LOUISIANA BLUE

Plugs for Anal Fistula Repair

Policy # 00598
Original Effective Date: 04/01/2018
Current Effective Date: 02/10/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material for the repair of anal fistulas to be **investigational.***

Background/Overview

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.

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several plugs for fistula repair have been cleared for marketing by the U.S. 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	• Reinforce soft tissue to repair enterocutaneous fistulas	• SIS Fistula Plug (Cook Biotech)	FTM

		flange to increase plug retention and improve fistula blockage			
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: U.S. Food and Drug Administration; PGA:TMC: polyglycolide-co-trimethylene carbonate; SIS: small intestinal submucosa

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration

approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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 4 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 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.

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. 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.

Ongoing and Unpublished Clinical Trials
There are currently no relevant ongoing clinical trials of plugs for anal fistula repair in ClinicalTrials.gov through October 1, 2024.

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Policy History

Original Effective Date: 04/01/2018
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01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. New policy.
01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. No change to coverage.
01/03/2020	Medical Policy Committee review
01/08/2020	Medical Policy Implementation Committee approval. No change to coverage.
01/07/2021	Medical Policy Committee review
01/13/2021	Medical Policy Implementation Committee approval. No change to coverage.
01/06/2022	Medical Policy Committee review
01/12/2022	Medical Policy Implementation Committee approval. No change to coverage.
01/05/2023	Medical Policy Committee review
01/11/2023	Medical Policy Implementation Committee approval. No change to coverage.
01/04/2024	Medical Policy Committee review
01/10/2024	Medical Policy Implementation Committee approval. No change to coverage.
03/27/2024	Coding update
01/02/2025	Medical Policy Committee review
01/08/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2026

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Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	46707
HCPCS	C9796
ICD-10 Diagnosis	K60.0-K60.529

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.