BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.123 Plugs for Anal Fistula Repair

Annual Effective Policy Date: April 1, 2024

Original Policy Date: December 2011

Related Policies:

None

Plugs for Anal Fistula Repair

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of anal fistula plugs improves the net health outcome for anal fistulas compared with other approaches.

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.

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

FDA REGULATORY STATUS

Several plugs for anal fistula repair have been cleared for marketing by the 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)	Mar 2005	• Manufactured from porcine SIS	• Repair of anal, rectal, and enterocutaneous fistulas	• Surgisis Soft Tissue Graft (Cook Biotech) • Stratasis Urethral Sling (Cook Biotech)	t
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	• Reinforce soft tissue to repair anorectal fistulas	• Gore Bioabsorbable Mesh (W.L.	FTL

		• Supplied in a 3-dimensional configuration of a disk with attached tubes		Gore & Associates) • SIS Fistula Plug (Cook Biotech)	
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: U.S. Food and Drug Administration; PGA:TMC: polyglycolide-co-trimethylene carbonate; SIS: small intestinal submucosa.

RATIONALE

Summary of Evidence

For individuals who have anal fistula(s) who receive placement of AFP(s), the evidence includes 4 randomized controlled trials (RCTs), a number of 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: 1 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 (RCT) 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. An RCT comparing AFP with surgeon's preference reported significantly higher complication rates with AFP. 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Colon and Rectal Surgeons

The 2022 practice guideline on the treatment of anorectal abscess, fistula-in-ano, and rectovaginal fistula from the Society provided a strong recommendation based on moderate-quality evidence that anal fistula plug and fibrin glue are relatively ineffective treatments for fistula-in-ano.[15,

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence updated its guidance on the suturable bioprosthetic plug.[16,] The Institute determined 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.

Medicare National Coverage

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

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
December 2012	Replace policy	Literature review update, Rationale and references updated, Policy statement unchanged.
December 2013	Replace policy	Policy updated with literature review. References 1-3 added. No change to policy statement
December 2014	Replace policy	Policy updated with literature review. References 1-3 and 15-17 added. Rationale and background sections revised. Policy statement unchanged.
December 2015	Replace 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	Replace policy	Policy updated with literature review; references 4-6 and 13 added. Policy statement changed from not medically necessary to investigational.
March 2018	Replace policy	Policy updated with literature review through September 19, 2017; reference 24 added; reference 25 updated. Policy statement unchanged.
March 2019	Replace policy	Policy updated with literature review through September 6, 2018; reference 24 added. Policy statement unchanged.
March 2020	Replace policy	Policy updated with literature review through September 6, 2019; reference on NICE updated. Policy statement unchanged.
March 2021	Replace policy	Policy updated with literature review through August 20, 2020; reference added. Policy statement unchanged.
March 2022	Replace policy	Policy updated with literature review through September 12, 2021; reference added. Policy statement unchanged.
March 2023	Replace policy	Policy updated with literature review through September 21, 2022; reference added. Policy statement unchanged.
March 2024	Replace policy	Policy updated with literature review through September 15, 2023; no references added; Policy statement unchanged.