



# MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an independent Licensee of the Blue Cross and Blue Shield Association

## Medical Policy Plugs for Anal Fistula Repair

### Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

### Policy Number: 528

BCBSA Reference Number: 7.01.123 (For Plan internal use only)  
NCD/LCD: N/A

### Related Policies

None

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material, are [INVESTIGATIONAL](#) for the repair of anal fistulas.

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>SM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>SM</sup>	This is <b>not</b> a covered service.

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT code is considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

### CPT Codes

CPT codes:	Code Description
46707	Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])

### HCPCS Codes

HCPCS codes:	Code Description
C9796	Repair of enterocutaneous fistula small intestine or colon (excluding anorectal fistula) with plug (e.g., porcine small intestine submucosa [sis])

## Description

### 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.<sup>1</sup>

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.

## Summary

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.

For individuals who have anal fistula(s) who receive placement of AFP(s), the evidence includes 4 RCTs, a number of nonrandomized studies, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, and treatment-related morbidity. Two RCTs comparing AFP with surgical flap treatment have reported disparate findings: 1 found significantly higher rates of fistula recurrence with AFP; the other found similar rates of recurrence for AFP and surgical treatment. Another RCT that compared AFP with seton drain removal alone for patients with fistulizing Crohn disease, found no significant difference in healing rates at 12 weeks between groups. An RCT comparing AFP with surgeon's preference reported significantly higher complication rates with AFP. Systematic reviews of AFP repair have demonstrated a wide range of

success rates and heterogeneity in 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.

## Policy History

Date	Action
4/2024	Clarified coding information.
1/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2018	Annual policy review. New references added.
12/2016	Annual policy review. New references added.
11/2015	Annual policy review. Policy statement changed to clarify that the policy refers to anal fistulas. Title of policy changed to "Plugs for Anal Fistula Repair." 11/2015
10/2014	Annual policy review. New references added.
12/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/1/2012	New policy, effective 01/01/2012, describing ongoing non-coverage.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Simpson JA, Banerjee A, Scholefield JH. Management of anal fistula. *BMJ*. Oct 15 2012; 345: e6705. PMID 23069597
2. Sahnun K, Askari A, Adegbola SO, et al. Persistent Fistula After Anorectal Abscess Drainage: Local Experience of 11 Years. *Dis Colon Rectum*. Mar 2019; 62(3): 327-332. PMID 30451763
3. Ozturk E. Treatment of recurrent anal fistula using an autologous cartilage plug: a pilot study. *Tech Coloproctol*. May 2015; 19(5): 301-7. PMID 25850629
4. Campbell ML, Abboud EC, Dolberg ME, et al. Treatment of refractory perianal fistulas with ligation of the intersphincteric fistula tract: preliminary results. *Am Surg*. Jul 2013; 79(7): 723-7. PMID 23816007
5. Cheung XC, Fahey T, Rogers AC, et al. Surgical Management of Idiopathic Perianal Fistulas: A Systematic Review and Meta-Analysis. *Dig Surg*. 2021; 38(2): 104-119. PMID 33503621
6. 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. PMID 21383557
7. Ortiz H, Marzo J, Ciga MA, et al. 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. PMID 19402190

8. Narang SK, Jones C, Alam NN, et al. Delayed absorbable synthetic plug (GORE(R) BIO-A(R)) for the treatment of fistula-in-ano: a systematic review. *Colorectal Dis.* Jan 2016; 18(1): 37-44. PMID 26542191
9. Nasser Y, Cassella L, Berns M, et al. The anal fistula plug in Crohn's disease patients with fistula-in-ano: a systematic review. *Colorectal Dis.* Apr 2016; 18(4): 351-6. PMID 26749385
10. 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. PMID 27680894
11. 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 01 2021; 273(3): 433-441. PMID 32516229
12. Senejoux 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. PMID 26351393
13. Christoforidis D, Pieh MC, Madoff RD, et al. 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. PMID 19273951
14. Wang JY, Garcia-Aguilar J, Sternberg JA, et al. Treatment of transsphincteric anal fistulas: are fistula plugs an acceptable alternative?. *Dis Colon Rectum.* Apr 2009; 52(4): 692-7. PMID 19404076
15. 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 01 2022; 65(8): 964-985. PMID 35732009
16. National Institute for Health and Care Excellence (NICE). Bioprosthetic plug insertion for anal fistula [IPG662]. September 25, 2019; <https://www.nice.org.uk/guidance/ipg662>. Accessed September 15, 2023.