



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Vas Deferens Ligation Clip
(VasClip®)**

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Coverage Policy

CIGNA does not cover the vas deferens ligation clip (i.e., VasClip®) because it is considered experimental, investigational or unproven.

General Background

Vasectomy is a minor surgical procedure that is usually performed as a means of permanent male sterilization. More than four million vasectomy procedures are performed each year on a worldwide basis, with over 500,000 performed in the United States by urologists, family practitioners or general surgeons. The procedure can be performed with or without a scalpel, using one of several techniques for occluding the vas (e.g., ligation, suturing, cauterization), on an outpatient basis under local anesthesia (Dassow, 2006; American Urological Association [AUA], 2004a; Peterson, 2003; Goldstein, 2002; Schwingl, 2000).

Vasectomy is considered one of the most reliable family-planning methods currently available to males. Pregnancy rates associated with failed vasectomies are reported in the range of 0–2%, with most studies reporting less than 1%. Vasectomy reversals may be attempted via microsurgical re-anastomosis of the vas deferens. Re-anastomosis procedures are estimated to be 90% effective. Pregnancy rates after re-anastomosis are reported in 30–75% of women, depending upon the length of time from the vasectomy until the reversal. Another means of regaining male fertility after vasectomy is the extraction of sperm from the testicle or the epididymis (AUA, 2004b).

Although vasectomy, in general is considered highly effective, the specific failure rates associated with the various techniques, as well as the safety and effectiveness of these techniques, have not been well quantified in clinical trials (Schwingl, 2000; AUA, 2004a; Labrecque, 2004; 2006).

Vasectomy Techniques

Scalpel Technique: In the scalpel technique, two small incisions are made in the skin of the scrotum. The vas deferens is pulled to the surface and typically cut in two places, with each end being tied off or cauterized. The skin is closed with absorbable sutures, and the patient can go home immediately after the procedure.

No-Scalpel Technique: The no-scalpel technique is a faster procedure. The physician uses a special clamp to grasp the vas deferens through a small puncture hole made in the scrotum. Using the forceps, the small hole is stretched, exposing the vas deferens while it is lifted out, cut, and sutured or cauterized. It is then slipped back into the scrotal sac. Because the puncture sites are very small, no sutures are required with this approach.

Recovery time using either of these techniques is usually 3–5 days, limiting both mobility and lifting of heavy objects in order to reduce the incidence of swelling, discomfort and bleeding. Prolonged pain sometimes occurs as a result of inflammation along the vas due to sperm leakage (i.e., sperm granuloma) or congestion of sperm at the epididymis (i.e., epididymitis). These conditions typically improve with rest and anti-inflammatory medication.

The clinical success of a vasectomy, regardless of type (e.g., ligation, cauterization or occlusion), is measured by a post-procedure semen analysis that demonstrates azoospermia; the time interval until azoospermia is reached varies from patient to patient (AUA, 2004b). Vasectomy failures are measured by the documentation of post-procedure pregnancies, as well as the presence of sperm in ongoing semen analysis samples.

Vas Deferens Ligation Clips (i.e., VasClip®)

In an attempt to decrease both the possibility of inflammation and the recovery time from a vasectomy, a newer technique has been developed. This procedure, which uses a small plastic clip (i.e., VasClip®, The VasClip® Company [VMBC, LLC], Roseville, MN), does not require cutting, suturing or cauterization of the vas deferens and is reported to be less painful than a routine vasectomy.

The VasClip has been proposed as an alternative to conventional vasectomy. Two small puncture wounds are made in the scrotum to expose the vas deferens. A small polymeric clip, about the size of a grain of rice, is then locked around a small loop of the vas deferens to stop the flow of sperm through the vessel.

The VasClip manufacturer website states that the effectiveness of using the VasClip for permanent male sterilization has not been evaluated in comparison to standard vasectomy procedures. At this time, the VasClip is recommended for use only as a means of permanent sterilization; studies will need to be done to determine if removal of the VasClip would allow for the normal flow of sperm to resume with return of adequate sperm count and subsequent fertilization.

U.S. Food and Drug Administration (FDA)

The VasClip was granted 510(k) marketing approval by the FDA in August 2002 because it was considered to be substantially equivalent to another device already on the market. The FDA 510(k) summary stated that the VasClip was determined to be substantially equivalent to the Hem-O-Lok, a clip used to ligate blood vessels. The VasClip is a Class II device intended for ligation of the vas deferens.

Literature Review

Sterilization outcomes and adverse events, using the VasClip implant, were studied in 124 consecutive patients by Kirby and colleagues (2006). Successful outcomes were measured by azoospermia, patient satisfaction and adverse events. At 90 days post-procedure, 100 patients were reported as azoospermic, while 16 others were reported as reaching azoospermia between 135 days and their 10–14 month follow-ups. Five patients were lost, and three failed to reach azoospermia after 362 days. These three individuals then underwent an open vasectomy with excision of the VasClip for tissue and device examination. This examination demonstrated the critical significance of proper device placement. Although the devices were found to be locked, tissue within the device was viable. However, if the device had pierced the vas, granuloma formation (n=1) and tubular proliferation (n=3) were noted. Subsequent sections of the lumen showed recanalization and the presence of

viable sperm. The researchers concluded that rates of infertility could be comparable to those obtained with vasectomy when the device is properly implanted.

Between September 2003 and March 2004, eight patients underwent elective VasClip vasectomies and were then studied to determine the efficacy and mechanisms of failure of the VasClip device. Levine and colleagues (2006) asked the patients to return at four weeks for semen analyses. Six of the eight (75%) patients were found to be azoospermic, while two (25%) had essentially normal semen analyses. These two patients then underwent surgical exploration and repeat vasectomies. The VasClips were found to be in position, intact and secure; however, free flow dilute methylene blue solution could be injected through the vas, indicating patency. The outcomes of histological examination showed inflammatory infiltrate consistent with sperm granuloma. The researchers concluded that additional studies should be conducted that utilize the application of two VasClips, similar to the hemoclips used during other vasectomy procedures to determine the efficacy of sterilization using this approach.

According to the manufacturer's website, VMBC conducted a prospective clinical study of 124 patients using the VasClip to determine possible complications of using the device and to gather patient acceptance ratings. VMBC reported that one of the subjects had significant swelling; no patients reported infection; two patients developed sperm granulomas; and, on a patient-response questionnaire, 109 of 110 patients responded that they would recommend the procedure to others. It is important to note that this study has not been published to date and as such has not been subjected to the peer-review process. Limitations to this study include failure to report study-population demographics, failure to use a control group and lack of randomization to established sterilization alternatives. In addition, results are reported based on nonevidence-based patient response questionnaires. At 373 days, only 68 patients were available for semen analysis (lost to follow-up: 45% [56/124 no data available]). Patient responses regarding the VasClip device were compared to retrospective outcome results concerning patient responses to conventional vasectomies; patient follow-up time was not reported, and the source of this data is unknown. The manufacturer also reported that three patients (2.5%) did not become azoospermic and received traditional vasectomies. After an analysis of the VasClips that were used on these patients, it was determined that the clip had not been properly placed and that this emphasizes the need for careful placement and proper technique adherence.

According to the VMBC website, a second study has been conducted by the manufacturer, referred to as the Semen Analysis Post-Procedure (SAPP) Study. A total of 78/124 (63%) patients from the original prospective study agreed to participate in this analysis. The manufacturer findings were: 1) five of seven patients who had non-motile sperm present at 373 days were now azoospermic; 2) one of these seven patients did not return after 853 days; and 3) one patient continued to have the presence of non-motile sperm.

Cook et al. (2004) reported in a Cochrane review of the published, peer-reviewed literature that only two studies had been published to date comparing a conventional vasectomy procedure to a vas occlusion with titanium clips. Both of these studies are small and lack randomization, and each reported focusing on differing endpoints to measure success: failure to reach azoospermia by six months, adverse events and operating time versus total time needed to reach azoospermia, and consumer acceptability. Each study used different sperm-measuring time intervals; semen analysis techniques are unknown; and adverse events, outcome measures and follow-up time frames were not reported as part of the outcome data. The author concluded that, due to the low quality and underpowered populations of the studies, no conclusions can be made about the effectiveness, safety, acceptability of vas occlusion technique or vas irrigation. Randomized controlled trials examining other techniques were not available, and thus the authors concluded that additional research is needed to examine the various techniques.

After reviewing the studies conducted on male sterilization, the Royal College of Obstetricians and Gynecologists (RCOG, 2004) determined that, except when technical considerations dictate otherwise, a no-scalpel approach should be used to identify the vas, as this approach results in a lower rate of early complications. Division of the vas on its own is not an acceptable technique because of its failure rate. It should be accompanied by fascial interposition or diathermy. Clips should not be used for occluding the vas, as failure rates are unacceptably high.

Professional Societies/Organizations

American College of Obstetricians and Gynecologists (ACOG, 2007): According to ACOG, a vasectomy is a method of male sterilization in which a portion of the vas deferens is removed. The doctor locates each vas in

the scrotum. One or two small openings are then made into the skin of the scrotum. Each vas is pulled through the opening until it forms a loop. A small section is cut out of the loop and removed. The two ends are tied and may be sealed with heat. This causes scar tissue to grow to block the tubes. Each vas then is placed back in the scrotum.

Recently, some doctors have begun to use a "no-scalpel" technique for vasectomy. In this procedure, the vas deferens is cut the same way, but instead of making an incision, a special tool is used to puncture the scrotum in one place. No stitches are needed after the procedure. Patients have less pain afterward, and recovery time is shortened (ACOG, 2007).

Association of Reproductive Health Professionals (ARHP, 2006): The definition of no-scalpel vasectomy is described as a surgical approach for isolating and delivering the vas that uses conventional methods of vas occlusion. The recommended methods of vas occlusion include: ligation with excision and fascial interposition; and cauterization (ARHP, 2006).

Planned Parenthood (2006): Vasectomy is considered permanent birth control for men. It is a medical procedure that is intended to cause sterility. Vasectomy is a low-risk procedure. There is the potential for pregnancy after this procedure; therefore, semen analyses should occur about three months after the procedure and repeated until no sperm are seen (Planned Parenthood, 2006).

Summary

There is insufficient evidence in the published, peer-reviewed scientific literature to support the use of vas deferens ligation clips (VasClip[®]) as a means of permanent male sterilization. The procedure has not been adequately compared to traditional vasectomy, the established surgical standard, through well-designed randomized, controlled clinical trials.

There is insufficient evidence in the literature documenting the following:

- successful achievement of azoospermia
- the time interval needed to achieve successful azoospermia
- notation of adverse events (e.g., infection, pain, epididymitis).

The long-term safety and effectiveness of the vas deferens clip has not been demonstrated.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
	No specific codes

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
V. 25.2	Sterilization
	All other codes

*Current Procedural Terminology (CPT[®]) © 2007 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2007	0291	Vas Deferens Ligation Clip (VasClip®)

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