BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Plugs for Anal Fistula Repair

Policy #: 399
Category: Surgical

Latest Review Date: November 2020
Policy Grade: A

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

For dates of service on or after March 24, 2020:

Blue Advantage will treat **biosynthetic fistula plugs**, including plugs made of porcine small intestine submucosa or of synthetic material as a **non-covered** benefit and as **investigational** for the repair of anal fistulas.

Effective for dates of service on or after February 26, 2018 through March 23, 2020, refer to LCD L36954

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat **biosynthetic fistula plugs**, including plugs made of porcine small intestine submucosa or of synthetic material as a **non-covered** benefit and as **investigational** for the repair of anal fistulas.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Anal fistula plugs (AFPs) are biosynthetic devices used to promote healing and prevent the recurrence of anal fistulas (fistula-in-ano). 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 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.

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 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 trans-sphincteric, intersphincteric, suprasphincteric, or extrasphincteric. More simply, anal fistulas are described as low (present distally and not extending up to anorectal sling) or high (extending up to or beyond the ano-rectal sling). The repair of high fistula can be associated with incontinence. Diagnosis may involve fistula probe, anoscopy, fistulography, ultrasound, or magnetic resonance imaging.

Treatment
Treatment is aimed at repairing the fistula without compromising continence.

Surgical treatments for anal fistulas include fistulotomy/fistulectomy, endorectal/anal sliding flaps, ligation of the intersphincteric fistula tract (LIFT) technique, Seton drain, and fibrin glue. Fistulotomy involves a division of the tissue over the fistula and lying 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 for the purpose of draining 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 the 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 small studies, but long-term follow-up is unavailable. Fibrin glue is a combination of fibrinogen, thrombin, and calcium in a matrix, which is injected into the fistula tract. 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. Several fistula plugs have been cleared for marketing by the U.S. Food and Drug Administration (FDA).

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

KEY POINTS:
The most recent literature search was performed for the period through August 20, 2020.

Summary
For individuals who have anal fistulas who receive placement of anal fistula plugs (AFP), the evidence includes 4 randomized comparative trials (RCTs), a number of comparative and

noncomparative nonrandomized studies, and systematic reviews of these studies. The relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, and treatment-related morbidity. Two RCTs comparing AFP with surgical flap treatment reported disparate findings: one reported significantly higher rates of fistula reoccurrence with AFP, while the other found similar rates of reoccurrence between AFP and surgical treatment. Another RCT compared AFP with seton drain removal alone for patients with fistulizing Crohn disease, with 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 studies of AFP repair of anal fistulas demonstrate a wide range of success rates and heterogeneity in study results. Nonrandomized studies have also reported conflicting results. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American Society of Colon and Rectal Surgeons

The 2017 practice guidelines on the management of anal fistulas from the American Society of Colon and Rectal Surgeons did not evaluate the use of plugs for anal fistula repair.

The 2016 practice guidelines for the treatment of anorectal abscess, fistula-in-ano, and rectovaginal fistula from the American Society of Colon and Rectal Surgeons provided a weak recommendation with moderate-quality evidence. With recent evidences of success rate of less than 50% in most studies for treatment of complex anal fistulas with an anal fistula plug the guidelines concluded that the fistula plug is relatively ineffective in treatment of fistula-in-ano.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2019) published an updated guidance on the suturable bioprosthetic plug. The Institute determined that evidence 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."

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Biosynthetic fistula plugs, SIS Fistula Plug, modified SIS Fistula Plug, GORE BIO-A Fistula Plug, porcine small intestine submucosa plugs, synthetic fistula plug, suturable bioprosthetic plug, anal fistula plug, fistula plug, LIFT technique, SURGISIS soft Tissue Graft, STRATASIS Urethral Sling

APPROVED BY GOVERNING BODIES:

Several plugs for anal fistula repair have received clearance for marketing from 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 Inc.)	March 2005	Manufactured from porcine SIS	Repair of anal, rectal, and enterocutaneous fistulas	SURGISIS® Soft Tissue Graft (Cook Biotech Inc.) STRATASIS® Urethral Sling (Cook Biotech Inc.)	FTM
Surgisis RVP Recto-Vaginal Fistula Plug (Cook Biotech Inc.)	Oct. 2006	Manufactured from porcine SIS Tapered configuration with a button to provide increased plug retention and improved blockage of the fistula	Reinforce soft tissue for the repair of rectovaginal fistulas	SIS Fistula Plug (Cook Biotech Inc.)	FTM
Surgisis Biodesign Enterocutaneous Fistula Plug (Cook Biotech, Inc.)	Feb. 2009	Manufactured from porcine SIS Tapered configuration with a flange to provide increased retention of the plug and improved blockage of the fistula	Reinforce soft tissue for the repair of enterocutaneous fistulas	SIS Fistula Plug (Cook Biotech Inc.)	FTM

Gore Bio-A Fistula Plug (W.L. Gore & Associates Inc.)	Mar. 2009	Manufactured from bioabsorbable polyglycolide-co-trimethylene carbonate (PGA:TMC) copolymer Supplied in a 3-dimensional configuration of a disk with attached tubes	Reinforce soft tissue for the repair of anorectal fistulas	Gore Bioabsorbable Mesh (W.L. Gore & Associates Inc.) SIS Fistula Plug (Cook Biotech Inc.)	FTL
Biodesign Anal Fistula Plug (Cook Biotech)	May 2016	Manufactured from porcine SIS Additional wash steps have been added in processing	Reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal and enterocutaneous fistulas	SIS Fistula Plug (Cook Biotech)	FTM

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

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CODING:

CPT Codes:

46707	Repair of anorectal fistula with plug (e.g. porcine small intestine mucosa [SIS])

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POLICY HISTORY:

Adopted for Blue Advantage, January 2010
Available for comment January 26-March 11, 2010
Medical Policy Group, January 2012
Medical Policy Group, June 2012
Medical Policy Group, November 2013
Medical Policy Group, October 2014
Medical Policy Group, September 2015
Medical Policy Group, November 2016
Medical Policy Group, November 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated effective March 24, 2020.