



## **Clinical Review Criteria**

### **Fibrin Glue Injection for Treatment of Perianal Fistula**

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### **Criteria**

No criteria were developed at this time for Commercial Members as there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

### **Background**

An anal fistula is a chronically infected, abnormal tunnel between the anal canal and the outer skin of the anus. Anal fistulae often drain watery pus which can irritate the surrounding outer tissues. Anal fistulae can occur as a result of an unhealed sore and they are also associated with Crohn's disease, tuberculosis, cancer of the large intestine and gonorrhoea.

The standard treatment for anal fistulae is fistulotomy, a surgical procedure in which the infected area is opened up and allowed to drain. Possible complications of surgery are fecal incontinence and permanent gas incontinence. Modifications to fistulotomy (e.g., island flap anoplasty) have been found to reduce the rates of incontinence; they may have lower rates of efficacy.

Fibrin glue is an alternative to fistulotomy. The FDA approved commercially made fibrin sealants in 1998 (although not specifically for repair of anal fistulae). The two products approved by the FDA are Tisseel and ViGuard. The main active ingredient in fibrin glue is fibrinogen, a protein from human blood. Fibrinogen forms a clot when combined with thrombin, another human blood protein. Before the availability of these products, fibrinogen was extracted from the patients' blood (autologous fibrin glue). The commercial fibrin sealants have a higher concentration of fibrinogen, the quantity is standardized and the sealants are quicker to prepare.

Fibrin glue is applied in the operating room. The basic procedure (Cintron) is to examine the patient and identify primary and secondary fistula tract openings that are then cleaned. Any abscess identified during the examination is drained. The two components of the fibrin glue are injected simultaneously into the secondary fistula tract opening until the glue is seen coming from the primary tract opening. Vaseline gauze is then placed over both the primary and secondary openings.

### **Medical Technology Assessment Committee (MTAC)**

#### **Fibrin Glue**

#### **08/12/2002: MTAC REVIEW**

**Evidence Conclusion:** In the articles reviewed, autologous fibrin glue as well as two commercial products, Tisseel and ViGuard, were used. The single RCT identified (Hwang) found that autologous fibrin glue healed anal fistulae faster than conservative treatment with total parenteral nutrition. The RCT is not strong evidence because only 13 patients were included in the study and fibrin glue was not compared to standard treatment (fistulotomy). The cohort study (Cintron) compared autologous fibrin glue to the two commercial products and did not find significant differences in treatment success (no drainage). Overall, 62% of patients with transsphincteric fistulae and 82% of patients with intersphincteric fistulae had no draining after treatment. The Patrli article was a case

series with 69 patients who received treatment with Tisseel. Wounds healed in a median of 12 days. Both the Partlj and Cintron studies reported relatively high rates of recurrence. Recurrence was 54% in wounds under 3.5 cm and 11% in wounds  $\geq 3.5$  cm; comparative studies on recurrence and wound size are needed. Only the Partlj study reported on incontinence; all patients in the case series remained continent. However, this case series is subject to selection bias. No studies compared fibrin sealants to the standard surgical procedure.

**Articles:** The search yielded 13 articles, most of which were case reports or case series. There was one small (n=13) randomized controlled trial and one prospective cohort study which were reviewed. A large case series, which had the longest follow-up, was also reviewed. Hwang TL, Chen MF. Randomized trial of fibrin tissue glue for low output enterocutaneous fistula. *Br J Surg* 1996; 83: 112. See [Evidence Table](#).

The use of fibrin glue in the treatment of perianal fistula does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Date Reviewed	Date Last Revised
08/12/2002	8/12/2002 <sup>MPC</sup> , 07/07/2015 <sup>MPC</sup> , 05/03/2016 <sup>MPC</sup>	07/07/2015

<sup>MPC</sup> Medical Policy Committee

Revision History	Description

## Codes

CPT: 46706