states that “The anal fistula plug and fibrin glue are relatively ineffective treatments for fistula-in-ano”. For individuals who have anal fistulas who receive placement anal fistula plugs, the evidence includes several randomized and nonrandomized studies, and systematic reviews of the studies. Systematic reviews of anal fistula plug repair have demonstrated a wide range of success rates and an assortment of study results. Nonrandomized studies have also reported conflicting results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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: No National Coverage Determinations (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

REFERENCES:

1. Blue Cross Blue Shield Association (BCBSA) Evidence Positioning System®; 7.01.123 Plugs for Anal Fistula Repair, 12/25.
2. Champagne BJ. Operative management of anorectal fistulas, 2024. In: UpToDate, Weiser M, Chen W (Eds), UpToDate, Waltham, MA; accessed at uptodate.com.
3. Cheung XC, Fahey T, et al. Surgical Management of Idiopathic Perianal Fistulas: A Systematic Review and Meta-Analysis. Dig Surg. 2021;38(2):104-119. PMID: 33503621.
4. Ellis, CN. Et al. Long-Term Outcomes With the Use of Bioprosthetic Plugs for the Management of Complex Anal Fistulas. Dis Colon Rectum. 2010 May; 53(5):798-802.
5. Ellis, CN. Bioprosthetic Plugs for Complex Anal Fistulas: An Early Experience. J Surg Educ. 2007 Jan-Feb; 64(1):36-40.

6. Gaertner WB, Burgess PL, et al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anorectal Abscess, Fistula-in-Ano, and Rectovaginal Fistula. *Dis Colon Rectum*. 2022 Aug 1;65(8):964-985; accessed at [fascrs.org](https://ascrs.org).
7. Girona et al. Percutaneous Embolization of Vascular Fistulas Using Coils or Amplatzer Vascular Plugs. *Rev Esp Cardiol*. 2009 Jul; 62(7):765-73.
8. Hansen MS, Kjaer ML, Anderson J. Efficacy of Plug Treatment for Complex Anorectal Fistulae: Long-term Danish Results. *Ann Coloproctol*. 2019 Mar 20:123-128.
9. Jayne DG, Scholefield J, et al. Anal fistula plug versus surgeon's preference for surgery for transsphincteric anal fistula: the FIAT RCT. *Health Technol Assess*. 2019 May;23(21):1-76. doi: 10.3310/hta23210. PMID: 31113531.
10. Jayne DG, Scholefield J, et al. A Multicenter Randomized Controlled Trial Comparing Safety, Efficacy, and Cost-effectiveness of the Surgisis Anal Fistula Plug Versus Surgeon's Preference for Transsphincteric Fistula-in-Ano: The FIAT Trial. *Ann Surg*. 2021 Mar 1;273(3):433-441. PMID: 32516229.
11. Leng Q, Jin H-Y. Anal fistula plug vs mucosa advancement flap in complex fistula-in-ano: A meta-analysis. *World J Gastrointest Surg*. 2012 November 27; 4(11): 256–261. Published online 2012 November 27.
12. National Institute for Health and Care Excellence (NICE). Bioprosthesis plug insertion for anal fistula Interventional procedures guidance [IPG662]Published date: September 2019; accessed at [nice.org.uk](https://www.nice.org.uk).
13. Saba RB, Tizmaghz A, et al. Treating anal fistula with the anal fistula plug: case series report of 12 patients. *Electron Physician*. 2016 Apr 25;8(4):2304-7.
14. Sahnan K, Askari A, et al. Persistent Fistula After Anorectal Abscess Drainage: Local Experience of 11 Years. *Dis Colon Rectum*. 2019 Mar;62(3):327-332. PMID: 30451763.
15. Schwandner et al. Surgical treatment of complex anal fistulas with the anal fistula plug: a prospective, multicenter study. *Dis Colon Rectum*. 2009 Sep;52(9):1578-83.
16. 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.
17. 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.
18. U.S. Food and Drug Administration (FDA); accessed at [fda.gov](https://www.fda.gov).
19. 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](https://ascrs.org).
20. Wang et al. Treatment of transsphincteric anal fistulas:are fistula plugs an acceptable alternative? *Dis Colon Rectum*. 2009 Apr;52(4):692-7.
21. 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 and Coverage Committee on 02/26/26.

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.
02/15/19	Review; investigational position maintained; title, position statement, and references updated.
02/15/20	Review; position statement maintained and references updated.
02/15/22	Review: position statement maintained; program exceptions and references updated.
05/25/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.
03/15/24	Review: Position statement maintained; description and references updated.
03/15/25	Review: Position statement maintained and references updated.
03/15/26	Annual review. Position statement maintained; references updated.