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| **Policy Number** | **SUR709.032** |
| **Policy Effective Date** | **08/15/2025** |

# Plugs for Anal Fistula Repair

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| Related Policies (if applicable) |
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| None |
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## Disclaimer

**Carefully check state regulations and/or the member contract.**
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

## Coverage

Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material, **are considered experimental, investigational and/or unproven** for the repair of anal fistulas.

## Policy Guidelines

None.

## 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.

**Background**

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. (1)

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 (MRI).

**Regulatory Status**

Several plugs for anal fistula repair have been cleared for marketing by the U.S. FDA through the 510(k) process and are outlined in Table 1.

**Table 1. Devices for Anal Fistula Repair**

| Device | Year | Description | Indication(s) | Predicate Device(s) | FDA Product Code |
|---|---|---|---|---|---|
| SIS Fistula Plug (Cook Biotech) | Mar 2005 | • Manufactured from porcine SIS | • Repair of anal, rectal, and entero-cutaneous fistulas | • Surgisis® Soft Tissue Graft (Cook Biotech)<br>• Stratasis® Urethral Sling (Cook Biotech) | FTM |
| Surgisis RVP Recto-Vaginal Fistula Plug (Cook Biotech) | Oct 2006 | • Manufactured from porcine SIS<br>• Tapered configuration | • Reinforce soft tissue to repair recto- | • SIS Fistula Plug (Cook Biotech) | FTM |

| | | | | | |
|---|---|---|---|---|---|
| | | with a button to increase plug retention and improve fistula blockage | vaginal fistulas | | |
| Surgisis Biodesign Enterocutaneous Fistula Plug (Cook Biotech) | Feb 2009 | • Manufactured from porcine SIS<br>• Tapered configuration with flange to increase plug retention and improved fistula blockage | • Reinforce soft tissue to repair entero-cutaneous fistulas | • SIS Fistula Plug (Cook Biotech) | FTM |
| Gore Bio-A Fistula Plug (W.L. Gore & Assoc.) | Mar 2009 | • Manufactured from bioabsorb-able PGA:TMC copolymer<br>• Supplied in a 3-dimensional configuration of a disk with attached tubes | • Reinforce soft tissue to repair anorectal fistulas | • Gore Bioabsorb-able Mesh (W.L. Gore & Assoc.)<br>• SIS Fistula Plug (Cook Biotech) | FTL |
| Biodesign Anal Fistula Plug (Cook Biotech) | May 2016 | • Manufactured from porcine SIS<br>• Additional wash steps added in processing | • Reinforce soft tissue where a rolled configurati on is required to repair anal, rectal, and entero-cutaneous fistulas | • SIS Fistula Plug (Cook Biotech) | FTM |

FDA: Food and Drug Administration; PGA:TMC: polyglycolide-co-trimethylene carbonate; SIS: small intestinal submucosa.

## Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has

specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Anal Fistula Repair**

Clinical Context and Therapy Purpose

The purpose of placing anal fistula plugs (AFPs) in individuals who have anal fistulas is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

*Populations*

The relevant population of interest is individuals with anal fistulas.

The prevalence of anal fistulas is not well characterized. The mean age of individuals presenting with anal abscess and fistula is 40 years (range, 20 to 60 years). Men are more likely to develop an abscess and fistula than women. (2)

*Interventions*

The therapy being considered is an AFP.

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 fistula plugs have been cleared for marketing by the United States (U.S.) Food and Drug Administration (FDA) (see Regulatory Status section).

A fistula plug derived from autologous cartilage tissue has been investigated in a small (N=10) pilot study. (3)

*Comparators*
The following therapies are currently being used to treat anal fistulas: fistulotomy or fistulectomy, endorectal or anal sliding flaps, seton drains, and fibrin glue.

Treatment is aimed at repairing the fistula without compromising continence.

Surgical treatments for anal fistulas include fistulotomy or fistulectomy, endorectal or anal sliding flaps, ligation of the intersphincteric fistula tract (LIFT) technique, seton drain, and fibrin glue. Fistulotomy involves division of the tissue over the fistula and laying open of the fistula tract. Although fistulotomies are widely used for low fistulas, lay-open fistulotomies in high fistulas carry the risk of incontinence. A seton is a thread placed through the fistula tract to drain fistula material and preventing the development of a perianal infection. Draining setons can control sepsis, but few patients heal after removal of the seton, and the procedure is poorly tolerated long-term. A "cutting seton" refers to the process of regular tightening of the seton to encourage gradual cutting of the sphincteric muscle with subsequent inflammation and fibrosis. Cutting setons can cause continence disturbances. Endorectal advancement flaps involve the advancement of a full or partial thickness flap of the proximal rectal wall over the internal (rectal) opening of the fistula tract. The intersphincteric fistula tract technique involves identifying the intersphincteric plane and then dividing the fistula tract; its use has been reported in small studies, but long-term follow-up is unavailable. (4) Fibrin glue is a combination of fibrinogen, thrombin, and calcium in a matrix, which is injected into the fistula track. The glue induces clot formation within the tract, which is then closed through the overgrowth of new tissue.

*Outcomes*
The general outcomes of interest are fistula repair and healing, elimination of symptoms, treatment-related complications (e.g., abscess), and fistula recurrence.

Short-term postsurgical follow-up can range between 2 and 12 weeks while longer-term follow-up monitoring can range from weeks to months.

<u>Study Selection Criteria</u>
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

<u>Systematic Reviews</u>

An et al. (2023) compared clinical outcomes of AFP versus endoanal advancement flap repair (EAFR) for treatment of complex anal fistula in a systematic review and meta-analysis. (5) Twelve studies were included (5 RCTs; 7 nonrandomized trials) with a total of 847 patients. The difference between pooled healing rates of AFP 48.3% and EAFR 64.4% was statistically significant (p=0.03), with EAFR having a higher healing rate. There was no significant difference between groups for recurrence rate, wound infection rate, or complication rate.

Cheung et al. (2021) completed a systematic review and meta-analysis of all the available evidence (N=28 studies) on the surgical management of adults with non-Crohn-related perianal fistulas. (6) The primary outcomes were fistula recurrence and fecal incontinence. Since the included studies had a range of different comparison groups, pooling of data from all 28 studies was not possible. In the review, 2 studies (van Koperen et al. [2011] [7] and Ortiz et al. [2009] [8], described in the Randomized Controlled Trials section) compared fistula plug with advancement flap, with an increased recurrence rate in the plug group. Pooled data analysis on recurrence revealed an odds ratio (OR) favoring the advancement flap (OR=4.22; 95% confidence interval [CI], 1.76 to 10.13; p=.03). No difference in incontinence scores between groups was noted.

Narang et al. (2016) published a systematic review of the Gore Bio-A plug for anal fistulas, which included 6 studies (N=221 patients) in a qualitative synthesis. (9) Fistula healing rates ranged from 15.8% to 72.7%. Reviewers assessed the overall quality of the underlying studies as poor.

Nasseri et al. (2016) reported on a systematic review of AFP for patients with Crohn disease and anal fistulas. (10) Twelve studies were included: 8 nonrandomized prospective studies and 4 retrospective studies (N=84; range, 1 to 20 patients per study). Due to study heterogeneity, reviewers did not perform a weighted analysis with summary efficacy estimates. The total success rate of AFPs was 49 (58.3%) of 84 placed (95% CI, 47% to 69%).

Xu et al. (2016) reported on a meta-analysis of 10 comparative studies of AFPs and mucosal advancement flaps (MAFs) for complex anal fistulas (N=778 patients). (11) Three studies were randomized trials; the remaining were observational studies or did not describe designs. In the pooled analysis, there were no significant differences in healing rates at the end of follow-up between the AFP and MAF groups (OR, 0.79; 95% CI, 0.36 to 1.73; p=0.55, $I^2$=74%). None of the 7 studies reporting on recurrence rates found significant differences in recurrence rates (OR=2.29; 95% CI, 0.59 to 8.88; p=0.23, $I^2$=83%). However, conclusions were limited by shortcomings in the underlying evidence base.

Randomized Controlled Trials

Jayne et al. (2021) compared the use of porcine AFPs (Biodesign Surgisis) with surgeon's preference (advancement flap, cutting seton, fistulotomy, or Ligation of the Intersphincteric Fistula Tract [LIFT] procedure) in 304 patients with transsphincteric fistulas in the pragmatic, multicenter, randomized FIAT trial. (12) The primary outcome was fecal incontinence quality of life (FIQoL) at 12 months. Secondary outcome measures included fistula healing, incontinence

rates, and complications. No significant differences were seen in FIQoL between groups at 12 months. Clinical fistula healing was reported in 66/122 (54%) of the AFP group and 66/119 (55%) of the surgeon's preference group at 12 months. Marginal improvement in fecal incontinence rates was observed in both groups. Frequent complications and reinterventions were observed, with significantly more complications in the AFP group at 6 weeks (49/142, 35% vs 25/137 (18%); P=0.002).

Senejoux et al. (2016) reported on an RCT comparing AFP with seton removal alone in 106 patients who had Crohn disease with non- or mildly active disease but at least 1 ano-perineal fistula drained for at least 1 month. (13) The trial was powered for the superiority of AFP, and analysis was intention-to-treat. At 12 weeks of follow-up, in the AFP group (n=54), the clinical remission rate was 31.5% compared with 23.1% in the control group (relative risk, 1.31; 95% CI, 0.59 to 4.02; p=0.19). Fistula tract healing rates on magnetic resonance imaging did not differ significantly between groups at 12 weeks.

van Koperen et al. (2011) reported on a double-blinded, multicenter, randomized trial comparing AFP with mucosal advancement flap in 60 patients with high perianal fistulas. (7) At 11-month follow-up, trialists reported fistula recurrence in 22 (71%) patients in the AFP group and 15 (52%) patients in the advancement flap group; these rates did not differ significantly (p=0.126). Postoperative pain scores, quality of life after surgery, and functional outcomes did not differ significantly between groups. Despite disappointing results, trialists indicated the plug might be considered as an initial treatment option because the procedure is simple and minimally invasive.

Ortiz et al. (2009) compared the use of porcine submucosal (Surgisis) AFPs with an endorectal anal flap (ERAF) procedure in an RCT of 43 patients with high anal fistula. (8) The primary end point was fistula healing. Recurrence was defined as the presence of an abscess in the same area or obvious evidence of fistulization. Five patients in the AFP group and 6 in the ERAF group did not receive the allocated intervention, leaving 32 patients. One patient in the AFP group was lost to follow-up. A large number of fistula recurrences in the fistula plug group led to the premature closure of the trial. After 1 year, fistula recurrence was seen in 12 of 15 patients treated with an AFP versus 2 of 16 patients who underwent the flap procedure (relative risk, 6.40; 95% CI, 1.70 to 23.97; p<0.001). A trend for more sphincter involvement and more women in the ERAF group was noted. Complications were not reported.

Nonrandomized Comparative Studies

Because several RCTs exist, non-randomized studies will be summarized briefly below only if they capture longer periods of follow-up (>1 year), larger populations, or particular subgroups of interest.

*Retrospective Studies*

Christoforidis et al. (2009) retrospectively analyzed patients from a U.S. center with transsphincteric fistulas treated with ERAF (n=43) or anal plug (Surgisis; n=37) between 1996 and 2007. (14) Success was defined as closed external opening in the absence of symptoms at

minimal follow-up of 6 months. The success rate was 63% in the ERAF group and 32% in the AFP group after a mean follow-up of 56 months (range, 6-136 months) for ERAF and 14 months (range, 6-22 months) for AFP. After exclusion of patients with early AFP extrusion, which may be considered a technical failure, the ERAF advantage was not statistically significance (p=0.06). Twenty-three of 27 patients who had ERAF and 7 of 12 patients who had AFP responded to a questionnaire addressing functional outcomes. In the ERAF group, 11 of 23 patients had no continence disturbance versus 6 of 7 in the AFP group. The lack of prospectively collected incontinence scores before the procedure, and a low response rate in the AFP group does not permit valid comparisons on functional outcomes. Complication rates were low in both groups; only 2 patients in the ERAF group required reoperation for bleeding.

Wang et al. (2009) compared outcomes for patients who had transsphincteric fistulas treated using an AFP from 2005 to 2006 (n=29) with historical controls treated with ERAF (2001-2005) (n=26). (15) Of 26 initial flap procedures, 10 failed and 16 healed. Of 29 initial plug procedures, 19 failed and 10 healed. In total, 30 advancement flaps and 34 plug procedures were performed (including additional treatments for failed initial procedures). Closure rates were 34% for plugs (mean follow-up, 279 days; range, 110-690 days) and 62% for flaps (median follow-up, 819 days; range, 93-1928 days; p=0.045). Complications were not reported.

**Summary of Evidence**

For individuals who have anal fistula(s) who receive placement of an anal fistula plug (AFP), 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: one 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.

**Practice Guidelines and Position Statements**

American Society of Colon and Rectal Surgeons

The 2022 practice guidelines on the treatment of anorectal abscess, fistula-in-ano, and rectovaginal fistula from the Society provided a strong recommendation based on moderate-quality evidence that anal fistula plugs and fibrin glue are relatively ineffective treatments for fistula-in-ano. (16)

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence updated its guidance on the suturable bioprosthetic plug. (17) The Institute determined that "evidence on the safety and

efficacy of bioprosthetic plug insertion for anal fistula is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent, and audit." Though, it was noted that "the procedure should only be done by a surgeon experienced in managing anal fistulas."

**Ongoing and Unpublished Clinical Trials**

An online search of ClinicalTrials.gov through October 1, 2024 identified no clinical trials that would likely influence this policy.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

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| **CPT Codes** | 46707 |
| **HCPCS Codes** | None. |

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

| Policy History/Revision | |
|---|---|
| **Date** | **Description of Change** |
| 08/15/2025 | Document updated with literature review. The following change was made to Coverage: Revised coverage statement to address only anal fistula plugs. Added references 2 and 5; others removed. Title changed from: Plugs for Fistula Repair. |
| 12/15/2024 | Reviewed. No changes. |
| 07/15/2023 | Document updated with literature review. Coverage unchanged. The following reference was added 22; others were updated and some removed. |
| 04/15/2022 | Document updated with literature review. Coverage unchanged. The following reference was added: 4. |
| 10/01/2021 | Reviewed. No changes. |
| 01/15/2021 | Document updated with literature review. Coverage unchanged. The following references were added/updated: 15, 32 and 34. |
| 04/01/2019 | Reviewed. No changes. |
| 07/15/2018 | Document updated with literature review. Coverage unchanged. References 4-6, 15, and 32-33 added. |
| 04/15/2017 | Reviewed. No changes. |
| 04/15/2016 | Document updated with literature review. Coverage unchanged. |
| 04/15/2015 | Reviewed. No changes. |
| 01/01/2014 | Document updated with literature review. Coverage unchanged. CPT/HCPCS code(s) updated. |
| 08/15/2011 | Document updated with literature review. Coverage language changed as follows: Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material are considered experimental, investigational and unproven for all indications including, but not limited to, repair of anal and rectal fistulas. Complete revision of description and rationale. Codes updated. |
| 05/01/2009 | Revised/updated entire document |
| 02/15/2007 | New medical document |