Corporate Medical Policy

Plugs for Fistula Repair

File Name: plugs_for_fistula_repair
Origination: 3/2010
Last Review: 11/2023

Description of Procedure or Service

Anal fistula plugs are biosynthetic devices used to promote healing and prevent recurrence of anal fistulas. 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 Sling, 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 Surgisis RVP Recto-Vaginal Fistula Plug (Cook Biotech), also manufactured from porcine small intestinal submucosa, 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, using 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. The Biodesign Anal Fistula Plug (Cook Biotech) received 510(k) clearance from FDA in May 2016. It is manufactured from porcine small intestinal submucosa, and is intended to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal, and enterocutaneous fistulas.

******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 are considered investigational for all indications. 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.

When Plugs for Fistula Repair are covered

Plugs for Fistula Repair

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 fistulas.

Policy Guidelines

For individuals who have anal fistula(s) who receive placement of anal fistula plug(s), the evidence includes four randomized comparative trials (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 anal fistula plug with surgical flap treatment reported disparate findings: one reported significantly higher rates of fistula recurrence with anal fistula plug; the other found similar rates of recurrence between anal fistula plug and surgical treatment. Another RCT, which compared AFP to 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 anal fistula plug repair of anal fistulas demonstrate 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.

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 bioprosthetic plug. June 2007. Accessible at wttp://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

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 5/10/2012

Specialty Matched Consultant Advisory Panel – 12/2012

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 9/12/2013

Specialty Matched Consultant Advisory Panel – 11/2013

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 9/11/2014

Specialty Matched Consultant Advisory Panel – 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 9/10/2015

Specialty Matched Consultant Advisory Panel – 11/2015

Specialty Matched Consultant Advisory Panel – 11/2016

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 11/10/2016

Specialty Matched Consultant Advisory Panel – 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 11/9/2017

Specialty Matched Consultant Advisory Panel – 11/2018

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 11/8/2018

Specialty Matched Consultant Advisory Panel – 11/2019

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 11/14/2019

Specialty Matched Consultant Advisory Panel – 11/2020

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.123, 11/12/2020

Specialty Matched Consultant Advisory Panel – 11/2021

Specialty Matched Consultant Advisory Panel – 11/2022

Specialty Matched Consultant Advisory Panel - 11/2023

Medical Director Review- 11/2023

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)

1/1/13 Reference added. Specialty Matched Consultant Advisory Panel review 12/4/12. No change to policy statement. (sk)

1/14/14 Reference added. Specialty Matched Consultant Advisory Panel review 11/20/2013. No change to Policy statement. (sk)

12/9/14 Reference added. Specialty Matched Consultant Advisory Panel review 11/24/2014. No change to Policy statement. (sk)

12/30/15 Reference added. Specialty Matched Consultant Advisory Panel review 11/18/2015. The word "rectal" removed from the policy statement. (sk)

1/27/17 Specialty Matched Consultant Advisory Panel review 11/30/2016. Reference added. (sk)

12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)

1/26/18 Reference added. (sk)

12/14/18 Reference added. Specialty Matched Consultant Advisory Panel review 11/28/2018. (sk)

12/10/19 Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)

3/10/20 Reference added. (sk)

12/8/20 Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)

11/30/21 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)

5/2/23 Policy review. Specialty Matched Consultant Advisory Panel review 11/16/2022. (sk)

12/5/23 Reference added. Specialty Matched Consultant Advisory Panel review 11/2023. Medical Director review 11/2023. (rp)