Select Health Medical Policies

Genitourinary Policies

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MEDICAL POLICY

OPTILUME

Policy # 672
Implementation Date:9/26/23
Review Dates: 10/21/24
Revision Dates: 12/14/23, 5/5/25

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Urethral stricture (US) is an abnormal narrowing of the urethra that can be caused by acute injury, inflammation, postsurgical complications, infections, and cancer. Though urethral strictures can occur in either sex, they are rare in female persons. The incidence rate of US in the United States is 0.9% annually, resulting in 1.5 million hospital visits every year. US can be anterior or posterior with anterior US comprising 92% of cases. Symptoms include decreased urinary stream, incomplete emptying, dysuria, bloody or dark urine, urethral leaking, and urinary tract infection.

Treatment options for urethral strictures depend on the site, length, etiology, and whether it is primary or recurrent. Common treatments include urethroplasty, urethral dilation, urinary diversion procedures, and direct visual internal urethrotomy (DVIU). Urethroplasty is considered the reference standard for treatment, but it is more invasive than endoscopic treatments, and can be associated with complications of sexual dysfunction, neuropathy, and pain. Endoscopic treatments such as mechanical dilation and DVIU are associated with high recurrence rates, especially after retreatment. Repeated endoscopic interventions may lead to cumulative injury, lengthening of strictures, and ultimately impairment of urethroplasty success. Recurrent strictures and those undergoing repeat endoscopic treatment are considered high-risk, with low success rates for repeat endoscopic treatment.

The Optilume urethral drug-coated balloon (DCB) (Laborie) is a medical device used for treatment and management of US. It exerts radial force to dilate narrow urethral segments (strictures) while slowing or stopping the stricture formation and includes a drug coating which prevents additional stricture.

Optilume is designed to treat urethral strictures that are ≤ 3 centimeters (cm) long in adult males. The device is inserted into the urethra and advanced to the site of the stricture during an outpatient procedure. Once in position, the balloon is inflated, exerting radial force to dilate the narrow urethral segment. The drug coating on the balloon is released into the surrounding tissue to limit cell proliferation and prevent the formation of fibrotic scar tissue, which can cause stricture recurrence. The catheter is designed to reduce the risk of tissue trauma or perforation during insertion and positioning (U.S. Food and Drug Administration [FDA], 2021).

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers implantation of the Optilume drug coated balloon when all the following criteria are met:

1. Member ≥ 18 years of age; and
2. Member has urinary symptoms associated with urethral stricture; and

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Optilume, continued

3. Member has urethral stricture of ≤ 3 cm in length; and
4. Member has recurrent bulbar urethral strictures.

Select Health does not cover any repeat applications of Optilume as there is insufficient data to support safety and efficacy; this meets the plan's definition of experimental/investigational.

Select Health does not cover Optilume for the treatment of any other indication, including but not limited to benign prostatic hyperplasia (BPH), as the effectiveness of these interventions has not been established; this meets the plan's definition of experimental/investigational.

Contraindications:

The Optilume Urethral Drug Coated Balloon is contraindicated for use in patients with known hypersensitivity to paclitaxel or structurally related compounds, and in patients with urologic implants such as penile implants or artificial urinary sphincters.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Billing/Coding Information

CPT CODES

Covered for the indications listed above when criteria are met

52284 Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed

Not covered: considered investigational for the indications listed above

0619T Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed

Key References

1. Hayes, Inc. Evidence Analysis Research Brief. Optilume Urethral Drug-Coated Balloon (Laborie) for Treatment of Urethral Strictures. May 10, 2023.

Revision History

Optilume, continued

Revision Date	Summary of Changes
12/14/23	For Commercial Plan Policy, revised exclusionary statement regarding repeat applications: "Select Health does not cover any repeat applications of Optilume as there is insufficient data to support safety and efficacy; this meets the plan's definition of experimental/investigational."
5/5/25	For Commercial Plan Policy, added the following exclusion: Select Health does not cover Optilume for the treatment of any other indication, including but not limited to benign prostatic hyperplasia (BPH), as the effectiveness of these interventions has not been established; this meets the plan's definition of experimental/investigational.

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MEDICAL POLICY

PELVIC VEIN PROCEDURES FOR PELVIC CONGESTION SYNDROME AND PELVIC VARICES

Policy # 268
Implementation Date:3/5/05
Review Dates: 1/26/06, 2/15/07, 2/21/08, 2/26/09, 2/17/11, 2/16/12, 4/25/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/4/19, 8/20/20, 6/17/21, 5/19/22, 6/1/23, 6/20/24
Revision Dates: 2/18/10, 11/23/15, 5/27/25

Related Medical Policies:

#193 Varicose Vein Procedures

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Pelvic congestion syndrome (PCS) is caused by utero-ovarian varices. It is the sole cause of pain in 30% of outpatients presenting with chronic pelvic pain, a condition that accounts for approximately 15% of outpatient gynecologic visits in the United States. Pelvic congestion syndrome is defined by visibly engorged pelvic veins of more than 10 mm in diameter on selective transuterine venography in multiparous, premenopausal women with a history of chronic, noncyclic pelvic pain for more than 6 months. Nulliparous women may also be affected, although this is uncommon. Patients may report pelvic pain in the following situations:

- when standing or in the upright position (relieved in the supine position)
- during or after intercourse
- in association with varices in the thigh, buttock, perineum, vulva, or vagina
- in association with bladder urgency

The symptoms may increase after giving birth. Differential diagnoses include endometriosis, pelvic adhesions, chronic pelvic inflammatory disease, fibroids, pelvic floor muscle pain, urologic disorders, irritable bowel syndrome, and psychosocial issues.

Partial suppression of ovarian function with medroxyprogesterone acetate may relieve symptoms in some patients with PCS. Psychotherapy is sometimes used as an adjunct treatment. Patients who do not respond to pharmacological treatment and/or psychotherapy, or who experience recurrence of symptoms, may be referred for surgical therapies, including ovarian vein ligation or hysterectomy with removal of one or both ovaries. However, surgical therapies are associated with significant morbidity, and hysterectomy may be undesirable, especially in younger women who desire children.

Several procedures are also performed to treat pelvic congestion/pelvic varicosities. One such treatment is percutaneous transcatheter coil embolization. This has been proposed as an alternative treatment strategy to surgery and as an adjunct procedure to embolization with detachable balloons, sclerosing agents, or glue (e.g., enbucrilate). Percutaneous access to the ovarian vein is generally gained via the femoral venous approach. Several coils are inserted into the affected ovarian vein under fluoroscopic guidance, using contrast media to locate the varices. The ovarian and internal iliac veins are in close communication, therefore, in some cases, embolization of the iliac veins may also be required. Embolization of the iliac vein is usually performed after treatment of the ovarian vein.

Foam sclerotherapy is another procedure sometimes performed and using an intravascular foam which scars the vessels (scleroses) closed. It has been found to be safe and effective treatment for high-flow

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Pelvic Vein Procedures for Pelvic Congestion Syndrome and Pelvic Varices, continued

female varicoceles and should be considered as an alternative to other endovascular and surgical options.

Percutaneous transcatheter with coils, plugs, or sclerotherapy, usually as combination treatment, has become the standard approach for management of both pelvic congestion syndrome and varices arising from a pelvic source.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers treatment of pelvic congestion syndrome and pelvic varices using coil embolization, plugs, or transcatheter sclerotherapy, alone or in combination, when the following criteria are met.

1. Pelvic Congestion Syndrome (Documentation must demonstrate all the following):
   A. Pelvic pain of at least six months duration without other etiology.
   B. Imaging consistent with pelvic venous changes.
   C. Have tried and failed conservative therapy of at least 3 months duration; conservative therapy must include use of prescription anti-inflammatories, unless contraindicated.

2. Pelvic/Labial Varicosities: (Documentation must demonstrate all the following):
   A. The patient is unable to perform ADLs (activities of daily living) such as feeding, bathing, dressing, grooming, meal preparation, house chores, and occupational tasks for functioning.
   B. Patient has failed to respond to conservative therapy of at least 3 months duration; conservative therapy must include use of prescription anti-inflammatories, unless contraindicated.
   C. Varicose veins to be treated must be 4mm or greater in diameter.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A search of the peer-reviewed medical literature identified 3 very small case series studies and 1 larger randomized comparative clinical trial investigating the efficacy and safety of coil embolization of the ovarian vein for the treatment of PCS. Small sample sizes, lack of control groups, insufficiently defined patient selection criteria, non-standardized procedures, and the predominant use of patient self-assessed

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Pelvic Vein Procedures for Pelvic Congestion Syndrome and Pelvic Varices, continued

subjective outcome measures compromised the quality of most of the studies. In addition, the case series used only 1 instrument to assess outcomes.

The 3 case series studies included 6−11 patients, and the randomized study included 106 patients. Clinical diagnosis was confirmed with selective venography. Relief of symptoms was the only outcome measure and was assessed using standardized questionnaires or a visual analogue scale. Patients were followed for between 3 months and 4 years.

Initial technical success rates were determined by using repeat angiography and ranged from 88.9%−100%. The treatment effect varied considerably among and within studies, and symptom relief ranged from 40%−100%. In 1 very small case series study (n = 6), the treatment effect was maintained for all patients for 1−4 years, whereas a second case series study reported recurrence in 1 patient at 6 months and 1 at 22 months.

The only randomized trial compared the efficacy of coil embolization (group 1, n = 52) with hysterectomy and bilateral oophorectomy (group 2, n = 27) or hysterectomy and unilateral oophorectomy (group 3, n = 27). Furthermore, patients were stratified according to stress scores (using a social readjustment rating scale) into 3 subgroups; normal, moderate high, and very high stress levels. A significant improvement in pain symptoms versus baseline values were observed for patients in all 3 groups. Patients with normal to moderate high stress levels who received coil embolization experienced superior symptom relief compared with patients who underwent hysterectomy with unilateral or bilateral oophorectomy. However, patients with very high stress levels did not derive as much treatment benefit as patients with normal to moderate high stress levels. The treatment effect was maintained for 12 months in all patients.

The preliminary evidence indicates that coil embolization of the ovarian vein is a relatively safe procedure that causes only minor, transient side effects (e.g., hematoma at the percutaneous access site and slightly elevated temperature). Coil embolization of the ovarian vein should not be performed in patients with significant contraindications to venography or endovascular procedures, or who have sensitivities/allergies to contrast material. Some investigators caution against the use of coil embolization in the internal iliac veins since emboli may be dislodged and carried to the lungs, causing pulmonary emboli.

In a study by Machan, et al., ovarian and pelvic vein embolization was performed in 22 women with chronic pelvic congestion and angiographical demonstrated ovarian varicosities. In 10 cases, embolization produced complete resolution of symptoms, while partial resolution was achieved in another 6 cases. Six patients experienced no improvement. That study demonstrated that, in properly selected and screened patients, embolization is a safe and effective treatment for pelvic congestion syndrome.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation

HCPCS CODES

No specific codes identified

Key References

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Revision History

Revision Date	Summary of Changes
5/27/25	For Commercial Plan Policy, aligned requirements for failure of conservative therapy in criterion #1-C with those listed in criterion #2-B.

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Pelvic Vein Procedures for Pelvic Congestion Syndrome and Pelvic Varices, continued

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MEDICAL POLICY

PENILE IMPLANTS

Policy # 611
Implementation Date:4/27/17
Review Dates: 7/16/18, 4/17/19, 4/13/20, 4/15/21, 3/11/22, 5/1/23, 4/26/24, 5/15/25
Revision Dates:

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Description

Male Erectile Dysfunction (ED) is defined as the inability of a man to attain and maintain an erection sufficient for sexual intercourse. ED may be organic in nature, which is, caused by a detectable physiological or structural change, or may be psychologically related to underlying behavioral health issues. For more severe disease, usually associated with advanced diabetes, surgical or radiation treatment for prostate or bladder cancer, or Peyronie's disease, implantation of a penile prosthesis is a therapeutic alternative.

Penile implants are devices placed inside the penis to allow men with erectile dysfunction (ED) to get an erection. There are three basic kinds of penile implants: semi-rigid (malleable) implant, two-piece inflatable implant, and three-piece inflatable implant.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover penile implants as a standard benefit. Only plans with a sexual dysfunction rider will cover penile implants, when the following criteria are met:

1. The history and physical exam of the member are consistent with sexual dysfunction.
   a) The member has a medical (organic) condition that directly contributes to sexual dysfunction; **and**
   b) Appropriate covered medical therapies have been tried and failed, such as testosterone replacement therapy, if appropriate, or intracavernous aprastadil injections, suppositories, or PDE5 inhibitors.
2. Replacements of a penile implant are covered if:
   a) The device malfunctions, breaks, or becomes infected; **and**
   b) Medically necessity criteria continue to be met; **and**
   c) Replacement is not part of the manufacturer's warranty.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits

Penile Implants, continued

outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

The American Urological Association (AUA) *Guideline on the Management of Erectile Dysfunction: Diagnosis and Treatment Recommendations* defines the index case of ED as the absence of hypogonadism or hyperprolactinemia in a man who develops, after a well-established period of normal erectile function, ED that is primarily organic in nature (AUA, 2005, Update 2007). The European Association of Urology (EAU) defines ED as the: "Persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance" (Hatzimouratidis, 2015).

The AUA (2007) guidelines note: "Cardiovascular disease and ED may share a common etiology when endothelial dysfunction and atherosclerosis affect both coronary arteries and penile vasculature." The EAU guideline notes: "ED shares both unmodifiable and modifiable common risk factors with CVD (e.g., obesity, diabetes mellitus, dyslipidemia, metabolic syndrome, lack of exercise, and smoking)" (Hatzimouratidis, 2015). The Princeton guideline for sexual medicine addresses sexual dysfunction and cardiac risk, and was updated in 2006, with the publication of the second consensus statement. The guideline noted individuals with no known cardiovascular disease but presenting with ED may have other comorbidities (e.g., diabetes, hypertension, hyperlipidemia, heart disease) (Jackson, 2006).

The AUA (2007) guideline update for erectile dysfunction states:

The management of erectile dysfunction begins with the identification of organic comorbidities and psychosexual dysfunctions; both should be appropriately treated, or their care triaged. The currently available therapies that should be considered for the treatment of erectile dysfunction include the following: oral phosphodiesterase type 5 [PDE5] inhibitors, intra-urethral alprostadil, intracavernous vasoactive drug injection, vacuum constriction devices, and penile prosthesis implantation. These appropriate treatment options should be applied in a stepwise fashion with increasing invasiveness and risk balanced against the likelihood of efficacy.

The EAU guidelines on male sexual dysfunction: erectile dysfunction and premature ejaculation (Hatzimouratidis, 2015) recommend the implanted penile prosthesis as a third line of therapy for individuals that have failed other non-surgical treatments. As the placement of a penile prosthesis requires the dislocation of cavernosal tissue, it is considered a permanent and irreversible procedure that should be reserved in those who have failed or are intolerant of conservative measures (Trost, 2016).

Damage to nerves, arteries, smooth muscles, and fibrous tissues, often because of disease, is the most common cause of ED. Vascular disease and neurologic disease account for about 70% of ED cases. Between 35 and 50 percent of men with diabetes experience ED. Surgery (especially radical prostate and bladder surgery for cancer) and radiotherapy can injure nerves and arteries near the penis, causing ED (AUA, 2007; Chung, 2014; NCCN, 2015). Injury to the penis, spinal cord, prostate, bladder, and pelvis can lead to ED by harming nerves, smooth muscles, arteries, and fibrous tissues of the corpora cavernosa.

Use of a penile prosthesis is an established technique for treating male impotence due to neurogenic or vasculogenic disease processes after failure of less invasive medical treatments with approximately 20,000 procedures performed annually (AUA, 2007; Chung, 2014; Hatzimouratidis, 2015; Lee, 2015). Penile implants involve surgical insertion of malleable or inflatable rods or tubes into the penis. The surgery is not without possible complications. Minervini and colleagues (2006) studied 447 men who had 504 penile prosthetics implanted and found that infection was the most frequent complication. Other

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Penile Implants, continued

complications were implant migration and tissue erosion. In a review by Phé (2012), the rate of infection had decreased to 1% with the utilization of antibiotic impregnated implants.

Zermann and colleagues (2006) studied 245 neurologically impaired men who had penile prosthetics implanted. There were 3 groups based on the indication for penile prosthetic surgery. Group 1 consisted of 134 participants with urinary management only, Group 2 had 60 participants with erectile dysfunction only, and Group 3 had 51 participants with urinary management and erectile dysfunction. At a mean follow-up of 7.2 years (maximum 17 years), 195 participants were reevaluated in the clinic. Outcomes showed that in 122 participants (90.3%), urinary management problems were resolved, and erectile dysfunction treatment was successful in 76 participants (82.6%). Forty-three revisions were performed for complications (e.g., infections and device perforation). The U.S. Food and Drug Administration (FDA) considers the rigid penile implant as a Class II device. The semi-rigid rods are implanted into the corpora cavernosa of the penis to provide rigidity. Inflatable penile implants are considered Class III devices by the FDA. Inflatable cylinders are implanted in the penis and are connected to a reservoir filled with fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. Penile rigidity is achieved when the cylinders are filled with fluid.

Billing/Coding Information

CPT CODES

54115	Removal foreign body from deep penile tissue (eg, plastic implant)
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
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue

HCPCS CODES

C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, noninflatable
L8699	Prosthetic implant, not otherwise specified

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Penile Implants, continued

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Disclaimer

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Select Health® makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. Select Health updates its Coverage Policies regularly, and reserves the right to amend these policies without notice to healthcare providers or Select Health members.

Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

Select Health

Penile Implants, continued

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MEDICAL POLICY

PERCUTANEOUS RENAL NERVE ABLATION

Policy # 432

Implementation Date:12/27/09

Review Dates: 4/28/10, 5/19/11, 6/21/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/3/18, 10/15/19, 10/15/20, 11/18/21, 9/15/22, 12/28/23, 11/29/24

Revision Dates: 9/28/12

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

According to the National Health and Nutritional Examination Survey (NHANES) 2005–2006 data set it has been estimated that overall, 29% of adults aged 18 years and older has hypertension. The prevalence of hypertension did not change during 1999–2006. Among hypertensives, 78% were aware of their hypertension and 68% were taking antihypertensive medication. Among those taking medication, 64% had controlled BP (under 140/90 mmHg).

Hypertension is classified based upon the average of 2 or more properly measured readings at each of 2 or more visits after an initial screen. This is further classified as:

- Normal blood pressure: systolic < 120 mmHg and diastolic < 80 mmHg
- Prehypertension: systolic 120–139 mmHg or diastolic 80–89 mmHg
- Hypertension:
  - Stage 1: systolic 140–159 mmHg or diastolic 90-99 mmHg
  - Stage 2: systolic ≥ 160 or diastolic ≥ 100 mmHg

These definitions apply to adults on no antihypertensive medications and who are not acutely ill. If there is a disparity in category between the systolic and diastolic pressures, the higher value determines the severity of the hypertension. The systolic pressure is the greater predictor of risk in patients over the age of 50–60.

Some patients have hypertension seemingly resistant to conventional medical therapy. This is usually defined as failure to achieve goal blood pressure (BP) despite adherence to an appropriate 3-drug regimen including a diuretic. In most patients, the blood pressure goal is less than 140/90 mmHg and less than 130/80 mmHg in those with diabetes, proteinuric chronic kidney disease, or coronary artery disease or a coronary equivalent.

It is postulated that renal sympathetic efferent and afferent nerves are crucial for the initiation and maintenance of systemic hypertension. It has been proposed that catheter-based radiofrequency ablation of renal sympathetic nerves may lower the blood pressure in patients with resistant hypertension. The nerves lie within and immediately adjacent to the wall of the renal artery. During the procedure, the tip of the catheter is directed into the distal renal artery and 2 minutes of RF energy is applied. The tip is withdrawn, circumferentially rotated within the artery, and a further two minutes of energy is applied, and so on all the way back through the renal artery, with a cumulative 4–6 applications of the RF energy.

Percutaneous Renal Nerve Ablation, continued

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover percutaneous renal nerve ablation. There is limited literature and research on this technology; this meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

In a Medical Technology Assessment completed by SelectHealth in October 2009, there was only 1 proof-of-concept study that met criteria for review. This 2009 study by Krum et al. evaluated 50 patients with resistant hypertension (systolic pressure ≥ 160 mmHg [mean 177/101 mmHg] on 3 or more antihypertensive medications) who underwent percutaneous radiofrequency catheter-based treatment. The treatment led to reductions in systolic blood pressure of more than 10 mmHg in 39 of 45 patients, with mean reductions in blood pressure of 14/10, 21/10, 22/11, 24/11, and 27/17 mmHg at 1, 3, 6, 9, and 12 months respectively. In contrast, the mean blood pressure increased by 26/17 mmHg at 9 months in the 5 patients who were excluded from sympathectomy for anatomical reasons. Complications of the intervention included 1 renal artery dissection and 1 femoral artery pseudoaneurysm.

This study suggests some potential for this procedure in treating resistant hypertension. However, a single study is insufficient to determine whether the procedure is safe and effective, particularly over the long-term. Likewise, patient selection criteria and contraindications cannot be clearly identified through this single study. Additional research is needed to address such concerns before percutaneous renal artery ablation can be considered a legitimate treatment for treatment resistant hypertension.

The National Institute for Health and Clinical Excellence (NICE) in the UK published an Interventional Procedure Guidance in January 2012. They could only identify evidence on a limited number of patients on a short- or medium-term basis, but no long-term data could be identified. The limited data did suggest a low incidence of serious complications, but the evidence was inadequate for long-term safety. NICE noted though treatment of drug-resistant hypertension may be difficult, and sympathetic denervation of the renal artery is promising, a larger number of evidence-based, well-designed trials are required to determine its safety and efficacy.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

0338T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast I njection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral

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Percutaneous Renal Nerve Ablation, continued

0339T Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral

HCPCS CODES

No specific codes identified

Key References

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MEDICAL POLICY

POSTERIOR TIBIAL NERVE STIMULATION (PTNS)

Policy # 473

Implementation Date:12/13/10
Review Dates: 12/15/11, 12/19/13, 12/18/14, 8/17/17, 7/16/18, 6/20/19, 6/18/20, 6/17/21, 5/19/22, 6/15/23, 6/24/24, 6/19/25
Revision Dates: 12/11/12, 7/21/16, 2/19/21, 6/9/22, 6/12/24, 7/3/24, 12/11/24, 5/2/25, 6/24/25

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Overactive bladder (OAB) is a problem with bladder storage function that causes a sudden urge to urinate. The urge may be difficult to suppress, and overactive bladder can lead to the involuntary loss of urine (incontinence). The overactive bladder is defined as urgency, with or without urge incontinence, usually with frequency and abnormally excessive urination during the night (nocturia).

Behavioral therapy and operative procedures may be used to treat OAB, but pharmacologic therapy remains first-line treatment. The medications used to treat overactive bladder problems are antimuscarinic and anticholinergic receptor inhibitors which block the effect of nerve signals coming to, or originating within the bladder, causing the muscles of the bladder to relax.

Percutaneous posterior tibial nerve stimulation (PTNS) uses the concept of neuromodulation to inhibit the urge to urinate. There is not a complete understanding of the exact mechanisms of how PTNS works but it is thought that by inhibiting a nerve entering the spinal cord near the exit point of the nerves going to the bladder, these nerves are also inhibited.

The procedure for PTNS consists of the insertion of a needle above the medial malleolus into the posterior tibial nerve followed by the application of low voltage (10mA, 1-10 Hz frequency) electrical stimulation, which produces sensory and motor responses (i.e., a tickling sensation and plantar flexion or fanning of all toes). Non-invasive PTNS has also been delivered with surface electrodes. The exact frequency and duration of PTNS therapy is not yet fully defined, though, most studies applied this therapy in 30-minute sessions given weekly for 12 weeks. The optimal interval for maintenance therapy is not yet established but is frequently performed every 3–4 weeks. Studies beyond 24 months have not been performed to identify any benefit of continued treatment beyond 24 months.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Select Health does not cover posterior tibial nerve stimulation (PTNS) when performed as first-line therapy for patients with overactive bladder (OAB). **Select Health may consider PTNS medically necessary** to treat patients with OAB and associated symptoms of urinary urgency, urinary frequency, and urge incontinence, when ALL the following criteria (1−4) have been met:

Covered Indications

1. Patient ≥ age 18

Posterior Tibial Nerve Stimulation (PTNS), continued

2. The patient has experienced OAB with associated symptoms of urinary urgency, urinary frequency, and urge incontinence for at least 12 months, and the condition has resulted in significant disability (i.e., the symptoms are limiting the patient's ability to participate in activities of daily living (ADLs)); **and**
3. The patient has tried at least two different anti-cholinergic drugs, or a combination of an anti-cholinergic and a tricyclic drug for a period of four to six weeks without improvement, or the documentation shows the patient is unable to tolerate these types of drugs; **and**
4. The patient has tried behavioral treatments (e.g., pelvic floor exercise, biofeedback, timed voids, or fluid management (not an all-inclusive list), without improvement in the symptoms.

B. Treatment Limitations

1. Initial PTNS treatments are covered weekly for 12 weeks. The patient must show a 50% improvement of OAB symptoms for treatment to be covered for every one to two months for the remainder of one year.

2. Continued treatment after the initial 12 months is not covered unless it has been 24 months since the completion of the initial PTNS treatment, and the patient has returning symptoms of OAB. In these instances, a new PTNS trial (weekly for 12 weeks) is required.

C. Exclusions

Contraindications

PTNS treatment is contraindicated for patients with pacemakers or implantable defibrillators, for patients prone to excessive bleeding, for patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, or for patients who are pregnant or who are planning to become pregnant during the duration of the treatment. Caution should be exercised for patients with heart problems related to pacing.

Select Health does not cover leadless neuromodulation systems (e.g., BlueWind Revi, eCoin, Freedom systems); these technologies are considered experimental/investigational due to safety concerns and lack of long-term outcomes.

Select Health does not cover wearable neuromodulation systems (e.g., Vivally and ZIDA systems) as the effectiveness of these treatments has not been established; this meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Select Health

Posterior Tibial Nerve Stimulation (PTNS), continued

Summary of Medical Information

Evidence has evolved since the PTNS was first approved in 2007. Hayes published an updated Directory Report on PTNS in 2015, with an additional update in 2016. Hayes now gives PTNS a 'B' rating for adults, with refractory OAB (non-neurogenic) and associated symptoms of urinary urgency, urinary frequency, and UUI. This rating is based on the large body of moderate-quality evidence that PTNS is superior to sham therapy, and at least as effective as active comparator treatments (e.g., antimuscarinic therapy, transvaginal electrical stimulation), with a treatment benefit that may persist for 12 to 36 months with maintenance PTNS therapy. It continues to provide a 'D2' rating for adults with lower urinary tract disease (LUTD), secondary to multiple sclerosis (MS) or Parkinson's disease (PD), and for children with LUTD. In both latter instances, the rating is reflective of the small body of very-low-quality evidence demonstrating the efficacy of PTNS as treatment for LUTD.

From 2006 to 2010, only 10 papers met review standards for consideration. These papers evaluated over 500 patients. Since 2010, three systematic reviews and 12 primary studies were identified which met review standards. Results from 362 patients were reported in this cohort of primary literature articles. Notably, the quality of the studies had improved with new studies often being randomized and prospective, and comparative to other available therapies or sham treatment.

Important take-aways from the current literature regarding outcomes and methods include a lack of consensus regarding a standard treatment regimen, though, for the most part, efficacy of weekly treatments for 12 weeks followed by maintenance treatment every 3–4 weeks is the most common regimen employed. Currently the body of evidence has not illustrated a standardized, evidence-based maintenance protocol for these patients.

Regarding use of the PTNS technology in patients with Parkinson's disease or MS, current published evidence remains limited to 2 papers, with outcomes reported on 60 patients and little evidence for outcomes of patients with multiple sclerosis. Though suggestive of benefit, the evidence remains insufficient to reach conclusions regarding efficacy or safety of the therapy in these clinical settings.

In conclusion, evidence for efficacy and safety of PTNS for urinary incontinence in adults suggests some level of efficacy equivalent to currently available medications, though, the entire body of literature remains limited. The literature generally illustrates an improvement in OAB/UI symptoms at follow-up and there is now evidence of durability of effect out to 3 years follow-up time. There is discord among the articles regarding a standard treatment protocol for the treatment of these symptoms, but all regimens resulted in symptom reduction.

Billing/Coding Information

Covered for the indications listed above

CPT CODES

64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

HCPCS CODES

No specific codes identified

Not covered for the indications listed above

CPT CODES

0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous
0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial

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Posterior Tibial Nerve Stimulation (PTNS), continued

0818T Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis programming, and imaging, when performed, posterior tibial nerve, subcutaneous

0819T Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis programming, and imaging, when performed, posterior tibial nerve, subfascial

64590 Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

HCPCS CODES

E0737 Transcutaneous tibial nerve stimulator, controlled by phone application

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Revision History

Revision Date	Summary of Changes
6/12/24	For Commercial Plan Policy, modified criteria for Treatment Limitations in section #B as follows: "1. Initial PTNS treatments are covered weekly for 12 weeks, then every one to two months for the remainder of one year. 2. If the patient fails to improve after 6 PTNS treatments, continued treatment is not considered medically necessary. 3. Continued treatment after the initial 12 months is not covered unless it has been 24 months since the completion of the initial PTNS treatment, and the patient has returning symptoms of OAB. In these instances, a new PTNS trial (weekly for 12 weeks) is required. 4. PTNS treatment is contraindicated for patients with pacemakers or implantable defibrillators, for

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	patients prone to excessive bleeding, for patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, or for patients who are pregnant or who are planning to become pregnant during the duration of the treatment. Caution should be exercised for patients with heart problems related to pacing."
7/3/24	For Commercial Plan Policy, added the following exclusion in section #C: "Select Health does not cover either the BlueWind Revi neuromodulation system or the eCoin leadless tibial neurostimulator. These technologies are considered experimental/investigational due to safety concerns and lack of long-term outcomes."
12/11/24	For Commercial Plan Policy, modified exclusion in section #C as follows: "Select Health does not cover leadless neuromodulation systems (e.g., BlueWind Revi, eCoin, Freedom systems); these technologies are considered experimental/investigational due to safety concerns and lack of long-term outcomes."
5/2/25	For Commercial Plan Policy, added the following exclusion to section #C: "Select Health does not cover wearable neuromodulation systems (e.g., Vivally and ZIDA systems) as the effectiveness of these treatments has not been established; this meets the plan's definition of experimental/investigational."
6/24/25	For Commercial Plan Policy, modified requirements in section B (Treatment Limitations), "1. Initial PTNS treatments are covered weekly for 12 weeks. The patient must show a 50% improvement of OAB symptoms for treatment to be covered for every one to two months for the remainder of one year. 2. Continued treatment after the initial 12 months is not covered unless it has been 24 months since the completion of the initial PTNS treatment, and the patient has returning symptoms of OAB. In these instances, a new PTNS trial (weekly for 12 weeks) is required."; also moved previous criterion #B-4 to section C (Exclusions) under the header Contraindications.

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MEDICAL POLICY

SYNTHETIC BULKING AGENTS FOR STRESS URINARY INCONTINENCE

Policy # 218

Implementation Date: 1/27/04

Review Dates: 1/13/05, 1/18/06, 2/16/06, 5/17/07, 6/19/08, 6/11/09, 6/17/10, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 7/16/18, 4/17/19, 4/13/20, 4/15/21, 3/11/22, 5/1/23, 4/26/24, 5/15/25

Revision Dates: 4/17/20, 6/3/24

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Periurethral bulking agents are substances that are injected into the submucosal tissues of the urethra and/or the bladder neck and into tissues adjacent to the urethra for the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). Improvement in stress incontinence is achieved by increasing the tissue bulk and thereby increasing resistance to the outflow of urine. Cross-linked collagen (e.g., Contigen) has been commercially available for many years, but the use of carbon-coated beads (e.g., Durasphere) has also received approval by the U.S. Food and Drug Administration (FDA) as a periurethral bulking agent. The use of collagen is preceded by a skin test to rule out hypersensitivity. No such testing is required when carbon-coated beads are used. The substances may be injected over a course of several treatments until the desired effect is achieved. Since cross-linked collagen is slowly absorbed over time, symptoms may recur, requiring retreatment. The use of carbon-coated beads, Durasphere, is thought to provide a more durable effect. Periurethral bulking agents have been widely used for incontinence in women, and their FDA-labeled indication is limited to their use in women. However, men have also been treated, most commonly those with post-prostatectomy incontinence. Polytetrafluoroethylene (Teflon), silicone microimplants, autologous ear chondrocytes, and autologous fat are other implant materials that have been investigated. Their effectiveness has not yet been established in the medical literature.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers the Durasphere, Coaptite, Macroplastique, and Bulkamid synthetic bulking agents for the treatment of stress urinary incontinence, as current evidence suggests that injection of these products is at least as effective as the currently covered implant procedure using collagen bulking agents (e.g., Contigen); and patient benefits, due to the more durable nature of the bulking agent, are expected to also be more durable.

Select Health does NOT cover other synthetic bulking agents for the treatment of stress urinary incontinence. These include, but are not limited to, polytetrafluoroethylene (Teflon), silicone microimplants, autologous ear chondrocytes, and autologous fat. These agents are considered investigational as their effectiveness and durability have not been established, especially when compared with other covered agents.

Select Health

Synthetic Bulking Agents for Stress Urinary Incontinence, continued

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Neither Hayes, nor BCBS TEC, have produced reviews specific to the injection of synthetic bulking agents. However, there are several systematic reviews from the international body of literature, including 1 from Pickard et al., which stated: "... data from the available randomized trials suggest, but do not prove, that periurethral injection of established manufactured bulking agents results in subjective and objective short-term improvement of symptomatic female stress urinary incontinence in adults. Further, the 4 studies that compared different agents found that silicone particles and carbon spheres gave improvement at 12 months equivalent to collagen." Berman et al. further states that injection of collagen (demonstrated to be essentially equivalent to Durasphere) is substantially less effective than sling cystourethropexy.

There is only 1 controlled trial using carbon-coated beads (Durasphere). Lightner et al. reported that Durasphere for the treatment of stress urinary incontinence in women due to intrinsic sphincter deficiency was equally effective as bovine collagen and used less material (there was no placebo/sham control group in this trial).

"Data from the available randomized trials suggest, but do not prove, that periurethral injection of established manufactured bulking agents results in subjective and objective short-term improvement of symptomatic female stress urinary incontinence in adults. Future recommendation as a first line treatment would require evidence of patient benefit and cost-effectiveness from randomized trials involving placebo and conservative treatment arms. Future studies should also record long-term outcome and monitor for delayed particle migration. Injection therapy is probably inferior to surgery but a long-term comparative study against a single standard procedure (Burch colposuspension) is required to prove this. It is recommended that phase III studies of newer agents will not be worthwhile until the aforementioned trials have been performed and a rationale for the use of injection therapy decided. For women with extensive co-morbidity precluding anesthesia, injection therapy may represent a useful option for relief of symptoms for a 12-month period although 2–3 injections are likely to be required to achieve a satisfactory result."

Other trials on bovine collagen (i.e., Contigen) report good short-term benefits with few complications but poor mid- to long-term outcomes especially regarding durability.

Billing/Coding Information

Covered: For the conditions listed above

CPT CODES

51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
52327	Cystourethroscopy (including ureteral catheterization); with subureteric injection of implant material

Select Health

Synthetic Bulking Agents for Stress Urinary Incontinence, continued

HCPCS CODES

L8603 Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies

L8604 Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies

L8606 Injectable bulking agent synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

Key References

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Revision History

Revision Date	Summary of Changes
6/3/24	For Commercial Plan Policy, added Bulkamid to list of products eligible for coverage.

Select Health

Select Health

MEDICAL POLICY

TRANSURETHRAL LASER VAPORIZATION (TLV) PROSTATECTOMY FOR BENIGN PROSTATIC HYPERTROPHY (BPH)

Policy # 229

Implementation Date:5/15/04

Review Dates: 4/14/05, 5/5/06, 12/21/06, 12/20/07, 12/18/08, 4/23/09, 4/22/10, 8/16/11, 8/16/12, 8/15/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/16/18, 6/20/19, 6/18/20, 6/17/21, 5/19/22, 6/15/23, 6/24/24

Revision Dates:

Related Medical Policies:

#182 Transurethral Needle Ablation (TUNA)

#183 Transurethral Microwave Therapy (TUMT)

#553 Urolift System for the Treatment of Benign Prostatic Hyperplasia

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

In general, laser energy can be used to produce coagulation necrosis, vaporization of tissue, or resection of tissue; such procedures are commonly referred to as transurethral laser coagulation, transurethral laser vaporization, and transurethral holmium laser resection/ enucleation, respectively. Initial experiences with bare laser fibers using neodymium: yttrium-aluminum-garnet (Nd:YAG) laser technology have been disappointing, primarily because of their inability to penetrate deeply into the tissue. Investigators do not agree on the optimal technique of energy delivery. Some of the laser technologies produce coagulation necrosis with delayed slough of tissue. Other lasers result in immediate tissue vaporization and ablation.

Transurethral laser vaporization (TLV) is a technique where the prostate tissue is vaporized using laser energy. The laser fiber is maintained in contact (in contrast to the coagulation procedure during which the fiber is kept at a distance from the tissue) with the area to be treated (a "contact" technique) and a series of furrows is made until a wide channel is obtained. Any patient with an obstructive prostate, who fails medical therapy, or fails other forms of therapy, such as transurethral needle ablation or microwave therapy, would be a candidate for laser TLV. There is a prostate size limit of 120 cc for TLV, which is pretty much the limit for transurethral resection (TURP). When the prostate reaches 90–100 cc, urologists will usually perform "open" enucleation rather than TURP. Prostates as large as 120 cc volume, however, can be treated with TLV.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers transurethral laser vaporization (TLV) prostatectomy for benign prostatic hypertrophy (BPH). This technology has been shown to be as safe and effective as other methods of prostate surgery currently approved by Select Health.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

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Transurethral Laser Vaporization (TLV) Prostatectomy for Benign Prostatic Hypertrophy (BPH), continued

please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Although the available data on the effectiveness of laser therapies for the treatment of BPH are not definitive, especially so for the "emerging" high power potassium-titanyl-phosphate (KTP) laser device, it is clear from the literature, that these devices offer significant benefits for many patients with moderate-to-severe BPH, when applied by an experienced urologic surgeon. All options available for these patients are in a constant state of advancement, particularly the surgical therapies, as the tools for removing excessive prostatic tissue continue to become more efficient with less morbidity.

Laser vaporization of the prostate results in equivalent short-term improvements in symptom scores, urinary flow rate, and quality-of-life indices when compared to TURP. In addition, the rates of postoperative urinary retention and the need for unplanned secondary catheterization reported with laser vaporization also appear to be higher than for TURP.

Data suggests the intermediate-term, symptomatic improvement obtained after holmium laser resection may be comparable to that obtained after TURP, with a slightly reduced risk of bleeding and need for blood transfusions and an absence of TURP syndrome.

Early studies of a 60W high power KTP laser in living canine and human cadaveric prostates showed effectiveness in creating large cavities. Preliminary results of clinical experience with the high power KTP laser (60W) as a vaporizing modality have been published by Carter et al. They treated 22 consecutive patients using Addstat (Laserscope) side-fire laser delivery. Sixteen patients had their catheters removed on day one and only 1 failed a trial of void while the remaining 6 patients were left without a catheter and all voided freely post-operatively. Mean peak flow rates improved from 10 mL/s to 22.4 mL/s and mean IPSS decreased from 17.3 to 9.6 at 6 weeks of follow-up.

Transurethral laser coagulation of the prostate is an effective surgical treatment for men with BPH. Although improvements in symptom scores, quality-of-life indices, and flow rate, are equivalent to those attained after TURP, significantly higher rates of unplanned, prolonged, postoperative urinary catheterization and a higher incidence of post-procedure irritative voiding symptoms are reported. The American Urology Association (AUA) panel's meta-analysis found that the rate of acute urinary retention requiring secondary catheterization post-transurethral laser coagulation was 21% in the single-arm analysis, significantly higher than that observed post-TURP (5%, single-arm analysis only). The rate of post-procedure irritative voiding symptoms observed after transurethral laser coagulation in the meta-analysis of two randomized, direct comparison trials was not significantly different from the rate (15%) observed after TURP. However, the single-arm rate of irritative voiding symptoms after laser coagulation (66%) appears significantly higher than the 15% rate observed after TURP. The reason for this variation is not clear.

Billing/Coding Information

CPT CODES

52648	Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)

HCPCS CODES

C1726	Catheter, balloon dilatation, non-vascular

Transurethral Laser Vaporization (TLV) Prostatectomy for Benign Prostatic Hypertrophy (BPH), continued

C1758	Catheter, ureteral
C1769	Guide wire
C1782	Morcellator
C2627	Catheter, suprapubic/cystoscopic

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21. "Photoselective Vaporization of the Prostate (PVP) for the Treatment of Benign Prostatic Hyperplasia: a 3-year Experience". (Mahmood A. Hai* and Muzammil M. Ahmed, Wayne, MI)
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Disclaimer

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Select Health

Transurethral Laser Vaporization (TLV) Prostatectomy for Benign Prostatic Hypertrophy (BPH), continued

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

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MEDICAL POLICY

TRANSURETHRAL RADIOFREQUENCY (RF) FOR STRESS URINARY INCONTINENCE (SUI) (E.G., RENESSA)

Policy # 352

Implementation Date:5/12/07

Review Dates: 4/24/08, 4/23/09, 6/21/12, 11/29/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 7/16/18, 4/17/19, 4/13/20, 4/15/21, 3/11/22, 5/1/23, 4/26/24, 5/15/25

Revision Dates: 5/6/11

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Urinary incontinence is loss of bladder control. Symptoms can range from mild leaking to uncontrollable wetting. It can happen to anyone, but it becomes more common with age. Stress urinary incontinence (SUI) is the most common cause of urinary incontinence in younger women and the second most common cause in older women. Stress leakage occurs when increases in intra-abdominal pressure overcome sphincter closure mechanisms in the absence of a bladder contraction. Stress incontinence often coexists with urge incontinence in middle-aged and older women. This is considered "mixed" incontinence. The prevalence of specific types of incontinence is difficult to estimate because of wide variation in definitions. In general, about half of affected women have stress incontinence, with mixed stress and urge next common, and urge incontinence least common.

Surgery is the most effective treatment and may be an option for women who fail more conservative therapies. A minimally invasive alternative to surgical procedures involves using radiofrequency (RF) to generate controlled heat at low temperatures in tissue targets within the lower urinary tract. The Renessa System (Novasys Medical, Inc) is a transurethral procedure that uses RF energy to generate heat to denature collagen in the tissue at multiple small treatment sites but is low enough to prevent gross tissue destruction. Upon healing, the treated tissue is firmer, increasing resistance to involuntary leakage at times of heightened intra-abdominal pressure, such as laughing, coughing, or during exercise, thereby reducing or eliminating SUI episodes.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover transurethral radiofrequency (RF) for stress urinary incontinence (SUI) (e.g., Renessa). Current evidence demonstrates inferior efficacy and durability to other standard approaches; this meets the plan's definition of not medically necessary.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Transurethral Laser Vaporization (TLV) Prostatectomy for Benign Prostatic Hypertrophy (BPH), continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The literature identified on this technology was limited to reviews of 6 empiric studies. A Hayes 2007 Health Technology Brief noted that the limited literature suggests some efficacy among patients with severe SUI, but conclusions are tempered by a lack of blinded assessment, long-term follow-up, comparisons to alternatives, and a high rate of placebo responses. The Australia and New Zealand Horizon Scanning Network also noted the potential benefits of the Renessa system but concluded that long-term safety and efficacy must be established before coverage could be recommended.

Our review of the literature yielded similar conclusions. The literature offers 2 pilot studies and 1 manufacturer-sponsored randomized controlled trial with limited follow-up. In Appel et al., 173 women with SUI were treated with RF or a sham procedure. Treatment outcomes were incontinence quality of life (IQoL) and leak point pressure (LPP). The incidence of adverse events was similar between groups. At 12 months, there was no difference in the percentage of RF and sham recipients who achieved a ≥ 10-point improvement in self-reported IQoL (48% vs. 44%, respectively). In moderate-to-severe SUI patients, 74% of RF patients achieved a ≥ 10-point improvement in IQOL compared to 50% of sham patients. This RF subgroup also had a mean increase in LPP of 13.2 ± 39.2 cm H_2O compared to a mean decrease of 2.0 ± 33.8 cm H_2O. Two additional studies reported 6 and 12-month follow-up outcomes in 41 patients with SUI who underwent the Renessa procedure. At 6 months, 75%−80% of patients had experienced a ≥ 10-point improvement in self-reported IQoL, a rate maintained at the 12-month follow-up. Neither of these studies reported any statistical analyses of these results, and without an appropriate control group, conclusions about these results are limited.

Typically, a single randomized controlled trial is insufficient to establish the efficacy of a treatment. In this case, the large placebo effect in the sham treatment group, lack of blinded outcomes measurement, limited long-term follow-up, and manufacturer sponsorship weaken any conclusions that could be made from these results. Additional randomized controlled trials that include surgical comparators are needed before the efficacy of transvaginal radiofrequency is established as legitimate treatment for SUI.

A Medical Technology Assessment performed in May 2011 identified 4 systematic reviews and 3 peer-reviewed journal articles regarding transurethral radiotherapy for the treatment of urinary incontinence published since the previous review in 2007.

In March 2010, Hayes published a brief on this particular technology and reported: “This therapy can be performed safely and relatively painlessly using local anesthesia and an oral sedative and may be an option for patients who cannot tolerate conscious sedation or anesthesia. Despite these positive findings, the strength of the existing data is somewhat weakened by flaws in study design and execution, particularly the loss of high numbers of patients to follow up and the lack of controls in some studies. Although no serious adverse events were reported, minor complications occurred such as dysuria, urinary retention and urinary tract infection. Additional independent studies are required to establish the long-term safety and efficacy of this technology since the manufacturer sponsored the existing studies. Nevertheless, RF energy-therapy might be an appropriate option for patients who are not eligible for or who wish to avoid invasive surgery.”

The Australia and New Zealand Horizon Scanning Network (ABZHSN) completed in 2007 reached similar conclusions, noting that although no serious adverse events were reported in any of the studies reviewed, further long-term studies be completed to establish the long-term safety and efficacy of the device and procedure.

Contrary to these findings, in 2008, the California Technology Assessment Forum (CTAF) found that Renessa met all 5 of their criteria for safety, effectiveness, and improvement in health outcomes for the treatment of moderate-to-severe female stress urinary incontinence in non-pregnant women, who are either not able, or who are not willing to undergo surgery for their SUI treatment.

Transurethral Laser Vaporization (TLV) Prostatectomy for Benign Prostatic Hypertrophy (BPH), continued

Supporting the CTAF review, Appell et al., and Elser et al., both concluded durability of the procedure out to 3 years to be present. However, they defined durability of the effect to be at least a 50% reduction in urinary frequency. It was notable that in the Appell study this was achieved in only 56% of patients and only 50% in the Elser study. Though the systematic reviews and peer-reviewed literature conclude that radiofrequency ablation in this setting is safe, it is evident that the procedure is not as effective as current treatments in decreasing voiding frequency to a statistically significant degree.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for the indication listed above

CPT CODES

53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

HCPCS CODES

No specific codes identified

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Transurethral Laser Vaporization (TLV) Prostatectomy for Benign Prostatic Hypertrophy (BPH), continued

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MEDICAL POLICY

PROSTATIC URETHRAL LIFT (UROLIFT) FOR THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

Policy # 553

Implementation Date:7/29/14
Review Dates: 8/20/15, 8/25/16, 8/17/17, 7/16/18, 6/20/19, 2/10/20, 6/17/21, 5/19/22, 6/15/23, 6/24/24
Revision Dates: 1/1/15, 3/22/16, 4/22/16, 12/5/18, 2/27/20, 10/19/20, 2/16/22, 6/1/22

Related Medical Policies:
#229 Transurethral Laser Vaporization (TLV) Prostatectomy for Benign Prostatic Hypertrophy (BPH)
#182 Transurethral Needle Ablation (TUNA)
#183 Transurethral Microwave Therapy (TUMT)

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Benign prostatic hyperplasia (BPH) is the nonmalignant proliferation of the epithelial and stromal cells of the prostate gland. It is a gradually progressive histologic change that leads to the enlargement of the prostate, primarily in older men. BPH may or may not be symptomatic. When BPH produces symptoms, it is termed BPH-lower urinary tract symptoms (BPH-LUTS) or clinical BPH.

The prevalence of histologic BPH is estimated at 90% among men in the eighth decade of life. The prevalence of clinical BPH is approximately 50% in the same age group. Advanced age, obesity, increased fat intake, decreased physical activity, and diabetes, increase the risk of BPH development.

BPH is diagnosed based on the clinical history, digital rectal examination (DRE) findings, and focused urologic examination findings. Urinalysis is the only laboratory test universally recommended for BPH. Serum prostate-specific antigen (PSA) levels can be used as a marker for prostatic diseases, including BPH.

The decision to treat is usually based on the severity of symptoms and the patient's tolerance for these symptoms. Symptoms only require therapy if they have a significant impact on a patient's quality of life. Even without therapy, many men will experience stabilization or improvement in symptoms over time. Surgical and medical therapy is used to treat BPH, with surgery usually reserved only for patients who have failed conservative medical therapy, are intolerant to the medications, or have persisting symptoms/evidence for clinically significant persisting lower urinary obstruction despite maximal medical therapy. Alpha-1-adrenergic antagonists, 5-alpha-reductase inhibitors, and PDE-5 inhibitors represent the majority of medicinal treatments for BPH. Surgical interventions are typically employed only after failure or intolerance of conservative therapy or if the patient has obstructive symptoms requiring more immediate intervention. Transurethral resection of the prostate (TURP), laser prostatectomy, transurethral incision of the prostate, electrovaporization, open prostatectomy, transurethral needle ablation of the prostate (TUNA), transurethral microwave thermotherapy (TUMT), urethral stents, and botulinum toxin (this therapy is not FDA approved in the US and is not widely used in routine practice in the US) represent surgical options for BPH.

The UroLift System (NeoTract, Inc., Pleasanton, CA) is a minimally invasive approach to treating BPH that holds the enlarged prostate tissue out of the way, so it no longer blocks the urethra. There is no cutting, heating, or removal of prostate tissue. This minimally invasive procedure is routinely done under local anesthesia in the office or outpatient setting. The delivery system is used by the physician to mechanically open the prostatic urethra by placing permanent implants across the lobes of the prostate to

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Urolift System® for the Treatment of Benign Prostatic Hyperplasia, continued

separate the encroaching prostatic lobes. Every implant is assembled and tailored *in situ* as it is delivered, based on the unique prostatic lobe characteristics. The transprostatic implants hold the prostatic urethra in a less obstructed configuration, thereby mitigating BPH symptoms. Each delivery device deploys one implant, and a typical procedure requires 4 implants (manufacturer reports since launch put the average number of implants used per procedure at 4.9), while most of the literature to date states mean slightly < 4 clips were used with a range of 2–7.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers prostatic urethral lift (UroLift) for the treatment of benign prostatic hyperplasia when the following criteria are met:

1. For men ≥ 45 years of age with prostate volumes less than 100 cc; and

2. Failure of ≥ 3 months of conservative therapy, which would include failed treatment with both an alpha-1-adrenergic antagonist and a 5-alpha-reductase inhibitor, or intolerance of BPH medications, or medical therapy is contraindicated in the member.

Select Health will cover a maximum of 7 prostatic urethral lift implants for the procedure. If more than 7 implants are recommended, then clinical documentation to justify medical necessity is required.

If a second prostatic urethral lift procedure is requested, an explanation of why other prostatic removal procedures are not clinically indicated, is required.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
Studies of urethral lift devices so far have lacked comparison to alternative available technologies to treat BPH. A review by NICE published in 2014, stated: "Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent, and audit." However, a 2019 update from NICE recommended UroLift as follows:

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Urolift System® for the Treatment of Benign Prostatic Hyperplasia, continued

- The clinical case for adopting the UroLift system for treating lower urinary tract symptoms of benign prostatic hyperplasia is supported by the evidence. The UroLift system relieves lower urinary tract symptoms while avoiding the risk to sexual function associated with TURP and holmium laser enucleation of the prostate (HoLEP). Using the system reduces the length of a person's stay in hospital. It can also be used in a day-surgery unit.
- The UroLift system should be considered as an alternative to current surgical procedures for use in a day-case setting in men with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe.

Roehrborn et al. have two studies in print extending past 2 years There is data from 19 centers in North America and Australia for 206 patients (randomized 140 to UroLift, 66 to control [sham]). 15 patients (10.7%) required revisions up to the 3-year follow-up and 13.6% required revisions at 5 years. Statistically significant improvements in International Prostate Symptom Scores (IPSS), peak flow-rate (Qmax), male sexual health questionnaire for ejaculatory dysfunction (MSHQ-EjD), and quality of life (QoL) scores were demonstrated; however, approximately one-third of the initial study patients experienced unsatisfactory results at 5 years.

Concerns regarding the lack of comparison of UroLift to standard treatment options, not just sham, were addressed in a 2015 prospective, randomized, controlled, multi-centered trial by Sonksen et al. of 80 men followed for 1 year, in which UroLift was compared to TURP. The study concluded that statistically significant superiority was illustrated with use of UroLift than with TURP in preservation of ejaculation function, symptom relief, and QoL. Overall, current published evidence supports safety and efficacy of UroLift implants out to 5 years, likely resulting in similar outcomes to alternatively available treatments.

Billing/Coding Information

CPT CODES

52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant, each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)

HCPCS CODES

C9739	Cystourethroscopy with insertion of transprostatic implant 1 to 3 implants
C9740	Cystourethroscopy with insertion of transprostatic implant; 4 or more implants

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Disclaimer

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Select Health® makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. Select Health updates its Coverage Policies regularly, and reserves the right to amend these policies without notice to healthcare providers or Select Health members.

Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

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MEDICAL POLICY

VARICOCELE EMBOLIZATION

Policy # 612
Implementation Date: 10/3/17
Review Dates: 10/15/18, 10/15/19, 12/18/20, 12/8/21, 1/17/23, 10/19/23, 10/21/24
Revision Dates: 11/7/23

Related Medical Policies:
#268 Pelvic Vein Procedures for Pelvic Congestion Syndrome and Pelvic Varices

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Varicoceles (dilations of the pampiniform venous plexus) are found in 10 to 15% of the male population and they occur predominantly on the left side. The etiology may be a longer left spermatic vein with its right-angle insertion into the left renal vein and/or absence of valves, which results in a higher hydrostatic pressure in the left spermatic vein causing dilatation. Also, the left renal vein may be compressed between the superior mesenteric artery and the aorta. This "nutcracker phenomenon" may result in elevated pressure in the left testicular venous system. Moreover, the incidence of varicocele in men with impaired fertility is about 30%; varicoceles are the most common surgically correctable cause of male infertility. A clinical grading system classifies varicoceles into 3 grades, grade 1 (small)—palpable only during a Valsalva maneuver, grade 2 (moderate)—palpable without the need of the Valsalva maneuver, and grade 3 (large)—visible.

Although varicoceles can be diagnosed by a thorough physical examination, ultrasonography is the most practical and accurate non-invasive method in diagnosing this condition. Surgical ligation (varicocelectomy) is the conventional approach in managing varicoceles. However, percutaneous embolization by means of balloon or metallic coil has been shown to be a safe and effective alternative to ligation in treating varicoceles.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Select Health covers microsurgical varicocelectomy as an acceptable alternative method of treating a varicocele when any of the following coverage criteria are met.

Coverage criteria for surgery (any one of the following must be met):

1. Adolescents with grade 2 or 3 varicoceles associated with ipsilateral testicular growth retardation (covered under the medical benefit); or
2. Scrotal pain associated with varicoceles (covered under medical benefit); or
3. Males with infertility problems who have decreased sperm motility and lower sperm concentrations (covered under fertility benefit).

Select Health

Varicocele Embolization, continued

B. Select Health covers percutaneous embolization (by means of balloon or metallic coil) as medically necessary for the treatment of varicocele when the following criteria are met:

1. Meets one of the above criteria for surgery

   OR

2. Post-surgical (ligation) recurrence of varicoceles

Select Health does NOT cover surgical treatment (ligation, embolization) for subclinical varicocele as it is considered experimental and investigational because of insufficient evidence to support its effectiveness.

Select Health does NOT cover endoluminal occlusion devices (e.g., the ArtVentive endoluminal occlusion system) as it is considered experimental and investigational for the treatment of varicoceles because their effectiveness has not been established.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

As it relates to fertility, Polito and colleagues in 2004 stated the impact of varicocele on male infertility is still controversial since its role on the impairment of semen quality has never been fully demonstrated. Their study included a series of 426 young adult males who underwent percutaneous treatment of varicocele. Their semen parameters were evaluated at baseline and 12 months after the procedure. They concluded that the correction of varicocele in young adults is not a major indication when semen alteration is the only clinical problem. This agrees with the findings of Nabi et al., also from 2004 who compared the semen quality in 102 men with or without pregnancy after percutaneous embolization of varicoceles in the management of infertility. They concluded that varicocele embolization is a technically feasible, minimally invasive, outpatient procedure that improves semen quality significantly in patients with a pre-embolization semen density of 10 to 30 million/ml. However, no correlation was found between the improvements in semen quality and the pregnancy rate.

In a systematic review and meta-analysis, Kim et al. in 2015 noted that recent meta-analysis by the Cochrane collaboration concluded that treatment of varicocele may improve an infertile couple's chance of pregnancy. However, there has been no consensus on the management of subclinical varicocele. These researchers determined the impact of varicocele treatment on semen parameters and pregnancy rate in men with subclinical varicocele. Although there was also no statistically significant difference in pregnancy rate (OR 1.29, 95% CI: 0.99 to 1.67), surgical treatment resulted in statistically significant improvements on forward progressive sperm motility (MD 3.94, 95% CI: 1.24 to 6.65). The authors concluded that there is insufficient evidence to allow final conclusions because the quality of included studies was very low and further research is needed.

Percutaneous embolization versus laparoscopic varicelectomy was assessed by Bechara et al. in 2009 in patients with symptomatic varicoceles. Outcomes were assessed out to 5 years. Treatment outcome and

Varicocele Embolization, continued

hospital costs of these two minimally invasive treatment modalities were compared. Most parameters measured did not show significant difference including mean operative time, effectiveness, or recurrence. Embolization treatment was associated with a lower complication rate than laparoscopic repair (9.7% versus 16.3%, p = 0.03). They concluded both laparoscopic varicocelectomy and coil embolization are effective treatment modalities for varicoceles. With lower treatment complication rates in the interventional treatment group, coil embolization of the testicular vein appears to offer treatment advantage compared with laparoscopic repair in patients with varicoceles.

These findings conflict with another study Ayechu-Diaz et al. in 2009, where they reviewed the records of 135 males (mean age of 12.8 years) over 7 years. The authors concluded their experience showed a high degree of relapses after embolization. Section of the spermatic vessels (including the artery) with no lymphatic preservation is highly effective but involves 27% post-surgical hydroceles, usually self-limiting (only 1 patient had to undergo surgery later), with no testicular atrophy or other complications. Embolization must be reserved for patients with 1 testicle or with bilateral disease.

Microsurgical Varicocelectomy: Kondoh et al., in 2010, stated surgical ligation for varicocele is primarily used in the management of male infertility patients. However, effectiveness of the ligation for painful varicocele is still controversial. These investigators reviewed records from 18 patients (average age of 17.8 years) who underwent varicocele ligation done for pain at the authors' institution from June 1999 to May 2010. The varicocele was on the left side and was grade III in 15 cases and grade II in 3 cases. The pain was classified into 3 types: discomfort, dull pain, and sharp pain. Microsurgical varicocelectomy was done with inguinal or subinguinal approach. Evaluation of post-operative pain was available in 17 patients, and 15 patients (88%) reported complete resolution of the pain with average follow-up durations of 11 months (3 to 53 months). The authors concluded that microsurgical varicocelectomy using the inguinal or subinguinal approach was an effective treatment modality for varicocele-associated pain.

In a study by Seo et al. in 2010, the improvement of seminal characteristics and pregnancy rates after microsurgical varicocelectomy in men with subclinical varicocele were evaluated. A total of 143 patients with a subclinical left-sided varicocele were included in this study. Patients who agreed to microsurgical varicocelectomy (n = 25, surgery group), medical treatment with L-carnitine (n = 93 drug group), and those who did not agree to any treatment (n = 25, observation group) were enrolled. Semen characteristics were re-evaluated twice 6 months after treatment. The natural pregnancy rates were estimated by telephone interview between 1 and 2 years after treatment. In the surgery group, sperm counts improved significantly after microsurgical varicocelectomy. In the drug group, however, sperm parameters did not significantly improve after treatment. Natural pregnancy rates were 60% in the surgery group, 34.5% in the drug group, and 18.7% in the observation group. The natural pregnancy rate of the surgery group was higher than the other groups, and there were statistically significant differences among the 3 groups. The authors concluded that surgical treatment is the best option for management of subclinical varicocele.

These findings were further validated in a prospective, non-masked, parallel-group randomized, controlled trial, by Abdel-Meguid et al. in 2011. They examined if varicocele treatment is superior or inferior to no treatment in male infertility from an evidence-based perspective. 132 married men, 20 to 39 years of age, who had experienced infertility greater than or equal to 1 year, had palpable (Grade 2) varicoceles, and with at least 1 impaired semen parameter (e.g., sperm concentration less than 20 million/ml, progressive motility less than 50%, or normal morphology less than 30%) were eligible. Exclusions included subclinical or recurrent varicoceles, normal semen parameters, and azoospermia. Participants were randomly allocated to observation (the control arm [CA]) or subinguinal microsurgical varicocelectomy (the treatment arm [TA]). Semen analyses were obtained at baseline (3 analyses) and at follow-up months 3, 6, 9, and 12. The mean of each sperm parameter at baseline and follow-ups were determined. These researchers measured the spontaneous pregnancy rate (the primary outcome), changes from baseline in mean semen parameters, and the occurrence of adverse events (AE-the secondary outcomes) during the 12-month follow-up; $p < 0.05$ was considered significant. In CA within-arm analysis, none of the semen parameters revealed significant changes from baseline (sperm concentration [$p = 0.18$], progressive motility [$p = 0.29$], and normal morphology [$p = 0.05$]). Conversely, in TA within-arm analysis, the mean of all semen parameters improved significantly in follow-up versus baseline ($p < 0.0001$). In between-arm analysis, all semen parameters improved significantly in the TA versus CA ($p < 0.0001$); no AEs were reported. The authors concluded these findings provided level 1b evidence of the superiority of varicocelectomy over observation in infertile men with palpable varicoceles

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and impaired semen quality, with increased odds of spontaneous pregnancy and improvements in semen characteristics within 1-year of follow-up.

Finally, Diegidio et al., in 2010, reviewed all the various techniques, and their results and efficiencies, to provide practicing urologists with some guidance for choice of technique. Pregnancy rates were highest with microsurgical subinguinal technique. Varicocele recurrence rates were lowest with microsurgical subinguinal technique. Hydrocele formation rates were lowest with microsurgical inguinal technique. Surgical complications were highest in the laparoscopic technique. Varicocelectomy by itself or in conjunction with in-vitro fertilization is cost-effective. The authors concluded that microsurgical subinguinal or microsurgical inguinal techniques offer best outcomes; and varicocelectomy is a cost-effective treatment modality for infertility.

The European Association of Urology (EAU)'s guidelines on pediatric urology (Tekgul et al., 2009) stated that for the treatment of varicocele in children and adolescents, surgical intervention is based on ligation or occlusion of the internal spermatic veins. Ligation is performed at different levels, inguinal (or subinguinal) microsurgical ligation, and suprainguinal ligation, using open or laparoscopic techniques. The advantage of the former is the lower invasiveness of the procedure, while the advantage of the latter is a considerably lower number of veins to be ligated and safety of the incidental division of the internal spermatic artery at the suprainguinal level. Moreover, lymphatic-sparing varicocelectomy is preferred to prevent hydrocele formation and testicular hypertrophy development and to achieve a better testicular function according to the luteinizing hormone-releasing hormone stimulation test. The methods of choice are subinguinal or inguinal microsurgical (microscopic) repairs, or suprainguinal open or laparoscopic lymphatic-sparing repairs.

Endoluminal Occlusion Device: The ArtVentive EOS device has been developed for percutaneous, peripheral occlusion of the peripheral arterial and venous vasculature. The system is comprised of an implantable occlusion device and a delivery catheter. At present, there are 2 device sizes, size 1 for target vessels ranging between 3.5 and 5.5 mm in diameter, and size 2 for target vessels 5.5 to 8.5 mm in diameter. Venbrux et al. in 2014 studied the ArtVentive endoluminal occlusion system (EOS), to occlude the spermatic vein in symptomatic males with varicoceles, to determine the safety and effectiveness of this new endoluminal occlusion device. The treatment group included 6 adult males, aged 22 to 34 years; 9 target vessels were occluded and a total of 20 devices were implanted in 6 subjects. The acute occlusion rate at the end of the procedure was 100%, occurring in 9 of 9 vessels. The spermatic veins of all patients remained occluded on venography at 30 days follow-up. Pain scores related to varicoceles decreased in 5 of 6 patients. The authors concluded that although they recognized this study was limited, initial experience indicated that the ArtVentive EOS is a safe and effective new device for occlusion of vessels (varicoceles). They stated that the device has potential applications in other clinical conditions requiring occlusion of veins or arteries; further studies have not been identified.

Billing/Coding Information

CPT CODES

37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)
55530	Excision of varicocele or ligation of spermatic veins for varicocele; (separate procedure)
55535	Excision of varicocele or ligation of spermatic veins for varicocele; abdominal approach
55540	Excision of varicocele or ligation of spermatic veins for varicocele; with hernia repair
55550	Laparoscopy, surgical, with ligation of spermatic veins for varicocele

HCPCS CODES

No specific codes identified

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Revision History

Revision Date	Summary of Changes
11/7/23	For Commercial Plan Policy, modified requirements in criteria #B: "1. Meets one of the above criteria for surgery **OR** 2. Post-surgical (ligation) recurrence of varicoceles."