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 **Penile Prostheses for Erectile Dysfunction**

Effective Date 5/15/2009
Next Review Date 5/15/2010
Coverage Policy Number 0055

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Hyperlink to Related Coverage Policies

Oral Phosphodiesterase-5 Inhibitors
Surgery for Male Sexual Dysfunction

INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. Proprietary information of CIGNA. Copyright ©2009 CIGNA*

Coverage Policy

The treatment of male sexual dysfunction, including erectile dysfunction, is specifically excluded under some benefit plans; therefore, penile prostheses of any kind are frequently not covered.

When coverage is available for an external penile prosthesis, 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.

If coverage is available for an internal or external penile prosthesis, the following conditions of coverage apply.

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 covers the surgical implantation of an internal penile prosthesis as medically necessary when the above medical necessity criteria have been met and consideration has been given to a vacuum constriction device.

CIGNA covers the removal of an internal penile prosthesis as medically necessary for ANY of the following indications:

- infection
- mechanical failure
- urinary obstruction
- intractable pain

Following the medically necessary removal of an internal penile prosthesis, when benefit coverage is available for the internal penile prosthetic device, CIGNA covers the surgical reimplantation of a medically necessary internal penile prosthetic device.

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.

General Background

Erectile dysfunction (ED) (i.e., impotence) is defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance (National Institutes of Health Consensus Statement, 1992). ED affects between 15 and 30 million American men. The disorder usually has an underlying physical cause in older men and, normally, is treatable in men of 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 multiple causes of ED including disease processes, psychological conditions, trauma, drug and alcohol use/abuse, as well as smoking. 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 first step in 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 Societé 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).

The method of treatment for ED is dependent upon the etiology of the condition. ED can occur as a secondary condition to 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. Psychologically-based ED (e.g., secondary to depression, anxiety, stress) may dissipate with successful treatment of the underlying problem. If the ED is persistent, treatment options may include oral medications (e.g., phosphodiesterase-5 [PDE-5] inhibitors, sildenafil, tadalafil and vardenafil), hormone replacement therapy, intracavernosal injectable agents (e.g., alprostadil, phentolamine mesylate and papavarine hydrochloride), intraurethral deposition of pellets (i.e., medicated urethral system for erection [MUSE]), vacuum constriction devices, and penile implants. 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], 2005). 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 erective function (NIDDK, 2003; Morales, 2003; Fazio, et al., 2004; Carson, 2005; Jain and Terry, 2006; Brant, et al., 2007; McVary, 2007; Sadeghi-Nejad, 2007).

U.S. Food and Drug Administration (FDA)
There are two types of penile prostheses, external (e.g., vacuum constriction devices) and internal (i.e., implants). Both types 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 Praire, MN).

Internal 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.

External Prostheses
When medical modalities are unsuccessful or contraindicated, a vacuum constriction device offers a viable alternative treatment. This device functions as an external aid or prosthesis; 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.

Internal Prostheses
When nonsurgical therapies have proven ineffective, an internal 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 implanted 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). 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.

Professional Societies/Organizations
In May of 2006 the AUA updated their 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 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).

Summary
Erectile dysfunction (ED) is the inability to achieve and maintain an erection and may be due to an organic or psychological state. The first step in treating ED is to determine if there is an underlying condition, and treating the condition accordingly. If unresolved, treatment is typically progressive in nature, beginning with the least invasive modality and advancing to surgical implantation using prosthetic devices. As evidenced by peer-reviewed, published scientific literature, including published guidelines from professional societies and organizations, 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.

Coding/Billing Information

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

Covered when medically necessary:

CPT®* Codes	Description
54400	Insertion of penile prosthesis; noninflatable (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
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 noninflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis
54416	Removal and replacement of noninflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of noninflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue

HCPCS Codes	Description
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, noninflatable
L7900	Male vacuum erection system

ICD-9-CM Diagnosis Codes	Description
607.84	Other specified disorders of penis: Impotence of organic origin
996.39	Mechanical complication of genitourinary device, implant, and graft, other
996.65	Infection and inflammatory reaction due to other genitourinary device, implant, and graft
996.76	Other complications due to genitourinary device, implant, and graft

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2008	0055	Penile Prostheses for Erectile Dysfunction
Great-West Healthcare	8/23/2007	95.310.06	Penile Prosthesis Implantation for Erectile Dysfunction