

**EVIDENCE-BASED CRITERIA  
SECTION: SURGERY**

<b>ORIGINAL EFFECTIVE DATE:</b>	<b>09/19/22</b>
<b>LAST REVIEW DATE:</b>	<b>01/03/23</b>
<b>CURRENT EFFECTIVE DATE:</b>	<b>01/03/23</b>
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**NEXT ANNUAL REVIEW DATE: 1ST QTR 2024**

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## **PLUGS FOR ANAL FISTULA REPAIR**

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**Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.**

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.**

**This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Evidence-Based Criteria are subject to change as new information becomes available.**

**For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.**

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## **PLUGS FOR ANAL FISTULA REPAIR (cont.)**

### **Description:**

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.

### **Anal Fistulas**

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.

Other causes of fistulas include tuberculosis, cancer, prior radiotherapy, and inflammatory bowel disease. Fistulas may occur singly or in multiples. Symptoms include a purulent discharge and drainage of pus and/or stool near the anus, which can irritate the outer tissues causing itching and discomfort. Pain occurs when fistulas become blocked, and abscesses recur. Flatus may also escape from the fistulous tract.

The most widely used classification of anal fistulas is the Parks classification system, which defines anal fistulas by their position relative to the anal sphincter as transsphincteric, intersphincteric, suprasphincteric, or extrasphincteric. More simply, anal fistulas are described as low (present distally and not extending up to the anorectal sling) or high (extending up to or beyond the anorectal sling). The repair of high fistulas can be associated with incontinence. Diagnosis may involve a fistula probe, anoscopy, fistulography, ultrasound, or magnetic resonance imaging.

### **Fistula Plugs**

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 (e.g., 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 plugs for anal fistula repair have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Approved anal fistula plugs include: SIS Fistula Plug, Surgisis RVP Recto-Vaginal Fistula Plug, Surgisis Biodesign Enterocutaneous Fistula Plug, Gore Bio-A Fistula Plug, and Biodesign Anal Fistula Plug.

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## **PLUGS FOR ANAL FISTULA REPAIR (cont.)**

### **Criteria:**

- Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material, for the repair of anal fistulas are considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

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### **Resources:**

**Literature reviewed 01/03/23. We do not include marketing materials, poster boards and non-published literature in our review.**

**Resources prior to 01/03/23 may be requested from the BCBSAZ Medical Policy and Technology Research Department.**

1. Campbell ML, Abboud EC, Dolberg ME, Sanchez JE, Marcet JE, Rasheid SH. Treatment of refractory perianal fistulas with ligation of the intersphincteric fistula tract: preliminary results. *Am Surg*. Jul 2013;79(7):723-7.
2. Cheung XC, Fahey T, Rogers AC, Pemberton JH, Kavanagh DO. Surgical Management of Idiopathic Perianal Fistulas: A Systematic Review and Meta-Analysis. *Dig Surg*. 2021;38(2):104-119. doi:10.1159/000512652
3. Christoforidis D, Pieh MC, Madoff RD, Mellgren AF. Treatment of transsphincteric anal fistulas by endorectal advancement flap or collagen fistula plug: a comparative study. *Dis Colon Rectum*. Jan 2009;52(1):18-22. doi:10.1007/DCR.0b013e31819756ac
4. Chung W, Kazemi P, Ko D, et al. Anal fistula plug and fibrin glue versus conventional treatment in repair of complex anal fistulas. *Am J Surg*. May 2009;197(5):604-8. doi:10.1016/j.amjsurg.2008.12.013
5. Cirocchi R, Trastulli S, Morelli U, et al. The treatment of anal fistulas with biologically derived products: is innovation better than conventional surgical treatment? An update. *Tech Coloproctol*. Jun 2013;17(3):259-73. doi:10.1007/s10151-012-0948-9
6. Fisher OM, Raptis DA, Vetter D, et al. An outcome and cost analysis of anal fistula plug insertion vs endorectal advancement flap for complex anal fistulae. *Colorectal Dis*. Jul 2015;17(7):619-26. doi:10.1111/codi.12888

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### Resources: (cont.)

7. Gaertner WB, Burgess PL, Davids JS, 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*. Aug 1 2022;65(8):964-985. doi:10.1097/DCR.0000000000002473
8. Hall JF, Bordeianou L, Hyman N, et al. Outcomes after operations for anal fistula: results of a prospective, multicenter, regional study. *Dis Colon Rectum*. Nov 2014;57(11):1304-8. doi:10.1097/dcr.0000000000000216
9. Hyman N, O'Brien S, Osler T. Outcomes after fistulotomy: results of a prospective, multicenter regional study. *Dis Colon Rectum*. Dec 2009;52(12):2022-7. doi:10.1007/DCR.0b013e3181b72378
10. Jayne DG, Scholefield J, Tolan D, 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*. Mar 1 2021;273(3):433-441. doi:10.1097/sla.0000000000003981
11. Leng Q, Jin HY. Anal fistula plug vs mucosa advancement flap in complex fistula-in-ano: A meta-analysis. *World J Gastrointest Surg*. Nov 27 2012;4(11):256-61. doi:10.4240/wjgs.v4.i11.256
12. Narang SK, Jones C, Alam NN, Daniels IR, Smart NJ. Delayed absorbable synthetic plug (GORE® BIO-A®) for the treatment of fistula-in-ano: a systematic review. *Colorectal Dis*. Jan 2016;18(1):37-44. doi:10.1111/codi.13208
13. Nasseri Y, Cassella L, Berns M, Zaghiyan K, Cohen J. The anal fistula plug in Crohn's disease patients with fistula-in-ano: a systematic review. *Colorectal Dis*. Apr 2016;18(4):351-6. doi:10.1111/codi.13268
14. National Institute for Health and Care Excellence (NICE). Bioprosthetic plug insertion for anal fistula [IPG662]. September 25, 2019. Accessed September 21, 2022. <https://www.nice.org.uk/guidance/ipg662>
15. O'Riordan JM, Datta I, Johnston C, Baxter NN. A systematic review of the anal fistula plug for patients with Crohn's and non-Crohn's related fistula-in-ano. *Dis Colon Rectum*. Mar 2012;55(3):351-8. doi:10.1097/DCR.0b013e318239d1e4
16. Ortiz H, Marzo J, Ciga MA, Oteiza F, Armendáriz P, de Miguel M. Randomized clinical trial of anal fistula plug versus endorectal advancement flap for the treatment of high cryptoglandular fistula in ano. *Br J Surg*. Jun 2009;96(6):608-12. doi:10.1002/bjs.6613
17. Ozturk E. Treatment of recurrent anal fistula using an autologous cartilage plug: a pilot study. *Tech Coloproctol*. May 2015;19(5):301-7. doi:10.1007/s10151-015-1299-0

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## PLUGS FOR ANAL FISTULA REPAIR (cont.)

**Resources:** (cont.)

18. Pu YW, Xing CG, Khan I, Zhao K, Zhu BS, Wu Y. Fistula plug versus conventional surgical treatment for anal fistulas. A system review and meta-analysis. *Saudi Med J*. Sep 2012;33(9):962-6.
19. Senéjoux A, Siproudhis L, Abramowitz L, et al. Fistula Plug in Fistulising Ano-Perineal Crohn's Disease: a Randomised Controlled Trial. *J Crohns Colitis*. Feb 2016;10(2):141-8. doi:10.1093/ecco-jcc/jjv162
20. Simpson JA, Banerjee A, Scholefield JH. Management of anal fistula. *Bmj*. Oct 15 2012;345:e6705. doi:10.1136/bmj.e6705
21. van Koperen PJ, Bemelman WA, Gerhards MF, et al. The anal fistula plug treatment compared with the mucosal advancement flap for cryptoglandular high transsphincteric perianal fistula: a double-blinded multicenter randomized trial. *Dis Colon Rectum*. Apr 2011;54(4):387-93. doi:10.1007/DCR.0b013e318206043e
22. Wang JY, Garcia-Aguilar J, Sternberg JA, Abel ME, Varma MG. Treatment of transsphincteric anal fistulas: are fistula plugs an acceptable alternative? *Dis Colon Rectum*. Apr 2009;52(4):692-7. doi:10.1007/DCR.0b013e31819d473f
23. Xu Y, Tang W. Comparison of an anal fistula plug and mucosa advancement flap for complex anal fistulas: a meta-analysis. *ANZ J Surg*. Dec 2016;86(12):978-982. doi:10.1111/ans.13751

**Coding:**

CPT: 46707

**History:**

**Date:**

**Activity:**

Medical Policy Panel	01/03/23	Review with revisions
Medical Policy Panel	08/16/22	Approved guideline (Effective 9/19/22)



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### **Policy Revisions:**

01/03/23	Added:	"Insufficient evidence to support improvement of the net health outcome; or", and "Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or" to experimental or investigational criteria.
01/03/23	Revised:	"is" to "are" in criteria statement; "Insufficient evidence to support improvement outside the investigational setting" from #3 to #5 in experimental or investigational criteria.
01/03/23	Updated:	Resources section

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### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Dii kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éi doodago Háida bíjá anilyeedigií t'áadoo le'é yina'idilkidgo beehaz'áanii hólo dii t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóo. Ata' halne'ígíí kójj' bich'í' hodílnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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