MEDICAL POLICY

Excellus
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Medical Policy Title	**Plugs for Fistula Repair**
Policy Number	**7.01.86**
Current Effective Date	**February 19, 2026**
Next Review Date	**February 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa (SIS) or of synthetic material, are considered **investigational** for all indications, including, but not limited to, the repair of anal and rectal fistulas.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational

11.01.27 New/Emerging Technology and Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

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. 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.

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. When the abscess opens spontaneously into the anal canal (or has been opened surgically), a fistula may occur. 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.

SUPPORTIVE LITERATURE

Overall, the evidence of efficacy of anal fistula plug (AFP) treatment is limited and is insufficient to determine that the technology results in an improvement in net health outcomes. Early randomized controlled trials (RCTs) did not show improved healing, recurrence rates, or functional outcomes with AFP compared with established surgical approaches such as advancement flap repair (Van Koperen 2008; Ortiz 2009). Nonrandomized comparative studies likewise failed to show benefit and generally favored advancement flap or demonstrated no meaningful difference between procedures (Christoforidis 2009; Wang 2009). Systematic reviews of this early evidence identified substantial heterogeneity and frequently noted higher recurrence with AFP when direct comparisons were available (Garg 2010). Numerous case series (e.g., Ellis 2010; Champagne 2006; Gonsalves 2009) reported widely variable healing rates without control groups, limiting conclusions regarding long-term efficacy and functional outcomes. Collectively, these early data do not support improved net health outcomes with AFP use, and well-designed RCTs with adequate follow-up remain necessary to establish comparative effectiveness.

Jayne et al (2021) conducted the FIAT randomized controlled trial comparing porcine AFPs (Biodesign Surgisis) with surgeon's choice of procedure (e.g., advancement flap, cutting seton, fistulotomy, or LIFT) in 304 adults with transsphincteric fistulas. At 12 months, clinical healing rates were similar between groups: 54% in the AFP arm (66/122) versus 55% in the surgeon's preference arm (66/119). No significant differences were observed in fecal incontinence quality-of-life measures, and both groups showed only marginal improvements in continence. However, AFP recipients experienced significantly earlier postoperative complications (at 6 weeks) and underwent more frequent reinterventions overall. The authors concluded that AFPs offered no clinical advantage over conventional surgical management.

Cheung et al (2021) performed a systematic review and meta-analysis of 28 studies evaluating surgical management of non-Crohn-related perianal fistulas. Primary outcomes included fistula recurrence and fecal incontinence. Due to substantial heterogeneity across comparison groups and study designs, pooled analysis across all procedures was not feasible. Among the subset of randomized trials, both RCTs comparing AFP with advancement flap demonstrated higher recurrence rates with AFP. Pooled recurrence outcomes favored advancement flap repair (odds ratio < 1), while no significant differences were identified in postoperative fecal incontinence. The review concluded that evidence supporting AFP is weak relative to established surgical options.

An et al (2023) conducted a systematic review and meta-analysis comparing AFP with EAFR for complex anal fistulas, including 12 studies (4 RCT and 7 nonrandomized trials; n = 847). Pooled healing rates were significantly higher with EAFR (64.4%) than with AFP (48.3%; p = 0.03). No

significant differences were observed between groups for recurrence, wound infection, or overall complication rates. The authors concluded that available evidence favors EAFR over AFP, though additional high-quality RCTs are needed.

Harsanyi et al (2025) conducted the first-in-human, prospective, multicenter evaluation of the BioHealx-assisted fistula treatment (BAFT) procedure for non-branching transsphincteric cryptoglandular anal fistulas. The single-arm study enrolled 32 adults across three Hungarian centers, using the BioHealx implant, a novel bioabsorbable helical coil implant, designed to achieve compression-based closure of the fistula tract alongside distal fistulectomy. At a medium-term follow-up of 12–40 months, 84.4% (27/32) of patients achieved primary fistula healing with no recurrence, and no device-related complications were reported. Fecal continence quality-of-life scores remained stable or improved in 96.8% of patients, indicating effective healing with continence preservation. Limitations of this pilot study include the small sample size and lack of comparison group. Overall, the authors concluded that the BAFT procedure demonstrated high healing rates, low complication risk, and favorable functional outcomes, supporting its potential as a sphincter-preserving option for transsphincteric fistula-in-ano.

PROFESSIONAL GUIDELINE(S)

In 2022, the American Society of Colon and Rectal Surgeons (ASCRS) practice guidelines on the treatment of anorectal abscess, fistula-in-ano, and rectovaginal fistula recommended (Gaertner 2022):

- Anal fistula plug and fibrin glue are relatively ineffective treatments for fistula-in-ano (strong recommendation, level 1B evidence).
- Local administration of mesenchymal stem cells is a safe and effective treatment for selected patients with refractory anorectal fistulas in the setting of Crohn's disease (weak recommendation, level 2B evidence.

In 2019, the National Institute for Health and Care Excellence (NICE) determined that "current 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." The issued guidance notes that the procedure should only be done by a surgeon experienced in managing anal fistulas.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates fistula plugs as a medical device. All fistula plugs require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jan 22].

The FDA lists the most serious type of medical device recalls and early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2026 Jan 22].

Several fistula plugs have been cleared for marketing through the FDA 510(k) premarket notification process:

- SIS Fistula Plug (Cook Biotech Incorporated) was cleared in March 2005 for repair of anal, rectal, and enterocutaneous fistulas.
- Surgisis RVP Recto-Vaginal Fistula Plug (Cook Biotech), made from porcine SIS, was cleared in October 2006. It is designed to reinforce soft tissue to repair rectovaginal fistulas using a tapered configuration with a button to increase plug retention and improve fistula blockage.
- Surgisis Biodesign Enterocutaneous Fistula Plug (Cook Biotech), made from porcine SIS, was cleared in February 2009. Designed to reinforce soft tissue and repair enterocutaneous fistulas, the tapered body and flange increase plug retention and improve fistula blockage.
- GORE BIO-A Fistula Plug (W.L. Gore & Associates) received clearance in March 2009 to reinforce soft tissue to repair anorectal fistulas. The surgical mesh is composed of a porous structure of synthetic, bioabsorbable PGA/TMC copolymer fiber and not derived from animal or human tissue.
- Biodesign Anal Fistula Plug (Cook Biotech) was cleared in May 2016 to reinforce soft tissue where a rolled configuration is required to repair anal, rectal, and enterocutaneous fistulas.
- BioHealx Anal Fistula Device (Signum Surgical) was granted FDA De Novo clearance in July 2024. This single-use, synthetic, bioabsorbable polymer implant is indicated for closure of the internal opening of mature, cryptogenic, transsphincteric, non-branching fistulas.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
46707 (E/I)	Repair of anorectal fistula with plug (e.g., porcine small intestine mucosa [SIS])

HCPCS Codes

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

ICD10 Codes

Code	Description
J86.0	Pyothorax with fistula
K50.013	Crohn's disease of small intestine with fistula
K50.113	Crohn's disease of large intestine with fistula
K50.813	Crohn's disease of both small and large intestine with fistula
K50.913	Crohn's disease, unspecified, with fistula
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.213	Ulcerative (chronic) proctitis with fistula
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.413	Inflammatory polyps of colon with fistula
K51.513	Left sided colitis with fistula
K51.813	Other ulcerative colitis with fistula
K51.913	Ulcerative colitis, unspecified with fistula
K60.3 - K60.5	Anal rectal fistulas (code range)
K63.2	Fistula of intestine
N32.1	Vesicointestinal fistula
N32.2	Vesical fistula, not elsewhere classified
N82.2 - N82.4	Female intestinal-genital tract fistula (code range)

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CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Repair of anal fistula with a fistula plug is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do

not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
07/19/12, 06/20/13, 05/22/14, 04/16/15, 03/17/16, 03/16/17, 03/15/18, 03/21/19, 02/20/20, 02/18/21, 02/17/22, 02/16/23, 02/22/24, 02/20/25, 02/19/26	
Date	**Summary of Changes**
02/19/26	• Annual review, policy intent unchanged.
02/20/25	• Annual review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
08/18/11	• Original effective date