FEP 7.01.123 Plugs for Anal Fistula Repair

Effective Date: April 1, 2019
Related Policies: None

Medical Policy Title

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.

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 (eg, 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.3

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 investigative 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).

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

<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)</td>
<td>Mar 2005</td>
<td>Manufactured from porcine SIS</td>
<td>Repair of anal, rectal, and enterocutaneous fistulas</td>
<td>Surgisis® Soft Tissue Graft (Cook Biotech) Stratasis® Urethral Sling (Cook Biotech)</td>
<td>FTM</td>
</tr>
<tr>
<td>Surgisis RVP Recto-Vaginal Fistula Plug</td>
<td>Oct 2006</td>
<td>Manufactured from porcine SIS Tapered configuration with a button to increase plug retention and improve fistula blockage</td>
<td>Reinforce soft tissue to repair rectovaginal fistulas</td>
<td>SIS Fistula Plug (Cook Biotech)</td>
<td>FTM</td>
</tr>
<tr>
<td>Surgisis Biodesign Enterocutaneous Fistula Plug (Cook Biotech)</td>
<td>Feb 2009</td>
<td>Manufactured from porcine SIS Tapered configuration with flange to increase plug retention and improve fistula blockage</td>
<td>Reinforce soft tissue to repair enterocutaneous fistulas</td>
<td>SIS Fistula Plug (Cook Biotech)</td>
<td>FTM</td>
</tr>
<tr>
<td>Gore Bio-A Fistula Plug (W.L. Gore &amp; Associates)</td>
<td>Mar 2009</td>
<td>Manufactured from bioabsorbable PGA:TMC copolymerSupplied in a 3-dimensional configuration of a disk with attached tubes</td>
<td>Reinforce soft tissue to repair anorectal fistulas</td>
<td>Gore Bioabsorbable Mesh (W.L. Gore &amp; Associates) SIS Fistula Plug (Cook Biotech)</td>
<td>FTL</td>
</tr>
<tr>
<td>Biodesign Anal Fistula Plug (Cook Biotech)</td>
<td>May 2016</td>
<td>Manufactured from porcine SIS Additional wash steps added in processing</td>
<td>Reinforce soft tissue where a rolled configuration is required to repair 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.
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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 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Society of Colon and Rectal Surgeons
The 2017 practice guidelines on management of anal fistulas from the American Society of Colon and Rectal Surgeons did not evaluate use of plugs for anal fistula repair.22

The 2016 practice guidelines on the treatment of anorectal abscess, fistula-in-ano, and rectovaginal fistula from the Society provided a weak recommendation with moderate-quality evidence.23, 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 2011.24, The Institute determined that while there are no major safety concerns, evidence on the efficacy of the procedure was inadequate 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.

REFERENCES

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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**POLICY HISTORY**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td></td>
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<tr>
<td>December 2012</td>
<td>Update Policy</td>
<td>Literature review update, Rationale and references updated, Policy statement unchanged.</td>
</tr>
<tr>
<td>December 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review. References 1-3 added. No change to policy statement.</td>
</tr>
<tr>
<td>December 2015</td>
<td>Update Policy</td>
<td>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 &quot;Plugs for Anal Fistula Repair.&quot;</td>
</tr>
<tr>
<td>March 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 4-6 and 13 added. Policy statement changed from not medically necessary to investigational.</td>
</tr>
<tr>
<td>March 2019</td>
<td>Update Policy</td>
<td>Policy updated with literature review through September 6, 2018; reference 24 added. Policy statement unchanged.</td>
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