Policy: MP243
Section: Medical Benefit Policy
Subject: Anorectal Fistula Repair Using an Acellular Xenogeneic Plug

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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or
development effects of an illness, condition, injury or disability.

(iii) the service or benefit 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.

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.

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


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 PA Medicaid Business segment, this
policy applies as written

REFERENCES:


Thekkinkattil D, Botterill I, Ambrose S, Lundby L, Sagar P, Buntzen S, Finan P. Efficacy of the Anal Fistula Plug in

van Koperen PJ, D’Hoore A, Wolthuis AM, Bemelman WA, Slors JF. Anal fistula plug for closure of difficult anorectal

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.


Lawes DA, Efron JE, Abbas M, Heppell J, Young-Fadok TM. Early experience with the bioabsorbable anal fistula plug.


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


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

Devised: 04/2010

Revised: 10/16 (added coding)

Reviewed: 10/11, 10/12, 10/13, 10/14, 10/15,