BCN Provider *News*

Medical Policy updates

- The following applies to BCN members.
- The effective date is indicated for the service, technology or procedure.

Covered services

Aquablation (transurethral waterjet ablation) of the prostate

- **Revised policy**
- **Effective date: 05/01/24**
- **Covered, criteria apply**
- **Procedure code(s):**
  - **Established –** 0421T, C2596
  - **Other codes (investigational, not medically necessary, etc.) –** N/A

Benign prostatic hyperplasia (BPH) is a condition that occurs in men when the prostate gland becomes enlarged due to noncancerous proliferation of smooth muscle and epithelial cells of the prostate. As the prostate enlarges, it presses against the urethra, causing lower urinary tract symptoms (LUTS) such as urinary frequency, urinary urgency, trouble starting a urine stream, a weak or an interrupted urine stream, dribbling at the end of urination, nocturia, urinary retention, urinary incontinence, and pain during urination or after ejaculation.

The medical therapeutic options for BPH have evolved significantly over the last 3 decades, and include drugs in two major classifications, alpha-antagonists, and 5-alpha-reductase inhibitors, used alone or in combination therapy. Hormonal drugs have also been used.

If medical therapy fails, or the man wishes to terminate medical therapy, surgical intervention may be considered. The indications to proceed with a surgical intervention for BPH include acute urinary retention, failed voiding trials, and frequent urinary tract infections which may progress to renal insufficiency secondary to obstruction in severe cases.

There are a number of surgical interventions for BPH, including, but not limited to:

- Transurethral resection of the prostate (TURP), which has long been accepted as the criterion standard for relieving bladder outlet obstruction secondary to BPH
- Transurethral incision of the prostate (TUIP)
- Transurethral microwave thermotherapy (TUMT)
- Transurethral needle ablation (TUNA)
- Laser prostatectomy
- Laser-based procedures including contact laser ablation of the prostate (CLAP), holmium laser procedures of the prostate (HoLAP, HoLEP, HoLRP), photoselective laser vaporization of the prostate (PVP), transurethral ultrasound-guided laser induced prostatectomy (TULIP), and visually-guided laser ablation of the prostate (VLAP, also called non-contact laser ablation of the prostate)

A new minimally invasive surgical technique has been developed which uses a high-velocity, image-guided saline stream to ablate prostatic tissue. According to Procept BioRobotics, the AquaBeam® system is a minimally invasive medical device that allows removal of prostate tissue without leaving a zone of thermal damage on the treated tissue. The AquaBeam® platform technology utilizes a waterjet for automated tissue resection as well as for optical energy delivery for cauterization in the treatment of BPH. No heat sources are used for cutting.

The AquaBeam® system consists of three components: a single-use probe, a robotic hand piece, and a console. The procedure is carried out under transrectal ultrasound imaging. The probe is attached to the hand piece and inserted in the urethra; cystoscopic visualization is available continuously during the procedure. After mapping the desired tissue to be ablated, high-velocity sterile saline is delivered to the prostate tissue via the AquaBeam® probe, which also provides a channel for aspiration of ablated tissue during the procedure.

Inclusions

Aquablation (transurethral waterjet ablation) for the treatment of urinary outlet obstruction due to benign prostatic hyperplasia (BPH) is considered established **ONCE per lifetime** when all of the following criteria are met:

- The individual has prostate volume of 30-150 cc by transrectal ultrasound (TRUS) and persistent moderate to severe symptoms despite maximal medical management including **ALL** of the following attributed to BPH:
  - The individual has an International Prostate Symptom Score (IPSS) of equal to or greater than 12.
  - The individual has a peak urine flow rate (Qmax) less than or equal to 15mL/sec on a voided volume that is greater than 125 cc.
  - The individual has had a failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride).

Exclusions

The individual has none of the following:

- Severe obesity (BMI ≥ 42kg/m2)
- Known or suspected prostate cancer or a prostate specific antigen (PSA) >10 ng/mL unless there has been a negative prostate biopsy within the last 6 months
- Bladder cancer, neurogenic bladder, bladder calculus, or clinically significant bladder diverticulum
- Damaged external urinary sphincter
- Treatment for chronic prostatitis
- Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture
- Active urinary tract or systemic infection
- Known allergy to device materials
- Inability to safely stop anticoagulants or antiplatelet agents preoperatively

Contrast-Enhanced Computed Tomography Angiography (CTA, CCTA, MDCT, MSCT) of the heart and/or coronary arteries

- **Revised policy**
- **Effective date: 05/01/24**
- **Covered, criteria apply**
- **Procedure code(s):**
  - **Established –** 75572, 75573, 75574
  - **Other codes (investigational, not medically necessary, etc.) –** 75571

Contrast-enhanced coronary computed tomography angiography (CCTA) is a noninvasive imaging test that requires the use of intravenously administered contrast material and high-resolution, high-speed computed tomography (CT) machinery to obtain detailed volumetric images of blood vessels. It is a potential diagnostic alternative to current tests for cardiac ischemia (i.e., noninvasive stress testing and/or coronary angiography).

CORONARY ARTERY DISEASE

Various noninvasive tests are used in the diagnosis of coronary artery disease. These tests can be broadly classified as those that detect functional or hemodynamic consequences of obstruction and ischemia (exercise treadmill testing, myocardial perfusion imaging [MPI], stress echo with or without contrast), and others identifying the anatomic obstruction itself (CCTA and coronary magnetic resonance imaging [MRI]). Functional testing involves inducing ischemia by exercise or pharmacologic stress and detecting its consequences. However, not all patients are candidates. For example, obesity or obstructive lung disease can make obtaining echocardiographic images of sufficient quality difficult. Conversely, the presence of coronary calcifications can

impede detecting coronary anatomy with coronary CCTA.

Diagnostic Testing

Some tests will be unsuitable for particular patients. The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening artifacts and may preclude a satisfactory imaging. The presence of an uncontrolled rapid heart rate or arrhythmia hinders the ability to obtain diagnostically satisfactory images. Evaluation of the distal coronary arteries is more difficult than visualization of the proximal and mid-segment coronary arteries due to greater cardiac motion and the smaller caliber of coronary vessels in distal locations.

Evaluation of obstructive CAD involves quantifying arterial stenoses to determine whether significant narrowing is present. Lesions with stenosis more than 50% to 70% in diameter accompanied by symptoms are considered significant.

CCTA is a noninvasive imaging test that requires the use of intravenously administered contrast material and high-resolution, high-speed computed tomography machinery to obtain detailed volumetric images of blood vessels. It has been suggested that CCTA may help rule out CAD and avoid invasive coronary angiography in patients with a low clinical likelihood of significant CAD. Also, of interest is the potentially important role of nonobstructive plaques (i.e., those associated with <50% stenosis) because their presence is associated with increased cardiac event rates. CCTA also can visualize the presence and composition of these plaques and quantify plaque burden better than conventional angiography, which only visualizes the vascular lumen. Plaque presence has been shown to have prognostic importance.

Inclusions

Note: CCTA may be done in an inpatient, outpatient or emergency department setting.

The following patients are considered appropriate candidates for CT angiography:

- Those with stress test results that are equivocal or discordant with other clinical evidence, in lieu of invasive coronary angiography.
- Those with low-intermediate risk acute chest pain in order to exclude coronary artery disease in the emergency department or inpatient setting.
- Those with new onset chest pain in low-intermediate risk patients in the outpatient setting.
- Symptomatic patients for the evaluation of coronary bypass graft or coronary stent patency, in order to facilitate decision making for invasive angiography.
- Those with suspected coronary anomalies.
- Patients scheduled for cardiac or major thoracic surgery, such as aortic valve replacement or aortic aneurysm repair, in order to exclude coronary artery disease, as an alternative to invasive coronary angiography
- Patients with incomplete invasive catheterization results as an alternative to repeat invasive catheterization.
- Patients anticipating cardiac surgery who require an assessment of coronary or pulmonary venous anatomy. This application of CTA for the coronary and pulmonary veins is primarily for pre-surgical planning. Evaluation of coronary venous anatomy can be useful for the cardiologist who needs to place a pacemaker lead in the lateral coronary vein in order to resynchronize cardiac contraction in patients with heart failure. This may be helpful to guide biventricular pacemaker placement. Pulmonary vein anatomy can vary from patient to patient. Pulmonary vein catheter ablation can isolate electrical activity from the pulmonary veins and allow for the elimination of recurrent atrial fibrillation. The presence of a pulmonary venous anatomic map may help eliminate procedural complications and allow for the successful completion of the intracardiac catheter ablation of an arrhythmogenic focus.

The following patients are considered appropriate candidates for coronary computed tomography-angiography (CCTA).

Suspected CAD in symptomatic patients who have not had evaluation for CAD within the preceding 60 days

CCTA is considered established in **ANY** of the following scenarios:

- Chest pain with or without other symptoms of myocardial ischemia
  - With pretest probability of CAD > 15%
- Patients without chest pain whose predominant symptom is dyspnea
  - With pretest probability of CAD > 15%
- Patients with any cardiac symptom who have diseases/conditions with which CAD commonly coexists, such as **ANY** of the following:
  - Abdominal aortic aneurysm
  - Established and symptomatic peripheral vascular disease
  - Prior history of stroke, transient ischemic attack (TIA), carotid endarterectomy (CEA), or high-grade carotid stenosis (> 70%)
  - Chronic kidney disease

Established flow-limiting CAD in patients who have new or worsening symptoms

CCTA is considered established in the following scenario:

- Patients whose symptoms persist despite maximal anti-ischemic medical therapy or contraindication thereto
  - Patients with established CAD and typical angina pectoris despite maximal anti-ischemic therapy maybe better served with invasive coronary angiography

Established or suspected CAD

CCTA is considered established in **ANY** of the following scenarios:

- Patients who have undergone cardiac transplantation
  - With new or worsening cardiac symptoms
  - With new or worsening physical examination abnormalities
- Clinically stable patients who have not had evaluation for CAD in the preceding year

Patients (symptomatic or asymptomatic) with ANY of the following new onset arrhythmias who have not had evaluation for CAD since the arrhythmia was recognized

- Sustained (lasting more than 30 seconds) or non-sustained (more than 3 beats but terminating within 30 seconds) ventricular tachycardia
- Atrial fibrillation or flutter and high or intermediate risk of CAD (using ASCVD Pooled Cohort Equations*)
- Atrial fibrillation or flutter and established CAD
- Frequent premature ventricular contractions (PVC) defined as more than 30 PVCs per hour on ambulatory EKG (Holter) monitoring
  - CCTA is not clinically indicated for evaluation of infrequent premature atrial or ventricular depolarizations

Patients (symptomatic or asymptomatic) with new onset congestive heart failure (CHF) or recently recognized LV systolic dysfunction who have not had evaluation for CAD since the onset of LV dysfunction/CHF

- For patients in this category with established CAD, or those with suspected CAD whose CAD risk (using ASCVD Pooled Cohort Equations*) is high, coronary angiography may be more appropriate than noninvasive evaluation

Abnormal resting EKG

- Patients with **ANY** of the following newly recognized and not previously evaluated resting EKG changes:
  - Left bundle branch block
  - ST depression ≥ 1 mm
  - Left ventricular (LV) hypertrophy with repolarization abnormality
- Patients who would otherwise undergo exercise EKG testing (without imaging) but have **ANY** of the following resting EKG findings that would render the interpretation of an exercise EKG test difficult or impossible:
  - Left bundle branch block
  - Ventricular paced rhythm
  - Left ventricular hypertrophy with repolarization abnormality
  - Digoxin effect
  - ST depression ≥ 1 mm on a recent EKG (within the past 30 days)
  - Pre-excitation syndromes (e.g., Wolff-Parkinson-White syndrome)

Patients with abnormal exercise treadmill test (performed without imaging) who have not undergone evaluation for CAD since the treadmill test

- Abnormal findings on an exercise treadmill test include chest pain, ST segment change, abnormal blood pressure response, or complex ventricular arrhythmias

Patients who have undergone recent (within the past 60 days) stress testing with adjunctive imaging (MPI, SE, perfusion PET, stress MRI)

- When the stress imaging test is technically suboptimal, technically limited, inconclusive, indeterminate, or equivocal, such that myocardial ischemia cannot be adequately excluded
  - A stress imaging test is deemed to be abnormal when there are abnormalities on the imaging portion of the test. Electrocardiographic abnormalities without imaging evidence of ischemia do not render a stress imaging test abnormal.
- When the stress imaging test is abnormal and **ALL** of the following apply:
  - The stress test demonstrates moderate or severe ischemia
  - CCTA is requested to exclude left main CAD
  - In the absence of left main CAD GDMT will be instituted
  - Invasive coronary angiography will be reserved for persistent symptoms on GDMT

Preoperative evaluation of patients undergoing non-coronary cardiac valve surgery

- Patients undergoing evaluation for transcatheter aortic valve implantation/replacement (TAVI or TAVR) at low risk for CAD (using ASCVD Pooled Cohort Equations*) to avoid invasive angiography, where all the necessary preoperative information can be obtained using cardiac CT
- Patients undergoing evaluation for valve surgery (not including TAVR) at low or intermediate risk for CAD (using ASCVD Pooled Cohort Equations*)

* Factors included in ASCVD Pooled Cohort Equations:

- Age
- Sex
- Race
- Lipid profile
- Diabetes mellitus
- Hypertension
- Antihypertensive medication use
- Tobacco use

The atherosclerotic cardiovascular disease (ASCVD) Pooled Cohort Equations risk calculation tool is used to estimate risk of atherosclerotic cardiovascular disease. This tool, which is endorsed by several professional societies, incorporates age, gender, race, several clinical conditions known to affect ASCVD risk (including diabetes, dyslipidemia, hypertension), and tobacco use.

Preoperative cardiac evaluation of patients undergoing non-emergency non-cardiac surgery (includes surveillance for CAD in those awaiting solid organ transplant)

Prior to considering elective surgery, patients with active cardiac conditions such as unstable coronary syndromes (unstable angina), decompensated heart failure (NYHA class IV, worsening or new onset heart failure), significant arrhythmias (third degree AV block Mobitz II AV block, uncontrolled supraventricular arrhythmia, symptomatic ventricular arrhythmias, ventricular tachycardia), symptomatic bradycardia or severe stenotic valvular lesions should be evaluated and managed per ACC/AHA guidelines. That evaluation may include CCTA.

- **Low-risk surgery** (endoscopic procedures, superficial procedures, cataract surgery, breast surgery, ambulatory surgery)
  - Provided that there are no active cardiac conditions (as outlined above), CCTA prior to low-risk surgery is considered **not medically necessary**
- **Intermediate-risk surgery** (including but not limited to intraperitoneal and intrathoracic surgery, carotid endarterectomy, head and neck surgery, orthopedic surgery, prostate surgery, gastric bypass surgery) **or high-risk surgery** (including but not limited to aortic and other major vascular surgery, peripheral vascular surgery) when **BOTH** of the following apply:
  - Patient has not had a negative evaluation for CAD or a coronary revascularization procedure within the previous one (1) year
  - At least **ONE** of the following applies:
    - Patient has established CAD (prior MI, prior PCI or CABG) or presumed CAD (Q waves on EKG, abnormal MPI, SE, or cardiac PET)
    - Patient has compensated heart failure or prior history of CHF
    - Patient has diabetes mellitus
    - Patient has chronic kidney disease
    - Patient has a history of cerebrovascular disease (TIA, stroke, or documented carotid stenosis requiring carotid endarterectomy)
    - Patient is unable to walk on a treadmill for reasons other than obesity
- **Patients awaiting solid organ transplant**
  - Asymptomatic patients who have not undergone evaluation for CAD within the preceding one (1) year
  - Patients with symptoms consistent with myocardial ischemia

Miscellaneous indications for CCTA

CCTA is considered established in **ANY** of the following scenarios:

Inability to perform exercise EKG test

- Patients who would otherwise undergo exercise EKG testing (without imaging) but are unable (for reasons other than obesity) to perform exercise to a degree that would yield a diagnostic test. This provision includes patients with musculoskeletal, neurological or pulmonary limitation.

Established Kawasaki disease

- Periodic surveillance up to one year following diagnosis when previous imaging study reveals **ANY** of the following: Coronary abnormalities
  - Left ventricular dysfunction
  - Pericardial effusion
  - Valvular regurgitation (other than trace or trivial regurgitation)
  - Aortic dilation
  - Annual evaluation in patients who have small or medium-sized coronary artery aneurysms
  - Semiannual evaluation (every 6 months) in patients who have large or giant coronary artery aneurysms, or coronary artery obstruction

Congenital coronary artery anomalies

- Evaluation of suspected congenital anomalies of the coronary arteries in **ANY** of the following scenarios:
  - Exertional syncope
  - History of anomalous coronary artery in a first-degree relative
  - Following coronary angiography which failed to adequately define the origin or course of a coronary artery
  - Coronary ostia appear to be abnormally positioned on echocardiography

CCTA is also established for the evaluation of intra- and extra-cardiac structures, including but not limited to:

- Evaluation of cardiac mass (suspected tumor or thrombus) and patients with technically limited images from echocardiogram, MRI or TEE.
- Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis, or complications of cardiac surgery) and patients with technically limited images from echocardiogram, MRI or TEE.
- Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation (e.g., pulmonary vein isolation).
- Non-invasive coronary arterial mapping, including internal mammary artery prior to repeat cardiac surgical revascularization.
- Evaluation of suspected aortic dissection or thoracic aortic aneurysm.
- Evaluation of suspected pulmonary embolism.

The following patients are considered appropriate candidates for cardiac CT.

Congenital heart disease

Cardiac CT is considered established in **ANY** of the following scenarios:

- Evaluation of suspected or established congenital heart disease in patients whose echocardiogram is technically limited or non-diagnostic
- Further evaluation of patients whose echocardiogram suggests a new diagnosis of complex congenital heart disease
- Evaluation of complex congenital heart disease in patients who are less than one year post-surgical correction
- Consideration for surgical repair of congenital heart disease
- Evaluation of complex congenital heart disease in patients who have new or worsening symptoms and/or a change in physical examination
- Assist in surgical planning for patients with complex congenital heart disease
- Surveillance in asymptomatic patients with complex congenital heart disease who have not had cardiac MRI or cardiac CT within the preceding year
  - Cardiac MRI or transesophageal echocardiography may be preferable to cardiac CT in order to avoid radiation exposure.

Cardiomyopathy

Cardiac CT is considered established in **ANY** of the following scenarios:

- Evaluation of patients with suspected arrhythmogenic right ventricular dysplasia (ARVD) who have **ANY** of the following:
  - Severe right ventricular dysfunction on another cardiac imaging study
  - Precordial T wave inversion not associated with RBBB
  - First-degree relative with established ARVD or unexplained sudden cardiac death at age younger than35 years
  - Ventricular tachycardia or frequent PVCs (> 500 in 24 hours or > 30 per hour)
- To assess left ventricular (LV) function in patients with suspected or established cardiomyopathy when all other noninvasive imaging is not feasible or technically suboptimal

  - Other modalities providing noninvasive evaluation of LV function include transthoracic and transesophageal echocardiography, blood pool imaging (MUGA or First pass), and cardiac MRI

- To assess right ventricular function in patients with suspected right ventricular dysfunction when all other noninvasive imaging is not feasible or technically suboptimal
  - Other modalities providing noninvasive evaluation of right ventricular function include transthoracic and transesophageal echocardiography, blood pool imaging (MUGA or First pass), and cardiac MRI

Valvular heart disease

Cardiac CT is considered established in **EITHER** of the following scenarios:

- Evaluation of suspected dysfunction of native or prosthetic cardiac valves when all other cardiac imaging options are not feasible or technically suboptimal
  - Other modalities providing noninvasive evaluation of native or prosthetic valves include transthoracic and transesophageal echocardiography, and cardiac MRI
- Evaluation of established dysfunction of native or prosthetic cardiac valves when all other cardiac imaging options are not feasible or technically suboptimal
  - Other modalities providing noninvasive evaluation of native or prosthetic valves include transthoracic and transesophageal echocardiography, and cardiac MR

Evaluation of patients with established coronary artery disease (CAD)

Cardiac CT is considered established for the following:

- Noninvasive localization of coronary bypass grafts or potential grafts (including internal mammary artery)and/or evaluation of retrosternal anatomy in patients undergoing repeat surgical revascularization

Intra-cardiac and para-cardiac masses and tumors

Cardiac CT is considered established in **ANY** of the following scenarios:

- Patients with a suspected cardiac or para-cardiac mass (thrombus, tumor, etc.) suggested by transthoracic echocardiography, transesophageal echocardiography, blood pool imaging or contrast ventriculography who have not undergone cardiac CT or cardiac MRI within the preceding 60 days
- Patients with established cardiac or para-cardiac mass (thrombus, tumor, etc.) who are clinically unstable
- Patients with established cardiac or para-cardiac mass (thrombus, tumor, etc.) who are clinically stable and have not undergone cardiac CT or cardiac MRI within the preceding year
- Patients with established cardiac or para-cardiac mass (thrombus, tumor, etc.) who have undergone treatment (chemotherapy, radiation therapy, thrombolysis, anticoagulation or surgery) within the preceding year and have not had cardiac CT or cardiac MRI within the preceding 60 days

Left atrial appendage closure device

Cardiac CT is considered established in EITHER of the following scenarios:

- Evaluation of cardiac anatomy prior to implantation of a left atrial appendage closure device
- Following placement of a left atrial appendage closure device, a single study may be performed as an alternative to TEE to assess for intracardiac thrombus

Cardiac aneurysm and pseudoaneurysm

Cardiac CT is considered established for evaluation of cardiac aneurysm or pseudoaneurysm.

Evaluation of pericardial conditions (pericardial effusion, constrictive pericarditis, or congenital pericardial diseases)

Cardiac CT is considered established in **ANY** of the following scenarios:

- Patients with suspected pericardial constriction
- Patients with suspected congenital pericardial disease
- Patients with suspected pericardial effusion who have undergone echocardiography deemed to be technically suboptimal in evaluation of the effusion
- Patients whose echocardiogram shows a complex pericardial effusion (loculated, containing solid material)

Evaluation of cardiac venous anatomy

Cardiac CT is considered established in **EITHER** of the following scenarios:

- For localization of the pulmonary veins in patients with chronic or paroxysmal atrial fibrillation/flutter who are being considered for ablation
- Coronary venous localization prior to implantation of a biventricular pacemaker

Evaluation of the thoracic aorta

Cardiac CT is considered established in **ANY** of the following scenarios:

- Patients with suspected thoracic aortic aneurysm/dilation who have not undergone CT or MRI of the thoracic aorta within the preceding 60 days
- Patients with confirmed thoracic aortic aneurysm/dilation with new or worsening signs/symptoms
- Ongoing surveillance of stable patients with confirmed thoracic aortic aneurysm/dilation who have not undergone surgical repair and have not had imaging of the thoracic aorta within the preceding 6 months
- Patients with suspected aortic dissection
- Patients with confirmed aortic dissection who have new or worsening symptoms
- Patients with confirmed aortic dissection in whom surgical repair is anticipated (to assist in preoperative planning)
- Ongoing surveillance of stable patients with confirmed aortic dissection who have not undergone imaging of the thoracic aorta within the preceding year
- Patients with confirmed aortic dissection or thoracic aortic aneurysm/dilation who have undergone surgical repair within the preceding year and have not undergone imaging of the thoracic aorta within the preceding6 months
- Patients who have sustained blunt chest trauma, penetrating aortic trauma or iatrogenic trauma as a result of aortic instrumentation
- Patients being evaluated for potential transcatheter aortic valve implantation/replacement (TAVI or TAVR) provided that the patient has not undergone cardiac CT or cardiac MRI within the preceding 60 days

Exclusions

- Those individuals who do not meet the criteria stated above.
- For screening purposes.
- Multidetector CT scanners that have fewer than 64 detectors.
- Computed tomography of the heart, without contrast material, with quantitative evaluation of coronary calcium. Calcium scoring reported in isolation is considered a screening service. See JUMP policy “Computed Tomography to Detect Coronary Artery Calcification.”

Magnetic resonance imaging – targeted biopsy of the prostate

- **New policy**
- **Effective date: 05/01/24**
- **Plan approval with clinical review**
- **Procedure code(s):** 55700, 55705. 55706, 77021

Before a transrectal ultrasound (TRUS)-guided biopsy, a magnetic resonance imaging (MRI) scan can be used to pinpoint the location of suspicious lesions in the prostate. MRI permits a targeted biopsy (as opposed to a blind biopsy, which is the current standard of care). The use of an MRI-guided prostate biopsy serves two functions: (1) to identify areas in the prostate that could harbor a high-grade tumor; and (2) to divert attention from any clinically insignificant cancers not needing treatment. In accomplishing the secondary function, patients are placed into one of two categories: those only needing active surveillance; and those needing definitive intervention.

Magnetic resonance imaging and transrectal ultrasound (MRI-TRUS) fusion-guided biopsy uses software to combine detailed images obtained from an MRI with the less detailed real-time TRUS, through an overlaid three-dimensional view. These "fused" images guide the placement of the biopsy needle to suspicious lesions identified from the MRI for prostate biopsy.

The safety and effectiveness of a prostate biopsy using an FDA approved magnetic resonance imaging guided device, including the direct (in-bore) approach, and fusion imaging of multi-parametric MRI with TRUS has been established. It may be considered useful when criteria are met.

Inclusions

The use of magnetic resonance imaging (MRI), both direct (in-bore) or MRI-TRUS fusion, to guide targeted biopsy of the prostate for cancer when **one** of the following criteria are met:

- As **initial/repeat biopsy** when there is a suspicion for prostate cancer (i.e., rising/elevated prostate specific antigen [PSA][a] or very suspicious digital rectal exam [DRE])
- To guide **management** when life expectancy is greater than 10 years and **one** of the following are met:
  - Active surveillance for very-low, low, or favorable intermediate-risk of prostate cancer
  - Re-biopsy after a first negative standard biopsy in men with persistent suspicion of disease, including those with persistently increased prostate-specific antigen levels, suspicious digital rectal exam, previous biopsy with an atypical focus on histology, or extensive high-grade prostatic intraepithelial neoplasia
  - To determine initial eligibility for active surveillance
  - To assess progression of disease over time
  - For local recurrence after external-beam radiotherapy, or after high-intensity focused ultrasound.

[a] Elevated PSA levels defined as > 3 ng/ml in men 40-75 years old with high risk **or** 45-75 years old with average risk. PSA levels ≥ 4 ng/ml is considered elevated in men greater than 75 years old.

Note: High risk individuals include: Black/African American individuals, those with germline mutations that increase the risk for prostate cancer, and those with concerning family or personal history.

Exclusions

The use of MRI in any of the following:

- To guide targeted biopsy of the prostate for any indications not listed above
- When used for individuals in observation

Pressure gradient garments and support stockings

- **New policy**
- **Effective date: 05/01/24**
- **Covered, criteria apply**
- **Procedure code(s):**
  - **Established –** Multiple (see policy)
  - **Other codes (investigational, not medically necessary, etc.) –** A4467, A4490, A4495, A4500, A4510

Gradient compression garments and support stockings are used to give external compression to the extremities, which prevents or reduces swelling, enhances venous circulation and prevents venous pooling and venous hypertension in individuals with incompetent venous circulation (i.e., varicose veins). They may also be used as prophylaxis against venous thrombosis and to enhance healing of extremity wounds by reducing venous pressure and edema. Special silicone compression garments may be prescribed in burn patients to minimize scarring responses in deep burns.

Some garments are custom made from precise measurements of the body and can vary from lymphedema sleeves for the arm, knee-length to full-length stockings, waist-high leotard, to various other body parts such as the hands. Custom-ordered/fitted compression garments require fitting and measuring by a specially trained individual and require a physician's order. Advances in technology allow many of compression garments to be pre-made. Very few need to be custom made unless the degree of gradient pressure is one that cannot be provided in a pre-made garment.

A *lymphedema sleeve* is a custom-fabricated garment that applies gradient pressure to a limb affected by loss of lymphatic channels, usually as a result of cancer surgery and/or radiation therapy. It is worn to reduce or maintain the volume of the upper limb (e.g., ReidSleeve®, ArmAssist, Jobst, Juzo, Circaid, Sigvaris, Tribute™ by Solaris). There are two types of lymphedema sleeves; those made of specialized elastic knit two-way stretch sleeves or stockings (e.g., Jobst or Juzo) and those in which gradient compression is achieved through high to low pressure ratios created by variations in density, type, size, proportion and insertion pressure of foam (e.g., Reidsleeve® or Tribute by Solaris). The elastic garments are usually prescribed for the initial treatment of lymphedema and worn under clothing during the day (including while exercising). Lymphedema sleeves such as the Reidsleeve® or Tribute™ by Solaris garments are used in addition to the elastic garments and typically after decongestive therapy to maintain limb volume. These sleeves can replace bandaging of the affected extremity and are usually worn at night. They are usually prescribed for intractable lymphedema (lymphedema which has been difficult to manage and nonresponsive to decongestive treatment). The Tribute™ by Solaris garment can also be used for the treatment of lymphedema of the lower extremity. The garment is boot-shaped, applies gradient compression to the lower extremity and usually replaces bandaging of the affected extremity.

The Compressure Comfort® Bra by Belisse® is contoured similarly to a bra however it is not considered a mastectomy bra. The garment applies gentle compression all around the torso and is used for treatment of lymphedema of the armpit, chest, breast, and/or back.

High compression support stockings, socks and hosiery provide increased support for relief from:

- Moderate to severe varicosities (varicose veins)
- Moderate edema (swelling) of legs, ankles and feet
- Moderate to severe varicose veins during pregnancy
- Severe edema and lymphedema

They may also be used for:

- Management of active venous ulcerations
- Preventing recurrence of venous ulcerations
- Preventing post-thrombotic syndrome. This is a complication that may follow a deep vein thrombosis and includes symptoms such as edema, purpura,

increased skin pigmentation, itchiness, rash, ulceration and cellulitis.

Inclusions

Pressure Gradient Support Garments

The pressure gradient support garments must be at or above 18 mm Hg and meet **one** of the following criteria:

- Pressure gradient support stockings are considered established for the treatment of severe circulatory conditions, moderate to severe varicose veins during pregnancy or post-surgical care.
- Treatment of complications of chronic venous insufficiency:
  - Varicose veins (except spider veins)
  - Stasis dermatitis (venous eczema)
  - Venous ulcers (stasis ulcers)
  - Venous edema
  - Lipodermatosclerosis
  - Treatment of phlebitis and thrombophlebitis
  - Prevention of thrombosis in immobilized persons (e.g., immobilization due to surgery, trauma, general debilitation)
  - Post-thrombotic syndrome (post-phlebitic syndrome)
  - Chronic intractable lymphedema (lasting longer than 3 months), including lymphedema as a physical complication of mastectomy (e.g., lymphedema sleeves)
  - Edema following surgery, fracture, burns, or other trauma
  - Post sclerotherapy
  - Postural hypotension/orthostatic hypotension
  - Severe edema in pregnancy
  - Deep vein thrombosis (DVT) prophylaxis during pregnancy and postpartum
  - Edema accompanying paraplegia, quadriplegia, etc.
  - Significant burn with risk of post burn contracture, skin grafting and hypertrophic scarring

Burn Pressure Garments

Considered established to enhance healing, reduce swelling, treat contractures and hypertrophic scars suffered by severely burned patients.

Custom-ordered/fitted compression garments or surgical stockings (e.g., Jobst, Sigvaris, Circaid, Juzo, ReidSleeve®, Sigvaris, Solaris, including the Tribute™ garment, and Belisse® garments)

Custom-ordered/fitted compression garments (e.g., stocking/burn garment/gradient pressure aid garment/sleeve) are considered established for patients when the garment functions as a gradient pressure aid with a degree of pressure which is at least 18 mm Hg, requires a physician order (prescription) to be dispensed, standard compression garments have been tried and/or ruled out, and meets **one or more** of the following conditions:

- Treatment of complications of chronic venous insufficiency:
  - Varicose veins (except spider veins)
  - Stasis dermatitis (venous eczema)
  - Venous ulcers (stasis ulcers)
  - Venous edema
  - Lipodermatosclerosis
- Treatment of phlebitis and thrombophlebitis
- Prevention of thrombosis in immobilized persons (e.g., immobilization due to surgery, trauma, general debilitation)
- Post-thrombotic syndrome (post-phlebitic syndrome)
- Chronic intractable lymphedema (lasting longer than 3 months), including lymphedema as a physical complication of mastectomy (e.g., lymphedema sleeves)
- Edema following surgery, fracture, burns, or other trauma

- Post sclerotherapy
- Postural hypotension/orthostatic hypotension
- Severe edema in pregnancy
- DVT prophylaxis during pregnancy and postpartum
- Edema accompanying paraplegia, quadriplegia, etc.
- Significant burn with risk of post burn contracture, skin grafting and hypertrophic scarring

Exclusions

- No more than four (4) pressure gradient support garments per year unless the member's primary care physician determines they are required due to significant gain or loss in weight or change in the patient's condition.
- Pressure garments of any kind (including burn pressure garments) are not covered for individuals that do not have coverage for external prosthetics or orthotics.
- Pressure garments and non-prescription support garments such as "support hose" used for comfort, or for conditions other than described above. Support hose A4490 - A4510 are not covered.
- Over the counter TED hose, elastic stockings, support hose, foot coverings, leotards, surgical leggings and fabric supports that typically have a compression of less than 18 mm Hg are not a benefit.
- Pressure garments worn by a patient in order to provide sensory and body awareness for conditions characterized by impaired motor control, such as autism, autism spectrum disorder, proprioceptive deficits, deep-sensory deficits or hypersensitivity are not covered.
- Gradient compression stockings solely for the purpose of air travel in those individuals at low-risk for DVT are not considered established, as they do not improve patient outcomes.
- Silver impregnated compression stockings are not considered established because there is insufficient evidence that silver impregnated compression stockings are superior to standard compression stockings.
- Compression garments are considered experimental/investigational for members with severe peripheral arterial disease or septic phlebitis because they are contraindicated in these conditions.
- Gradient compression garments/stockings are not considered established for any one of the following conditions with or without a written physicians order (this list may not be all inclusive):
  - Backache
  - Carpal tunnel syndrome
  - Cellulitis
  - Chest pain
  - Chronic airway obstruction
  - Cystocele
  - Esophageal reflux
  - Fibromatosis
  - Hammer toe
  - Lupus erythematosus
  - Neurogenic bladder
  - Osteoarthrosis
  - Osteomyelitis
  - Paralysis agitans
  - Sleep apnea
  - Sprained and/or strained joints or ligaments
  - Tendonitis
  - Urine retention

Prostatic Artery Embolization (PAE) for Benign Prostatic Hypertrophy (BPH)

- **Revised policy**
- **Effective date: 05/01/24**
- **Plan approval with clinical review**
- **Procedure code(s):** 37242, 37244

Prostatic arterial embolization (PAE) is a procedure for benign prostatic hyperplasia that may help improve urinary symptoms caused by an enlarged prostate with minimizing the risk of sexual side effects. Using fluoroscopic x-ray guidance, interventional radiologists insert a catheter into an artery in the groin or wrist and advanced it to the arteries supplying blood to the prostate gland. Tiny round particles (microspheres) are injected into the arteries, partially blocking the blood flow to the prostate. This procedure is called embolization. Areas of the prostate which are most affected by benign prostatic hyperplasia (BPH) are deprived of oxygen which results in necrosis of targeted areas. Over months the body's immune system reabsorbs the dead tissue and replaces it with scar tissue which slowly contracts and results in shrinkage of the prostate which alleviates some of the symptoms associated with BPH.

Prostatic arterial embolization (PAE) for benign prostatic hyperplasia (BPH) is established. It may be considered a useful therapeutic option when criteria are met.

Prostatic artery embolization for treatment of hematuria of prostatic origin is established. It may be considered a useful option when criteria are met.

PAE for BPH may be considered established when **ALL** the following are met:

- Selection is done by a multidisciplinary team involving both a urologist and an interventional radiologist
- Gland size 50 grams or greater
- Preserved bladder function

AND ONE of the following are met:

- Moderate to severe lower urinary tract symptoms (LUTS) by International Prostate Symptoms Score (IPSS)[a] refractory to medical management[b]
- Moderate to severe LUTS in individuals who are poor surgical candidates (e.g., advanced age, multiple comorbidities, or inability to stop anticoagulation or antiplatelet therapy)
- Acute or chronic urinary retention, requiring urinary catheter use.

PAE for hematuria of prostatic origin may be considered medically necessary when **one** of the following are met:

- 5-alpha reductase inhibitor(s)[c] (ARI) therapy has failed
- Acute bleeding that is uncontrolled with conservative measures
- Recurrent bleeding that is uncontrolled with conservative measures

[a] IPSS is a reproducible, validated index designed to determine disease severity and response to therapy. Scores range from 0 to 35. Mild (≤7), moderate (8-19), or severe (20-35).

[b] Documented failure (no clinical improvement after 3 months of therapy), inability to tolerate, or undesirable side effects or pharmacologic intervention for BPH.

[c] Examples consist of finasteride and dutasteride (brand names: Proscar, Propecia, Avodart, and Jalyn).

Note: Procedure should only be done by an interventional radiologist with specific training and expertise in prostatic artery embolization.

Exclusions

- Bladder cancer
- Catheter dependence over 12 months
- Detrusor/bladder dysfunction
- Gland size < 50 grams
- High-grade prostate cancer/Gleason Score >7
- Large bladder diverticula
- Neurogenic lower urinary tract dysfunction/neurogenic bladder
- Repeat PAE for BPH treatment
- Uncorrectable coagulopathy

Radioembolization for primary and metastatic tumors of the liver

- **Revised policy**
- **Effective date: 05/01/24**
- **Covered, criteria apply**
- **Procedure code(s):**
  - **Established –** S2095, 37243, 79445
  - **Other codes (investigational, not medically necessary, etc.) –** N/A

Treatments for hepatic and neuroendocrine tumors

The use of external-beam radiotherapy and the application of more advanced radiotherapy approaches (e.g., intensity-modulated radiotherapy) may be of limited use in patients with multiple diffuse lesions due to the low tolerance of the normal liver to radiation compared with the higher doses of radiation needed to kill the tumor.

Various nonsurgical ablative techniques have been investigated that seek to cure or palliate unresectable hepatic tumors by improving locoregional control. These techniques rely on extreme temperature changes (cryosurgery or radiofrequency ablation [RFA]), particle and wave physics (microwave or laser ablation), or arterial embolization therapy including chemoembolization, bland embolization, or radioembolization.

Radioembolization

Radioembolization (referred to as selective internal radiotherapy in older literature) delivers small beads (microspheres) impregnated with yttrium 90 intra-arterially via the hepatic artery. The microspheres, which become permanently embedded, are delivered to tumors preferentially because the hepatic circulation is uniquely organized, whereby tumors greater than 0.5 cm rely on the hepatic artery for blood supply while the normal liver is primarily perfused via the portal vein. Yttrium 90 is a pure beta-emitter with a relatively limited effective range and a short half-life that helps focus the radiation and minimize its spread. Candidates for radioembolization are initially examined by hepatic angiogram to identify and map the hepatic arterial system. At that time, a mixture of technetium 99-labeled albumin particles is delivered via the hepatic artery to simulate microspheres. Single-photon emission computed tomography is used to detect possible shunting of the albumin particles into the gastrointestinal or pulmonary vasculature.

Currently, 2 commercial forms of yttrium-90 microspheres are available: a glass sphere (TheraSphere) and a resin sphere (SIR-Spheres). Noncommercial forms are mostly used outside the United States. While the commercial products use the same radioisotope (yttrium 90) and have the same target dose (100 gray), they differ in microsphere size profile, base material (i.e., resin vs glass), and size of commercially available doses. The physical characteristics of the active and inactive ingredients affect the flow of microspheres during injection, their retention at the tumor site, spread outside the therapeutic target region, and dosimetry calculations. The Food and Drug Administration (FDA) granted premarket approval of SIR-Spheres for use in combination with 5-floxuridine chemotherapy by hepatic arterial infusion to treat unresectable hepatic metastases from colorectal cancer. In contrast, TheraSphere's glass sphere was approved under a humanitarian device exemption for use as monotherapy to treat unresectable hepatocellular carcinoma (HCC). In 2007, this humanitarian device exemption was expanded to include patients with HCC who have partial or branch portal vein thrombosis. For these reasons, results obtained with a product do not necessarily apply to another commercial (or non-commercial) products.

Inclusions

Radioembolization referred to as Selective internal radiation therapy (SIRT), using radioactive Yttrium-90 (^{90}Y) microspheres, is considered medically necessary when **ALL** of the following criteria are met:

- Unresectable and/or medically inoperable primary or metastatic liver malignancies from **ANY** of the following:
  - Unresectable liver only or liver dominant metastases from neuroendocrine tumors (e.g.,

carcinoids, pancreatic islet cell tumors, endocrine tumors).

  - Unresectable primary hepatocellular carcinoma (HCC) as a bridge to liver transplantation.
  - Unresectable metastatic liver tumors from primary colorectal cancer.
  - Treatment of unresectable liver metastases from breast carcinoma, ocular melanoma, cutaneous melanoma, or intrahepatic cholangiocarcinoma in the absence of available systemic or liver-directed treatment options to relieve symptoms and/or possibly extend life expectancy.
  - Treatment of other radiosensitive tumors metastatic to the liver with liver-limited or liver-dominant disease for symptom palliation or prolongation of survival.

- The tumor burden should be liver dominant, not necessarily exclusive to the liver.
- Life expectancy should be at least 3 months.
- Radioactive Yttrium-90 (^{90}Y) microspheres treatment is allowed only in the outpatient setting unless the documentation supports the medical necessity of inpatient treatment.

Repeat radioembolization is considered medically necessary for new or progressive primary or metastatic liver cancers when **ALL** of the following criteria are met:

- The individual has had a previous satisfactory response to an initial radioembolization treatment as evidenced on results of a computed tomography (CT) scan or positron emission tomography (PET)/CT scan performed 3 months following the previous procedure. Response should be graded according to the revised Response Evaluation Criteria in Solid Tumors (RECIST) guideline.
- The disease still must be liver dominant.
- Life expectancy of at least 3 months
- There are no other effective systemic or liver-directed treatment options.
- An individual has compensated liver function tests (LFTs).
- Estimated lung dose and combined lung dose from previous embolizations are within acceptable dose volume constraints. Exclude an individual with lung shunting in which the lung radiation dose is greater than 25 to 30 Gy per treatment or greater than 50 Gy cumulatively for all treatments.
- Treatment should be given to a targeted tumor volume.

Exclusions

- Used to treat previously untreated, or unresectable hepatic metastases from colorectal carcinoma.
- Repeat whole liver irradiation is considered experimental, investigational, and/or unproven (EIU) and will not be certified.
- A third radioembolization treatment is considered not medically necessary.
- For all other hepatic metastases not described above.
- For all other indications not described above.

Yttrium-90 is contraindicated for patients who have:

- Had previous external beam radiation therapy of the liver
- Bleeding diathesis not correctable using standard medical means
- Severe pulmonary insufficiency
- Treatment that would result in greater than 25 to 30 Gy dose to the lung in one session or 50 Gy cumulative as assessed by Technetium MAA scan
- Pre-assessment angiogram that demonstrates vascular anatomy abnormalities that would result in significant reflux of hepatic arterial blood to the stomach, pancreas or bowel
- Disseminated and significant extrahepatic malignant disease

- History of treatment with capecitabine within two previous months, or who will be treated with capecitabine at any time following treatment with SIR-Spheres®
- Portal vein thrombosis (relative)

Radioembolization is not recommended in pregnant women, nursing mothers or children.

Noncovered services

Miscellaneous and genetic and molecular diagnostic tests

- **Revised policy**
- **Effective date: 05/01/24**
- **Plan approval with clinical review**
- **Procedure code(s):** Multiple

There are numerous commercially available genetic and molecular, diagnostic and prognostic tests for individuals with certain diseases. This evidence review evaluates miscellaneous genetic and molecular diagnostic tests not addressed in a separate review. If a separate evidence review exists, then conclusions reached there supersede conclusions here. The main criterion for inclusion in this review is the limited evidence on the clinical validity for the test. As a result, these tests do not have clinical utility, and the evidence is insufficient to determine that technology results in an improvement in the net health outcome.

Diagnostic and prognostic genetic testing of an affected (symptomatic) individual's germline to benefit the individual (excluding reproductive testing) **or** (2) of an asymptomatic individual to determine future risk of disease is considered experimental/investigational for the following:

- Prometheus® Celiac PLUS
- Prometheus® Crohn's Prognostic
- DNA Methylation Pathway Profile
- GI Effects® (Stool)
- Prometheus® IBD sgi Diagnostic®
- Know Error™
- Envisia™ Genomic Classifier (Veracyte™)

All miscellaneous laboratory diagnostic tests[a] listed in this policy are considered investigational. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

[a] If a separate policy exists, then the criteria in that policy supersedes the guidelines herein.

Percutaneous and implantable tibial nerve stimulation

- **Revised policy**
- **Effective date: 05/01/24**
- **Plan approval with clinical review**
- **Procedure code(s):** 64566, 97014, 97032, 0587T, 0588T, 0589T, 0590T, 64999, 0816T, 0817T, 0818T, 0819T

Percutaneous tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is a technique of electrical neuromodulation used for treating voiding dysfunction. The tibial nerve is stimulated using a fine-needle electrode inserted slightly above the ankle, and low-voltage electrical current is delivered.

The current indication approved by the FDA for subcutaneous tibial nerve stimulation and subfascial tibial nerve stimulation is urgency urinary incontinence in individuals who are intolerant or who have had an inadequate response to more conservative treatments or who have undergone a successful trial of PTNS. Subcutaneous tibial nerve stimulation is administered through a coin-sized leadless battery-powered implant, whereas subfascial tibial nerve stimulation is a 3 cm length x 3 mm in diameter device which does not contain a battery. A magnetic wrap is place around the ankle to activate the device and provide impulses to the tibial nerve. The manufacturer advertises that this tibial implant delivers reliable and long-lasting performance in a compact form factor with hopes that future surgery for battery depletion, lead fracture, or lead migration will not

be necessary.

The safety and effectiveness of percutaneous posterior tibial nerve stimulation (TNS) for non-neurogenic urinary dysfunction have been established when criteria are met. It may be considered a useful therapeutic option when indicated.

Implantable TNS devices are considered experimental and investigational. Evidence is insufficient and has not been shown to improve clinical health outcomes.

Inclusions

Initial 12-week course of percutaneous tibial nerve stimulation (PTNS) for non-neurogenic urinary dysfunction including overactive bladder when the following are met:

- **BOTH** of the following have been attempted and have failed to yield adequate relief:
  - Behavioral therapy (i.e., biofeedback, fluid management, pelvic floor exercises) following an appropriate duration of 8 to 12 weeks of treatment.
  - Pharmacologic therapy (i.e., anti-cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant) following 4 to 8 weeks of treatment.

Maintenance[a] therapy at a frequency of 1 per month, following a 12-week initial course of percutaneous tibial nerve stimulation up to a total of 2 years. The 2-year time period begins with the induction of the initial course.

[a] For continuation of treatment, evidence of improvement of symptoms (e.g., urinary frequency, nocturia, and/or urinary urgency) should be obtained within the initial course of the PTNS treatment.

Exclusions

- Percutaneous tibial nerve stimulation for all other indications including but not limited to:
  - Neurogenic bladder dysfunction
  - Fecal incontinence
  - Stress incontinence
- PTNS treatment beyond 2 years
- Implantable tibial nerve stimulation devices for all indications, including individuals with non-neurogenic urinary dysfunction (e.g. overactive bladder)
  - Subcutaneous peripheral neurostimulator system (e.g., eCoin)
  - Subfascial peripheral neurostimulator system (e.g., Revi)

Established

Laser interstitial thermal therapy for neurological conditions

- **Maintenance Policy**
- **Effective date: 05/01/24**
- **Procedure code(s):** 61736, 61737

Laser interstitial thermal therapy (LITT) involves the introduction of a laser fiber probe to deliver thermal energy for the targeted ablation of diseased tissue. Thermal destruction of tissue is mediated via DNA damage, necrosis, protein denaturation, membrane dissolution, vessel sclerosis, and coagulative necrosis.[1] The goal of therapy is selective thermal injury through the maintenance of a sharp thermal border, as monitored via the parallel use of real-time magnetic resonance (MR) thermography and controlled with the use of actively cooled applicators.[2] In neurological applications, LITT involves the creation of a transcranial burr hole for the placement of the laser probe at the target brain tissue. Probe position, ablation time, and intensity are controlled under MRI guidance.

The majority of neurological LITT indications described in the literature involve the ablation of primary and metastatic brain tumors, epileptogenic foci, and radiation necrosis in surgically inaccessible or eloquent brain areas.[2] LITT may offer a minimally invasive treatment option for patients with a high risk of morbidity with traditional surgical approaches. The most common complications following LITT are transient and permanent weakness, cerebral edema, hemorrhage, seizures, and hyponatremia.[3] Delayed neurological

deficits due to brain edema are temporary and typically resolve after corticosteroid therapy. Contraindications to MRI are also applicable to the administration of LITT.

Regulatory Status

In August 2007, the Visualase™ MRI-guided Laser Ablation System (Medtronic; formerly Biotex, Inc.) received initial marketing clearance by the U.S. Food and Drug Administration (FDA) through the 510(k) pathway (K071328). In January 2022 (K211269), the system (software version 3.4) was classified as a neurosurgical tool with narrowed indications for use, including "to ablate, necrotize or coagulate intracranial soft tissue including brain structures (for example, brain tumor, radiation necrosis and epileptic foci as identified by non-invasive and invasive neurodiagnostic testing, including imaging) through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 800 nm through 1064 nm lasers." The device is contraindicated for patients with medical conditions or implanted medical devices contraindicated for MRI and for patients whose physician determines that LITT or invasive surgical procedures in the brain are not acceptable. Data from compatible MRI sequences can be processed to relate imaging changes to relative changes in tissue temperature during therapy. The Visualase™ cooling applicator utilizes saline.

In April 2013, the NeuroBlate® System (Monteris Medical) received initial clearance for marketing by the FDA through the 510(k) pathway (K120561). As of August 2020, the system is indicated for use “to ablate, necrotize, or coagulate intracranial soft tissue, including brain structures (e.g., brain tumor and epileptic foci as identified by non-invasive and invasive neurodiagnostic testing, including imaging), through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers” (K201056). The device is intended for planning and monitoring of thermal therapy under MRI guidance, providing real-time thermographic analysis of selected MRI images. The NeuroBlate® system utilizes a laser probe with a sapphire capsule to promote prolonged, pulsed laser firing and a controlled cooling applicator employing pressurized CO2.

Medical Policy Statement

Laser interstitial thermal therapy is considered established for the treatment of epilepsy, radiation necrosis, recurrent glioblastoma and relapsed brain metastases, in individuals who meet the selection criteria.

Laser interstitial thermal therapy is considered experimental/investigational for all other neurological conditions.

Inclusionary and Exclusionary Guidelines

Inclusions

Laser interstitial thermal therapy (LITT) is considered established in the treatment of refractory epilepsy when all of the following criteria are met:

- There is documentation of disabling seizures* despite use of 2 or more antiepileptic drug regimens** (i.e., medication-refractory epilepsy), **AND**
- There are well-defined epileptogenic foci accessible by LITT, **AND**
- A multidisciplinary team of physicians that includes at least 2 specialties (e.g., neurology, neurosurgery), after considering all possible treatments, agrees that LITT is the best treatment option for the patient.

*Disabling seizures can be defined as seizures that result in impairment or a loss of functional status.

**Antiepileptic drug regimens are defined as 2 tolerated and appropriately chosen and used antiepileptic drug schedules (as monotherapies or in combination) to achieve sustained seizure freedom.

***LITT should be performed by a neurosurgeon who has completed procedure-specific training in the use of a Food and Drug Administration (FDA) approved LITT ablation system and who has been granted hospital privileges to perform brain tumor surgery and LITT ablation procedures.

1. Laser interstitial thermal therapy (LITT) is considered established for individuals who are poor candidates for craniotomy or resection when the following criteria are met:
   - Relapsed brain metastases, or
   - Radiation necrosis, or
   - Recurrent glioblastoma, AND
2. The treatment plan to use LITT has been agreed upon by a multidisciplinary team of physicians to include at least 2

specialists (e.g., neurosurgery, oncology) and after considering all relevant possible treatment approaches, is determined to be the best treatment option.

Exclusions

Laser interstitial thermal therapy for epilepsy radiation necrosis, recurrent glioblastoma and relapsed brain metastases that does not meet the above criteria.

Laser interstitial thermal therapy is considered experimental/investigational for all other neurological conditions.

Percutaneous Arteriovenous Fistula (pAVF)

- **New Existing Policy**
- **Effective date: 05/01/24**
- **Procedure code(s):** 36836, 36837

Chronic kidney disease (CKD) means your kidneys are damaged and can't filter blood the way they should. The disease is called "chronic" because the damage to your kidneys happens slowly over a long period of time. This damage can cause wastes to build up in your body. CKD can also cause other health problems.

Once chronic kidney disease reaches an advanced state, it leads to end stage renal disease (ESRD). Once an individual reaches ESRD, dialysis is usually required will likely be ordered by an individual's physician. Vascular access to the bloodstream is often preferred in order to administer dialysis treatment. An arteriovenous fistula (AVF) creates a direct connection between a vein and an artery in an individual's arm. When the artery and vein is joined, blood flow increases from the artery into the vein. As a result, the vein gets bigger over time. The enlarged vein provides easier access to the blood for a treatment for dialysis. Surgery is the traditional method of creating this AVF.

While these procedures are typically straightforward, overall maturation-to-use rates remain low, with nearly 25% failing to mature despite high utilization of subsequent procedures to aid in maturation. Over 50% of individuals may ultimately require reintervention to maintain patency of the AV access once maturation has occurred. Other complications of traditional AV hemodialysis access include infection, steal syndrome, aneurysm formation, and pulmonary and venous hypertension. As a result of complications or AV access failure, individuals often require several different access procedures performed in multiple extremities.

The available percutaneous hemodialysis AV fistula systems create a connection between a forearm artery (ulnar or radial artery) and a perforating vein or the names vein that corresponds to the artery (ulnar or radial vein). Once the connection is created, blood is shunted from the arterial system to the deep venous system and subsequently to the superficial venous system via the perforating vein. Once matured, the arterialized superficial veins can then be accessed for hemodialysis in a manner like surgically created AV fistulas using these superficial veins. See Table 1.

Ellipsys® Vascular Access System

The Ellipsys® Vascular Access System (Medtronic, Minneapolis, MN) is a percutaneous catheter system intended to create an AVF for hemodialysis access in individuals with chronic kidney disease. The system is indicated for use in individuals with a minimum vessel diameter of 2 mm and less than 1.5 mm of separation between the artery and vein at the fistula creation site. The anastomosis is created in the proximal radial artery and adjacent vein using direct current thermal heating. Using ultrasound guidance, the system uses an outer access cannula, guidewire and vessel capture construct that creates a connection of the vein to the artery using an intravascular approach. A low power thermal energy source is used to cut the walls of the vessels and fuse the tissue, creating an anastomosis without leaving any foreign material, including sutures, in the resulting AV fistula.

WavelinQ™ Endovascular Arteriovenous Fistula (EndoAVF) System

The WavelinQ™ EndoAVF System (Becton, Dickinson and Company [BD], Franklin Lakes, NJ) (originally marketed at EverlinQ) is a minimally invasive electrosurgical tool intended to create AVFs for individuals with minimum artery and vein diameters of 2 mm at the fistula creation site with catheters that are each inserted into an artery (brachial) and a vein (brachial, ulnar or radial) in the arm through a small puncture or incision. Using fluoroscopy, the catheters are both advanced to the appropriate location for endovascular AVF creation. The magnets in the catheters allow them to be precisely aligned while pulling the two adjacent vessels closer together. The venous catheter, which contains the electrode, delivers a burst of radiofrequency energy to create a connection between the artery and the vein.

Table 1. Comparison of the Two Percutaneous Arteriovenous Fistula Devices

	WavelinQ™ EndoAVF System	Ellipsys® Vascular Access System
Device Components	Two 4Fr, magnetic, hydrophilic coated catheters (venous catheter with radiofrequency electrode and arterial catheter with backstop for receiving the electrode), ESU-1 electrosurgical unit, and electrosurgical pencil	Access needle, 6Fr over-the-wire tissue fusion and cutting catheter, and a power controller
Mechanism of Fistula Creation	Radiofrequency energy	Thermal resistance energy and pressure
Access Sites	Arterial and venous: brachial artery/vein, ulnar artery/vein, or radial artery/vein	Venous: cephalic, median cubital, median basilic, or brachial vein
Site of Fistula Creation	Proximal ulnar artery and ulnar vein or proximal radial artery and radial vein	Proximal radial artery and deep communicating vein
Contrast Required?	Yes, fluoroscopic imaging used to confirm alignment and for confirmation fistulogram	No, ultrasound guidance only

Regulatory Status

The U.S. Food and Drug Administration (FDA) granted 510k(k) marketing clearance for the Ellipsys® System (K191114) in August 2019 based on its substantial equivalence to a previous device model, which initially received 510(k) clearance in October 2018 (K181725). The FDA first cleared Ellipsys® through the De Novo pathway in January 2017 (DEN170004).

The WavelinQ™ Plus EndoAVF System was granted 510(k) marketing clearance by the FDA in October 2019 (K192239) and the WavelinQ™ 4F EndoAVF System in February 2019 (K182796). Prior to the 510(k) clearance, the FDA granted De Novo clearance to the EverlinQ EndoAVF System in June 2018 (DEN160006).

Medical Policy Statement

The use of an endovascular percutaneous device for the creation of an arteriovenous fistula (pAVF) for hemodialysis (HD) access is considered established

when criteria are met.

Inclusionary and Exclusionary Guidelines

Note: Percutaneous arteriovenous fistula (pAVF) placement should be performed by a physician who has completed procedure-specific training with insertion of FDA approved systems.

Inclusions and Exclusions

WavelinQ Inclusionary Criteria

All of the following must be met:

- Individuals with ESRD
- Life expectancy greater than one year
- Individuals who are not candidates for a distal surgical AVF
- Adult (age ≥ 18 years old)
- Procedural access vessels > 2 mm in diameter
- Perforator vein ≥ 2 mm in diameter
- Ulnar artery and paired ulnar vein OR radial artery and paired radial vein > 2 mm in diameter at the fistula creation site
- Less than 2.0 mm separation between the artery and vein at the fistula creation site

WavelinQ Exclusions

- When above criteria are not met
- Known central venous stenosis or central vein narrowing > 50% based on imaging on the same side as the planned endoAVF creation
- Upper extremity venous occlusion(s) and/or vessel abnormality(ies) on the same side as the planned endoAVF creation that precludes endoAVF creation
- New York Heart Association class III or IV heart failure despite optimal therapy
- Hypercoagulable state

Ellipsys Inclusionary Criteria

All of the following must be met:

- Individuals with ESRD
- Life expectancy greater than one year
- Individuals who are not candidates for a distal surgical AVF
- Adult (age ≥ 18 years old)
- Proximal radial artery and adjacent perforating vein with a minimum vessel diameter of 2.0 mm
- Distance between the artery and vein at the fistula creation site <1.5 mm

Ellipsys Exclusions

- When above criteria are not met
- Known central venous stenosis or central vein narrowing > 50% based on imaging on the same side as the planned endoAVF creation
- Upper extremity venous occlusion(s) and/or vessel abnormality(ies) on the same side as the planned endoAVF creation that precludes endoAVF creation
- Hypercoagulable state
- New York Heart Association class III or IV heart failure despite optimal therapy

Suprachoroidal delivery of pharmacologic agents

- **New Existing**
- **Effective date: 05/01/24**
- **Procedure code(s):** 67516

The structure of the eye is classified under two subheadings: (1) anterior segment, and (2) posterior segment. The anterior segment consists of the front one-third of the eye and includes the pupil, cornea, iris, ciliary body, aqueous humor, and lens. The posterior segment consists of the back two-thirds of the eye that includes the vitreous humor, retina, choroid, macula, and optic nerve. Posterior segment ocular diseases (e.g., age-related macular degeneration, macular edema, diabetic neuropathy, posterior uveitis, open-angle glaucoma,) are the most prevalent causes of visual impairment.

The most common route for ocular drug administration is by intravitreal injection. Other routes for drug delivery include topical, systemic, iontophoretic, juxtascleral and other injection routes. Extended-release intravitreal implants are relatively new delivery modes.

Topical application has remained the most preferred delivery route due to ease of administration. Topical application is useful in the treatment of disorders affecting the anterior segment of the eye. Although topical and systemic routes are convenient, lack of bioavailability and failure to deliver therapeutic levels of drugs to the retina has prompted vision scientists to explore alternative routes of administration.

The suprachoroidal space is a potential space between the sclera and the choroid, and is a method to deliver therapeutics to the back of the eye. A potential advantage of suprachoroidal injection is the ability to minimize systemic adverse effects while delivering higher drug levels to local tissues. This proposed benefit assumes that high drug local levels lead to improved outcomes. Weighed against this potential benefit is the risk of localized tissue damage from microcannula. A microcannula system combines a drug delivery channel with a fiberoptic light source for localization of the cannula tip. This technique is being investigated for the treatment of subchoroidal neovascularization related to retinal diseases.

Uveitis

Uveitis is inflammation inside your eye. Inflammation usually happens when your immune system is fighting an infection. Sometimes uveitis means your immune system is fighting an eye infection but it can also happen when your immune system attacks healthy tissue in your eyes. Uveitis can cause problems like pain, redness, and vision loss. Uveitis damages the part of the eye called the uvea but it often affects other parts of the eye, too. Sometimes uveitis goes away quickly, but it can come back. Sometimes it's a chronic (long-term) condition. It can affect one eye or both eyes. Uveitis can cause vision loss if it isn't treated so it's important to see your eye doctor right away if you have symptoms. Early uveitis symptoms usually start suddenly. Symptoms include blurry vision, floaters, eye pain, red eyes, and sensitivity to light. Uveitis can cause vision loss if you don't treat it.

Xipere

Xipere (triamcinolone acetonide injectable suspension) for suprachoroidal use is a corticosteroid indication for the treatment of macular edema associated with uveitis. Additionally, Xipere comes packaged and supplied with one Suprachoridal Space (SCS) Microinjector® syringe with vial adapter attached, one 30-G x 900-µm needle, and one 30-G x 1100-µm needle (for administration in the back of the eye).

Regulatory Status

The iTrack™, formerly known as iScience (Ellex, Adelaide, South Australia), a flexible microcannula designed to allow atraumatic cannulation of spaces in the eye for infusion and aspiration of fluids during surgery, received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2004. The microcannula incorporates an optical fiber to allow transmission of light to the microcannula tip for surgical illumination and guidance. The microcannula "is indicated for fluid infusion and aspiration, as well as illumination, during surgery." In a review of patented ocular drug delivery devices, Gilger, et al. (2014) describe several suprachoroidal drug delivery devices and products (e.g., sustained-release hydrogels and microparticles) in development.

March 30, 2023 FDA approved iTrack™ Advance Canaloplasty Microcatheter with Advanced Delivery System. The newest generation canaloplasty device for canal-based glaucoma surgery was available in May 2023 to surgeons in the U.S. to treat glaucoma. The iTrack microcatheter is the only product that is indicated for canal surgery to treat glaucoma with viscodilation alone. iTrack Advance is the latest addition to the iTrack family and is a high precision hand-held delivery system that places the clinically proven iTrack microcatheter into the main drainage canal of the eye for injection of viscoelastic fluid (canaloplasty) to clear blockages that cause elevated eye pressure (glaucoma). The original iTrack is principally used by glaucoma surgeons, whereas the new iTrack Advance, with the extended feature set, is expected to appeal to glaucoma surgeons

as well as cataract surgeons and comprehensive surgeons, for use in a combination procedure alongside cataract surgery. iTrack Advance can be used by surgeons for both standalone procedures as well as in combination with cataract surgery.

Xipere was approved by the U.S. Food and Drug Administration (FDA) in October 2021 for the treatment of macular edema associated with uveitis. Xipere is administered as a suprachoroidal injection using the Suprachoridal Space (SCS) Microinjector®.

The SCS Microinjector has not been approved by the FDA, only as part of the Xipere approval.

Medical Policy Statement

Suprachoroidal injection for the treatment of macular edema associated with uveitis is considered **established** when criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions

The use of suprachoroidal injection of triamcinolone acetonide injectable suspension (Xipere®) is considered established for the following indications:

- Individual is 18 years of age of older, **and**
- Individual has diagnosis of macular edema associated with uveitis, **and**
- Individual does not have infectious uveitis, **and**
- Prescriber will not exceed the U.S. Food and Drug Administration (FDA) labeled dose of 4 mg per affected eye.

Exclusions

Suprachoroidal injection is not covered for all other indications.

Experimental/Investigational

Genetic testing multicancer early detection testing (e.g., Galleri)

- **New Policy**
- **Effective date: 05/01/24**
- **Procedure code(s):** 81479, 81599, 86849

Cancer is the second leading cause of death in the US following heart disease. Cancer is the cause of death in 1 of every 5 deaths in the US. In the US, more than 1.7 million new cases of cancer were reported in 2019, and almost 600,000 people died of cancer.

Many cancers appear to have a better prognosis if diagnosed early in their natural history. This has led to efforts to detect preclinical cancers in asymptomatic persons through screening. However, screening tests have associated benefits and harms that must be considered when evaluating whether a test should be used in a population.

Early detection of cancer has 2 components: early diagnosis and screening. Early diagnosis is the early identification of cancer in *symptomatic* individuals with the aim of reducing the proportion of individuals diagnosed at a late stage. Screening is the identification of preclinical cancer or precursor lesions in apparently healthy, *asymptomatic* populations by tests that can be applied rapidly and widely in the target population. This review focuses on tests for screening indications.

Cancer screening tests such as ‘liquid biopsies’ that are minimally invasive and can simultaneously detect multiple types of cancer have been called multicancer early detection (MCED) tests.

The review will focus on MCED tests that are available in the US. The Galleri test is the only commercially available MCED test in the US at this time. This review will not include tests that screen for only 1 cancer (e.g., colon).

While advocates of the test might claim the simplicity of a blood test will improve compliance over existing cancer screening tests and offer screening for cancers

that currently do not have recognized screening tests available, no evidence exists to support these claims or to estimate the potential harms of false positives.

Regulatory Status

No MCED tests have been approved or cleared by the U.S. Food and Drug Administration (FDA). GRAIL, Inc., announced in 2019 that its MCED test (Galleri®) had been granted breakthrough device designation by the FDA.

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Galleri is available under the auspices of the Clinical Laboratory Improvement Amendments.

Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the FDA has chosen not to require any regulatory review of this test.

Plans may need to alter local coverage medical policy to conform to state law regarding coverage of biomarker testing

Medical Policy Statement

The use of multicancer early detection (MCED) tests (e.g., Galleri) is considered experimental/investigational for cancer screening. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Inclusionary and Exclusionary Guidelines

N/A