Regence

Medical Policy Manual Surgery, Policy No. 175

Plugs for Enteric and Anorectal Fistula Repair

Effective: September 1, 2026

Next Review: May 2027
Last Review: July 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Fistula plugs are anchored in the fistulae (abnormal openings, usually in the intestine or anus) to provide scaffolding for new tissue growth, aiming to promote healing and fistula closure. The plug is absorbed into the body in six to eight weeks.

MEDICAL POLICY CRITERIA

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

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

ENTERIC FISTULA

Enteric fistulas are an abnormal passage between the gastrointestinal (GI) tract and other abdominal organs, the chest, or skin. Eighty-five percent of enteric fistulas occur following surgery; 20% to 30% are in patients with Crohn's disease; other causes include infectious diseases, malignancy, radiation therapy, and ulcer.[1] Symptoms associated with fistulas vary depending on anatomical location, and may be accompanied by infection; one fourth of mortality from fistulas occurs as a result of infection and related sepsis. Internal or external enteric fistula are classified based upon whether they drain externally to the skin or internally to the gastrointestinal tract or other organ (e.g., bladder, vagina), and with respect to which segment(s) of bowel is involved.[2] Anorectal fistula are detailed in a separate section below.

Successful treatment of enteric fistulae includes control and maintenance of drainage, appropriate treatment of infection and avoidance of sepsis, and adequate nutrition. Fistula involved with the GI tract often resolve with no surgical intervention; with appropriate initial treatment approximately one-third of enteric fistulas heal spontaneously, however, most exposed fistulas (enteroatmospheric) will not.[1] External fistulas require management of fluid output, which may include bag drainage, pharmacologic therapy, and negative pressure wound therapy. Deep, exposed fistula may require immediate surgery to cover exposed bowel sections, and patients with any enteric fistula who have not responded to five to six weeks of nonoperative treatment are likely to require surgery. Surgical techniques may include resecting the segment of bowel containing the fistula, then reestablishing GI continuity. In addition to closing the fistula opening, the goal of surgical management of enteric fistula is to close the abdominal wall, which may include flap techniques. Complete resection may not be possible in patients with short bowel syndrome, whereas patients with Crohn's disease require complete fistula resection in addition to adjacent diseased bowel to prevent future recurrence.

ANAL FISTULA

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 into 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.[3]

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 trans-sphincteric, 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 ano-rectal sling). The repair of high fistulas can be associated with incontinence. Diagnosis may involve fistula probe, anoscopy, fistulography, ultrasound, or magnetic resonance imaging (MRI).

Treatment for anal fistula is aimed at repairing the fistula without compromising continence. Surgical treatments include fistulotomy/fistulectomy, endorectal/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 carries the risk of incontinence. A seton is a thread placed through the fistula tract to drain the 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 LIFT technique involves identifying the intersphincteric plane and then dividing the fistula tract; its use has been reported in two studies, but long-term follow-up is unavailable.[4, 5] 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 overgrowth of new tissue.

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. A fistula plug derived from autologous cartilage tissue has been investigated in a small (n=10) pilot study.[6]

REGULATORY STATUS

The following table includes examples of fistula plugs that have received U.S. Food and Drug Administration (FDA) 510(k) approval.

Device name (FDA no.), FDA product code	Company	Date approved
SIS Fistula Plug (K050337), FTM	Cook Biotech Inc.	3/9/2005
Surgisis RVP Recto-Vaginal Fistula Plug (K062729), FTM	Cook Biotech Inc.	10/10/2006
Surgisis Biodesign Enterocutaneous Fistula Plug (K082682), FTM	Cook Biotech Inc.	2/27/2009
GORE® BIO-A® Fistula Plug (K083266), FTL	W.L. Gore & Associates, Inc.	3/27/2009
Biodesign Enterocutaneous Fistula Plug (K150668), FTM	Cook Biotech Inc.	12/09/2015

EVIDENCE SUMMARY

ENTERIC FISTULA

Initial treatment for enteric fistulas includes nutritional therapy, treatment of infection, and for external fistulas, controlling drainage. When fistulas do not close following initial measures, surgical treatment becomes necessary. The surgical procedure will vary based on the fistula classification, and depending on the indication, a gold-standard procedure might not exist. The majority of the evidence for the use of biosynthetic fistula plugs focuses on anal fistulae, which is detailed in the next section. Other publications on the use of fistula plugs as a treatment for enterocutaneous fistulae (non anal/rectal) are limited to a small number of nonrandomized studies.

Nonrandomized Studies

Darrien and Kasem (2014) published a case series on seven patients with gastrocutaneous fistulas, unfit for surgical repair, who underwent repair with a Surgisis® (Cook Biotech Inc.) fistula plug between November 2008 and January 2010.[7] All patients had fistulae which failed to heal following previous conservative management, and showed no radiological or clinical

evidence of tissue disease at the site of the fistula, ongoing sepsis, or distal obstruction. Four patients had non-healing gastrostomies; the other fistulae were a result of anastomotic leak following oesophagectomy and distal gastrectomy. Five patients underwent direct repair under local anesthesia; fistula output ceased at a median of day twelve, and none of the five cases have had fistula recurrence at 30 to 59 months follow-up. Two patients underwent endoscopic repair; fistula output ceased immediately, and neither of the two cases had fistula recurrence at 30 to 59 months follow-up. While this case series demonstrates successful fistula closure, durable for at least two years, this is a highly selective group of patients with no comparative group.

Other studies are limited to case reports in duodenocutaneous fistula treated with a Biodesign enterocutaneous fistula plug (Cook Biotech Inc.)[8]; multiple complex gastro-bronchial fistulae[9]; enteroatmospheric fistulae treated with silicone fistula plug in conjunction with negative pressure wound therapy[10]; enterocutaneous fistula following stab wound[11]; and a persistent gastrocutaneous fistula treated with a porcine anal fistula plug[12].

ANAL FISTULA

Conventional treatments for anal fistulas include fistulotomy/fistulectomy, endorectal/anal sliding flaps, seton drains, and fibrin glue. Evidence from randomized controlled trials (RCTs) are necessary to establish how fistula plugs compare with conventional treatment on outcomes including safety, healing, fistula recurrence, and sphincter function. Evidence from RCTs as well as nonrandomized studies on outcomes of anal fistula plug (AFP) procedures are limited overall in quantity and quality.

Systematic Reviews

An (2023) published a systematic review and meta-analysis comparing anal fistula plug to endoanal advancement flap.[13] Outcomes of interest were healing rate, recurrence rate, wound infection rate, and complication rate. A total of 12 studies were included of which five were RCTs and seven were nonrandomized studies. The included studies involved 847 people; 341 treated with anal fistula plug and 506 treated with endoanal advancement flap. Endoanal advancement flap was found to have a better healing rate (p=0.03) The difference in recurrence rate was not significant (p=0.17). The difference in wound infection rate was also not significant (p=0.07). The rates of several complications were assessed and stratified by grade. There was no significant difference in grade I-II complications (p=0.25), grade III-IV complications (p=0.46), or the pooled result of all grades of complications (p=0.77) High heterogeneity in multiple measures was noted. The authors concluded that neither procedure is clearly superior, but endoanal advancement flap may be preferable to anal fistula plug due to the higher healing rate.

Cheung (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.[14] 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, two studies (van Koperen 2011,[15] and Ortiz 2009,[16] 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=0.03). No difference in incontinence scores between groups was noted.

A systematic review published by Lin (2019) compared AFP to rectal advancement flap (RAF) for patients with complex cryptoglandular anal fistulas.[7] The review included 11 studies, four of which were RCTs, and a total of 810 patients. A pooled analysis of all studies showed no significant differences between treatments for healing rate, recurrence rate, and incidence of complications. However, when analysis was restricted only to studies with long-term follow-up, RAF was associated with a higher healing rate (OR 0.32, 95% CI 0.13 to 0.78, p=0.01, and lower recurrence rate (OR 4.45, 95% CI 1.45 to 13.65) compared with AFP.

Narang (2016) published a systematic review of the Gore Bio-A plug for anal fistulas, which included six studies (total n=221 patients) in a qualitative synthesis.[17] Fistula healing rates ranged from 15.8% to 72.7% at 2 to 19 months follow-up. Of the 187 patients included in the review, 16 (8.5%) experienced early or delayed plug extrusion, and 11 (5.8%) experienced deterioration in continence. Reviewers assessed the overall quality of the underlying studies as poor. Meaningful conclusions cannot be drawn from the small number of included studies, limited follow-up duration, and noncomparative nature of the studies presented.

Nasseri (2016) reported on a systematic review of AFP for patients with Crohn disease and anal fistulas.[5] Twelve studies were included: eight nonrandomized prospective studies and four retrospective studies (total n=84 patients, range 1 to 20 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 (2016) reported on a meta-analysis of comparative studies of AFPs and mucosal advancement flaps for complex anal fistulas, which included 10 studies (total n=778).[6] Three studies were randomized trials; the remaining were observational studies or did not describe designs. In pooled analysis, there were no significant differences in healing rates at the end of follow-up between the AFP and mucosal advancement flap groups (odds ratio [OR] 0.79, 95% CI 0.36 to 1.73, p=0.55, I^2=74%). None the seven 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.

Cirocchi (2013) published results of a systematic review with meta-analysis of studies that compared biologically derived products for fistula repair, including fibrin glue, AFPs, and acellular dermal matrix, with surgical therapy for fistula repair.[18] Seven studies were considered eligible for their evidence review, four of which included comparisons of AFPs with surgery, and two of which were RCTs,[15, 16] described below). In a combined analysis, AFP placement was not significantly different than surgical treatment in terms of rates of healing (pooled risk ratio [RR] 1.19, 95% CI 0.51 to 2.76). Recurrence of anal fistulas was not significantly different between patients treated with AFP compared with those treated with surgery, although the confidence interval for the pooled analysis was very wide (pooled OR 3.12, 95% CI 0.52 to 18.83).

In 2012, three systematic reviews were published comparing AFP to conventional surgical treatments for anal fistulas.[19-21] The reviews reported either no difference between groups or a higher rate of recurrence in the AFP group. In addition, authors pooled data from RCTs and retrospective studies which may have compromised conclusions reached in all three reviews.

Randomized Controlled Trials

The pragmatic, multicenter, randomized FIAT trial, published by Jayne (2019 and 2021) compared the safety and efficacy of the Surgisis® anal fistula plug to the surgeon’s choice of

treatment (e.g., fistulotomy, cutting seton, ligation of intersphincteric fistula tract [LIFT], or advancement flap) at hospitals in the United Kingdom between 2011 and 2016.[9, 22] A total of 304 patients were included in the study, with 152 in each group. The primary outcome assessed was the quality of life as measured by the Faecal Incontinence Quality of Life (FIQoL) questionnaire at 12 months following treatment. No difference was seen in this outcome. The 12-month healing rates varied between procedures: 55% for fistula plug, 64% for cutting seton, 75% for fistulotomy, 53% for advancement flap and 42% for LIFT. 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 six weeks (49/142, 35% vs 25/137, 18%; p=0.002).

Senejoux (2016) published an RCT comparing AFP to seton removal alone in 106 patients who had Crohn's disease with non- or mildly-active disease but at least one anoperitoneal fistula drained for at least one month.[23] The trial was powered for superiority of AFP, and analysis was intention-to-treat. At 12 weeks of follow-up, there was no significant difference in clinical remission rates between the AFP group (n=54) and the control group (n=52), which were 31.5% and 23.1%, respectively (RR 1.31, 95% CI 0.59 to 4.02, p=0.19). Fistula tract healing rates on magnetic resonance imaging also did not differ significantly between groups at 12 weeks.

Ortiz (2009) compared use of porcine submucosal (Surgisis) anal fistula plug (AFP) with an endorectal anal flap (ERAF) procedure in an RCT with 43 patients who had high anal fistula.[16] The primary endpoint 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 six 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 recurrences in the fistula plug group led to premature closure of the trial. After one year, fistula recurrence was seen in 12 of 15 patients treated with an anal fistula plug versus 2 of 16 patients who underwent the flap procedure (RR 6.40 95% CI 1.70 to 23.97, p<0.001). Fistulas recurred in 9 of 16 patients who had previously undergone fistula surgery; 8 of the 9 patients had an AFP. A trend for more sphincter involvement and more females in the ERAF group was noted. Complications were not reported in this paper.

Van Koperen (2011) reported on a double-blinded multicenter randomized trial comparing anal fistula plug with mucosal advancement flap in 60 patients with high perianal fistulas.[15] The authors reported results at 11 months in both treatment groups with fistula recurrence in 22 patients (71%) in the anal plug group and 15 patients (52%) in the advancement flap group; these rates were not significantly different (p=0.126). Postoperative pain scores, quality of life after surgery and functional outcomes were not significantly different between groups. Despite disappointing results, the authors indicated the plug might be considered as an initial treatment option because the plug procedure is simple and minimally invasive.

Nonrandomized Studies

Nonrandomized studies in patients with anal fistulas (including transsphincteric fistulas, and fistulas with and without inflammatory bowel disease) comparing AFP with fistulotomy, ligation of the intersphincteric fistula tract (LIFT) technique, endorectal advancement flap, fibrin glue, draining seton, and cutting seton have been reported in single-center and multi-center settings.[1, 24-30] Follow-up has ranged from 12 weeks to median of 819 days. Though non-differing complication rates have been reported between AFP and conventional procedure

groups, healing rates have been reported with wide, and non-statistically significant confidence intervals (suggesting underpowered studies), and in heterogeneous patient groups. The remainder of the published evidence for anal fistula plug consists of case series, most with small numbers of subjects, and studies which did not compare fistula plug to conventional treatment options.[8, 31-42] Authors have repeatedly called for longer term and larger RCTs to fully evaluate the utility of AFP for the treatment of anal fistula.

PRACTICE GUIDELINE SUMMARY

AMERICAN SOCIETY OF COLON AND RECTAL SURGEONS

The American Society of Colon and Rectal Surgeons published updated recommendations for the management of anorectal abscess, fistula-in-ano, and rectovaginal fistula in 2022.[43] The guideline states that anal fistula plugs and fibrin glue are relatively ineffective treatments for fistula-in-ano, primarily due to early plug failure and poor healing rates.

SUMMARY

There is not enough research to show that the use of anal fistula plugs and non-anal enteric fistula treatments improve health outcomes. The current research reports a wide range of results and does not demonstrate that anal fistula plugs improve healing rates or reduce recurrence. No practice guidelines recommend the use of these plugs for any indication. Therefore, biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material, are considered investigational for the repair of enteric and anal fistulas.

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CODES

Codes	Number	Description
CPT	46707	Repair of anorectal fistula with plug (e.g., porcine small intestine mucosa [SIS])
	44799	Unlisted procedure, small intestine
	45499	Unlisted laparoscopy procedure, rectum
	58999	Unlisted procedure, female genital system (nonobstetrical)
HCPCS	None	

Date of Origin: *August 2010*