Clinical Policy Bulletin:
Implantable Vas Deferens Ligation Clip (Vasclip)

Number: 0027

Policy

Aetna considers the implantable vas deferens ligation clip (Vasclip, VMBC, LLC, Roseville, MN) experimental and investigational for ligation of the vas deferens for male sterilization because there is insufficient evidence in the peer-reviewed literature that the Vasclip procedure provides clinically significant benefits over standard vasectomy procedures.

Background

According to a guideline on sterilization by the American College of Obstetricians and Gynecologists (ACOG, 2003), approximately 500,000 vasectomies are performed annually in the United States by urologists, general surgeons, and family physicians.

During vasectomy, an incision or puncture (no-scalpel technique) is made in the scrotum and the vas deferens is then cut to disconnect it, thereby interrupting the sperm's route from the testicles to the penis. A piece of the vas is removed (to reduce the chances of the two ends of the vas rejoining) and the two ends are then clipped, tied, or cauterized. Fascial interposition, in which one end of the vas is covered by either the sheath tissues of the vas itself or with adjacent connective tissue, is also widely used in conjunction with occlusion techniques to reduce the risk of re-canalization. A controversial and less widespread practice involves leaving the testicular end of the vas unsealed to allow sperm to flow out of the vas in order to minimize pressure on and damage to the epididymis (Errey, et al., 1986). Once the vasectomy is performed, the testicles still generate sperm, but their movement is blocked.
The rate of vasectomy failure, defined as lack of azoospermia on follow-up semen analysis (SA) or presence of pregnancy, has generally been reported to be between 0% to 2% (Cook, et al., 2004; ACOG, 2003). The three main causes of vasectomy failure are operative failure, unprotected intercourse before the semen is cleared of sperm, and spontaneous early or late recanalization of the vas (Cook, et al., 2004). Failure rates are reportedly lower when traditional vasectomy is performed by more experienced surgeons (Schwingl, et al., 2000). Vasectomy is considered a low-risk procedure with fewer than 3% of cases resulting in complications; complications include: infection, bleeding, hematoma, acute and chronic pain and congestive epididymitis.

Since the late 1960s, attempts have been made to develop an alternative method of vasectomy that would be more easily reversible than a standard vasectomy. Most of these efforts focused on the use of mechanical valves that could be opened and closed. The Vasclip, a locking ligation clip the size of a grain of rice, was cleared for marketing by the Food and Drug Administration (FDA) based on a 510(k) application. Thus, the manufacturer was not required to supply the evidence of effectiveness that would be required to support a pre-market approval application (PMA). The FDA 510(k) summary of substantial equivalence stated the Vasclip is identical in use to the Hem-o-lok, a polymer ligating clip that is used to close off vessels that supply blood to organs.

An unpublished prospective clinical study available through VMBC, LLC, the VASCLIP Company and on their website, reported the results of 124 men who had the Vasclip procedure. Three of the men (2.5 %) did not become infertile due to improper placement of the Vasclip, 0.8 % developed a hematoma and 0.8 % developed a sperm granuloma. Sixty-eight of the patients who returned for a SA all tested as infertile (no live sperm) at an average of 373 days after the Vasclip procedure and all of the 78 patients who returned for a SA tested as infertile at an average of 853 days after. Reported range of significant pain was 5 %. Statistics on reversal are not yet available.

The potential for enhancing reversal is one main rationale for the use of vas occlusion with clips (Schwingl, et al., 2000). In addition, the manufacturer states that the Vasclip results in lower complication rates than conventional male sterilization procedures. However, it is not known whether the Vasclip compresses the vas so tightly that the blood supply to the underlying portion of vas is permanently damaged. There is no adequate evidence in the peer-reviewed published medical literature that the Vasclip has a reduced late failure rate, lower complication rate or improved reversal rate then traditional vasectomy.

There is inconsistent evidence regarding the effectiveness of the Vasclip implant compared to standard vasectomy procedures. Kirby et al (2006) examined if the Vasclip implant procedure would (i) be equivalent to vasectomy in producing azoospermia, (ii) produce greater patient satisfaction post-operatively, and (iii) result in lower complication rates, post-operative pain, hematoma formation, spermatic granuloma, and surgical site infection when compared with historical controls. Successful sterilization, defined by azoospermia at 10 to 14 months, was observed in 116 of 119 subjects. The authors stated that effectiveness seemed to
be equivalent to that of vasectomy, although the study did not include an internal control group of subjects receiving vasectomy. The authors observed that the incidence of post-operative pain and hematoma formation was similar to that which had been reported for standard vasectomy. The Vasclip procedure also had similar infection rates. The authors reported that the Vasclip procedure seemed to have lower rates of sperm granuloma formation compared to standard vasectomy. In three subjects with persistent presence of sperm, histological examination after traditional vasectomy indicated that misalignment of the device led to partial vas incision with recanalization. The authors reported that 99% of survey respondents would recommend that other men considering a vasectomy have the Vasclip procedure.

On the other hand, Levine et al (2006) found persistent motile sperm after the Vasclip procedure. The authors assessed the effectiveness and mechanism of failure in a small case series of Vasclip vasectomies. Microscopic semen analysis was done a minimum of 4 weeks post-operatively and after at least 15 ejaculations. The number of sperm and motility were quantified in 15 or more high power fields. Successful vasectomy was defined as 2 consecutive post-operative unspun semen analyses containing no sperm. Patients with failed vasectomy underwent bilateral surgical removal of the vas deferens segments containing the ligation band for gross and histological analysis. Six of 8 patients (75%) were deemed azoospermic after 2 semen analyses at a mean follow-up of 7 and 11 weeks post-operatively, respectively. Two of 8 patients (25%) had semen analyses containing multiple motile sperm after vasectomy. In the 2 failed cases 1 side was patent, as demonstrated by vasal cannulation and irrigation with dilute methylene blue despite a well positioned, intact and secure ligation band. Histological analysis showed extravasation and sperm granuloma on the patent side. The authors concluded that the Vasclip was found to fail at an unexpectedly high rate. Pathological analysis suggests sperm extravasation and fistula tract formation as the mechanism. One failure resulted in an unwanted pregnancy, which demonstrates the need for patient counseling regarding post-operative follow-up.

Cook, et al. (2004) systematically reviewed the evidence comparing male sterilization techniques. They identified two controlled clinical trials (Gupta, et al., 1997 [n = 110]; Clausen, et al., 1983 [n = 79]) comparing vas occlusion with clips (no transection of the vas) versus a conventional vasectomy technique (transaction of the vas with both ends of the vas ligated and looped back). Neither trial found a significant difference between the two groups with regard to the primary outcome of failure to reach azoospermia. However, Cook, et al. stated that no firm conclusions can be made about the comparative effectiveness, safety, and acceptability of these vas occlusion techniques due to the poor quality of the studies.

In a Cochrane review on vasectomy occlusion techniques for male sterilization that include excision and ligation, thermal or electrocautery, mechanical/chemical occlusion, as well as vasectomy with vas irrigation or with fascial inter-position (Cook et al, 2007), the authors concluded that for vas occlusion with clips or vasectomy with vas irrigation, no conclusions can be made as those studies were
of low quality and under-powered. Fascial inter-position reduced vasectomy failure. An intra-vas device was less effective in reducing sperm count than was no-scalpel vasectomy. They noted that randomized controlled studies evaluating other vasectomy techniques were not available; more and better quality research is needed to examine vasectomy techniques.

CPT Codes / HCPCS Codes / ICD-9 Codes

Other CPT codes related to the CPB:

52402
55250
55450
89310

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

V25.2 Encounter for sterilization

The above policy is based on the following references:

9. VBMC, LLC. Vasclip clinical study results. VMBC, LLC, The VASCLIP


