

(701123)

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<b>Preauthorization</b>	No	<b>Review Dates:</b> 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 11/15, 11/16, 03/17, 03/18, 03/19, 03/20	

***This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>• With anal fistula(s)</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Placement of anal fistula plug(s)</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Fistulotomy or fistulectomy</li> <li>• Endorectal/anal sliding flaps</li> <li>• Seton drains</li> <li>• Fibrin glue</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Change in disease status</li> <li>• Morbid events</li> <li>• Functional outcomes</li> <li>• Treatment-related morbidity</li> </ul>

### 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.

### SUMMARY OF EVIDENCE

For individuals who have anal fistula(s) who receive placement of AFP(s), the evidence includes three randomized controlled trials, 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. Two randomized controlled trials 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 randomized controlled trial 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. 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 the effects of the technology on health outcomes.

## POLICY

Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material, are considered **investigational** for the repair 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.<sup>1</sup>

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.

### Treatment

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 technique, seton drain, and fibrin glue. Fistulotomy involves a 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 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 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.<sup>2</sup> 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 the 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 (see Regulatory Status section).

A fistula plug derived from autologous cartilage tissue has been investigated in a small (n=10) pilot study.<sup>3</sup>

## REGULATORY STATUS

Several plugs for fistula repair have been cleared for marketing by the U.S. Food and Drug Administration 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	<ul style="list-style-type: none"> <li>Manufactured from porcine SIS</li> </ul>	<ul style="list-style-type: none"> <li>Repair of anal, rectal, and enterocutaneous fistulas</li> </ul>	<ul style="list-style-type: none"> <li>Surgisis® Soft Tissue Graft (Cook Biotech)</li> <li>Stratasis® Urethral Sling (Cook Biotech)</li> </ul>	FTM
Surgisis RVP Recto-Vaginal Fistula Plug (Cook Biotech)	Oct 2006	<ul style="list-style-type: none"> <li>Manufactured from porcine SIS</li> <li>Tapered configuration with a button to increase plug retention and improve fistula blockage</li> </ul>	<ul style="list-style-type: none"> <li>Reinforce soft tissue to repair rectovaginal fistulas</li> </ul>	<ul style="list-style-type: none"> <li>SIS Fistula Plug (Cook Biotech)</li> </ul>	FTM
Surgisis Biodesign Enterocutaneous Fistula Plug (Cook Biotech)	Feb 2009	<ul style="list-style-type: none"> <li>Manufactured from porcine SIS</li> <li>Tapered configuration with flange to increase plug retention and improve fistula blockage</li> </ul>	<ul style="list-style-type: none"> <li>Reinforce soft tissue to repair enterocutaneous fistulas</li> </ul>	<ul style="list-style-type: none"> <li>SIS Fistula Plug (Cook Biotech)</li> </ul>	FTM
Gore Bio-A Fistula Plug (W.L. Gore & Associates)	Mar 2009	<ul style="list-style-type: none"> <li>Manufactured from bio-absorbable PGA:TMC copolymer</li> <li>Supplied in a 3-dimensional configuration of a disk with attached tubes</li> </ul>	<ul style="list-style-type: none"> <li>Reinforce soft tissue to repair anorectal fistulas</li> </ul>	<ul style="list-style-type: none"> <li>Gore Bioabsorbable Mesh (W.L. Gore &amp; Associates)</li> <li>SIS Fistula Plug (Cook Biotech)</li> </ul>	FTL
Biodesign Anal Fistula Plug (Cook Biotech)	May 2016	<ul style="list-style-type: none"> <li>Manufactured from porcine SIS</li> <li>Additional wash steps added in processing</li> </ul>	<ul style="list-style-type: none"> <li>Reinforce soft tissue where a rolled configuration is required to repair anal, rectal, and enterocutaneous fistulas</li> </ul>	<ul style="list-style-type: none"> <li>SIS Fistula Plug (Cook Biotech)</li> </ul>	FTM

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

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**REFERENCES**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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