

Corporate Medical Policy

Plugs for Fistula Repair

File Name:	plugs_for_fistula_repair
Origination:	3/2010
Last CAP Review:	11/2011
Next CAP Review:	11/2012
Last Review:	11/2011

Description of Procedure or Service

Anal fistula plugs are biosynthetic devices used to promote healing and prevent recurrence of anal fistula (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 6 to 8 weeks. The procedure may require 12–24 hours observation postoperatively. The procedure can be repeated in case of failure.

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 Slings, 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 porcine small intestinal submucosa (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, 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.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

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. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Plugs for Fistula Repair

When Plugs for Fistula Repair are covered

Not Applicable

When Plugs for Fistula Repair are not covered

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.

Policy Guidelines

Evidence of efficacy of anal fistula plug treatment is quite limited. Available evidence reports a wide range of results and does not demonstrate that anal plugs improve healing rates or reduce recurrence of anal fistulas. Randomized controlled trials with sufficient numbers of patients and with at least 6 months of follow-up reporting healing and recurrence rates and sphincter function before and after procedures are required. In light of the limited data available and inconsistent outcomes reported, use of anal fistula plugs is considered investigational; the impact on net health outcome is not known.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 46707

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 12/10/2009

National Institutes for Health and Clinical Excellence (NICE). Closure of anal fistula using a suturable bioprosthesis plug. June 2007. Accessible at <http://www.nice.org.uk/nicemedia/pdf/boardmeeting/IPG221guidance.pdf>

U.S. Food and Drug Administration. 501(k) Summary for SIS Fistula Plug Retrieved on 03/09/2005 from http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062729.pdf

U.S. Food and Drug Administration. 501(k) Summary for Gore Bio-A Fistula Plug Retrieved on 03/27/2009 from http://www.accessdata.fda.gov/cdrh_docs/pdf8/K083266.pdf

Senior Medical Director Review 03/2010

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 5/12/2011

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Policy Implementation/Update Information

- 4/13/10 New policy developed. Plugs for Fistula Repair are considered investigational.
- 6/22/10 Policy Number(s) removed (amw)
- 12/21/10 Specialty Matched Consultant Advisory Panel review 11/29/10. Policy accepted as written. (adn)
- 12/20/11 Removed code 0170T from Billing/Coding section. Specialty Matched Consultant Advisory Panel review 11/30/11. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.