Erectile Dysfunction and Peyronie's Disease Treatments



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Medicare Advantage Medical Coverage Policy

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Disclaimer

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/Transmittals.

Туре	Title	ID Number	Jurisdiction Medicare	Applicable States/Territories
			Administrative	States/Territories

			Contractors (MACs)	
NCD	Diagnosis and Treatment of Impotence	<u>230.4</u>		
LCD LCA	Vacuum Erection Devices (VED) Vacuum Erection Devices (VED) - Policy Article	<u>L34824</u> <u>A52712</u>	DME A - Noridian Healthcare Solutions, LLC (DME MAC) DME B - CGS Administrators, LLC (DME MAC) DME C - CGS Administrators, LLC (DME MAC) DME D - Noridian Healthcare Solutions, LLC (DME MAC)	CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT IL, IN, KY, MI, MN, OH, WI AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, U.S. VI AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands

Description

Erectile Dysfunction

Erectile dysfunction (ED) is the chronic inability to achieve or maintain an erection of sufficient duration and firmness to complete satisfactory intercourse. Causes may be psychological or organic (physical). Treatment options generally include devices, medications or surgical procedures.

Penile implants are prosthetic devices surgically inserted into the corpus cavernosum. Two types of penile implants are available; inflatable and semi rigid (noninflatable).

• Inflatable penile prostheses are designed to approximate the rigidity and flaccidity of the normally functioning penis and are available as two-piece or three-piece components. Inflation occurs by manually squeezing a pump.

• Semi-rigid (noninflatable) penile implants are made of firm yet malleable material so that the resulting permanent erection can be manually positioned downward close to the body unnoticeably.

Penile arterial revascularization is a surgical procedure to improve blood flow to the corpora cavernosa. The most commonly performed technique for penile revascularization involves anastomosis of the inferior epigastric artery to the dorsal penile artery (dorsal artery arterialization).

Nerve graft (eg, sural nerve graft) is a procedure that purportedly restores erectile function in an individual who has undergone deliberate excision of one or both neurovascular bundles during radical prostatectomy. An autologous sural nerve graft is interposed between the divided ends of the cavernous nerves.

Penile venous reconstructive or veno-occlusive surgery is a surgical procedure that purportedly improves blood flow to the corpora cavernosa, prevents the pathologic blood egress from the penis and corrects veno-occlusive ED.

Platelet-rich plasma (PRP) therapy is an adaptation of autologous whole blood injections. Whole blood is centrifuged to a concentrated state and is injected into penile erection tissue to purportedly assist in repairing and regenerating the tissue.

Shockwave therapy, also referred to as low-intensity extracorporeal shockwave therapy (LI-ESWT), is a noninvasive procedure that uses acoustic waves to purportedly induce neovascularization to improve erectile tissue function.

Stem cell therapy is an injection of stem cells into penile erection tissue that purportedly assists in replenishing, repairing or regenerating the tissue.

Vacuum erection devices (VEDs) offer a mechanical nonsurgical method of filling the penis with blood and creating an erection. VEDs are usually comprised of an airtight tube, a handheld or battery operated pump and a ring. Air is removed from the cylinder by the pump; thereby creating a vacuum and drawing blood into the penis. The erection is maintained by trapping the blood in the penis with a tight elastic band around its base.

Peyronie's Disease

Peyronie's disease (PD) is an acquired, localized fibrotic disorder of the tunica albuginea, which can cause significant penile deformity and lead to sexual dysfunction and psychological trauma. The exact cause of PD has not yet been defined, although most would agree that some injurious stimulus is necessary to trigger the cascade of events that leads to PD in the susceptible individual. Trauma may be perceived as a single event experienced by the individual or may take the form of repetitive microtrauma to the penis. The nature and extent of Peyronie's plaque, and therefore severity or complexity of penile deformity, varies widely. The most frequent presenting symptoms of an individual with PD include penile pain, erect deformity and palpable plaque, as well as ED.

There are two phases. The first is the acute (active) phase, which is commonly associated with painful erections and changing deformity of the penis. This is followed by a chronic (stable) phase, which is

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characterized by stabilization of the deformity and disappearance of painful erections. Complete spontaneous resolution of PD is a rare occurrence.

Nonsurgical treatment for PD may include oral medications, injections, traction, vacuum therapy or a combination. Additional nonsurgical treatments such as electromotive drug administration have limited evidence of efficacy while treatments such as extracorporeal shockwave therapy (ESWT) and radiation therapy are not recommended for the treatment of PD.

Surgical management of PD includes plication, plaque excision and grafting or placement of a penile prosthesis. Important factors to consider in determining the best surgical approach include the length of the penis, configuration (eg, hourglass, curved) and severity of the deformity, erectile capacity and individual expectations.

Tunica plication is a surgical procedure to straighten the penis where plication is accomplished by shortening the convex side of the penis (opposite the plaque). All plication procedures result in loss of penile length as the tunica albuginea is shortened on the longer side to match the shorter side. Since the stretched penile length is determined by the shorter, less elastic side, the objective loss of penile length after plication is often less than what is perceived by the individual. The most common plication techniques are the Lue, Nesbit and Yachia procedure.

Tunical lengthening procedure (plaque excision or partial excision and grafting) is a surgical procedure to improve plaque-induced penile deformities associated with PD. Following management or removal of the plaque, a graft is placed. Grafting the concave side of the penis serves to lengthen that side and, therefore, straighten the penis. For curvature associated with significant ED, a penile prosthesis can be placed, and additional corrective procedures (plication or grafting) may be performed if the prosthesis does not provide adequate straightening.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for erectile dysfunction and Peyronie's disease treatments.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

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The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
20999	Unlisted procedure, musculoskeletal system, general	
37788	Penile revascularization, artery, with or without vein graft	
37790	Penile venous occlusive procedure	
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor	
38241	Hematopoietic progenitor cell (HPC); autologous transplantation	
54110	Excision of penile plaque (Peyronie disease);	
54111	Excision of penile plaque (Peyronie disease); with graft to 5 cm in length	
54112	Excision of penile plaque (Peyronie disease); with graft greater than 5 cm in length	
54360	Plastic operation on penis to correct angulation	
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	
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	

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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	
55899	Unlisted procedure, male genital system	
64999	Unlisted procedure, nervous system	
77399	Unlisted procedure, medical radiation physics, dosimetry and treatment devices, and special services	
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day	
77402	Radiation treatment delivery, => 1 MeV; simple	
77407	Radiation treatment delivery, => 1 MeV; intermediate	
77412	Radiation treatment delivery, => 1 MeV; complex	
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes	
CPT® Category III Code(s)	Description	Comments
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	
HCPCS Code(s)	Description	Comments
C1813	Prosthesis, penile, inflatable	
C2622	Prosthesis, penile, noninflatable	
17000		
L7900	Male vacuum erection system	
L7900 L7902	Male vacuum erection system Tension ring, for vacuum erection device, any type, replacement only, each	
	Tension ring, for vacuum erection device, any type, replacement	

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References

- Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Vacuum Erection Devices (VED) (A52712). https://www.cms.gov. Published October 1, 2015. Updated January 1, 2020. Accessed November 1, 2023.
- 2. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Vacuum Erection Devices (VED) (L34824). https://www.cms.gov. Published October 1, 2015. Updated January 1, 2020. Accessed November 1, 2023.
- 3. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Diagnosis and Treatment of Impotence (230.4). https://www.cms.gov. Published January 1, 1966. Accessed November 1, 2023.

Change Summary

- 01/01/2024 New Policy.