

Protocol

Plugs for Fistula Repair

(701123)

Medical Benefit		Effective Date: 01/01/11	Next Review Date: 07/15
Preauthorization	No	Review Dates: 09/10, 07/11, 07/12, 07/13, 07/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.** 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.*

Description

Anal fistula plugs (AFP) 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 six to eight weeks. The procedure may require 12–24 hours of observation postoperatively and can be repeated in case of failure.

Background

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, 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. Anal fistulas are described as low (present distally and not extending up to the ano-rectal sling) or high (extending up to or beyond the ano-rectal sling). High fistulas can be associated with incontinence. Diagnosis may involve a fistula probe, anoscopy, fistulography, ultrasound, or magnetic resonance imaging (MRI). Treatment is aimed at repairing the fistula without compromising continence. Treatments include fistulotomy/fistulectomy, endorectal/anal sliding flaps, seton drain, and fibrin glue. Lay-open fistulotomy in high fistulas carries the risk of incontinence. Draining setons can control sepsis, but few patients heal after removal of the seton, and they are poorly tolerated long term. Cutting setons can cause continence disturbances.

The SIS Fistula Plug from Cook Biotech received 510(k) clearance from the U.S. Food and Drug Administration (FDA) in March 2005 based on similarity to predicate devices, including the SURGISIS® Soft Tissue Graft and the STRATASIS® Urethral Sling, both manufactured by Cook Biotech Incorporated. The SIS Fistula Plug is manufactured from porcine small intestinal submucosa (SIS) and is intended for repair of anal, rectal, and enterocutaneous fistulas. The modified SIS Fistula Plug, also manufactured from SIS, is supplied in a tapered configuration with a button to provide increased retention of the plug and improved blockage of the fistula. It received 510(k) clearance in October 2006. In March 2009, W.L. Gore & Associates received 510(k) clearance for the BIO-A® Fistula Plug intended for use in anorectal fistulas. The GORE BIO-A Fistula Plug device comprises a porous structure of synthetic bioabsorbable PGA/TMC copolymer fiber, degraded via a combination of hydrolytic and enzymatic pathways, using the same material, technology, and three-dimensional disk with tubes

mesh design as the predicate GORE Bioabsorbable Mesh hernia plug device. The indications for use and performance of the GORE BIO-A™ Fistula Plug are substantially equivalent to the predicate Cook SIS Fistula Plug.

Policy (Formerly Corporate Medical Guideline)

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

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment 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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9. Christoforidis D, Pieh MC, Madoff RD et al. Treatment of transsphincteric anal fistulas by endorectal advancement flap or collagen fistula plug: a comparative study. Dis Colon Rectum 2009; 52(1):18-22.
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13. National Institutes for Health and Clinical Excellence (NICE). Closure of anal fistula using a suturable bioprosthesis plug. November 2011. Available online at: <http://www.nice.org.uk/nicemedia/live/11331/57184/57184.pdf>. Last accessed May 2013.