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Sexual Dysfunctions, Assessment and Treatment

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Related Policies (if applicable)
SUR717.001: Gender Assignment Surgery and Gender Reassignment Surgery with Related Services
RX501.073: Clostridial Collagenase for Fibroproliferative Disorders

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

NOTE 1: The use of procedures, supplies, or medications for treatment of psychological or psychogenic sexual dysfunctions may be subject to contract benefit limitations. Check contract benefits carefully.

NOTE 2: Some benefit plans specifically exclude payment for the treatment of sexual dysfunction. This exclusion extends to prescriptions or medications for the treatment of sexual dysfunction.

This medical policy does NOT address Gender Reassignment Services (Transgender Services). This medical policy IS NOT TO BE USED for Gender Reassignment Services. Refer to SUR717.001 Gender Assignment Surgery and Gender Reassignment Surgery with Related Services

ASSESSMENT
The following diagnostic procedures **may be considered medically necessary** in the assessment of sexual dysfunction:

Male and Female

- Comprehensive medical, sexual, and psychosocial history and physical examination; and selective laboratory testing.

Male

- Men should be counseled that erectile dysfunction (ED) is a risk marker for underlying cardiovascular disease (CVD) and other health conditions that may warrant evaluation and treatment.
- Pharmacologic screening test, intracavernosal injection of Papaverine, Phentolamine, or Prostaglandin E_1 (PGE1) (e.g., Alprostadil- Only Alprostadil is FDA approved in the United States for intracevernous injection [ICI] injection);
- Nocturnal penile tumescence test and rigidity monitoring (Morning Sleep Nap) (Rarely used in clinical practice but it can be helpful in situations where the diagnosis is in doubt.);
- Evaluation of penile arterial flow:
  1. Penile brachial index using a Doppler signal transducer;
  2. Angiography (with ICI) using vasodilating agents;
  3. Duplex Doppler sonography or color Doppler sonography (with ICI) using vasodilating agents;
- Veno-occlusive dysfunction testing:
  1. Cavernosography utilizing radiocontrast solution (with ICI) using vasodilating agents;
  2. Cavernosometry with simultaneous infusion of saline solution (with or without ICI) using vasodilating agents.
- Laboratory testing:
  1. Hormonal evaluation (includes testosterone, luteinizing hormone, follicle stimulating hormone, prolactin levels);
  2. Complete blood count (CBC);
  3. Urinalysis;
  4. Thyroid function studies;
  5. Creatinine;
  6. Lipid profile;
  7. Diabetes screening (includes fasting blood sugar and A1C);
  8. Serum total testosterone levels;
  9. Morning serum total testosterone levels.

The following diagnostic procedures and laboratory tests for the assessment of sexual dysfunction **are considered experimental, investigational and/or unproven:**

- Corpora cavernosal electromyography (CCEMG);
- Single analysis of cavernous electrical activity (SPACE);
- Dorsal nerve conduction latencies;
- Evoked potential measurements;
- Penile plethysmography;
- Iron binding capacity;
- Prostatic acid phosphatase.

TREATMENT

Male

The following therapies for the treatment of sexual dysfunction **may be considered medically necessary** provided the contract does not contain any exclusion for any services related to sexual dysfunction. Should the contract not contain exclusions for services related to sexual dysfunction, coverage may be allowed if the patient has a documented disease process (e.g., diabetes mellitus, hypertension, blood lipid abnormalities, or peripheral vascular disease). Other causes of sexual dysfunction may be caused by penile trauma, spinal cord injuries, and abnormalities of the penis (e.g., penile fibrosis and Peyronie's disease).

Surgical procedures, supplies, or medications used for treatment of male sexual dysfunction include, but are not limited to:

- Medications
  1. Injection into the corpus cavernosa to cause an erection (Papaverine, Phentolamine, Alprostadil, [PGE1, Caverject]);
  2. Intracavernosal injection of Verapamil for treatment of Peyronie's disease (**NOTE 3:** For additional information on Injectable Clostridial Collagenase for Fibroproliferative Disorders see Medical Policy RX501.073);
  3. MUSE (medicated urethral system for erection) method of treatment for erectile dysfunction that involves inserting medication through a small catheter into the urethra;
  4. Oral medication.
- External and Implantable Devices:
  1. Inflatable or non-inflatable penile implants (prostheses);
  2. Vacuum erection devices.

Penile revascularization for vasculogenic erectile dysfunction **may be considered medically necessary** only in men less than 55 years old who meet all of the following criteria:

1. The erectile dysfunction is the direct result of an arterial injury caused by blunt trauma to the pelvis and/or perineum; and
2. A focal blockage of arterial inflow is demonstrated by duplex Doppler ultrasonography or arteriography; and
3. Diagnostic work-up reveals normal corporeal venous function; and
4. Patient is not diabetic and has no evidence of systemic vascular occlusive disease; and
5. Patient is a non-smoker.

Surgical correction of Peyronie's disease (e.g., plaque excisions and venous graft patching, tunica placation, Nesbit tuck procedure) **may be considered medically necessary** when the disease has been present for at least 12 months.

The following therapies, treatments or procedures for treatment of male sexual dysfunction **are considered experimental, investigational and/or unproven:**

- Arterial reconstructive procedures, dorsal vein arterialization procedures, or penile venous occlusive surgery (e.g., venous ligation, dorsal vein ligation) in men with erectile dysfunction secondary to arteriosclerotic occlusive disease;
- Topical cream or gel containing vasodilators, such as verapamil cream;
- Exogenous testosterone replacement therapy, including transdermal preparations for the treatment of non-hypogonadal sexual dysfunction;
- Extracorporeal shock wave therapy for Peyronie's disease;
- Oral drug therapy using Yohimbine;
- Temporary or permanent ganglionic block or sympathectomy for erectile dysfunction secondary to cavernous adrenergic hypertony;
- Low-intensity shock wave therapy (for erectile dysfunction);
- Acupuncture;
- Penile contracture devices;
- Platelet-rich plasma (PRP) therapy; and
- Penile venous occlusive surgery (e.g., venous ligation, dorsal vein ligation).

Female

Perineoplasty (also known as vaginal rejuvenation or tightening) performed as a "stand-alone" procedure **is considered not medically necessary.**

NOTE 4: The U.S. Food and Drug Administration (FDA) issued a warning regarding the use of energy-based devices, such as radiofrequency or laser, for vaginal rejuvenation or vaginal cosmetic procedures, or for the treatment of vaginal symptoms related to menopause, urinary incontinence or sexual function. These devices have not received FDA approval or clearance to treat symptoms or conditions such as vaginal laxity; vaginal atrophy, dryness or itching; pain during sexual intercourse, pain during urination; or decreased sexual sensation.

The following therapies, treatments or procedures for female sexual dysfunction **are considered experimental, investigational and/or unproven:**

- Vacuum therapy;
- Vaginal carbon dioxide fractional laser treatment;
- Vaginal electrical stimulation;
- Biothesiometry;
- Female genital cosmetic surgery.

Policy Guidelines

None.

Description

Sexual dysfunctions are disorders that interfere with a full sexual response cycle. It takes different forms in men and women and can be life-long and always present, acquired, situational, or generalized, occurring despite the situation. (1)

Male sexual dysfunction includes disorders of libido and of erectile and ejaculatory function. Erectile dysfunction is the inability to attain or sustain an erection satisfactory for normal intercourse. Causes contributing to male sexual or erectile dysfunction include, but are not limited to:

1. Organic as a result of or secondary to a disease process or treatment (e.g., diabetes mellitus, hypertension, blood lipid abnormalities, or peripheral vascular disease);
2. Penile trauma;
3. Spinal cord injuries;
4. Abnormalities of the penis (e.g., penile fibrosis and Peyronie's disease);
5. Veno-occlusive dysfunction;
6. As a result of radical pelvic surgery (e.g., radical prostatectomy or cystectomy);
7. Alcohol and/or drugs;
8. Smoking;
9. Psychological/psychogenic factors such as anxiety, fatigue, interpersonal stresses, and chronic illness. (4)

For women, female sexual dysfunction (FSD) is the persistent or recurrent decrease in sexual desire or arousal, the difficulty or inability to achieve an orgasm, and/or the feeling of pain during sexual intercourse. There are various stages of the female sexual response which traditionally include excitement, plateau, orgasm and resolution; desire and arousal are both part of the excitement phase. FSD should be approached as all other diseases are and should not be attributed solely to psychological causes until all possible biomedical etiologies are ruled out. Its multifactorial etiology and presentation creates a complex clinical challenge. A systematic approach including history, general and local examination can overcome this challenge. (2) Sexual dysfunctions that occur in women include but are not limited to: (3) sexual interest-arousal dysfunction, orgasmic dysfunction; and genito-pelvic pain-penetration disorder (includes dyspareunia and vaginismus).

Although widespread, women are unlikely to discuss the condition with their healthcare provider unless asked, and many healthcare providers are uncomfortable asking for a variety of reasons, including a lack of adequate knowledge and training in diagnosis and management, as well as an underestimation of the prevalence. Approximately 43% of American women report experiencing sexual problems according to the American College of Obstetrics and Gynecologists Practice Bulletin on Female Sexual Dysfunction. (5) In the United States, approximately 40 percent of women have sexual concerns based on a study among 31,581 women ages 18 years and older from 50,002 households sampled. (6)

Common causes and risk factors for female sexual dysfunction include:

- Anxiety disorder;
- Diabetes;

- Depression;
- Genitourinary syndrome of menopause;
- Medications;
- Neurologic disease;
- Emotional or environmental stress. (5)

Male Assessment

The evaluation of sexual dysfunction begins with a comprehensive history and physical examination. A careful sexual history and knowledge of concurrent illnesses and medications are essential. (4, 7)

A complete evaluation of sexual dysfunction includes, but is not limited to, the following tests:

1. Pharmacologic screening which includes administering vascular dilating agents testing the penile erection process;
2. Morning sleep nap/nocturnal penile tumescence testing;
3. Nocturnal penile tumescence and/or rigidity test;
4. Evaluation of penile arterial flow including Doppler studies, angiography or arteriography;
5. Venous-occlusion dysfunction tests to include cavernosography and cavernosometry;
6. Hormonal assessment;
7. Diabetes screening;
8. Laboratory testing (complete blood count, urinalysis, thyroid function studies, creatinine and lipid profile);
9. Dynamic cavernosometry, penile and plethysmography, or duplex scan of penis.

<u>Intracorporeal Injection</u>

Differentiating neurogenic and psychogenic impotence from vascular causes of impotence can be attained by the intracorporeal injection of smooth muscle relaxants. A rapid rigid erection following these injections is thought to be strong evidence for neurogenic impotence. Although a number of drugs induce erections on intracorporeal injection, the most widely used agents are papaverine, a papaverine-phentolamine combination or, more recently, prostaglandin E_1. (7)

<u>Nocturnal Penile Tumescence</u>

The nocturnal penile tumescence test determines whether a man is having normal erections during sleep. The presence of normal erections during rapid eye movement (REM) sleep indicates that no organic etiology is present. Tumescence monitoring alone, while it does provide useful information, imposes limitations on the diagnostic inferences that can be drawn concerning the adequacy of erectile function. This led to the development of nocturnal penile tumescence and rigidity monitoring (NPTR). (7)

<u>Doppler Ultrasonography</u>

Image directed Doppler ultrasonography of the cavernous arteries provides functional, quantifiable assessment of penile arterial flow during a pharmacological erection. In this respect, this modality is superior to arteriography as a means of evaluating arteriogenic

impotence. Peak flow velocity, arterial dilatation, and vessel pulsation are the most reliable ultrasonic indicators of arterial health. Aberrant arterial anatomy should be noted as this may contribute significantly to total penile blood flow. A thorough understanding of erectile physiology and anatomy is necessary to properly perform and interpret Doppler ultrasound results. In some practices, formal catheter angiography is reserved for those patients with a suspected stenotic or occlusive lesion causing arterial insufficiency. It is considered a second-line technique utilized as an adjunct to ultrasound. Catheterization of the internal pudendal artery allows formal documentation of arterial supply to the penis and will demonstrate the extent and location of any arterial lesion as preparation for bypass surgery/revascularization. (8)

Cavernosography/Cavernsometry

Venous-occlusion dysfunction (VOD) is an organic cause of erectile dysfunction and it occurs when an abnormal venous drainage prevents a rigid erection in the presence of a normal or abnormal penile arterial flow. VOD can be diagnosed by an abnormal cavernosometry and the site of the "leakage" can be assessed through cavernosography. (9)

Single Potential Analysis of Cavernous Electrical Activity

Single potential analysis of cavernous electrical activity (SPACE) is a minimally invasive diagnostic tool that assesses cavernous electrical activity to help evaluate erectile dysfunction (ED). (26) SPACE is a refined version of cavernous electromyography, which was introduced in 1988.

The test can help diagnose cavernous autonomic neuropathy and smooth muscle myopathy. In normal subjects, SPACE recordings show regular activity with low-frequency potentials and electrical silence in between. (27) In patients with ED, SPACE recordings show asynchronous potentials with higher frequencies and irregular shape.

Dorsal Nerve Conduction Latencies for Sexual Dysfunction

Nerve conduction latency (NCL) is a measure of the time it takes for a stimulus to cause a deflection in the compound muscle action potential from baseline. (28) NCL is made up of three parts:

- The time it takes for the nerve to conduction from the stimulus to the neuromuscular junction (NMJ).
- The time delay across the NMJ.
- The time it takes for the muscle to depolarize.

Nerve conduction measurement techniques can be made with the penis at rest or with gentle stretch of the penis with a 1-pound weight. Average velocity is 24.4 ± 3.2 milliseconds/33.0 ± 3.8 milliseconds respectively.

Evoked Potential Measurements

Pudendal somatosensory evoked potential (PSEP) is a neurophysiological examination that can be used to diagnose erectile dysfunction (ED). (29) The PSEP test assesses the integrity of the

afferent pathways that lead from the pudental nerve to the brain in patient that have undergone radical prostatectomy. It can also be used to differentiate between lesions in the upper motor neuron (UMN) type and lower motor neuron (LMN) type spinal cord.

Penile Plethysmography

Penile plethysmography (PPG) is a psychophysiological technique that measures a man's sexual arousal by measuring changes in the size of his penis in response to sexual stimuli to abnormal (i.e., paraphilic) and normal stimuli. (30) PPG has become a standard measure in the assessment and treatment of male sex offenders and men with paraphilic interests in both Canada and the United States, however, there is a lack of standardization of stimulus sets and interpretation of results. Limitations to the PPG include:

- Lack of standardization in the stimulus sets used and how the results are interpreted across different sites.
- Cost-PPG can be expensive.
- Invasive-PPG is an invasive procedure.
- Labor intensive.
- Subject motivation-the test ideally requires a motivated and responsive subject.
- Research on validity and reliability is limited.

Dynamic Infusion Cavernosometry

Dynamic infusion cavernosometry is a technique in which fluid is pumped into the penis at a known rate and pressure. It gives a measurement of the vascular pressure in the corpus cavernosum during an erection. To do this test a vasodilator like prostaglandin E-1 is injected to measure the rate of infusion required to get a rigid erection and to help find how severe the venous leak is. The cavernosography is an adjunct to this procedure, where a contrast material is injected and then x-rayed to visualize leakage. (9)

Plethysmography

A plethysmograph is an instrument that measures variations in the size of an organ or body part on the basis of the amount of blood passing through or present in the part. Penile or vaginal plethysmography is used to measure physiological sexual arousal. (10)

Total Iron Binding Capacity (TIBC)

A total iron binding capacity (TIBC) test is a type of blood test that measures the capacity of transferrin, a carrier protein, to bind with iron and carry it around the body. (30) In men, severe iron overload can negatively impact make sexual function and fertility.

Prostatic Acid Phosphatase (PAP)

Prostatic Acid Phosphatase is a type of enzyme that is primarily produced in the prostate gland. PAP was first linked to prostatic tissue in 1935 and subsequently used as a prostate cancer biomarker for the next 50 years until the discovery of prostate-specific antigen (PSA). (31) Development of a radioimmune assay for PAP in 1975 provided some improvement in test sensitivity, but the sensitivity levels were still inadequate for detection of early-stage disease.

Therefore, it was clear that a more sensitive and robust indicator of disease presence would be required to detect prostate cancer in its earlier stages, when cure is more likely.

Male Treatment

Treatments for sexual dysfunctions include, but are not limited to:

1. Inflatable or non-inflatable penile implants (prostheses);
2. Vacuum erection devices;
3. Intracavernosal injection therapy;
4. Urethral suppository;
5. Oral Medication;
6. Arterial reconstructive procedures;
7. Penile revascularization for vasculogenic erectile dysfunction. (11)

Penile Implants

Inflatable or non-inflatable penile implants (prostheses) are devices that provide an erection on demand. The inflatable penile implants are made of silicone rubber or polyurethane rubber. The multi-component inflatable prostheses consist of two inflatable cylinders implanted in the penis. These are connected to a reservoir filled with fluid implanted in the abdomen and a manual pump implanted in the scrotum. In order to get an erection, the pump must be squeezed. The non-inflatable prostheses are rigid, semi-rigid and malleable rods that produce varying degrees of penile rigidity to allow for vaginal penetration. (12)

Vacuum Erection Devices

The vacuum erection device is a plastic cylinder that is placed around the penis. When negative pressure is applied, the penis becomes rigid. A rubber ring traps the blood in the penis and keeps the penis rigid until ejaculation. These devices are made by a number of manufacturers and the devices are reusable. (11)

Intracavernosal Injection Therapy

Intracavernosal-injection therapy is a therapeutic option for men with erectile dysfunction. It does not involve surgery or devices and has reproducible erection responses and tolerable side effects. Physiologic mechanisms that relax penile smooth muscle and elicit erections are mimicked by vasoactive drugs administered intracavernosally that directly relax the smooth muscle. (4) Intracavernosal injection therapy is the direct introduction of vasodilator substances into the corpora cavernosa of the penis via syringe and needle, creating an erection. The most effective and well-studied agents are Papaverine, Phentolamine, Verapamil and Prostaglandin E_1 (PGE1). These have been used either singly (such as Caverject that contains Alprostadil as the naturally occurring form of PGE1) or in combination.

Urethral Suppository

The urethral suppository method introduces the medication into the urethra after urination, via an applicator stem, and is absorbed by the surrounding erectile tissues, creating an erection. On November 19, 1996, the Food and Drug Administration (FDA) approved a medicated urethral

system for erection (MUSE), the first and only non-injectable, transurethral delivery system of Alprostadil. (13, 14)

To ensure safe and effective use of these substances, the patient should be thoroughly instructed and trained in the self-injection technique and solution preparation or the self-insertion before urethral suppository.

The desirable dose should be initially established in the physician's office, known as titration. This may require two or more physician office visits. Dosage adjustments can be done via the telephone with the physician once self-injection training has been completed. The patient will have periodic routine follow-up visits and long-term therapy management, as often as three-month intervals.

Oral Medications

Oral medication acts by enhancing the smooth muscle relaxant effects of nitric oxide, a substance that is normally released locally in response to sexual stimulation. The medication does not directly cause penile erections, but the smooth muscle relaxation allows blood to enter and pool leading to an erection. (15)

Dorsal Vein Arterialization Procedures

Deep dorsal vein (DDV) arterialization has developed as a treatment option for patients with arteriogenic impotence, especially in situations where artery-to-artery bypass is not feasible. The inferior epigastric artery (IEA), harvested through a lower abdominal incision. The IEA is then surgically connected to the deep dorsal vein in the penis, turning the artery to a vein to improve blood flow and facilitate erection maintenance.

Penile Revascularization

Penile revascularization is vascular reconstructive surgery to improve blood flow to the penis. Revascularization involves bypassing blocked veins or arteries by transferring a vein from the leg and attaching it so that it creates a path to the penis that bypasses the area of blockage. Young, nonsmoking, otherwise healthy men with only a recently acquired focal arterial blockage are the best candidates for this procedure. (11, 16)

The arterial revascularization procedure usually involves taking an artery from a leg and then surgically connecting it to the arteries at the back of the penis, bypassing the blockages and restoring blood flow. In a related procedure called deep dorsal vein arterialization, a penile vein is used for the bypass. Young men with local sites of arterial blockage or those with pelvic injuries generally achieve the best results. In studies of selected patients, there was improvement in erectile dysfunction in 50% to 75% of men after five years. (16)

Penile Contracture Devices

Penile traction therapy (PTT) is a new therapeutic option for men with Peyronie’s disease (PD). However, it has a long history of use in other fields of medicine including bone, skin, skeletal muscle, and Dupuytren’s. Mechanotransduction, or gradual expansion of tissue by traction,

leads to the formation of new collagen tissue by cellular proliferation. A penile contracture device may be indicated for the treatment of Peyronie's disease, to correct penile curvature or indentation/hourglass deformity, restore penile length loss secondary to medical conditions, surgery or trauma, and to limit loss of erectile function post-prostatectomy. (19)

Venous Ligation

Venous ligation is performed when the penis is unable to store a sufficient amount of blood to maintain an erection. This operation ties off or removes veins that are causing an excessive amount of blood to drain from the erection chambers. The success rate is estimated at between 40% and 50% initially but drops to 15% over the long term. It is important to find a surgeon experienced in this surgery. In a variation of this technique called venous ablation, ethanol is injected into the deep dorsal vein, the main vein that drains blood from the penis. The ethanol causes scarring that closes off smaller veins and prevents blood leakage, thereby bolstering erectile function. (16)

Low-intensity Shock Wave Therapy for Erectile Dysfunction

Low-intensity extracorporeal shock wave therapy (Li-ESWT) has been used in other fields such as plastic surgery, cardiology and orthopaedics. ESWT uses externally applied shock waves to create a transient pressure disturbance. Neovascularization is thought to improve cavernosal arterial blood flow, a sign of erectile dysfunction. (17)

Acupuncture

Acupuncture is a traditional form of Chinese medical treatment that has been practiced for over 2,000 years. It involves piercing the skin with needles at specific body sites. The placement of needles into the skin is dictated by the location of meridians. These meridians, or channels, are thought to mark patterns of energy, called Q (Chi), which flow through the human body. According to traditional Chinese philosophy, illness occurs when the energy flow is blocked or unbalanced, and acupuncture is a way to influence chi and restore balance. Another tenet of this philosophy is that all disorders are associated with specific points on the body, on or below the skin surface. It is thought that the neurophysiological influence of acupuncture may positively affect the pathophysiology of erectile dysfunction. (18)

Ganglionic Block or Sympathectomy for Erectile Dysfunction

Ejaculation in men is controlled by the sympathetic branch of the autonomic nervous system, which includes the stellate ganglion. (33) Erectile blood tissue flow is permitted when sympathetic nervous system activity is reduced. A stellate ganglion block can improve the functional health of the sympathetic nervous system and can help alleviate symptoms of sexual dysfunction. The repeated administration of stellate ganglion blocks over time provides extended restoration of sexual function.

Female Assessment

The initial evaluation of a patient with female sexual dysfunction symptoms may require an extended visit and should include a comprehensive history and physical examination to

evaluate possible gynecologic etiologies. Laboratory testing is not usually necessary in the initial evaluation unless an undiagnosed medical issue is suspected. (5)

Biothesiometry

Biothesiometry measures the threshold of perception of vibration sense, which is of use when assessing peripheral neuropathies, as seen in diabetics. For sexual dysfunction, this evaluates the genital neurological function in women; and uses a small cylindrical instrument to evaluate the sensitivity of the clitoris and labia to pressure and temperature. (21)

Female Treatment

Vacuum Therapy

Similar to the devices used for erectile dysfunction, the EROS clitoral therapy device is a battery-operated pump that is placed over the clitoris to apply gentle suction to the region and increase blood flow, aiding in sexual arousal. (22)

Medications

Various medications may be provided in order to treat sexual problems in women. These may include systemic hormone therapy (androgen and estrogen treatment), serotonergic or dopaminergic agents, or phosphodiesterase inhibitors. Low-dose vaginal estrogen therapy and vaginal dehydroepiandrosterone (DHEA) are approved to treat menopausal dyspareunia but use of hormones for any other sexual problem would be considered off-label. (20)

Vaginal Laser Treatment

Laser Vaginal Rejuvenation® (LVR®) is an outpatient surgical procedure designed to enhance sexual gratification. These procedures are reported to be a modification of a gynecological surgical procedure used for the treatment of stress urinary incontinence. LVR is claimed to effectively enhance vaginal muscle tone, strength, and control, and effectively decrease the internal and external vaginal diameters as well as build up and strengthen the perineal body. (23)

Vaginal Electrical Stimulation

Vaginal electrical stimulation (VES) is sometimes used for pelvic floor physical therapy. The pelvic floor muscles support the organs of the pelvis. Normally, they work together to promote healthy bladder and bowel control. They also help with sexual function, especially arousal and orgasm. Like other muscles, pelvic floor muscles can weaken. Patients are often referred to therapy for incontinence, constipation, and pelvic pain. The treatment can also help with sexual disorders such as vaginismus. VES uses a low-voltage electrical current that causes the muscles to contract. In women, the current is delivered through a probe inserted into the vagina. This process can be done either at home or at a clinician's office. (24)

Genital Cosmetic Surgery

Female genital cosmetic surgery is a growing area within the field of gynecology, including procedures such as labiaplasty (reshape the labia minora), vaginoplasty (tightening of the

vagina following childbirth or from aging), clitoral hoodectomy (reducing the size of the clitoris), hymenectomy, labia majora augmentation, and G-spot amplification. (25)

Rationale

This policy is based on a review of coverage guidance from professional society guidelines.

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists (ACOG)

A statement by ACOG in a new Committee Opinion published in the January 2020 issue of Obstetrics & Gynecology stated: "The FDA has not cleared or approved any energy-based medical device for vaginal 'rejuvenation' or vaginal cosmetic procedures, or for the treatment of vaginal symptoms related to menopause, urinary incontinence, or sexual function." ACOG concluded that: "Patients should be made aware that surgery or procedures to alter sexual appearance or function (excluding procedures performed for clinical indications, such as clinically diagnosed female sexual dysfunction, pain with intercourse, interference in athletic activities, previous obstetric or straddle injury, reversing female genital cutting, vaginal prolapse, incontinence, or gender affirmation surgery) are not medically indicated, pose substantial risk, and their safety and effectiveness have not been established." (23)

Canadian Urological Association (CUA)

In 2021, the CUA published updated guidelines for erectile dysfunction. They stated, "These guidelines were developed using transparent and rigorous methods to provide the healthcare community with the most current data and recommendations regarding ED patient assessment and treatment through the Canadian lens. Special attention was taken to provide clarity on the most controversial aspects of ED treatment in Canada today." The committee opinion concluded that:

- "Reversible factors contributing to ED should be identified and corrected, including promoting positive lifestyle changes that optimize overall health. In patients requesting treatment, it is reasonable to begin with conservative and less invasive therapies and introduce additional therapeutic measures when necessary, through a shared decision-making process with the patient and their partner."
- "As technology evolves and a further understanding of the pathophysiological processes contributing to ED develops, we can expect that treatment options to improve erectile function will continue to advance. Regenerative therapies aim to restore the structure and function of the erectile tissue and offer a "cure" to the disease process as opposed to merely treating the symptoms of ED." (34)

Society of Obstetrician and Gynaecologists of Canada (SOGC)

In 2022, the SCOC updated their guidelines (from 2013) on Female Genital Cosmetic Surgery and Procedures. (35) Literature was retrieved through searches of MEDLINE, Scopus, and The Cochrane Library using appropriate controlled vocabulary and keywords. They recommended the following changes in practice:

- "Health professionals should provide comprehensive education for women of all ages on normal female genital anatomy and physiological function."
- "Physicians providing female genital cosmetic surgery and procedures should ensure that thorough counselling has been completed before they consider offering a procedure that is not medically indicated for cosmetic purposes."
- "Significant caution is warranted in the use of laser for genitourinary syndrome of menopause or cosmetic genital indications pending further rigorous short- and long- term clinical research on safety and effectiveness."

European Association of Urology (EUA)

In 2023, the EUA updated their Sexual and Reproduction Health Guidelines. (36) Their recommendation for the minimal diagnostic evaluation (basic work-up) in patients with erectile dysfunction should include:

- Medical and sexual history;
- Physical examination;
- Laboratory testing tailored to patient's complaints and risk factors (testing should include fasting blood sugar, lipid profile measurement, hormonal tests including total testosterone in a fasting state). Additional laboratory tests to be considered may include prostate-specific antigen, prolactin, and luteinizing hormone; and
- Cardiovascular system and sexual activity: the patient as risk.

Based on a patients' medical and sexual history, some may need specific tests (advanced work-up) such as:

- Nocturnal penile tumescence and rigidity test;
- Intracavernous injection test;
- Dynamic duplex ultrasound of the penis;
- Arteriography and dynamic infusion cavernosometry or cavernosography; or
- Psychopatholigical and psychosocial assessment.

American Urological Association (AUA)

The AUA guidelines (2018) on Erectile Dysfunction have five guideline statements regarding evaluation and diagnosis:

- Men presenting with symptoms of ED should undergo a thorough medical, sexual, and psychosocial history; a physical examination; and selective laboratory testing. (Clinical Principle)
- For the man with ED, validated questionnaires are recommended to assess the severity of ED, to measure treatment effectiveness, and to guide future management. (Expert Opinion)
- Men should be counseled that ED is a risk marker for underlying cardiovascular disease and other health conditions that may warrant evaluation and treatment. (Clinical Principle)
- In men with ED, morning serum total testosterone levels should be measured. (Moderate Recommendation; Evidence Level: Grade C)
- For some men with ED, specialized testing and evaluation may be necessary to guide treatment. (Expert Opinion)

- Specialized testing should only occur if findings will affect management.
- Nocturnal Penile Tumescence and Rigidity testing may be done but the test is prone to false negatives and may be less useful in men with impaired sleep schedules.
- Intracavernosal injection testing to assesses veno-occlusive function of penis.
- Penile duplex ultrasound (DUS) for the observation of plaques and/or fibrosis. Currently the DUS is the gold-standard in penile vascular evaluation.
- A variety of alternative modalities have been used to assess ED, including pudendal somatosensory evoked potentials, cavernous electromyograph, bulbocavernous reflex time, and sympathetic skin response). The clinical utility of these tests is unclear at this time; they are not recommended for use outside of a research setting. (37)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	37788, 37790, 54110, 54111, 54112, 54200, 54205, 54230, 54231, 54235, 54240, 54360, 54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417, 56700, 56810, 57335, 58999, 74445, 76870, 80061, 81002, 81003, 81005, 82540, 82550, 82552, 82553, 82554, 82565, 82570, 82575, 82951, 83001, 84146, 84402, 84403, 93980, 93981, 97014, 97032, 97810, 97811, 97813, 97814, 0864T
HCPCS Codes	E0201, E0740, J0270, J0275, J2440, J2760, L7900, L7902, S0090, S4988

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
01/01/2026	Document updated. The following changes were made to Coverage: 1) Added conditional coverage criteria for men relating to counseling and potential cardiac disease, serum total testosterone levels and morning serum total testosterone levels. 2) Moved penile revascularization surgery age limit from 50 to 55 years old. 3) Added platelet-rich plasma (PRP) therapy and penile venous occlusive surgery (e.g., venous ligation, dorsal vein ligation) to the list of experimental, investigational, and/or unproven list, 4) Moved Note 2 from Rationale to Coverage. Note 2 states: Some benefit plans specifically exclude payment for the treatment of sexual dysfunction. This exclusion extends to prescriptions or medications for the treatment of sexual dysfunction, 5) removed "Topical cream or gel containing vasodilators, such as verapamil cream " from the male treatment experimental, investigational and or unproven list, and 6) removed "Medication as an enhancement to sexual function and treatment of female sexual dysfunction" from the female sexual dysfunction experimental, investigational and or unproven list. References 6, 12, and 32 added; others updated.
05/15/2025	Document updated with literature review. The following changes were made to Coverage: 1) Note 2 removed as it was a duplicate to Note 3. Other Notes renumbered and 2) Penile contracture devices added to the list of male sexual dysfunction therapies, treatments or procedures that are experimental, investigational and unproven. References 18, 26-34, 38-39, 42, 44-46, 49, 51, 53, and 55-58 added, others updated. S4988 added to the policy.
03/15/2023	Reviewed. No changes.
10/01/2022	Document updated with literature review. Coverage unchanged. References 12, 23-25, 37 and 38 added; some updated and others deleted.
03/01/2021	Reviewed. No changes.
10/01/2020	Document updated with literature review. Policy was divided into male and female assessment and treatment. The following was added to Coverage for males as experimental, investigational and/or unproven: low-intensity

	shockwave therapy for erectile dysfunction and acupuncture. The following was added to Coverage for females: Note 4 identifying the FDA warning regarding the use of energy-based devices, such as radiofrequency or laser, for vaginal rejuvenation or vaginal cosmetic procedures, or for the treatment of vaginal symptoms related to menopause, urinary incontinence or sexual function. The following was added to Coverage for females as experimental, investigational and/or unproven: vaginal carbon dioxide fractional laser treatment, vaginal electrical stimulation, biothesiometry, and female genital cosmetic surgery. Added references 29-39.
06/15/2018	Reviewed. No changes.
06/01/2017	Document updated with literature review. The following changes were made to Coverage: 1) NOTE was added referencing medical policies that address additional treatments for Peyronie's disease and 2) removed "Perineoplasty (also known as vaginal rejuvenation or tightening) done as part of a cysto/rectocele repair is considered ineligible for separate reimbursement removed."
03/15/2016	CPT/HCPCS code(s) updated.
05/15/2015	Reviewed. No changes.
12/15/2014	Document updated with literature review. Coverage unchanged.
06/01/2012	Document updated with literature review. The following was added to Coverage: Intracavernosal injection of Verapamil for treatment of Peyronie's disease was added to the list that may be considered medically necessary. References and rationale updated.
12/15/2010	CPT/HCPCS code(s) updated.
06/01/2008	Coverage Revised
02/15/2007	New Medical Document