Name of Policy: 
Plugs for Anal Fistula Repair

Policy #: 399       Latest Review Date: November 2016
Category: Surgical       Policy Grade: A

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Anal fistula plugs (AFPs) are biosynthetic devices used to promote healing and prevent recurrence of anal fistulas (fistula-in-ano). The conical shaped plug is anchored in the anal fistula and acts as a scaffold into which new tissue can grow to close the fistula. The plug is absorbed into the body in 6 to 8 weeks. The procedure may require 12-24 hours observation post-operatively. The procedure can be repeated in case of failure. AFPs 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, 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.

Fistula Repair
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 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 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 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. 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.

**Policy:**
**Biosynthetic fistula plugs**, including plugs made of porcine small intestine submucosa or of synthetic material do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational for the repair of anal fistulas.

_Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate 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._

**Key Points:**
The most recent literature search was performed for the period through November 3, 2016.

Conventional treatments for anal fistulas include fistulotomy/fistulectomy, endorectal/anal sliding flaps, Seton drains, and fibrin glue. Evidence for new treatments must allow comparison with conventional treatment on outcomes including symptoms, change in disease status, morbid events, functional outcomes (i.e., sphincter function), and treatment-related morbidity (i.e. fistula recurrence).

**Systematic Reviews**
At least 9 systematic reviews have been undertaken on anal fistula plugs.

_In 2016, Narang et al published a systematic review of the Gore Bio-A plug for AFP, which included 6 studies (n=221) in a qualitative synthesis. Fistula healing rates ranged from 15.8% to 72.7%. The authors assessed the overall quality of the underlying studies as poor._
In 2016, Nasseri et al reported on a systematic review of AFP for patients with Crohn disease with anal fistulas. Twelve studies were included, 8 nonrandomized prospective studies and 4 retrospective studies, with total of 84 patients (n=1-20 per study). Due to study heterogeneity, authors did not perform a weighted analysis with summary efficacy estimates. The total success rate of AFP was 49/84 (58.3%, 95% confidence interval [CI] 47 to 69%).

Also in 2016, Xu et al reported on a systematic review and meta-analysis of comparative studies of AFP and mucosal advancement flaps for complex anal fistulas, which included 10 studies (n=778). Three of the studies were randomized trials; the remaining were observational studies or did not describe their methods. In pooled analysis, there were no significant differences in healing rate at the end of follow up between AFP and mucosal advancement flap groups: odds ratio (OR) 0.79, 95% CI 0.36 to 1.73 P=0.55, I²=74%. Of the 7 studies reporting on recurrence rates, there were no significant differences in recurrence rates: OR 2.29, 95% CI 0.59 to 8.88, P=0.23, I²=83%. However, the conclusions are limited by limitations in the underlying evidence base.

In 2013, Cirocchi et al published results of a systematic review and 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. Seven studies were considered eligible for their evidence review, 4 of which included comparisons of AFPs with surgery, and 2 of which were RCTs (Ortiz 2009 and van Koperen 2011, described next). In combined analysis, AFP placement was not significantly different than surgical treatment in terms of rates of healing (pooled risk ratio [RR], 1.19; 95% confidence interval [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 odds ratio [OR], 3.12; 95% CI, 0.52 to 18.83).

In 2012, 3 reviews were published comparing AFP to conventional surgical treatment for anal fistulas. Pu and colleagues undertook a meta-analysis of 5 studies (2 RCTs and 3 retrospective studies) published through April 2012. Treatment options in the conventional arm of this review included endorectal/mucosal advancement flaps, fibrin glue, and Seton drains. The 2 RCTs included in this analysis (Ortiz, 2009; van Koperen, 2011) are discussed below under randomized controlled trials. On combined analysis, AFP patients had a higher recurrence rate (62%) compared to those undergoing conventional treatment options (47%) after 3 months of follow-up (5 studies, 428 patients; p=0.004, OR= 1.91; 95% CI 1.23-2.97).

Leng and Jin undertook a meta-analysis of 6 studies published through April 2011 (3 RCTs, 2 retrospective studies, and 1 cohort study) involving 408 patients comparing AFP with mucosal advancement flap (MAF). Two of the RCTs in this analysis were included in the review by Pu and colleagues above; the third RCT was a Chinese trial of 90 patients comparing AFP (manufactured in China and similar in design to the SURGISIS®) to the MAF. On combined analysis, the differences in the overall success rates (6 studies) and incidence of fistula recurrence (4 studies including 3 RCTs) were not statistically significant between the AFP and MAF (risk difference [RD]: -0.12; 95% CI: -0.39 - 0.14; RD: 0.13; 95% CI: -0.18 - 0.43, respectively). The risk of continence postoperatively (3 studies including 2 RCTs), however, was reported to be lower with AFP (RD: -0.08; 95% CI: 0.15 to -0.02). In addition to the small
numbers of controlled studies and limited follow-up, the findings of this meta-analysis were further limited by significant heterogeneity across studies.

O’Riordan and colleagues undertook a systematic review of AFP (20 studies including 2 RCTs by Ortiz and van Koperan) for patients with Crohn’s and non-Crohn’s-related anal fistulas. The follow-up period across studies ranged from 3 months to 24.5 months. The pooled proportion of patients achieving fistula closure in patients with non-Crohn’s anal fistula was 0.54 (95% CI: 0.50-0.59). The proportion achieving closure in patients with Crohn’s disease was similar (0.55, 95% CI: 0.39-0.70). There were no reported cases of any significant change in continence after AFP insertion in any of the study patients (n=196). The findings of this systematic review are limited by the variability of operative technique and perioperative care across studies, which may influence the probability of success or failure associated with the AFP.

A 2010 systematic review reports a wide range of success rates. In the 12 case series included in the review, reported success rates for the AFP procedure ranged from 24% to 92%. Success rates in treating complex fistula-in-ano in the 8 prospective studies reviewed were 35% to 87%. The complications of abscess formation and/or sepsis ranged from 4% to 29%, and plug extrusion ranged from 4%-41%.

In a Cochrane review of surgical intervention for anorectal fistula, Jacob and colleagues found few randomized trials comparing procedures for surgical repair. Anal fistula plug was 1 procedure noted as needing further study with randomized trials.

Section Summary: Systematic Reviews
Several systematic reviews of studies of AFP repair of anal fistulas demonstrate a wide range of success rates and heterogeneity in study results. The net benefit of a strategy using AFP compared with open surgical repair is a lack of high-quality trials and uncertainty related to the tradeoff between a less invasive procedure and a higher fistula reoccurrence rate.

Randomized Controlled Trials
In 2016, Senejoux et al reported on an RCT comparing AFP with seton removal alone in 106 patients with Crohn disease with non- or mildly-active disease but at with at least 1 ano-peritoneal fistula drained for at least 1 month. The study was powered for superiority of AFP, and analysis was intention-to-treat. At 12 weeks of follow up, in the AFP group (n=54), clinical remission rates were 31.5%, compared with 23.1% in the control group (RR 1.31, 95% CI 0.59 to 4.02, P=0.19). Fistula tract healing rates on MRI did not differ significantly between groups at 12 weeks.

Ortiz and colleagues, compared use of porcine submucosal (Surgisis) AFP with an endorectal anal flap (ERAF) procedure in an RCT with 43 patients with high anal fistula. 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 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 recurrences in the fistula plug group led to 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
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 and colleagues reported on a double-blinded, multicenter, randomized trial comparing AFP with mucosal advancement flap in 60 patients with high perianal fistulas. At 11 months follow-up, the authors reported fistula recurrence in 22 patients (71%) in the AFP 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.

**Section Summary: RCTs of AFPs**

Two relatively small RCTs have compared AFP with surgical flap treatment for anal fistulas, 1 of which reported significantly higher rates of fistula reoccurrence with AFP and 1 of which found similar rates of reoccurrence between AFP and surgical treatment. Larger RCTs are needed, with longer follow-up, to determine comparative efficacy of AFPs compared with surgical repair. An additional RCT has compared AFP with seton drain removal alone for fistulizing Crohn disease, with no significant difference reported between groups.

**Non-randomized Comparative Studies**

A number of nonrandomized studies have compared AFP with various alternative treatments for anal fistula. In 1 of the larger, prospective studies, Hyman et al reported on prospective, multicenter registry outcomes data to compare a variety of procedures to treat anal fistulas in 245 patients at 13 hospitals. Data were collected as part of a prospective, multicenter outcomes registry created by colorectal surgeons in parts of New England. Fistulotomy was the most frequently performed procedure (n=120) followed by fistula plug (n=43), staged fistulotomy (n=36), Seton drain only (n=21), cutting Seton (n=13), fibrin glue (n=5), and advancement flap (n=4). Three other patients were listed as other or unrecorded. At 1 month and 3 months, 19.5% and 63.2% of patients were healed, respectively. At 3 months, 32% of fistula plug patients were healed in comparison to 87% of fistulotomy, 50% of staged fistulotomy, and 5% of Seton drain-only patients. The authors noted limitations to this registry-based study including concerns about data entry, lack of standardized surgical procedures, and heterogeneity of patients. The 3-month results may also indicate longer healing times may be needed.

Hall et al reported results from another larger study, which reported on a multicenter registry of prospectively-collected data on 240 operations for anal fistula, including those conducted with AFPs. Rates of utilization of fistulotomy, LIFT procedure, advancement flap, AFP placement, draining seton, and cutting seton were 61%, 18%, 6.3%, 4.2%, 8.3%, and 0.83%, respectively. The healing rate for patients treated with AFPs was 20% (95% CI 5 to 50%), compared with 95% after fistulotomy (95% CI 89 to 97%), 79% after LIFT procedure (95% CI 65 to 88%), 100% after cutting seton placement (95% CI 34 to 100%), and 60% after endorectal advancement flap (95% CI 33 to 77%).
Several smaller or retrospective studies have also compared AFP and alternative treatments. Fischer et al reported results of a retrospective study evaluating success rates after AFP (n=31) or endorectal advancement flap (n=40) in patients with anal fistula treated at a single institution from 2007 to 2012. For patients treated after May 2007, the Surgisis anal fistula plug was available. More patients treated with AFP had inflammatory bowel disease (IBD) (29.0% vs 5.0%; P=0.008). During follow-up, 12 (39%) patients treated with AFP and 17 (43%) treated with endorectal advancement flap had fistula recurrence (OR 0.94, 95% CI 0.32 to 2.72, P=1.00). Rates of complications did not differ significantly between groups.

Christoforidis et al performed a retrospective analysis of patients from a U.S. center with transsphincteric fistulas treated with ERAF (n=43) or anal plug (Surgisis) (n=37) between January 1996 and April 2007. Success was defined as closed external opening in absence of symptoms at minimal follow-up of 6 months. The success rate was 63% in the ERAF group and 32% in the in AFP group after a mean follow-up of 56 (range, 6–136) months for ERAF and 14 (range, 6–22) months for AFP. After exclusion of patients with early AFP extrusion, which may be considered a technical failure, the ERAF advantage did not meet statistical 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 prior to the procedure and low response rate in the AFP group prohibit valid comparisons on functional outcomes. Complication rates were low in both groups; 2 patients in the ERAF group required reoperation for bleeding. No serious complications occurred in the AFP group. The authors conclude that “randomized trials are needed to further elucidate the efficacy and potential functional benefit of AFP in the treatment of complex anal fistulas.”

Wang et al compared outcomes of all patients with transsphincteric fistulas treated with AFP from July 2005 to December 2006 (n=29) and compared them with historical controls treated with ERAF (2001–2005) (n=26). 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 the additional treatments for failed initial procedures). Closure rates were 34% for plugs (mean follow-up 279 days [range, 110–690]) and 62% for flaps (median follow-up 819 days [range, 93–1,928]; p=0.045). Complications were not reported. The authors conclude that a systematic randomized trial with long-term follow-up comparing advancement flaps with fistula plugs is needed, and they calculate that 112 patients would need to be randomized to detect a statistically significant difference in success rates for each procedure. Because the fistula plugs are costly, the authors recommend that cost-benefit analysis be performed.

A retrospective study of 232 patients treated in Canada between 1997 and 2008 by a variety of methods for high transsphincteric anal fistulas was reported by Chung et al. Postoperative healing rates at the 12-week follow-up for the fistula plug, fibrin glue, flap advancement, and Seton drain groups were 59.3%, 39.1%, 60.4%, and 32.6%, respectively. The authors conclude that closure of the primary fistula opening using a biologic AFP and anal flap advancement result in similar fistula healing rates in patients with high transsphincteric fistulas and that these strategies are superior to Seton placement and fibrin glue, stating, “Given the low morbidity and
relative simplicity of the procedure, the anal fistula plug is a viable alternative treatment for
patients with high transsphincteric anal fistulas.” The 12-week follow-up time in this study is
likely too short to evaluate the durability of treatment.

Section Summary: Nonrandomized Comparative Studies
Nonrandomized comparative studies report variability in rates of healing after AFP use
compared with other fistula closure methods. These studies are limited by patient heterogeneity
and generally relatively short-term follow up.

Noncomparative Studies
Retrospective and prospective studies have reported on outcomes after AFP placement. Two
larger such noncomparative studies are by Blom et al and Stamos et al.

Stamos et al prospectively evaluated healing rates after treatment with a bioabsorbable AFP
among 93 patients with complex trans-sphincteric anal fistulas. Seventy-three patients (78%)
also received draining setons preoperatively at the surgeon’s discretion. Over 1-year of follow
up, 13 patients were lost to follow up and 21 patients were withdrawn, most often due to need for
an alternative treatment. Of the 66 patients examined 6 months after plug implantation, 30 had a
healed fistula. Of the 55 patients examined 12 months after plug implantation, 36 had a healed
fistula, but plug implantation failed in 18 patients before the 12-month visit. Overall continence
scores improved from baseline (pre-surgery) to 6 months post-surgery.

Blom et al reported results from a retrospective analysis of outcomes after AFP placement (with
the Biodesign plug) at 4 hospitals. The authors identified 126 patients who underwent AFP
placement who were followed over a median of 13 months (range, 1 to 47). At the time of the
last assessment, 30 of 126 patients (24%) had no symptoms indicative of fistula (pain at the
fistula site or drainage). Anterior fistulas were less likely to have successful closure (12%) than
posterior (32%) or lateral (41%) fistulas.

Other studies have reported treatment of very small numbers of patients with rectovaginal
fistulas, endoscopic treatment of postoperative enterocutaneous fistulas after bariatric surgery, a
colocutaneous fistula, and a recurrent tracheoesophageal fistula treated with fistula plug.

Section Summary: Noncomparative Studies of AFPs
Several relatively small, noncomparative studies that evaluated outcomes after AFP demonstrate
a range of fistula reccurrence rates postprocedure. These types of studies provide limited
information about the relative performance of AFP compared with standard treatments for anal
fistulas.

Summary
For individuals who have anal fistulas who receive placement of anal fistula plugs (AFP), the
evidence includes 3 randomized comparative trials (RCTs), a number of comparative and
noncomparative nonrandomized studies, and systematic reviews of these studies. Relevant
outcomes are symptoms, change in disease status, morbid events, functional outcomes, and
treatment-related morbidity. The 2 available 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. An additional 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. Systematic reviews of studies of AFP repair of anal fistulas demonstrate a wide range of success rates and heterogeneity in study results. The body of evidence consists of RCTs and nonrandomized studies that have 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 2011 Practice Parameters for the Treatment of Perianal Abscess and Fistula-in-Ano from the American Society of Colon and Rectal Surgeons gives treatment with an anal fistula plug for complex anal fistulas a weak recommendation. The guidelines note the available evidence is of moderate quality with success rates of less than 50% in the majority of studies.

**National Institute for Health and Care Excellence**  
The National Institute for Health and Care Excellence (NICE) published an updated guidance on the suturable bioprosthetic plug in November 2011. NICE determined that while there are no major safety concerns, evidence on the efficacy of the procedure is not adequate for it to be used without special arrangements for consent and for audit or research. Further, clinicians wishing to perform the procedure are encouraged to enroll patients into the Fistula-In-Ano Trial (FIAT) (Available online at: www.birmingham.ac.uk/research/activity/mds/trials/bctu/trials/coloproctology/fiat/index.aspx). If the clinician chooses to perform the procedure outside of a clinical trial, the clinician should inform the clinical governance leads in their Trust, ensure that patients understand the uncertainty about the procedure’s efficacy and provide patients with clear written information (NICE recommends the information it developed for patients be provided) and audit and review clinical outcomes.

**U.S. Preventive Services Task Force Recommendations**  
Use of anal fistula plugs is not a preventive service.

**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 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

<table>
<thead>
<tr>
<th>Device</th>
<th>Year</th>
<th>Description</th>
<th>Indication(s)</th>
<th>Predicate Device(s)</th>
<th>FDA Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIS Fistula Plug (Cook Biotech Inc.)</td>
<td>March 2005</td>
<td>Manufactured from porcine SIS</td>
<td>Repair of anal, rectal, and enterocutaneous fistulas</td>
<td>SURGISIS® Soft Tissue Graft (Cook Biotech Inc.)</td>
<td>FTM</td>
</tr>
<tr>
<td>Surgisis RVP Recto-Vaginal Fistula Plug (Cook Biotech Inc.)</td>
<td>Oct. 2006</td>
<td>Manufactured from porcine SIS</td>
<td>Reinforce soft tissue for the repair of rectovaginal fistulas</td>
<td>SIS Fistula Plug (Cook Biotech Inc.)</td>
<td>FTM</td>
</tr>
<tr>
<td>Surgisis Biodesign Enterocutaneous Fistula Plug (Cook Biotech, Inc.)</td>
<td>Feb. 2009</td>
<td>Manufactured from porcine SIS</td>
<td>Reinforce soft tissue for the repair of enterocutaneous fistulas</td>
<td>SIS Fistula Plug (Cook Biotech Inc.)</td>
<td>FTM</td>
</tr>
<tr>
<td>Biodesign Anal Fistula Plug (Cook Biotech)</td>
<td>May 2016</td>
<td>Manufactured from porcine SIS Additional wash steps have been added in processing</td>
<td>Reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal and enterocutaneous fistulas</td>
<td>SIS Fistula Plug (Cook Biotech)</td>
<td>FTM</td>
</tr>
</tbody>
</table>

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.
ITS: Home Policy provisions apply
FEP: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Coding:**
CPT Codes:

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

**References:**

Policy History:
Medical Policy Group, December 2009 (2)
Medical Policy Administration Committee, January 2010
Available for comment January 26-March 11, 2010
Medical Policy Group, January 2012 (2): Key Points & References
Medical Policy Panel, May 2012
Medical Policy Group, June 2012 (2): Updated Key Points and References
Medical Policy Panel, September 2013
Medical Policy Group, November 2013 (2): No change to policy statement. Key Points and References updated based on literature search through August 2013
Medical Policy Panel, September 2014
Medical Policy Group, September 2014 (1): Update to Description, Key Points, Key Words, and References. No Policy change.
Medical Policy Panel, September 2015
Medical Policy Group, September 2015 (4): Updates to Description, Key Points, and References. Deleted “and rectal” and “all indications including, but not limited to” from the policy statement.
Medical Policy Panel, November 2016
Medical Policy Group, November 2016 (4): Updates to Key Points, Approved Governing Bodies and References. No change in policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.