Vasectomy Procedures

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aenta considers the following vasectomy procedures (not an all-inclusive list) experimental and investigational because of insufficient evidence of their effectiveness:

- Implantable vas deferens ligation clip (Vasclip, VMBC, LLC, Roseville, MN)
- Pro-Vas occlusion method
- Vasal injection (e.g., reversible inhibition of sperm under guidance (RISUG))
• Vasal occlusion (e.g., Intra Vas Plug)

Aetna considers a vasectomy reversal procedure in the treatment of post-vasectomy pain syndrome experimental and investigational because there is inadequate evidence in the peer-reviewed published literature regarding its effectiveness.

Aetna considers epididymectomy for the treatment of chronic post-vasectomy pain syndrome experimental and investigational because there is inadequate evidence in the peer-reviewed published literature regarding its effectiveness.

**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 2 ends of the vas rejoining) and the 2 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 3 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 than 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 3 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 2 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 2 groups with regard to the primary outcome of failure to reach azoospermia. However, Cook et al (2004) 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.

The Pro-Vas occlusion technique utilizes a titanium spring ligation clip that stops the flow of sperm without the need to cut or burn the sperm ducts. Pro-Vas has also been reported to result in less post-procedure pain and quicker return to normal activities compared with traditional vasectomy. Additionally, there were no complications following Pro-Vas occlusions, however, it is acknowledged the number of patients is not sufficient to provide statistically significant results. According to Dr. Swartz, the Pro-Vas occlusion technique has the potential to simplify and standardize the vasectomy technique. It may provide less experienced vasectomy surgeons a means for achieving clinical results similar to those of experienced surgeons. The Pro-Vas technique also spares sacrificing the vasal artery. Dr. Swartz added that there should be a lower recanalization rate with the Pro-Vas method because the spring ligation clip cannot dislodge or ever lose its constant low-pressure occlusion force. Additionally, the clip is designed not to apply so much pressure that may result in necrosis – a situation that sometimes occurs with other types of ligatures. Should the patient ever change his mind with regard to his vasectomy, reversal of the Pro-Vas procedure should be much easier as the clip is very easy to identify and dissection to find the two occluded ends of the vas will be much simpler. Patient acceptance may be higher with the Pro-Vas occlusion technique than traditional vasectomy because overall quality of the outcomes may be improved. However, these hypotheses need to be confirmed by additional clinical studies.
Michielsen and Beerthuizen (2010) performed a systematic Medline/PubMed and Cochrane Library review of the literature with regard to technique, effectiveness, safety and complications of male sterilization. Vasectomy is an outpatient procedure which can be performed under local anesthesia. The vas deferens is accessed by means of either a conventional incision with a scalpel or by using the "no-scalpel technique". A closed-ended vasectomy (by means of suture ligature, surgical clips or electro-cautery) or the open-ended alternative is then carried out. Each of these techniques has both advantages and drawbacks. Fascial interposition has been shown to reduce the risk of failure. A promising alternative for occluding the vas consists of placing an intra-vas device. Hematoma and pain are the most common complications. Non-steroidal anti-inflammatory drugs, narcotic analgesics and neuroleptic drugs are effective for treatment of pain. The success of vasectomy reversal ranges from 30 to 60 %. The data on record convincingly demonstrate that vasectomy is a safe and cost-effective intervention for permanent male contraception. The no-scalpel vasectomy under local anesthesia is recommended. Occlusion of the vas is most successful when performed by means of an electrocautery; fascial interposition should complete the procedure.

The American Urological Association’s guideline on “Vasectomy” (Sharlip et al, 2012) provided guidance to clinicians who offer vasectomy services. This guideline was peer-reviewed by 55 independent experts during the guideline development process. The guideline stated that vas isolation should be performed using a minimally-invasive vasectomy technique such as the no-scalpel vasectomy technique. Vas occlusion should be performed by any 1 of 4 techniques that are associated with occlusive failure rates consistently below 1
%. These are mucosal cautery of both ends of the divided vas without ligation or clips (1) with or (2) without fascial interposition; (3) open testicular end of the divided vas with mucosal cautery of abdominal end with fascial interposition and without ligation or clips; and (4) non-divisional extended electrocautery. Patients may stop using other methods of contraception when 1 un-centrifuged fresh semen specimen shows azoospermia or less than or equal to 100,000 non-motile sperm/ml. The authors concluded that vasectomy should be considered for permanent contraception much more frequently than is the current practice in the U.S. and many other nations.

The European Association of Urology’s guidelines on “Male infertility” (Jungwirth et al, 2013) stated that fascial interposition and cauterization appears to be the most effective vasectomy technique. Furthermore, methods of male contraception other than vasectomy are associated with high failure rates or are still experimental (e.g., hormonal approach).

In a Cochrane review, Cook et al (2014) compared the effectiveness, safety, acceptability and costs of vasectomy techniques for male sterilization. In February 2014, these investigators updated the searches of CENTRAL, MEDLINE, POPLINE and LILACS. They looked for recent clinical trials in ClinicalTrials.gov and the International Clinical Trials Registry Platform. Previous searches also included EMBASE. For the initial review, the authors searched the reference lists of relevant articles and book chapters. They included randomized controlled trials (RCTs) comparing vasectomy techniques, which could include suture ligature, surgical clips, thermal or electrocautery, chemical occlusion, vas plugs, vas excision, open-ended vas, fascial interposition, or vas irrigation. These researchers assessed all titles and abstracts located in the literature searches; 2 reviewers independently extracted data from articles identified for inclusion. Outcome measures include contraceptive efficacy, safety, discontinuation, and acceptability. Peto odds ratios (OR) with 95 % confidence intervals (CI) were used for dichotomous outcomes, such as azoospermia. The mean difference (MD) was used for the
continuous variable of operating time. A total of 6 studies met the inclusion criteria; 1 trial compared vas occlusion with clips versus a conventional vasectomy technique. No difference was found in failure to reach azoospermia (no sperm detected). Three trials examined vasectomy with vas irrigation; 2 studies looked at irrigation with water versus no irrigation, while 1 examined irrigation with water versus the spermicide euflavine. None found a difference between the groups for time to azoospermia. However, 1 trial reported that the median number of ejaculations to azoospermia was lower in the euflavine group compared to the water irrigation group. One high-quality trial compared vasectomy with fascial interposition versus vasectomy without fascial interposition. The fascial interposition group was less likely to have vasectomy failure. Fascial interposition had more surgical difficulties, but the groups were similar in side effects. Lastly, 1 trial found that an intra-vas was less likely to produce azoospermia than was no-scalpel vasectomy. More men were satisfied with the intra-vas device, however. 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 interposition reduced vasectomy failure. An intra-vas device was less effective in reducing sperm count than was no-scalpel vasectomy. Moreover, they stated that RCTs examining other vasectomy techniques were not available. More and better quality research is needed to examine vasectomy techniques.

Tan and Levine (2016) stated that post-vasectomy pain syndrome (PVPS) remains one of the more challenging urological problems to manage. This can be a frustrating process for both the patient and clinician as there is no well-recognized diagnostic regimen or reliable effective treatment. The authors noted that while excision of sperm granuloma, micro-denervation of the spermatic cord (MDSC), epididymectomy, vasectomy reversal or orchiectomy has been used in refractory cases of PVPS, the success rates of these procedures remain unclear due to the availability of only small case series of men undergoing surgical treatment for this
condition.

Smith and colleagues (2016) noted that variations in vasectomy techniques have failed to define a means of preventing PVPS. In addition, studies examining the pathophysiology of this condition have failed to elucidate a reproducible cause. Prevailing assumptions are focused upon epididymal congestion and obstruction. Potentially, up-and-coming techniques such as vasal occlusive gels, currently under development, offer novel alternatives to traditional vasectomy. Such an intra-vasal approach could involve the percutaneous puncture of the vasal lumen and instillation of a reversible, semi-permeable polymer gel. This intra-vasal option could theoretically decrease the negative side effects that result from direct scrotal manipulation. However, if the assumption of epididymal congestion holds true, it would stand to reason that any mechanism that retards the flow of sperm from the epididymis has the potential to result in post-vasectomy pain. Thus, potentially the best correction for post-vasectomy pain rests with the generation of a hypothetical male oral contraceptive. Such a medication, by avoiding the need to have an occlusive process for vasectomy, could eliminate post-vasectomy pain and its related sequelae.

Vasal Injection and Vasal Occlusion:

Kanakis and Goulis (2015) stated that despite the variety of available female contraceptive methods, many pregnancies are still undesired. Many men want to participate equally with their partner in family planning; however, male contraceptive methods (MCMs) account for only 14% of those used worldwide and no pharmaceutical MCM is available so far. The only 2 MCMs currently available are condoms, which despite protecting against sexually transmitted diseases have high failure rates, and vasectomy, which though very efficient (99%) is poorly reversible. Among MCMs under investigation, male hormonal contraceptives (MHCs) are those that have come closest to commercialization. The action of MHCs relies on the disruption of spermatogenesis that exogenous androgen
administration evokes by suppressing the hypophyseal-gonadal axis. Various regimens of androgens as monotherapy or in combination with progestins have been tested in clinical trials achieving a Pearl Index that is equal to that of the female oral contraceptive pill; however, concerns regarding the variable response rates observed (non-responders: 5 to 20%), the impracticality of parenteral administration and long-term prostate-associated or cardiovascular morbidity have deflected the interest of the pharmaceutical industry from further research. Non-hormonal contraception methods may be, at least theoretically, more specific by selectively disrupting spermatogenesis and sperm transport or fertilizing ability. The authors noted that only a few have been tested in clinical trials (Intra Vas Plugs, and reversible inhibition of sperm under guidance [RISUG]); most of them are still in pre-clinical development or have been abandoned due to toxicity (gossypol).

Ansari and colleagues (2016a) stated that among the vas-based methods on trial, RISUG, a co-polymer of styrene and maleic anhydride is being projected as an effective alternative to no-scalpel vasectomy (NSV). Reversible inhibition of sperm under guidance offers long-term contraception with safety, effectiveness in human trials and can be delivered by no-scalpel injection. Currently, the procedure is under phase-III clinical trial. However, reversal of this vas-based drug-induced contraception needs to be established in animal models prior to clinical trials to ensure its claim as an effective alternative for vasectomy. In the present investigation, the relative suitability of dimethyl sulphoxide (DMSO) and sodium bicarbonate (NaHCO3) for RISUG induced long-term vas occlusion reversal was carried out in albino rats. Animals were allocated into 4 groups: (i) sham-operated control (group-I), (ii) vas occlusion with RISUG for 360 days (group-II), (iii) vas occlusion with RISUG for 360 days and reversal with DMSO (group-III) and (iv) vas occlusion with RISUG for 360 days and reversal with NaHCO3 (group-IV); n = 10 for each group. A variable response in fertility was observed in different groups. Absolute sterility in group III at all mating intervals, while, 0 % fertility in groups II
and IV following 90 days of occlusion was observed. Following reversal restoration of fertility with DMSO at 45 days, whereas, reversal by NaHCO3 at 30 days was noticed. Ejaculated spermatozoa of RISUG injected and initial intervals of reversed animals exhibited various degrees of abnormalities. The testes exhibited focal degeneration in vas-occluded animals. The occluded lumen of the vas deferens contained an eosinated polymer with exfoliated epithelium. Following vas occlusion reversal, a complete regeneration in the vas epithelium was seen. All other parameters remained unaltered. The authors concluded that the reversal with NaHCO3 resulted in an early resumption of fertility when compared with DMSO and the procedure was found to be successful, feasible and safe up to F1 generation. They state that RISUG provides a hope for reversible male contraceptives.

Ansari and associates (2016b) evaluated reversal of short- and long-term vas occlusion with RISUG using DMSO and NaHCO3 in male rabbits; animals were divided into 7 groups (n= 5 for each group). Fortnightly, semen analysis revealed that sperm concentration and output steadily declined after vas occlusion and complete azoospermia was attained at 30 to 60 days post-injection. Spermatozoa re-appeared at 60 to 75 days of reversal and normal zoospermia was noticed between 135 days and 150 days in the reversal groups. All spermatozoa were found non-motile before azoospermia and a gradual recovery in sperm motility was observed between 105 days and 135 days of reversal. A significant decline in viability of sperms was noticed during vas occlusion up to 30 to 60 days, which recovered at 60 to 75 days post-reversal and normalized by 75 to 105 days in the reversal groups. A significant enhancement in the sperm abnormalities was recorded in all vas-occluded animals as well as those in initial periods of reversal. Other parameters, namely, semen volume, ejaculation time, pH, color, and consistency, remained unaltered during all phases of the study. Fertility test, at the intervals of 15 days, demonstrated that animals exhibited complete sterility during the entire period of vas occlusion. A gradual recovery in fertility was observed with the appearance of spermatozoa following vas occlusion reversal.
and 100 % fertility was observed following 135 to 150 days of reversal; F1 progeny of reversed animals was found normal. The authors concluded that these findings suggested that reversal with DMSO or NaHCO3 is feasible, with normal progeny, following short- and long-term contraception.

An UpToDate review on “Vasectomy and other vasal occlusion techniques for male contraception” (Viera, 2016) states that “Vasal occlusion with a plug (e.g., “Shug” or medical grade silicone rubber), requires microsurgery for implantation and later removal. Either a conventional open or no-scalpel technique may be used to isolate the vas deferens for the implantation of these devices. Surgical vasal occlusion procedures claim to produce reversible azoospermia without affecting spermatogenesis, but there are no human data on success rates. Vasal injection -- Percutaneous methods can be used for injecting chemicals directly into the vas deferens to effect temporary (polymer) or permanent (sclerosing agents) occlusion. One technique intended for permanent sterilization involves first injecting 2 dyes into the vas, using a different color for the left and right vas. Then, a sclerosing agent is then injected into the vas lumen distal to the previously injected dye. Successful occlusion is determined by having the patient void to see which, if any, dye is excreted in the urine. The chemicals required for this procedure are not available for use in the US. Another technique, reversible inhibition of sperm under guidance (RISUG) involves injection the non-sclerotic polymer, styrene maleic anhydride (SMA). It is claimed to offer long-term contraception without adverse side effects. The purported advantages of this method are that it provides long-term contraception without the side effects associated with male hormonal contraception, and in contrast to the other techniques listed above, is reversible without surgery. Clinical trials are ongoing.”
Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

**ICD-10 codes will become effective as of October 1, 2015:**

**Implantable clip: (Vasclip, VMBC, LLC, Roseville, MN):**

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**ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):**

| Z30.2 Encounter for sterilization |

**Vasectomy reversal procedures:**

**CPT codes not covered for indications listed in the CPB:**

| 54860 Epididymectomy; unilateral |
| 54861 bilateral                  |
| 55400 Vasovasostomy, vasovasorrhaphy |

**Other CPT codes related to the CPB:**

| 52402 Cystourethroscopy with transurethral resection or incision of ejaculatory ducts |
| 55250 Vasectomy, unilateral or bilateral (separate procedure), including postoperative semen examination(s) |
| 55450 Ligation (percutaneous) of vas deferens, unilateral or bilateral (separate procedure) |
| 89310 Semen analysis; motility and count (not including Huhner test) |

**ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):**

| G89.28 Other chronic postprocedural pain [post-vasectomy] |

The above policy is based on the following references:

1. American College of Obstetricians and Gynecologists (ACOG). Benefits and risks of sterilization. ACOG Practice


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Amendment to
Aetna Clinical Policy Bulletin Number: CPB 0027
Vasectomy Procedures

There are no amendments for Medicaid.

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