Medical Policy
Plugs for Fistula Repair

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Policy Number: 528
BCBSA Reference Number: 7.01.123

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material are INVESTIGATIONAL for all indications including, but not limited to, repair of anal and rectal fistulas.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.

<table>
<thead>
<tr>
<th></th>
<th>Outpatient</th>
<th>Inpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO BlueSM</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
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CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tr>
<td>46707</td>
<td>Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])</td>
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ICD-9 Diagnosis Codes

Investigational for all diagnoses.

Description

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 into 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.1

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 trans-sphincteric, 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.

Fistula Repair

Treatment is aimed at repairing the fistula without compromising continence. Surgical treatments for anal fistulas include fistulotomy/fistulectomy, endorectal/anal sliding flaps, ligation of the intersphincteric fistula tract (LIFT) technique, seton drain, and fibrin glue. Fistulotomy involves division of the tissue over the fistula and laying open of the fistula tract. Although fistulotomies are widely used for low fistulas, lay-open fistulotomies in high fistulas carries the risk of incontinence. A seton is a thread placed through the fistula tract for the purpose of draining fistula material and preventing the development of a perianal infection. Draining setons can control sepsis, but few patients heal after removal of the seton, and the procedure is poorly tolerated long-term. A “cutting seton” refers to the process of regular tightening of the seton to encourage gradual cutting of the sphincteric muscle with subsequent inflammation and fibrosis. Cutting setons can cause continence disturbances. Endorectal advancement flaps involve the advancement of a full or partial thickness flap of the proximal rectal wall over the internal (rectal) opening of the fistula tract. The LIFT technique involves identifying the intersphincteric plane and then dividing the fistula tract; its use has been reported in small studies, but long-term follow-up is unavailable.2 Fibrin glue is a combination of fibrinogen, thrombin, and calcium in a matrix, which is injected into the fistula track. The glue induces clot formation within the tract, which is then closed through overgrowth of new tissue.

Fistula Plugs

Fistula plugs are designed to provide a structure that acts as a scaffold for new tissue growth. The scaffold, which can be derived from animal (eg, porcine) tissue or a synthetic copolymer fiber, is degraded by hydrolytic or enzymatic pathways as healing progresses. The plug is pulled through the
fistula tract and secured at the fistula's proximal opening; the fistula tract is left open at the distal opening to allow drainage.

**Summary**
Anal fistula plugs are biosynthetic devices used to promote healing and prevent recurrence of anal fistula. 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 fistula 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, the impact on net health outcome is not known, and the use of anal fistula plugs is considered investigational.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>10/2014</td>
<td>New references from BCBSA National medical policy.</td>
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<tr>
<td>12/2013</td>
<td>New references from BCBSA National medical policy.</td>
</tr>
<tr>
<td>1/1/2012</td>
<td>New policy, effective 01/01/2012, describing ongoing non-coverage.</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**