



Medical Coverage Policy

Effective Date8/15/2025

Next Review Date8/15/2026

Coverage Policy Number..... 0403

Male Sexual Dysfunction Treatment: Non-pharmacologic

Table of Contents

Overview	2
Coverage Policy	2
Health Equity Considerations.....	2
General Background.....	3
Medicare Coverage Determinations	8
Coding Information	9
References.....	10
Revision Details.....	13

Related Coverage Resources

[Collagenase clostridium histolyticum](#)

[Sildenafil \(Viagra®\)](#)

[Erectile Dysfunction - Vardenafil](#)

[Erectile Dysfunction - Stendra](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. 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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

Overview

This Coverage Policy addresses devices and procedures used in the treatment of erectile dysfunction.

Coverage Policy

Coverage for male sexual dysfunction varies across plans. Refer to the customer's benefit plan document for coverage details.

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

Penile Prosthesis

Surgical implantation of a penile prosthesis is considered medically necessary for the treatment of erectile dysfunction when ALL of the following criteria are met:

- erectile dysfunction has persisted for at least six months
- a comprehensive history and physical exam, including appropriate laboratory testing, has been completed
- there is failure, contraindication or intolerance to conservative medical management including FDA pharmacological therapy (e.g., oral PDE5 inhibitors, intracavernosal injection, intraurethral medication) and/or a vacuum erection device

A penile prosthesis for ANY other indication is considered not medically necessary.

Not Medically Necessary

Each of the following procedures for the treatment of erectile dysfunction is considered not medically necessary:

- nerve grafting during or after a radical prostatectomy (e.g., sural nerve, genitofemoral nerve)
- application of amniotic-derived allografts to nerve bundles during a radical prostatectomy (e.g., AmnioFix®, BioDFence® G3)

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Erectile dysfunction (ED) affects up to 30 million people in the United States and is especially prevalent in the aging population affecting between 26–76% of this group. Retrospective analysis of claims data suggests that socioeconomic status may be independently associated with ED as low-income individuals were almost twice as likely to report ED compared to individuals at higher income levels with only diabetes mellitus having a greater adjusted odds ratio for ED. This is potentially due to greater exposure to chronic health conditions, stress, and reduced healthcare utilization. Additionally, research into treatment patterns reveals significant racial disparities in ED management with Asian and Hispanic men having a lower probability of receiving any ED treatment compared to Caucasian men and African Americans having a higher probability. These findings suggest that both socioeconomic status and race independently contribute to inequities in the diagnosis and treatment of ED (Macdonald, et al., 2023; Chen, et al., 2022).

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. An age correlation exists for the prevalence of ED, however it is not an inevitable part of the aging process. Burnett and Ramasamy reported the worldwide prevalence is 1%–10% for men younger than the age 40, up to 15% for men age 40–49, up to 30% for men age 50–59, up to 40% for men age 60–69, and 50%–100% for men between age 70–90. Additionally, it is estimated that in 1995, there were more than 152 million men worldwide who experienced ED. The 2025 prevalence projection was that approximately 322 million men would have ED. They report that the trend is maintained irrespective of racial/ethnic background or geographic region (Burnett and Ramasamy, 2021).

There are multiple causes of organic ED including disease processes, 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 also 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 (Hellstrom, 2022; McVary, 2007; Rosen, et al., 2005; Fazio, et al., 2004; Morales, 2003).

Men with symptoms of ED should have a complete medical, sexual, and psychosocial history taken along with a physical examination and selective laboratory testing. Patients should be informed that ED is a risk factor for underlying cardiovascular disease and other health conditions that may warrant further evaluation and treatment. The laboratory tests that are routinely performed as a part of an ED evaluation are serum testosterone, glucose/hemoglobin A1c, and in some cases serum lipids. No routine serum study is likely to alter ED management. However, serum studies

may provide information on the etiology of ED and reveal the presence of additional conditions that require treatment. In addition, a prostate specific antigen (PSA) may be appropriate in some men with ED (Burnett, et al., 2018).

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. 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 (Burnett et al., 2018; Taylor and Levine, 2007; Brant, et al., 2007; McVary, 2007; Seftel, et al., 2004; Morales, 2003).

Treatment algorithms for erectile dysfunction (ED) involve using medical therapies such as phosphodiesterase type 5 (PDE5) inhibitors, intracavernosal injection therapy of vasoactive agents, as well as vacuum erection devices (Chung, 2019). Current practice guidelines suggest that the choice of PDE5 inhibitor should be based upon on the patient's preferences, including cost, ease of use, and adverse effects (Burnett, et al., 2018). Oral agents (e.g., PDE-5 inhibitors) are 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 (Chung, 2019; Brant, et al., 2007; McVary, 2007; Sadeghi-Nejad, 2007; Jain and Terry, 2006; Carson, 2005; Fazio, et al., 2004; Morales, 2003).

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. The success rates for arterial revascularization are low but reasonable success rates may be achieved in young, nonsmoking, otherwise healthy men with recently acquired ED due to a focal arterial occlusion. Techniques to improve the veno-occlusive mechanism with ligation of the dorsal, cavernous, and crural veins have been largely abandoned in favor of medical therapies (PDE-5 inhibitors) (Lazarou, 2025). 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.

Penile Prosthesis

When nonsurgical therapies have proven ineffective, a penile prosthesis may be surgically implanted. Since surgery destroys the corpus cavernosum of the penis, this procedure precludes any future pharmacological treatment (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 (Hellstrom, 2022).

U.S. Food and Drug Administration (FDA):

Penile rigidity implants 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 Spectra™ (AMS Men's Health/Boston Scientific) and the Genesis® Penile Prosthesis (Coloplast, Minneapolis, MN) 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, 2025). The AMS 700™ (Boston Scientific) and the Titan® (Coloplast, Minneapolis, MN) are examples of inflatable penile prostheses.

Literature Review - Penile Prostheses: 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 (Paranhos, et al., 2010; Knoll, et al., 2009; Israilov, et al., 2005; Minervini, et al., 2006; Zermann, et al., 2006; Ferguson, et al., 2003). 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.

Nerve Graft During or After a Radical Prostatectomy

Despite advances in radical prostatectomy procedures, ED remains a significant postoperative complication. When both neurovascular bundles are spared during radical prostatectomy (RP), 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). Nerve grafting has been proposed as an intervention during or after a RP to prevent ED associated with the procedure. Some of the nerves studied include the sural nerve, ilioinguinal nerve and genitofemoral nerve.

In nerve grafting, a portion of the nerve is harvested and then anastomosed to the divided ends of the cavernous nerves which are resected during a radical prostatectomy.

Literature Review - Nerve Graft: There is limited data in the scientific peer-reviewed literature regarding the long-term outcomes of nerve grafting (e.g., sural nerve, genitofemoral nerve) during or after a radical prostatectomy. 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 sural nerve graft group versus the control group (p=0.962).

Nonrandomized controlled comparison studies and case series have also evaluated the safety and effectiveness of nerve grafting during or after a radical prostatectomy (Souza Trindade, et al., 2017; Siddiqui, et al., 2014; Satkunasivam, et al., 2009; Hanson, et al., 2008; Zorn, et al., 2008; Nelson, et al., 2006; Sim, et al., 2006; Porpiglia, et al., 2005; Kim, et al., 2001a; Kim, et al., 2001b). Study populations have ranged from 10–40 with a follow-up range of 12–36 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 nerve grafting.

Souza Trindade, et al. (2017) described a novel penile reinnervation technique using four sural nerve grafts and end-to-side neurorrhaphies connecting bilaterally the femoral nerve and the cavernous corpus and the femoral nerve and the dorsal penile nerves. Patients (n=10) who had undergone radical prostatectomy (RP) at least two years previously were included and underwent penile reinnervation. A total of 60% of patients were able to achieve full penetration, on average, 13 months after reinnervation surgery. The four patients not achieving penetration after three years after reinnervation surgery, all developed flaccid or semi-rigid erections, suggesting that partial reinnervation occurred. Limitations of the study included the small patient population, lack of a control group and short-term follow-up. Randomized controlled studies with large patient populations and long-term follow-up are needed. No health disparities were identified by the investigators.

Amniotic-Derived Allografts

Amniotic membrane-derived allografts are harvested from human placenta tissue soon after birth. The allografts are minimally manipulated, cleaned, dehydrated and sterilized and is available in sheets, wraps, particulate, and membrane configurations. Amniotic membrane-derived allografts are hypothesized to be effective in improving potency outcomes post radical prostatectomy. Dehydrated human amnion/chorion membrane (dHACM) is a human allograft comprised of laminated amnion and chorion membranes derived from the placenta.

U.S. Food and Drug Administration (FDA): Amniotic membrane is a banked human tissue regulated by the American Association of Tissue Banks® (AATB) and does not require FDA approval. However, the manufacturer must meet specific FDA regulations for the collection, processing, and selling of human cell, tissue, and cellular and tissue-based products (HCT/Ps). (FDA, 2024).

Literature Review – Amniotic-Derived Allografts: Evidence in the published peer-reviewed medical literature evaluating the use of an amniotic-membrane derived allograft wrapped around the nerve bundles during a radical prostatectomy includes observational studies with retrospective data collection.

Noël et al. (2022) assessed the functional and oncological outcomes of applying amniotic or dehydrated human amnion/chorion membrane (dHACM) on preserved neurovascular bundles (NVBs) during a nerve sparing (NS) robot-assisted laparoscopic prostatectomy (RALP) for prostate cancer. Five-hundred and ninety-nine patients underwent placement of a dHACM graft (AmnioFix by MiMedx, Marietta, GA, USA) and 529 patients were followed-up for a median of 42 months. Full NS was performed in 74% (391/529), no patient had a non NS procedure. The number of patients with positive surgical margins (PSM) was 86 (16%), and the overall biochemical recurrence (BCR) in the entire cohort was 10%. Postoperatively, 434 (82%) were sexually active. Median time to potency was 119 (37–420) days and time to continence was 42 (23–91) days. Days to return of potency was significantly higher in the full NS group ($p=0.003$) compared to the partial NS group. However, return to continence or American Urological Association (AUA) scores was independent of NS degree with dHACM. Author acknowledged limitations included the study design as an observational study with retrospective data without a control group. The authors concluded that the findings of the study indicated that the application of amniotic membrane/dHACM allowed for the return of potency at an average time of three months, with an overall shorter period for continence recovery. Additional long term randomized control trials with large patient populations are needed to validate the outcomes of the study and establish the efficacy of the placement of dHACM graft on potency. No health disparities were identified by the investigators.

Razdan et al (2019) conducted a retrospective matched longitudinal cohort study that assessed the potency outcomes in two systematically controlled, non-randomized, matched, homogenous patient cohorts, which either underwent intervention (INT) with placement of dehydrated human amniotic membrane (dHAM) around nerve bundles (NVB) during robotic-assisted laparoscopic radical prostatectomy (RALP) or did not (CON). The intervention group ($n=700$) had dHAM allograft (Amniofix™) wrapped around the NVB while the CON ($n=700$) did not. Potency was defined as the ability to have satisfactory penetrative intercourse > 50% of time with Sexual Health Inventory for Men (SHIM) score of ≥ 17 with or without of phosphodiesterase-5 inhibitors. Follow-up was performed at one year. INT had a significantly higher percentage of patients becoming potent ($p<0.005$) compared to CON every quarter post-surgery. A significantly higher ($p<0.005$) percentage (93.1%) of INT regained potency versus CON (87.1%) at the one year follow-up. With advancing age, the return to potency was delayed in both the groups, age being an independent predictor of return to potency. dHAM use was not associated with any membrane-related adverse effects or allergic reactions. Limitations noted by the authors included potential for placebo effect and recall bias during telephonic interviews due to the retrospective non-blinded study design. The authors concluded that a randomized prospective blinded study with different operators would eliminate the bias emanating out of a single surgeon, the same nerve-sparing technique, and single center study. No health disparities were identified by the investigators.

Ogaya-Pinies et al. (2018) conducted a retrospective analysis of prospectively collected data that evaluated if using dehydrated human amnion/chorion membrane (dHACM) allograft wrapped around the neurovascular bundles (NVB) during a robotic-assisted radical prostatectomy (RARP) accelerates the return of potency. Patients were divided into two similar groups using a 1:3 proportion, the dHACM group ($n=235$) and the control group or group 2 ($n=705$). The dHACM group underwent RARP, with bilateral placement of dHACM graft (AmnioFix® by MiMedx,® Marietta, GA, USA) around the NVBs. The control group or group 2 did not receive the allograft. Minimum follow-up was 12 months. Postoperative outcomes were analyzed between propensity-matched dHACM graft (group 1) and non-graft groups (group 2). Potency was defined as the ability to achieve and maintain satisfactory erections firm enough for sexual intercourse, with or without the use of PDE-5 inhibitors. The mean time to potency was significantly lower in group 1 (2.37 months) versus group 2 (3.94 months) ($p<0.0001$). The potency recovery rates were superior for group 1 at all early time points measured except at 12 months. At 12-months post-RARP potency recovery rates did not differ between groups. The authors concluded that patients who received the dHACM wrap had faster return to potency when compared to those who didn't

receive the allograft. Additionally, the results indicate that dHACM placement at the site of the prostatic NVB does not increase the risk of biochemical recurrence after RARP, neither in the presence of positive surgical margin, extra-prostatic disease nor high Gleason score. Author noted limitations included the lack of prospective randomization and potential placebo bias could have altered the outcome. No health disparities were identified by the investigators.

Patel, et al. (2015) conducted a propensity-matched observational study with retrospective data collection that assessed if placing dehydrated human amnion/chorion membrane allograft nerve wrap around the prostatic neurovascular bundle during nerve-sparing (NS) robot-assisted laparoscopic prostatectomy (RARP) accelerates early return to continence and potency. Patients (n=58) in group 1 received dHACM (AmnioFix; MiMedx Group, Marietta, GA, USA) and propensity matched patients (n=58) in group 2 did not receive dHACM. There was no significant difference between the groups in the return of continence or potency at eight weeks (p=0.373; p=0.132, respectively) but the mean time to continence and potency was significantly quicker in group 1 patients when compared to group 2 (p=0.033; p=0.007, respectively). Limitations noted by the authors included the observational, retrospective study design which is subject to patient recall bias. The authors concluded that graft placement enhanced the meantime to continence and potency and that postoperative Sexual Health Inventory for Men (SHIM) scores were higher in the dHACM group at maximal follow-up (mean score 16.2 vs 9.1). Additional long term randomized control trials with large patient populations are needed to validate the outcomes of the study and establish the efficacy of the placement of dHACM graft on potency. No health disparities were identified by the investigators.

There is insufficient evidence in the published peer-reviewed medical literature to support the application of amniotic derived allograft to nerve bundles during a radical retroperitoneal prostatectomy.

Professional Societies/Organizations

American Academy of Family Physicians (AAFP): According to the AAFP, oral phosphodiesterase-5 inhibitors are the first-line treatments for ED. Second-line treatments include alprostadil, vacuum devices and when all other options are ineffective surgically implanted penile prostheses are an option (Rew et al., 2016).

American Urological Association (AUA): In 2018, the AUA published revised guidelines on erectile dysfunction. According to the guidelines, men may choose to begin with the least invasive option, however any type of treatment as an initial treatment is a valid choice. The clinician is responsible to ensure that the man and his partner fully understand the benefits and risks/burdens associated with the choice and be informed of all the treatments (e.g., vacuum erection device, penile prosthesis) that are not contraindicated for the patient. The AUA also recommended against penile venous surgery and considered ESWT investigational (Burnett, et al., 2018).

National Comprehensive Cancer Network® (NCCN): According to the 2025 NCCN guidelines for prostate cancer, recovery of erectile function is directly related to factors such as 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.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Diagnosis and Treatment of Impotence (230.4)	This is a longstanding national coverage determination.

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Penile Prosthesis

Considered Medically Necessary when criteria in the applicable policy statements listed above are met and 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

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

Considered Not Medically Necessary:

CPT®* Codes	Description
64912 [†]	Nerve repair; with nerve allograft, each nerve, first strand (cable)
64913 [†]	Nerve repair; with nerve allograft, each additional strand (List separately in addition to code for primary procedure)
64999 ^{††}	Unlisted procedure, nervous system

HCPCS* Codes	Description
Q4100	Skin substitute, not otherwise specified
Q4138	Biodfense dryflex, per square centimeter
Q4140	Biodfense, per square centimeter
Q4145	Epifix, injectable, 1 mg
Q4148	Neox cord 1K, Neox cord rt, or clarix cord 1K, per square centimeter
Q4156	Neox 100 or clarix 100, per sq cm, per square centimeter

[†]Note: Considered Not Medically Necessary when used to report the application of amniotic-derived allografts to nerve bundles during a radical prostatectomy.

^{††}Note: Considered Not Medically Necessary when used to report sural nerve grafting during radical prostatectomy.

***Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.**

References

1. Brant WO, Bella AJ, Lue TF. Treatment options for erectile dysfunction. *Endocrinol Metab Clin North Am.* 2007 Jun;36(2):465-79.
2. Burnett AL, Nehra A, Breau RH, Culkin DJ, Faraday MM, Hakim LS, et al. Erectile Dysfunction: America Urological Association Guideline. *J Urol.* 2018 Sep;200(3):633-641.
3. Burnett AL, Ramasamy R. Evaluation and Management of Erectile Dysfunction. In: Partin AW, Dmochowski RR, Kavoussi LR, Peters CA. *Campbell-Walsh-Wein Urology.* 12th ed. Philadelphia, PA: Elsevier; 2021. Ch 69. pgs 1513-1538.e8.
4. Carson CC. Penile prosthesis implantation: surgical implants in the era of oral medication. *Urol Clin North Am.* 2005;32(4):503-vii.
5. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Jun 6, 2025. Available at URL address: <https://www.cms.gov/medicare-coverage-database/reports/local-coverage-final-lcds-alphabetical-report.aspx?lcdStatus=all>
6. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed June 6, 2025. Available at URL address: <https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=all&labOnly=allIncd&sortBy=title>
7. Chen T, Li S, Eisenberg ML. Associations between Race and Erectile Dysfunction Treatment Patterns. *Urol Pract.* 2022 Sep;9(5):423-430.
8. Chung E. A Review of Current and Emerging Therapeutic Options for Erectile Dysfunction. *Med Sci (Basel).* 2019;7(9):91.
9. Davis JW, Chang DW, Chevray P, Wang R, Shen Y, Wen S, et al. Randomized phase II trial evaluation of erectile function after attempted unilateral cavernous nerve-sparing retropubic

radical prostatectomy with versus without unilateral sural nerve grafting for clinically localized prostate cancer. *Eur Urol*. 2009 May;55(5):1135-43.

10. Fazio L, Brock G. Erectile dysfunction: management update. *CMAJ*. 2004 Apr 27;170(9):1429-37.
11. Ferguson KH, Cespedes RD. Prospective long-term results and quality-of-life assessment after Dura-II penile prosthesis placement. *Urology*. 2003 Feb;61(2):437-41.
12. Hanson GR, Borden LS Jr, Backous DD, Bayles SW, Corman JM. Erectile function following unilateral cavernosal nerve replacement. *Can J Urol*. 2008 Apr;15(2):3990-3.
13. Hellstrom WJG. Penile prosthesis implantation. Updated June 2022. Accessed Jun 6, 2025. Available at URL address: <https://emedicine.medscape.com/article/446761-overview>
14. Israilov S, Shmueli J, Niv E, Engelstein D, Livne P, Boniel J. Evaluation of a progressive treatment program for erectile dysfunction in patients with diabetes mellitus. *Int J Impot Res*. 2005 Sep-Oct;17(5):431-6.
15. Jain S, Terry TR. Penile Prosthetic Surgery and its Role in the Treatment of End-Stage Erectile Dysfunction – An Update. *Ann R Coll Surg Engl*. 2006 Jul; 88(4): 343–348.
16. Kim ED, Nath R, Slawin KM, Kadmon D, Miles BJ, Scardino PT. Bilateral nerve grafting during radical retropubic prostatectomy: extended follow-up. *Urology*. 2001a Dec;58(6):983-7.
17. Kim ED, Scardino PT, Kadmon D, Slawin K, Nath RK. Interposition sural nerve grafting during radical retropubic prostatectomy. *Urology*. 2001b Feb;57(2):211-6.
18. Knoll LD, Henry G, Culkin D, Ohi DA, Otheguy J, Shabsigh R, Wilson SK, Delk II J. Physician and patient satisfaction with the new AMS 700 momentary squeeze inflatable penile prosthesis. *J Sex Med*. 2009 Jun;6(6):1773-1778.
19. Lazarou S. Surgical treatment of erectile dysfunction. In: UpToDate, Richie JP, Chen W (Eds), UpToDate, Waltham, MA. Literature review current through: May 2025. Topic last updated: Nov 14, 2023. Accessed Jun 12, 2025.
20. Macdonald EJ, Gaines JM, Kim JJ, Paduch DA. Exploring the relationship between socioeconomic status and erectile dysfunction: an analysis of the National Health and Nutrition Examination Survey. *Int J Impot Res*. 2023 Aug;35(5):478-483.
21. McVary KT. Clinical practice. Erectile dysfunction. *N Engl J Med*. 2007 Dec 13;357(24):2472-81.
22. Minervini A, Ralph DJ, Pryor JP. Outcome of penile prosthesis implantation for treating erectile dysfunction: experience with 504 procedures. *BJU Int*. 2006 Jan;97(1):129-33.
23. Morales A. Erectile dysfunction: an overview. *Clin Geriatr Med*. 2003 Aug;19(3):529-38.
24. Mulhall JP, Ahmed A, Branch J, Parker M. Serial assessment of efficacy and satisfaction profiles following penile prosthesis surgery. *J Urol*. 2003 Apr;169(4):1429-33.

25. National Comprehensive Cancer Network® (NCCN). NCCN GUIDELINES™ Clinical Guidelines in Oncology™. Prostate Cancer. Version 2.2025 – Apr 16, 2025. Accessed Jun 6, 2025. Available at URL address: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
26. Nelson BA, Chang SS, Cook son MS, Smith JA Jr. Morbidity and efficacy of genitofemoral nerve grafts with radical retropubic prostatectomy. *Urology*. 2006; 67(4):789-792.
27. Noël J, Mascarenhas A, Patel E, Reddy S, Sandri M, Bhat S, et al. Nerve spare robot assisted laparoscopic prostatectomy with amniotic membranes: medium term outcomes. *J Robot Surg*. 2022 Jan 11:1-6.
28. Ogaya-Pinies G, Palayapalam-Ganapathi H, Rogers T, Hernandez-Cardona E, Rocco B, Coelho RF, et al. Can dehydrated human amnion/chorion membrane accelerate the return to potency after a nerve-sparing robotic-assisted radical prostatectomy? Propensity score-matched analysis. *J Robot Surg*. 2018 Jun;12(2):235-243.
29. Paranhos M, Andrade E, Antunes AA, Barbieri AL, Claro JA, Srougi M. Penile prosthesis implantation in an academic institution in Latin America. *Int Braz J Urol*. 2010 Sep-Oct;36(5):591-601.
30. Patel VR, Samavedi S, Bates AS, Kumar A, Coelho R, Rocco B, et al. Dehydrated Human Amnion/Chorion Membrane Allograft Nerve Wrap Around the Prostatic Neurovascular Bundle Accelerates Early Return to Continence and Potency Following Robot-assisted Radical Prostatectomy: Propensity Score-matched Analysis. *Eur Urol*. 2015 Jun;67(6):977-980.
31. Porpiglia F, Ragni F, Terrone C, Renard J, Musso F, Grande S, et al. Is laparoscopic unilateral sural nerve grafting during radical prostatectomy effective in retaining sexual potency? *BJU Int*. 2005 Jun;95(9):1267-71.
32. Rajpurkar A, Dhabuwala CB. Comparison of satisfaction rates and erectile function in patients treated with sildenafil, intracavernous prostaglandin E1 and penile implant surgery for erectile dysfunction in urology practice. *J Urol*. 2003 Jul;170:159-63.
33. Razdan S, Bajpai RR, Razdan S, Sanchez MA. A matched and controlled longitudinal cohort study of dehydrated human amniotic membrane allograft sheet used as a wraparound nerve bundles in robotic-assisted laparoscopic radical prostatectomy: a puissant adjunct for enhanced potency outcomes. *J Robot Surg*. 2019 Jun;13(3):475-481.
34. Rew KT, Heidelbaugh JJ. Erectile Dysfunction. *Am Fam Physician*. 2016 Nov 15;94(10):820-827. Accessed June 6, 2025. Available at URL address <https://www.aafp.org/afp/2016/1115/p820.html>
35. Rosen RC, Wing R, Schneider S, Gendrano N 3rd. Epidemiology of erectile dysfunction: the role of medical comorbidities and lifestyle factors. *Urol Clin North Am*. 2005 Nov;32(4):403-17, v.
36. Sadeghi-Nejad H. Penile prosthesis surgery: a review of prosthetic devices and associated complications. *J Sex Med*. 2007 Mar;4(2):296-309.
37. Satkunasivam R, Appu S, Al-Azab R, Hersey K, Lockwood G, Lipa J, et al. Recovery of erectile function after unilateral and bilateral cavernous nerve interposition grafting during radical pelvic surgery. *J Urol*. 2009 Mar;181(3):1258-63.

38. Seftel AD, Mohammed MA, Althof SE. Erectile dysfunction: etiology, evaluation, and treatment options. *Med Clin North Am*. 2004 Mar;88(2).
39. Siddiqui KM, Billia M, Mazzola CR, Alzahrani A, Brock GB, Scilley C, et al. Three-year outcomes of recovery of erectile function after open radical prostatectomy with sural nerve grafting. *J Sex Med*. 2014 Aug;11(8):2119-24.
40. Sim HG, Kliot M, Lange PH, Ellis WJ, Takayama TK, Yang CC. Two-year outcome of unilateral sural nerve interposition graft after radical prostatectomy. *Urology*. 2006 Dec;68(6):1290-4.
41. Souza Trindade JC, Viterbo F, Petean Trindade A, Fávaro WJ, Trindade-Filho JCS. Long-term follow-up of treatment of erectile dysfunction after radical prostatectomy using nerve grafts and end-to-side somatic-autonomic neurotaphy: a new technique. *BJU Int*. 2017 Jun;119(6):948-954.
42. Taylor FL, Levine LA. Peyronie's Disease. *Urol Clin N Am*. 2007 Nov; 34(4):517-34.
43. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification. Product code FAE. Page last updated: Jun 2, 2025. Access Jun 6, 2025. Available at URL address: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>
44. United States Food and Drug Administration (FDA). Code of Federal Regulations Title 21, Subpart D-- Sec. 876.3350 Penile inflatable implant. Jun 3, 2025. Accessed Jun 12, 2024. Available at URL address: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-876/subpart-D/section-876.3350>
45. United States Food and Drug Administration (FDA). Guidance for the content of premarket notifications for penile rigidity implants. Jan 16, 2000. Page last updated March 12, 2018. Accessed Jun 6, 2025. Available at URL address: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073769.htm>
46. U.S. Food and Drug Administration (FDA). Tissue and tissue products. Content current as of Mar 1, 2024. Accessed Jun 6, 2025. Available at URL address: <https://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm>
47. Wilson SK, Delk JR, Salem EA, Cleves MA. Long-term survival of inflatable penile prostheses: single surgical group experience with 2,384 first-time implants spanning two decades. *J Sex Med*. 2007 Jul;4(4 Pt 1):1074-9.
48. Zermann DH, Kutzenberger J, Sauerwein D, Schubert J, Loeffler U. Penile prosthetic surgery in neurologically impaired patients: long-term followup. *J Urol*. 2006 Mar;175(3 Pt 1):1041-4; discussion 1044.
49. Zorn KC, Bernstein AJ, Gofrit ON, Shikanov SA, Mikhail AA, Song DH, et al. Long-term functional and oncological outcomes of patients undergoing sural nerve interposition grafting during robot-assisted laparoscopic radical prostatectomy. *J Endourol*. 2008 May;22(5):1005-12.

Revision Details

Type of Revision	Summary of Changes	Date
------------------	--------------------	------

Annual Review	Removed the policy statements for: • vacuum erection devices • extracorporeal shock wave therapy	8/15/2025
Annual Review	Removed policy statement for venous occlusive surgery.	8/15/2024

“Cigna Companies” refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2025 The Cigna Group.