FEP 7.01.123 Plugs for Anal Fistula Repair

Effective Date: April 15, 2018

Related Policies: None

Plugs for Anal Fistula Repair

Description

Anal fistula plugs (AFPs) are biosynthetic devices used to promote healing and prevent 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.

FDA 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	• Manufactured from porcine SIS	• Repair of anal, rectal, and enterocutaneous fistulas	• Surgisis® Soft Tissue Graft (Cook Biotech) • Stratasis® Urethral Sling (Cook Biotech)	FTM
Surgisis RVP Recto-Vaginal Fistula Plug (Cook Biotech)	Oct 2006	• Manufactured from porcine SIS • Tapered configuration with a button to increase plug retention and improve fistula blockage	• Reinforce soft tissue to repair rectovaginal fistulas	• SIS Fistula Plug (Cook Biotech)	FTM
Surgisis Biodesign Enterocutaneous Fistula Plug (Cook Biotech)	Feb 2009	• Manufactured from porcine SIS • Tapered configuration with flange to increase plug retention and improve fistula blockage	• Reinforce soft tissue to repair enterocutaneous fistulas	• SIS Fistula Plug (Cook Biotech)	FTM
Gore Bio-A Fistula Plug (W.L. Gore & Associates)	Mar 2009	• Manufactured from bioabsorbable PGA:TMC copolymer • Supplied in a 3-dimensional configuration of a disk with attached tubes	• Reinforce soft tissue to repair anorectal fistulas	• Gore Bioabsorbable Mesh (W.L. Gore & Associates) • SIS Fistula Plug (Cook Biotech)	FTL
Biodesign Anal Fistula Plug (Cook Biotech)	May 2016	• Manufactured from porcine SIS • Additional wash steps added in processing	• Reinforce soft tissue where a rolled configuration is required to repair 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.

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POLICY STATEMENT

Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material, are considered **investigational** for the repair of anal fistulas.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have anal fistula(s) who receive placement of AFP(s), the evidence includes 3 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. Two RCTs 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 RCT, which 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Society of Colon and Rectal Surgeons

The 2016 practice guidelines on 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.[24] With recent evidence of success rates of less than 50% in most studies for the treatment of complex anal fistulas with an anal fistula plug, the guidelines concluded that the fistula plug is relatively ineffective in the treatment of fistula-in-ano.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence updated its guidance on the suturable bioprosthetic plug in 2011.[25] The Institute 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
December 2011	New Policy	

December 2012	Update Policy	Literature review update, Rationale and references updated, Policy statement unchanged.
December 2013	Update Policy	Policy updated with literature review. References 1-3 added. No change to policy statement.
December 2014	Update Policy	Policy updated with literature review. References 1-3 and 15-17 added. Rationale and background sections revised. Policy statement unchanged.
December 2015	Update Policy	Policy updated with literature review through July 30, 2015; references 13-14 and 18 added. Policy statement changed to clarify that the policy refers to anal fistulas. Title of policy changed to “Plugs for Anal Fistula Repair.”
March 2017	Update Policy	Policy updated with literature review; references 4-6 and 13 added. Policy statement changed from not medically necessary to investigational.
March 2018	Update Policy	Policy updated with literature review through September 19, 2017; reference 24 added; reference 25 updated. Policy statement unchanged.