



Cigna Medical Coverage Policy

**Subject Male Sexual Dysfunction
Treatment: Non-pharmacologic**

**Effective Date 8/15/2014
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Hyperlink to Related Coverage Policies

[Collagenase clostridium histolyticum \(Xiaflex®\)](#)
[Oral Phosphodiesterase-5 \(PDE5\) Inhibitors](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

Coverage Policy

The treatment of male sexual dysfunction, including erectile dysfunction, is specifically excluded under many benefit plans; regardless of underlying condition; therefore, penile prostheses and external erectile aids of any kind are generally not covered. Surgery for male sexual dysfunction is also generally not covered. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage is available for the treatment of male sexual dysfunction, the following conditions of coverage apply.

Vacuum Constriction Device

When coverage is available for a vacuum constriction device, it may be subject to the terms, conditions and limitations of the applicable benefit plan's External Prosthetic Appliances and Devices (EPA) or Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for EPA and DME is limited to the lowest-cost alternative.

Cigna covers a vacuum constriction device as medically necessary for the treatment of erectile dysfunction when BOTH of the following criteria are met:

- erectile dysfunction is due to an organic etiology and is not psychological in nature
- there is failure, contraindication or intolerance to pharmacological therapy*

Cigna does not cover a vacuum constriction device for ANY other indication because it is considered not medically necessary.

Penile Prosthesis

Cigna covers the surgical implantation of a penile prosthesis as medically necessary when ALL of the following criteria have been met:

- erectile dysfunction is due to an organic etiology and is not psychological in nature
- there is failure, contraindication or intolerance to pharmacological therapy*
- consideration has been given to intracavernosal injection, intraurethral medication, and a vacuum constriction device

Cigna covers the surgical reimplantation of a medically necessary penile prosthetic device, following the medically necessary removal of a penile prosthesis, when benefit coverage is available.

Cigna covers the removal of a penile prosthesis as medically necessary for ANY of the following indications:

- infection
- mechanical failure
- urinary obstruction
- intractable pain

Cigna does not cover a penile prosthesis for ANY other indication because it is considered not medically necessary.

***Note: Medications for the treatment of erectile dysfunction are specifically excluded under many pharmacy benefit plans. Please refer to the applicable pharmacy benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.**

Not Covered Procedures

Cigna does not cover ANY of the following for the treatment of erectile dysfunction because each is considered experimental, investigational or unproven (this list may not be all-inclusive):

- venous occlusive surgery (e.g., venous ligation)
- sural nerve grafting during radical retroperitoneal prostatectomy
- extracorporeal shock wave therapy (ESWT) for the treatment of Peyronie's disease

General Background

Erectile dysfunction (ED) (i.e., impotence) is defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance. ED usually has a physical cause in older men and is treatable at all ages. Although the incidence of ED increases with age, it is not an inevitable part of the aging process (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2003; Morales, 2003; Chang, 2004; Fazio, et al., 2004; Rosen, et al., 2005).

There are two main categories of erectile dysfunction: psychogenic and organic. There are multiple causes of organic ED including disease processes, trauma, drug and alcohol use/abuse, as well as smoking. There are four main types of health conditions that can cause physical problems resulting in ED (National Health Services [NHS], 2012):

- vasculogenic - affecting blood flow to the penis
- neurogenic - affecting the nervous system (i.e., brain, nerves, spinal cord)
- hormonal –affecting the levels of certain hormones (e.g., testosterone)
- anatomical –affecting the physical structure of the penis

ED may occur as a result of an underlying medical condition, such as diabetes, kidney disease, hormonal imbalance, multiple sclerosis, atherosclerosis, vascular disease or neurological disease. Injury to the penis, spinal cord, prostate, bladder, and pelvis may also cause ED due to damage to nerves smooth muscles, arteries or fibrous tissue of the corpora cavernosa. Surgery, especially radical prostate or bladder surgery can injure the nerves and arteries near the penis resulting in ED. One of the side effects of medications, such as antihypertensive drugs, antihistamines, antidepressants, tranquilizers, histamine-receptor antagonists for treatment of gastric ulcers, opiates, and appetite suppressants is ED. Peyronie's disease, which causes scarring of the fibrous tissue of the penis, and priapism (i.e., persistent, abnormal erection of the penis) are associated with ED. Other possible contributing factors of ED include smoking, which affects blood flow, and hormonal abnormalities. Psychological factors (e.g., stress, anxiety, depression, and low self-esteem) cause 10–20% of ED cases (NIDDK, 2003; Morales, 2003; Chang, 2004; Rosen, et al., 2005; McVary, 2007).

The most important component of diagnosing ED is obtaining a complete medical and psychosexual history. A psychogenic disorder can be the primary cause of ED; therefore, early recognition and appropriate referral for counseling may be recommended. Concurrent medical illnesses and medications should be reviewed. The history may reveal reversible or modifiable risk factors, such as inadequate diabetes control. The physical examination should focus on the vascular, neurological and endocrine systems. Laboratory investigations should follow clinical suspicion of specific disorders. The First International Consultation on Erectile Dysfunction, cosponsored by the World Health Organization (WHO), the International Consultation on Urological Diseases, and the Société Internationale d'Urologie, recommends obtaining a fasting glucose or glycosylated hemoglobin level, a lipid profile and a testosterone assay. Testing for prostate-specific antigen (PSA) level was not recommended by this international consultation; however, it would be in accordance with American Urological Association (AUA) and American College of Surgeons (ACS) guidelines (Broderick, et al., 2002; Fazio, et al., 2004; Baldo, et al., 2005; McVary, 2007). Vascular flow to the corpora cavernosa may be evaluated using a penile doppler examination. Color duplex ultrasonography, which measures cavernous artery diameter and pressures, may also be used to assess venous leakage. According to the American Association of Clinical Endocrinologists (AACE), "occasionally, the measurement of nocturnal penile tumescence and rigidity is useful, especially to distinguish between psychologic and organic erectile dysfunction" (AACE, 2003).

The method of treatment for ED is dependent upon the etiology of the condition. Psychologically-based ED, without organic cause (e.g., secondary to depression, anxiety, stress) may dissipate with psychotherapy and/or behavioral therapy. According to the American Urological Association (AUA), the management of ED begins with the identification of organic comorbidities and psychosexual dysfunctions; both should be appropriately treated. Organic ED can occur as a secondary condition to several diseases and/or their treatment. Treatment of underlying diseases such as diabetes mellitus, hypertension, heart disease and endocrine conditions (e.g., hypogonadism, hyperprolactinemia, and thyroid disorders), and cessation or modification of prescription medications (e.g., antihypertensives) may be indicated. Discontinuing alcohol consumption and illicit drug use, and/or making lifestyle modifications (e.g., avoiding smoking, maintaining ideal body weight and engaging in regular exercise) may reverse ED. Treatment of Peyronie's disease resulting in severe curvature may involve the concomitant use of incision/grafting and prosthesis insertion due to the significant incidence of erectile dysfunction following surgery on the penis for Peyronie's plaques (Taylor and Levine, 2007). There is some controversy regarding testosterone replacement therapy, which includes oral preparations, intramuscular injections, topical gels, and transdermal preparations. Topical gels are the most commonly prescribed forms of testosterone replacement (NIDDK, 2003; Morales, 2003; Chang, 2004; Seftel, et al., 2004; Brant, et al., 2007; McVary, 2007).

Therapy should be applied in a "stepwise fashion with increasing invasiveness and risk balanced against the likelihood of efficacy" (American Urological Association [AUA], 2006). Oral agents (e.g., PDE-5 inhibitors) have become the first-line treatment option for ED. Use of PDE-5 inhibitors is successful in 70–80% of men. With the availability of oral agents and minimally invasive options surgical implantation typically occurs when these less invasive options are unavailable, unsuccessful or provide inadequate erectile function (NIDDK, 2003; Morales, 2003; Fazio, et al., 2004; Carson, 2005; Jain and Terry, 2006; Brant, et al., 2007; McVary, 2007; Sadeghi-Nejad, 2007). In addition to the surgically implanted prostheses, other procedures may be recommended for ED that is refractory to medical therapy. Vascular surgical procedures include penile arterial bypass or revascularization and venous ligation for the treatment of vasculogenic ED. For those with ED unresponsive to nonsurgical treatments, vascular surgery may be the preferred treatment option that offers the possibility of spontaneous, unaided erections. Sural nerve grafting has been proposed as a surgical intervention for ED that occurs in association with radical prostatectomy. The Nesbit and Lue procedures are established for the correction of

penile deformities caused by Peyronie's disease. Extracorporeal Shock Wave Therapy (ESWT) has also been proposed as a treatment for Peyronie's disease.

U.S. Food and Drug Administration (FDA)

There are two types of mechanical devices for treatment of erectile dysfunction: vacuum constriction devices and implantable penile prosthetic devices. Both are regulated by the FDA. Vacuum constriction devices are classified by the FDA as Class II medical devices and are exempt from the premarket notification requirements of the 510(k) process (NIDDK, 2003; FDA, 2004). Examples of these devices are the Rejoyn Vacuum Therapy System (American Med Tech, Dodge City, KS) and Osbon ErecAid™ Vacuum Therapy (Endocare, Inc., Eden Prairie, MN).

Implantable penile prostheses are either noninflatable (i.e., semirigid rods) or inflatable. Noninflatable devices are classified by the FDA as Class II medical devices and consist of a pair of semi-rigid rods or cylinders that are surgically implanted in the corpora cavernosa. The purpose of the device is to provide adequate penile rigidity for intercourse. This classification includes the following designs (FDA, 2000):

- rod prosthesis: a flexible, solid cylinder of polymer material
- malleable prosthesis: a flexible polymer cylinder that incorporates an internal metal core
- single-hinged prosthesis: a highly flexible material that enables the user to position the penis downward for concealment
- multiple-hinged prosthesis: a series of hinged segments, encapsulated in a polymer sheath

The AMS Malleable 650 (American Medical Systems, Inc., Minnetonka, MN) and the Mentor Genesis™ Penile Prosthesis (Mentor Corporation, Santa Barbara, CA) are examples of rigid penile prostheses.

Inflatable devices are classified by the FDA as Class III medical devices and consist of paired cylinders, surgically implanted inside the penis, which can be expanded using pressurized fluid. Tubes connect the cylinders to a reservoir filled with radiopaque fluid implanted in the abdomen and a subcutaneous pump implanted in the scrotum. The user inflates the cylinders by pressing on the small pump, located under the skin in the scrotum (FDA, 2004; NIDDK, 2003). The AMS 700 CXM (American Medical Systems, Inc., Minnetonka, MN) and the Mentor Alpha 1® (Mentor Corporation, Santa Barbara, CA) are examples of inflatable penile prostheses.

Vacuum Constriction Device

When medical modalities are unsuccessful or contraindicated, a vacuum constriction device offers a viable alternative treatment. This device functions as an external aid; however, some users may find it difficult to use. The device causes an erection by creating a partial vacuum, drawing blood into the penis, engorging and expanding it. The device has three components: a plastic cylinder, in which the penis is placed; a pump that draws air out of the cylinder; and an elastic band that is placed around the base of the penis to maintain the erection when the cylinder is removed.

Penile Prosthesis

When nonsurgical therapies have proven ineffective, a penile prosthesis may be surgically implanted. Since surgery destroys the corpus cavernosus of the penis, this procedure precludes any future pharmacological treatment (NIH, 1992; NIDDK, 2003; Morales, 2003).

Complications of penile prostheses include erosion of the device, mechanical failure and the possibility of infection. Device extrusion, migration, urinary obstruction and prolonged or intractable pain are other potential risks. The average infection rate post-operatively ranges from 2–4% over a two year period, with most infections becoming evident during the first year. Some bacterial species can lie indolent for as long as two years before causing clinical signs of infection. Men with diabetes, spinal cord injuries or urinary tract infections have an increased risk of prosthesis-associated infections. If the infection cannot be successfully treated with antibiotics, it may be necessary to remove the prosthesis. Replacement with a new prosthesis should be delayed after removal of an infected prosthesis to allow adequate healing and eradication of the offending microorganism (NIH, 1993; FDA, 2004; Chang, 2004).

Literature Review: Due to the nature of these devices, outcomes reported in studies evaluating their effectiveness are largely self-reported and subjective (e.g., patient satisfaction questionnaires). Objective outcome measures that have been reported in the medical literature include rate of mechanical failures and defects, and complications. Published evidence supports improved patient satisfaction with the use of penile implants when compared to sildenafil or intracavernous injections (Rajpurkar, et al., 2003); improved quality of life (Ferguson, et al., 2003); and improved erectile function (Mulhall, et al., 2003). Patient satisfaction has been reported to range from 71% to 91.2% with the use of implantable penile prostheses (Ferguson, et al., 2003; Minervini, et al., 2005; Israilov, et al., 2005; Zermann, et al., 2005; Knoll, et al., 2009; Paranhos, et al., 2010). Wilson et al. (2007) reported an estimated mechanical revision rate of 79.4% for device survival at 10 years compared to 71.2% at 15 years. The authors also noted with newer devices a 10-year mechanical survival and freedom from mechanical breakage increased to 88.6% and 97.9%, respectively. In general, the medical literature indicates these devices are safe and effective for the treatment of ED for a carefully selected subset of individuals whose condition is organic in nature and have failed more conservative treatment.

Vascular Surgery

Patients who are considered for vascular surgical therapy typically have appropriate preoperative evaluation, which may include the combined injection and stimulation (CIS) test, dynamic infusion pharmacocavernosometry and cavernosography (DICC), duplex ultrasonography, and possibly arteriography. Penile arterial reconstructive surgery, also referred to as penile arterial bypass or revascularization, is one intervention that has the potential to cure patients with ED. During penile revascularization procedures, an arterial blockage is bypassed usually by anastomosing the inferior epigastric artery to the dorsal artery of the penis. Young men without other vascular risk factors (e.g., diabetes, high blood pressure, lipid disorders, cigarette smoking), who have ED due to pure artery blockage, are ideal candidates for this procedure. For posttraumatic arteriogenic ED in young patients, surgery penile revascularization has a 60–70% long-term success rate (Hatzimouratidis, et al., 2010).

Penile Vein Ligation: Venous ligation is a surgical procedure used to treat veno-occlusive ED, or erectile failure caused by venous insufficiency. The procedure involves the removal or ligation of the veins leaving the corpora cavernosa. Penile vein ligation techniques range from dorsal and accessory vein ligation to complete ligation and excision of the dorsal, cavernous, and crural veins. Surgery of the penile venous system has been reported to have some efficacy in patients with venous leakage. However, the tests necessary to establish this diagnosis have been incompletely validated. Therefore, it is difficult to select patients who will have a predictably good outcome. In general, the long-term benefits of venous ligation surgery have been limited. Success rates within the first year range from 23–80% but consistently decrease on longer follow-up (Rao and Craig, 2001).

Literature Review: Studies in the published peer-reviewed medical literature evaluating penile vein ligation for venogenic ED include case series primarily with small sample sizes. A larger series by Hsu et al. (2010) compared patients with veno-occlusive dysfunction who were treated with a venous stripping surgical method (n=178) patients who were treated without this surgery (n=163). At an average follow-up of 7.7 years, there were no statistically significant differences in outcomes between surgery and control groups as measured by IIEF-5 scores.

Cayan (2008) reported a series of 26 patients who underwent penile venous surgery with crural ligation for primary venous leakage. Postoperatively complete improvement in erectile function occurred in 11 men (42.3%), partial improvement occurred in eight (30.8%), and erectile function remained unchanged in seven (26.9%). Earlier case series have reported success rates of 31%–60% (Berardinucci, et al., 1996; Kim and McVary, 1995).

Sural Nerve Graft with Radical Prostatectomy

Despite advances in radical prostatectomy procedures, ED remains a significant postoperative complication. When both neurovascular bundles are spared during radical retropubic prostatectomy (RRP), potency rates of up to 70% have been reported, but rates of 30–60% have been observed. For intentional resection of both neurovascular bundles, the return of erectile function is the exception (Kim, et al., 2001). Sural nerve grafting has been proposed as an intervention at the time of RRP to prevent ED associated with the procedure. In sural nerve grafting, a portion of the sural nerve is harvested from one leg and then anastomosed to the divided ends of the cavernous nerves which are resected during a radical prostatectomy.

Literature Review: There is limited data in the scientific peer-reviewed literature regarding the long-term outcomes of sural nerve grafting. An RCT by Davis et al. (2009) compared outcomes of patients who underwent unilateral nerve-sparing radical prostatectomy with a sural nerve graft (n=66) to those who had unilateral nerve-sparing radical prostatectomy alone (n=41). At 24-month follow-up, there was no significant difference in the return of erectile function for the SNG group versus the control group (p=0.962).

Nonrandomized controlled comparison studies and case series have also evaluated the safety and effectiveness of sural nerve grafting with radical prostatectomy (Satkunasivam, et al., 2009; Hanson, et al., 2008; Zorn, et al., 2008; Sim, et al., 2006; Porpliglia, et al., 2005; Chang, et al., 2002; Kim, et al., 2001). Study populations have ranged from 28–40 with a follow-up range of 12–24 months. Small sample sizes have limited the generalizability of results. In addition, the results of these studies have not consistently shown a statistically significant difference in erectile function after sural nerve grafting.

Extracorporeal Shock Wave Therapy (ESWT) for Peyronie's Disease (PD)

Peyronie's disease (PD) is a localized connective tissue disorder of unknown cause, and is characterized by the formation of inelastic fibrous plaques within the tunica albuginea or erectile tissue of the penis. For many patients, PD results in sexual problems due to the difficulty in attaining and/or maintaining erections. In a significant number of patients, the disorder improves or resolves spontaneously. Medical therapies, including antioxidants (such as vitamin E and potassium aminobenzoate) and corticosteroids injected directly into the plaque, lack adequate scientific support. Surgery for PD is contemplated only after stabilization of the fibrotic process and is generally reserved for men with severe penile deformities that impede satisfactory sexual intercourse (Kendirci and Hellstrom, 2004).

ESWT has also been investigated as a treatment option for PD. Various hypotheses about its mechanism of action exist, including direct damage to the plaque resulting in an inflammatory reaction with increased macrophage reaction leading to plaque lysis, improved vascularity resulting in plaque resorption, and the creation of contralateral scarring of the penis resulting in "false" straightening (Taylor and Levine, 2007). There is a lack of standardization regarding issues such as shockwave dosage, energy levels and number of sessions required for a therapeutic effect in patients with PD (National Institute for Clinical Excellence [NICE], 2003). Currently, the treatment of PD is not a U.S. Food and Drug Administration (FDA)-approved indication for ESWT.

Literature Review: The use of ESWT for the treatment of PD has been examined in RCTs. Chitale et al. (2010) randomized men with Peyronie's disease to receive ESWT (n=16) or sham (n=20). At six months of follow-up there was no significant difference in the mean change between the control and intervention groups on any outcome measure.

Palmieri et al. (2009) compared the use ESWT as a treatment for PD with a duration of less than 12 months (n=50) to placebo (n=50). At 24 weeks, the mean visual analog scale (VAS) score was reported to be significantly lower in both groups compared to baseline. Mean plaque size and mean curvature degree were significantly higher in the placebo group compared to baseline and ESWT values. Study limitations include small sample size, restricted inclusion criteria, and short-term follow-up.

In general, the evidence evaluating the safety and efficacy of ESWT for PD consists of case series with relatively small sample sizes (n=44–157) and short-term follow-up (De Berardinis, et al., 2010; Poulakis, et al., 2006; Srirangam, et al., 2006; Strelbel, et al., 2004; Hauck, et al., 2004). These studies have yielded inconsistent results. In 2003, a NICE review of the literature found that "uncertainties exist regarding the efficacy of this procedure for the treatment of Peyronie's disease." According to NICE, this opinion was based on the lack of controlled data, the natural history of the disease, interpatient variability, outcome measurement and placebo response (NICE, 2003).

Professional Societies/Organizations

The American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) issued a guideline on the evaluation and treatment of male sexual dysfunction. The guideline supports the use of vacuum constriction pumps and internal implanted penile prostheses in the treatment of ED (AACE, 2003).

In May of 2006 the AUA published guidelines for the management of erectile dysfunction (AUA, 2006). According to the guidelines, the following therapies are considered standard treatment for ED: oral

phosphodiesterase type 5 (PDE-5) inhibitors, intra-urethral alprostadil, intracavernous vasoactive drug injection, vacuum constriction devices, and penile prosthesis implantation (AUA, 2006).

The AUA further recommends that arterial reconstructive surgery be used as a treatment option only in otherwise healthy individuals, age 55 or younger, with recently acquired focal arterial occlusion in the absence of any evidence of generalized vascular disease. Penile venous reconstructive surgery is not recommended by the AUA. The guidelines state that it is difficult to determine: 1) what percentage of veno-occlusive ED exists independent of general arterial hypofunction; 2) how to accurately diagnose this condition; and 3) whether there is a subset of patients with this disorder who would benefit from surgical intervention. Currently, there is no evidence from randomized controlled trials documenting a standardized approach to diagnosis or supporting the efficacy of treatment for veno-occlusive ED. There is no substantial evidence to support a routine surgical approach in the management of veno-occlusive ED (AUA, 2006).

According to the National Comprehensive Cancer Network[®] (NCCN) guidelines for prostate cancer, recovery of erectile function is directly related to age at radical prostatectomy, preoperative erectile function and the degree of preservation of the cavernous nerves. Replacement of resected nerves with nerve grafts has not been shown to be beneficial (NCCN, 2013).

Use Outside of the US

The European Association of Urology (EAU) guidelines on male sexual dysfunction states that if drug treatment fails, patients should be offered an alternative therapy such as intracavernosal injection therapy or use of a vacuum erection device. The surgical implantation of a penile prosthesis may be considered in patients who do not respond to pharmacotherapy or who prefer a permanent solution to their problem (Wespes, et al., 2013).

The EAU guidelines on penile curvature state that the mechanism of action involved in extracorporeal shock wave lithotripsy is unclear. According to the EAU, extracorporeal shock wave treatment may only be used to treat penile pain (Hatzimouratidis, et al., 2012). However, the cited evidence supporting this statement consists of a single placebo-controlled RCT (Palmieri et al. 2009) described previously.

Summary

Evidence in the peer-reviewed, published scientific literature, including published guidelines from professional societies and organizations, indicate vacuum constriction devices and penile prostheses are considered a safe and effective treatment option for the treatment of erectile dysfunction in a carefully selected subset of individuals whose condition is due to an organic etiology and in whom more conservative treatment has failed.

The overall body of literature suggests that penile arterial reconstructive surgery is indicated in a small subset of patients with erectile dysfunction (ED). However there is insufficient evidence in the published peer-reviewed medical literature to support the use of venous ligation as treatment for venogenic ED. Available studies have demonstrated low short- and long-term success rates. Further investigation is needed to define the role and support the efficacy of this surgical intervention.

There is insufficient evidence in the published peer-reviewed medical literature to support the efficacy of sural nerve grafting during radical prostatectomy. Further investigation is needed in the form of randomized controlled trials that compare sural nerve grafting to no surgical intervention for ED or to medical therapy to further define the role of this therapy in the treatment of ED associated with radical prostatectomy.

The available evidence in the published peer-reviewed medical literature is insufficient to support the use of extracorporeal shock wave therapy (ESWT) for the treatment of PD. Randomized controlled studies are needed to validate the efficacy of this therapy and identify the subset of PD patients most likely to benefit from its use.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Vacuum Constriction Device

Covered as medically necessary only when benefit coverage is available for the specific item:

HCPSC Codes	Description
L7900	Male vacuum erection system
L7902	Tension ring, for vacuum erection device, any type, replacement only, each

Penile Prosthesis

Covered as medically necessary only when benefit coverage is available for the specific service/item:

CPT ^{®*} Codes	Description
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders and reservoir

HCPSC Codes	Description
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable

Penile Prosthesis Removal

Covered when medically necessary:

CPT ^{®*} Codes	Description
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
37790	Penile venous occlusive procedure
55899 [†]	Unlisted procedure, male genital system
64999 ^{††}	Unlisted procedure, nervous system

[†]Note: Experimental/Investigational/Unproven and Not Covered when used to report extracorporeal shock wave therapy for the treatment of Peyronie's disease.

††Note: Experimental/Investigational/Unproven and Not Covered when used to report sural nerve grafting during radical retroperitoneal prostatectomy.

***Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.**

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