

Policy: MP243

Section: Medical Benefit Policy

Subject: Anorectal Fistula Repair Using an Acellular Xenogeneic Plug

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Anorectal Fistula Repair Using an Acellular Xenogeneic Plug

II. Purpose/Objective:

To provide a policy of coverage regarding Anorectal Fistula Repair Using an Acellular Xenogeneic Plug

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

An anorectal fistula repair involving the placement into the fistula tract of an acellular xenogeneic or bioprosthetic (biodegradable) "plug" is a minimally invasive procedure and affords the surgeon a sphincter-sparing option. The plug is derived from porcine small intestinal mucosa (SIS), which is a rolled and tapered configuration. The plug spans the entire length of the fistula tract from the internal to the external opening and is sutured into place. The plug was developed to close the primary opening of the fistula tracts, without incising into the sphincter muscle, to allow healing from point of blockage to skin surface.

EXCLUSIONS:

The Plan considers biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material **experimental, investigational, and unproven** for all indications including, but not limited to, repair of anal and rectal fistulas. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**.

CODING ASSOCIATED WITH: Anorectal Fistula Repair Using an Acellular Xenogeneic Plug

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

46707 Repair of anorectal fistula with plug (e.g., porcine small intestine mucosa [SIS])

C9364 Porcine implant, permacol, per square centimeter

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written

REFERENCES:

Geisinger TAC Triage Committee. Anorectal Fistula Repair. August 2010.

Geisinger TAC Triage Committee. Anorectal Fistula Repair. January 2014

(No Author). Surgisis AFP anal fistula plug: report of a consensus conference. *Colorectal Dis.* 2008 Jan;10(1):17-20.

Thekkinkattil D, Botterill I, Ambrose S, Lundby L, Sagar P, Buntzen S, Finan P. Efficacy of the Anal Fistula Plug in Complex Anorectal Fistulae. *Colorectal Dis.* 2008 Jul 15.

van Koperen PJ, D'Hoore A, Wolthuis AM, Bemelman WA, Slors JF. Anal fistula plug for closure of difficult anorectal fistula: a prospective study. *Dis Colon Rectum.* 2007 Dec;50(12):2168-72.

Garg P. To determine the efficacy of anal fistula plug in the treatment of high fistula-in-ano- an initial experience. *Colorectal Dis.* 2008 Jul 15.

Ky AJ, Sylla P, Steinhagen R, Steinhagen E, Khaitov S, Ly EK. Collagen fistula plug for the treatment of anal fistulas. *Dis Colon Rectum*. 2008 Jun;51(6):838-43. Epub 2008 Mar 11.

Lawes DA, Efron JE, Abbas M, Heppell J, Young-Fadok TM. Early experience with the bioabsorbable anal fistula plug. *World J Surg*. 2008 Jun;32(6):1157-9.

Ortiz H, Marzo J, Ciga MA et al. Randomized clinical trial of anal fistula plug versus endorectal advancement flap for the treatment of high cryptoglandular fistula in ano. *Brit J Surg* 2009; 96(6):608-12.

Christoforidis D, Pieh MC, Madoff RD et al. Treatment of transsphincteric anal fistulas by endorectal advancement flap or collagen fistula plug: a comparative study. *Dis Colon Rectum* 2009; 52(1):18-22.

El-Gazzaz G, Zutshi M, Hull T. A retrospective review of chronic anal fistulae treated by anal fistulae plug. [Colorectal Dis](#). 2010 May;12(5):442-7. Epub 2009 Feb 7.

National Institute for Health and Clinical Excellence (NICE) (UK). Closure of anal fistula using a suturable bioprosthesis plug: guidance. 2007. Note: does not specifically address either product.

National Institute for Health and Clinical Excellence (NICE) (UK). Closure of anal fistula using a suturable bioprosthesis plug. November 2011.

UptoDate. Anorectal fistula: Clinical manifestations, diagnosis, and management principles, Oct. 2013

Chan, S, McCullough, J, Schizas, A, Vasas, P, Engledow, A, Windsor, A, Williams, A, and Cohen, CR. Initial experience of treating anal fistula with the Surgisis anal fistula plug. *Tech Coloproctol*. 2012.

Kleif, J, Hagen, K, and Wille-Jorgensen, P. Acceptable results using plug for the treatment of complex anal fistulas. *Dan Med Bull*. 2011;58(3):A4254.

Buchberg, B, Masoomi, H, Choi, J, Bergman, H, Mills, S, and Stamos, MJ. A tale of two (anal fistula) plugs: is there a difference in short-term outcomes? *Am Surg*. 2010;76(10):1150-1153

Owen, G, Keshava, A, Stewart, P, Patterson, J, Chapuis, P, Bokey, E, and Rickard, M. Plugs unplugged. Anal fistula plug: the Concord experience. *ANZ J Surg*. 2010;80(5):341-343.

Cintron JR, Abcarian H, Chaudhry V, et al. Treatment of fistula-in-ano using a porcine small intestinal submucosa anal fistula plug. *Tech Coloproctol*. Apr 2013; 17(2):187-191.

Vogel, JD, Johnson, EK, Morris, AM, et al. Clinical Practice Guideline for the Management of Anorectal Abscess, Fistula-in-Ano, and Rectovaginal Fistula. *Dis Colon Rectum*. 2016 Dec;59(12):1117-33.

National Institute for Health and Care Excellence (NICE). Bioprosthesis plug insertion for anal fistula. Sep 2019. <https://www.nice.org.uk/guidance/ipg662>

Jayne DG, Scholefield J, Tolan D, et al. A Multicenter Randomized Controlled Trial Comparing Safety, Efficacy, and Cost-effectiveness of the Surgisis Anal Fistula Plug Versus Surgeon's Preference for Transsphincteric Fistula-in-Ano: The FIAT Trial. *Ann Surg*. Jun 09 2020.

Garg P, Kaur B, et al. Lessons learned from an audit of 1250 anal fistula patients operated at a single center: A retrospective review. *World journal of gastrointestinal surgery*. 2021;13(4):340-54.

Fält UA, Zawadzki A, et al.. Long-term outcome of the Surgisis® (Biodesign®) anal fistula plug for complex cryptoglandular and Crohn's fistulas. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland*. 2021;23(1):178-85

This policy will be revised as necessary and reviewed no less than annually.

Devised: 04/2010

Revised: 10/16 (added coding), 9/17 (Added Medicaid Section)

Reviewed: 10/11, 10/12, 10/13, 10/14, 10/15, 9/18, 9/19, 9/20, 9/21, 9/22, 9/23

Reviewed:

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.