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AUTOLOGOUS STEM CELL INFUSION FOR MYOCARDIAL INFARCTION

Policy # 394
Implementation Date: 3/5/08
Review Dates: 2/19/09, 2/17/11, 2/16/12, 4/25/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/5/19, 2/11/20, 2/18/21
Revision Dates: 2/18/10

Description
Acute myocardial infarction (AMI) is the death of heart muscle secondary to prolonged lack of oxygen due to blockage of the artery supplying the muscle. Approximately 1.5 million cases of AMI occur each year in the United States and cardiovascular disease is the leading cause of death in the U.S; approximately 500,000–700,000 deaths related to coronary artery disease (CAD) occur each year.

Dead heart muscle reduces the heart’s ability to function properly which can result in congestive heart failure or other complications which impair an individual’s ability to function and may ultimately lead to an early death.

Various therapies have been attempted to improve heart function in cases of ischemic heart disease. These include medical therapy, surgical excision of dead heart muscle, placement of left ventricular devices (LVD), and even heart transplantation or placement of a temporary artificial heart. Recently, stem cell transplantation has been tried to replace damaged heart cells with healthy viable cells. A relatively new concept of adult stem cell therapy predicts that stem cells can differentiate into cell types outside of their original lineage. Results from studies have suggested that blood line stem cells can change into heart muscle cells and vascular cells after transplantation into damaged heart tissue.

Many studies have been done investigating stem cell infusions for the replacement of damaged heart cells. Various methods of administering this therapy have been used with cells being implanted directly into heart muscle externally through the chest wall, through the veins leading to the heart and via heart catheterization into the coronary. Additionally, various cell lines have been used for this treatment including bone marrow cells, undifferentiated muscle cells, and peripheral blood cells, further clouding the question of efficacy. The exact mechanism in which stem cell transfer can improve perfusion and contractile performance of the injured heart remains unknown, and the controversies surrounding the ability of these cells to undergo this change continues to exist. However, irrespective of the mechanism, there appears to be a general agreement that stem cell transplantation has some impact on heart function post-MI. Questions remain, though, as to whether there is a significant clinical impact on patients.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

SelectHealth does NOT cover autologous stem cell infusion for myocardial infarction due to the lack of evidence proving clinical efficacy and many unanswered questions related to the optimal progenitor cells and methods to deliver stem cells. This meets the plan’s definition of investigational/experimental.
Cardiovascular Policies, Continued

Autologous Stem Cell Infusion for Myocardial Infarction, continued

SelectHealth Advantage (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 SelectHealth 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.

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Summary of Medical Information

A Medical Technology Assessment performed in March 2008 identified 37 articles, including a large number of randomized controlled trials, with most controls receiving normal saline injections or standard therapy. Most of these were small sample studies reporting outcomes over 3–6 months, and there was substantial heterogeneity in criteria for sample selection and infusion method. Of these studies, 28 studies focused on stem cells derived from bone marrow, 7 utilized circulating progenitor cells, and 2 used cells from skeletal myoblasts. A variety of cardiac outcomes were measured including change in left ventricular ejection fraction, global ejection fraction, various blood volume measures contractility, infarct size, and oxygen intake.

Many of these studies suggest potential for stem-cell infusion to improve cardiac function. For example, the largest study to date, REPAIR-AMI, is a multi-site randomized controlled trial of 204 patients with acute myocardial infarction successfully re-perfused with stent implantation. Patients were infused with either bone-marrow-derived progenitor cells or placebo. At 4 months, global LVEF was significantly higher in the treatment group, having increased from a mean of 48.3 ± 9.2% to 53.8 ± 10.2%, compared with a change from 46.9 ± 10.4% to 49.9 ± 13.0%, in the placebo group. The treatment group also experienced greater improvement in regional contractility.

In contrast, the ASTAMI randomized controlled trial of 100 patients found no difference between the bone marrow and placebo groups at 6 months in LVEF, end-diastolic volume, or infarct size. Similarly, LVEF was no different between treated and placebo patients at 18 months in the BOOST study of 60 patients.

Far fewer studies measured important clinical outcomes such as mortality, additional cardiac events, and quality of life post-infusion. The REPAIR-AMI study reported fewer deaths, repeat myocardial infarctions, or revascularization procedures, in the treatment group compared with placebo at the one-year follow-up. Stem cell infusion resulted in improved exercise capacity at 6 months in the ASTAMI trial and at 12 months in a nonrandomized cohort of 20 patients. Treatment with stem-cells conferred no improvement in quality of life at 6 months in the ASTAMI trial. The TOPCARE-AMI study of 59 patients reported no additional cardiac events at 12 months in patients treated with circulating progenitor cells.

Overall, while these studies suggest that stem cell infusion confers statistical improvement in cardiac functioning in the short-term, additional longitudinal studies are needed to evaluate whether the treatment reliably improves quality of life and reduces mortality from future cardiac events. Moreover, standardized procedures are needed for extraction and infusion in addition to better data on the appropriate patient population for this procedure. Several clinical trials are ongoing, which should contribute important data towards addressing these issues.

A literature review in February 2010 identified a BCBS TEC Summary, concluding there was insufficient evidence to allow a conclusion on the benefits of progenitor cell therapy.

Billing/Coding Information

CPT CODES

Not Covered: Investigational/Experimental/Unproven for This Indication
Autologous Stem Cell Infusion for Myocardial Infarction, continued

33999
Unlisted procedure, cardiac surgery

HCPCS CODES
No specific codes identified

Key References


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CAROTID ARTERY STENTING (CAS)

Policy # 461
Implementation Date: 9/28/10
Review Dates: 9/15/11, 11/29/12, 12/19/13, 12/18/14, 12/15/16, 12/21/17, 12/11/18, 12/15/19, 1/6/21, 3/25/22
Revision Dates: 6/17/22

Description
Carotid artery disease (CAD) develops due to atherosclerosis or fibromuscular dysplasia. Symptoms from carotid stenosis are due to a reduction in blood flow. Either a cerebrovascular event (CVA) or transient ischemic event (TIA) will create neurological symptoms attributable to the limited blood flow or carotid stenosis. Typically, when the narrowing exceeds 50%, symptoms may develop. Standard recommendations are to treat symptomatic disease if the stenosis is > 50% or asymptomatic disease when identified, if the stenosis is > 70%.

The standard method of correcting carotid artery stenosis is a carotid endarterectomy. Carotid artery stenting has been developed as a less invasive procedure for treatment of the stenosis. Carotid artery stenting (CAS) begins with carotid angioplasty, a non-surgical procedure performed after diagnostic testing. During angioplasty, a balloon catheter is guided to the area of the blockage or narrowing. When technically feasible, a specially designed guide wire with a filter (embolic protection) is placed beyond the site of stenosis in the carotid artery. Once the filter is in place, a small balloon catheter is guided to the area of the blockage. When the balloon is inflated, the atherosclerotic plaque is compressed against the arterial walls and the diameter of the blood vessel is dilated to increase blood flow. The balloon is removed, and the stent then placed to maintain patency of the carotid artery. Eliminating the obstruction or enhancing the blood flow reduces the risk for TIA or strokes. Because carotid stenting is performed percutaneously, it offers a less invasive approach than carotid endarterectomy and may reduce perioperative complications in high-risk patients who have co-morbid conditions.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers carotid artery stenting (CAS) in limited circumstances as the current literature demonstrates improved outcomes in select populations. Must meet either A or B.

A. Recommended by Intermountain Healthcare Cardiovascular Clinical Program; OR

B. For all other clinicians, the following criteria must be met:

1. Extracranial carotid artery angioplasty performed with an FDA approved stent system and distal embolic protection.

AND

2. The patient is considered to be at high risk for open carotid endarterectomy.
Carotid Artery Stenting (CAS), continued

A member may be considered at high risk for open endarterectomy if they meet 1 or more of the following criteria:

- New York Heart Association class III or IV congestive heart failure
- Left ejection fraction of less than 30%
- Myocardial infarction within past 30 days, unstable angina, known severe coronary artery disease (left main coronary artery or 2 or more major arteries with stenosis ≥ 70%), or concurrent requirement for open heart surgery within 30 days
- Severe chronic obstructive pulmonary disease
- Contralateral carotid artery occlusion
- Contralateral laryngeal nerve palsy
- Previous radiation therapy to the neck or radical neck dissection
- Previous ipsilateral endarterectomy with restenosis
- Surgically inaccessible lesion
- Inability to move the neck to a suitable position for surgery
- Tracheostomy
- Coagulopathy or other coagulation issues leading to contraindications for endarterectomy
- Previous contralateral nerve palsy

AND

3. Clinically, must have:

- Symptomatic stenosis equal to or greater than 50% or asymptomatic stenosis equal to or greater than 80% using carotid ultrasound or CT angiography. If the pre-procedural degree of stenosis was made with carotid ultrasound, the degree of stenosis must be confirmed by cerebral arteriography prior to stent deployment. If a lesser degree of stenosis is identified versus the listed indications, then CAS should not proceed;

OR

- Fibromuscular dysplasia with similar clinical and radiographic findings in carotid atherosclerosis;

AND

- Among symptomatic patients with recent stroke, a modified Rankin scale must be < 3.

SelectHealth Advantage (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 SelectHealth 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.

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Carotid Artery Stenting (CAS), continued

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
Several systematic reviews are available, and all describe the international studies comparing carotid artery stenting (CAS) and coronary artery endarterectomy (CEA). Most have concluded that CEA is the preferred method for symptomatic plaques over 50% and for asymptomatic patients with greater than 70% narrowing. The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) trial appears to have demonstrated a non-inferiority status for CAS compared with CEA. Previously, the international randomized studies have shown increased rates of intraoperative CVA during CAS limiting the role of CAS in CVD. CAS would be used only when there were strict contraindications for surgery.

CREST demonstrated low rates of periprocedural stroke and death in both treatment groups as compared with the other trials. For example, the rate of periprocedural stroke among symptomatic patients treated by carotid artery stenting was 6% in CREST but 9.6% in the EVA-3S. Compared with previous studies, CREST was the only trial which used MI (myocardial infarction) as an endpoint. CAS resulted in 1.1% risk of MI compared with CEA at 2.3%. Because MI was included as an endpoint along with CVA and death, the CREST trial results demonstrated that CAS showed comparative clinical outcomes compared with CEA. Critics have suggested that the increased rate of MI cannot be considered equivalent to CVA. They illustrate that both the increased economic and health status of the patient is much worse with a CVA. Thus, CEA should still be considered the standard of care for carotid revascularization.

Many factors are important to emphasize with CREST and previous studies. Besides the influence of choosing endpoints as discussed above, the following issues are significant in determining the clinical outcomes of the studies. These include:

- Technical proficiency of the proceduralist - Enhanced training improved results in CREST compared with previous studies where training for CAS was limited
- The age of the patient - Younger patients favored CAS
- Recent symptoms of either a TIA or CVA and the need for intervention favors CEA
- Associated co–morbid condition which could increase perioperative mortality favoring CAS.

Besides these factors, critics also illustrate there were different criteria to be included in the studies. For example, carotid ultrasound (US), magnetic resonance angiogram (MRA), and computed tomography (CT) carotid angiogram were the imaging techniques used for the diagnosis of carotid stenosis. International studies compared with CREST did not use the same thresholds, thus, direct comparisons of the studies, including their overall outcomes, are difficult to perform. Newer methods to avoid perioperative emboli have decreased the rate of stroke in CREST compared with previous studies. It is anticipated that future refinement will limit the events in the future.

Unfortunately, all randomized studies have excluded a medical arm. This omission, especially with enhanced hypertension and cholesterol control, could significantly influence the outcomes of invasive trial. Overall, CREST challenges the prior international studies and suggests that in certain patient subgroups, equal or improved health outcomes may be achieved with CAS compared with CEA.

Billing/Coding Information
Covered: For the conditions outline above

CPT CODES

37215 Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous: with distal embolic protection

37217 Transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, via open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation

37218 Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation
Carotid Artery Stenting (CAS), continued

HCPCS CODES

No specific codes identified

Key References


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Coronary artery disease (CAD) refers to any disease that affects the coronary arteries (coronary artery disease) or cardiac muscle. Atherosclerosis is an important risk factor in the development of CAD. Multiple factors contribute to the pathogenesis of atherosclerosis including endothelial dysfunction, dyslipidemia, inflammatory and immunologic factors, plaque rupture, and smoking.

Assessing risk for developing early CAD can be done using variously using multiple methods. First and foremost, a complete assessment of risk factors using a history and physical examination along with calculation of the Framingham risk score which is a validated risk assessment tool.

One method being promoted as a screen for early CAD in patients of low or intermediate cardiac risk is CT calcium scoring. This non-invasive imaging study assesses for the presence, location and extent of calcified plaque in the coronary arteries. Because calcium may be a marker of CAD, the amount of calcium detected on a cardiac CT scan has been proposed as a helpful prognostic tool in determining if further testing may be warranted. The findings on cardiac CT are expressed as a calcium score. A negative cardiac CT scan shows no calcification within the coronary arteries. A positive test suggests CAD to be present. Some studies have indicated the greater the calcium load, the more likely the presence of CAD. Recent studies have suggested a calcium score > 400 may be a cut-off level that correlates with a high probability of CAD being present and further testing being warranted especially in patients with no symptoms or at low or intermediate risk for developing CAD.

CT calcium scoring can be performed using a variety of computerized tomography (CT) technologies. These include, electron beam (ultrafast) CT (EBCT), spiral (helical) CT, and multi-slice or multi-detector CT (MSCT or MDCT).

**Commercial Plan Policy/CHIP (Children’s Health Insurance Program)**

SelectHealth does NOT cover cardiac CT calcium scoring for the assessment of cardiovascular risk using ANY technique. The literature showing clinical validity fails to clearly demonstrate a role for cardiac CT calcium scoring. This meets the plan’s definition of investigational/experimental.

**SelectHealth Advantage (Medicare/CMS)**

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Coronary Artery Disease Calcium Scoring (Cardiac CT Scan) to Assess Cardiovascular Risk, continued


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**Summary of Medical Information**

It is clear that calcium scoring by all of these methods is highly sensitive in detecting coronary artery calcification, with most of the evidence coming from studies performed with EBCT; evidence from multislice CT is clearly only emerging. There may be meaningful differences in the different CT technologies, including the CT protocols, calcium-scoring algorithms, and radiation exposure; but this is not yet well delineated. Additionally, there are many indications for which calcium scoring is being studied, and an extensive literature base.

Multiple studies using EBCT have shown a strong correlation between calcium scores and quantities of atherosclerotic plaque; however, no study has yet reported the use of coronary calcium scores to improve the direct health outcomes of myocardial infarction or coronary death, much less the gold standard of all-cause mortality. This gap in evidence between the value of calcium scoring in predicting coronary risk and the improvement in direct health outcomes is brought into further question by two studies by O’Malley et al. that demonstrate that risk information obtained from calcium scoring may have no impact on CAD-related risk factors. If fact, case management may be more effective in changing risk factors and thus health outcomes.

There is a distinct lack of consensus in the literature about the value and role of CT-based calcium scoring, and perhaps fluoroscopy-based calcium scoring; with multiple clinical trials examining the use of such scoring in many different settings, followed by multiple editorial comments discussing the pros and cons of the studies and use of calcium scoring. Additionally, O’Malley et al.’s recent economic study suggests that calcium scoring by EBCT is very expensive given its expected benefits (i.e., > $50,000/QALY). In this study, the projected marginal cost per QALY is sensitive to many variables, but most sensitive to the marginal cost of identifying additional patients for whom it is appropriate to treat, the efficacy of primary prevention, and the utility of life with a diagnosis of being “at risk” for CVD and taking lifelong medications. These figures were based on data from published trials and, where data was absent, expert opinion. In any case, this cost estimate likely represents the best-case scenario; i.e., what would be expected in controlled settings and not the real world of unfettered medical practice.

ICSI, in its 2004 technology assessment, arrived at the following conclusions:

- No study has yet reported the use of coronary calcium scores to improve the direct health outcomes of myocardial infarction or coronary death
- In asymptomatic persons EBCT tests for CAC:
  - Are not recommended as a screening test in the absence of risk factors.
  - May be useful as a screening test if one or a few risk factors are present (intermediate risk patients) and the test could be helpful in determining the need to begin a primary prevention regimen.
  - Have been found to be better than conventional risk factors alone in predicting future coronary artery events in high risk patients (Conclusion Grade I based on Class B evidence). However, risk factor assessment and other non-invasive tests are more widely available. EBCT is not usually necessary to start primary prevention treatment when diabetes or multiple risk factors are present.
  - Are highly sensitive but not specific enough in the individual patient to use for diagnosis or exclusion of coronary obstruction or stenosis (Conclusion Grade II based on Class C and D evidence).
Cardiovascular Policies, Continued

Coronary Artery Disease Calcium Scoring (Cardiac CT Scan) to Assess Cardiovascular Risk, continued

- In patients with symptoms of coronary artery disease the issue is not primary prevention but diagnosis and management. For diagnosis of obstructive coronary artery disease, coronary artery calcification is a stronger independent predictor than risk factors. Direct comparisons of EBCT with other non-invasive tests for diagnosis are lacking.
- Serial EBCT calcium scores indicate that the development of coronary artery calcification is slowed during lipid-lowering therapy. The clinical significance of this is unknown.
- EBCT and helical CT are safe procedures; there is no direct harm to the patient. The potential for inappropriate and invasive follow-up must be considered.
- Practitioners should use caution when comparing calcium scoring from different types of scanners (helical CT and EBCT). The use of helical CT to assess coronary artery calcification is not as well documented as is EBCT. There is insufficient data on the predictive value of a calcium score calculated from a helical CT scan (Conclusion Grade III based on Class C and D evidence). Although there are no prognostic data comparing the results of helical CT or EBCT studies, there are differences between the procedures that would suggest that findings from EBCT studies cannot be applied to helical CT studies.
- Additional questions remain about the relationship between calcium scoring and the likelihood of coronary events because of the following factors:
  - Calcium does not collect exclusively at sites with severe stenosis
  - EBCT calcium scores do not identify the location of specific vulnerable lesions
  - Substantial non-calcified plaque is frequently present in the absence of coronary artery calcification
  - There are no proven relationships between coronary artery calcification and the probability of plaque rupture

In the July 2004 Hayes report on multislice CT, this CT method is given ‘D’ ratings “across the board” based, apparently, on Hayes view that while “the technology is safe and feasible in selected patients, there is no evidence of improved diagnosis or health outcomes as a result of its use”. Yet, in a separate Hayes report on EBCT, 2 indications are given ‘B’ ratings in spite of making the very same statements about lack of direct evidence of benefit. This apparent incongruence would suggest that it may be appropriate to question the Hayes’ ratings for these technologies (including helical CT). At best, the ‘B’ ratings can be assumed to be limited to evidence of indirect benefit rather than direct benefit to patient outcomes.

A 2004 study from the Mayo Clinic by Meissner et al. has suggested that the use of calcium scoring of coronary arteries may require rethinking. ‘There is some data to suggest that “aortic” atherosclerosis may not be an independent risk factor for vascular events in the general population.”

An updated literature review completed in February 2010 continued to identify shortfalls in the current literature. Though the ACCF/AHA published a consensus document in 2007 on role of CT calcium scoring is cardiovascular risk assessment, it only reviewed literature from 1998 to 2005 and acknowledged limitations to the published literature making evidence-based conclusions difficult to draw. Further, this document noted the lack of unanimity to the conclusions and that current literature lacked “the scientific rigor to be evaluated by the formal American College of Cardiology/American Heart Association (ACC/AHA) Practice Guidelines process.” This document essentially represents level III evidence.

Subsequent to the ACC/AHHA consensus document the additional published literature also fails to conclusively demonstrate the role of CT calcium scoring due to questions as to the sensitivity and specificity in assessing the presence of coronary artery disease in asymptomatic patients. This was demonstrated by Cheng et al. in their study evaluating low to intermediate risk asymptomatic patients. In this study nearly 10% of patients had significant CAD despite low calcium scoring. This finding was similarly demonstrated by Henneman et al. in 2008. In this study, though assessing symptomatic patients, 39% of patients demonstrated non-calcified plaques and only 14% had calcified plaques with 13% demonstrating no coronary calcium.

Ho et al., however, reached opposite conclusions, identifying a high level of correlation between coronary calcium burden and coronary stenoses. They found no significant coronary disease in patients without coronary calcium and concluded a CAC score > 400 was significantly associated with multidetector CT angiographic stenoses independently of traditional risk factors. Though not completely refuting this
Coronary Artery Disease Calcium Scoring (Cardiac CT Scan) to Assess Cardiovascular Risk, continued

perspective, Nucifora et al. showed a strong positive relationship between Framingham Risk Scores and the extent of atherosclerosis and yet only identified obstructive CAD in 155 of low risk patients and 43% of intermediate risk patients for patients with a CACS > 400.

Other studies assessing comparing CACS with physiologic testing for CAD also demonstrated similar sensitivity and specificity issues. For instance, Ramakrishna et al. found only a limited correlation between CACS and exercise echocardiography, noting even in patients with a CACS > 400 66% had normal stress echo studies. Inversely, Schenker et al. in their study of 95 intermediate risk patients demonstrated a low calcium score < 400 holds 21.7% chance of having an abnormal PET myocardial perfusion study. Sung et al. also showed this lack of correlation between CACS in 9% and introduced the concept that other variables such as age impact the findings of CT calcium studies. Sosnowski et al. suggest gender may also bias the findings.

A Medical Technology Assessment performed in December 2011 did not identify any new systematic reviews but did identify 12 primary studies related to CT calcium scoring. These studies failed to conclusively demonstrate the role of CT calcium scoring due to questions as to the sensitivity and specificity in assessing the presence of coronary artery disease in asymptomatic patients. For all the methodological strengths of the studies, there is still considerable question as to who should have CT calcium scoring.

It has yet to be proven definitively that a relationship between calcium scoring and future heart events exists because of the following factors:

- Calcium does not present necessarily in the same places as severe stenosis
- Calcium scores do not ascertain the exact locations of calcified plaques
- Non-calcified plaque is often present in the absence of coronary artery calcification
- There is no proven relationship between calcification and the prospect of plaque rupture

The evidence for the role of CT calcium scoring in risk assessment remains undefined. Though some studies demonstrate favorable correlation others show lower specificity for significant coronary artery disease and raise continued questions as to the value of this test in ruling out CAD in asymptomatic patients.

In a recent Hayes report (2017), evidence meeting inclusion criteria for effectiveness outcomes are composed of prospective cohort studies and randomized control trials (RCTs) enrolling 450 to 9715 asymptomatic adults each. Four of the cohort studies evaluated the incremental predictive value of CAC when added to global risk assessment instruments (primarily FRS) with respect to clinical outcomes at 5 to 15 years follow-up; 1 assessed its use instead of FRS at a median of 8.1 years follow-up. The RCTs evaluated whether using CAC and informing patients of the results led to improved clinical outcomes. These studies were not designed to address safety issues.

In conclusion, moderate-quality evidence strongly suggests that CAC improves predictive value and risk level classification compared with office-based risk assessment in asymptomatic adults. This benefit is particularly marked in asymptomatic adults initially classified as at intermediate risk of a CAD event. Among 3 studies, 44% to 66% of those initially classified were reclassified once CAC scores were considered. However, current evidence is insufficient and does not yet demonstrate that use of CAC scoring translates into improved clinical outcomes (i.e., reduced cardiac events).

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>75571</td>
<td>Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium</td>
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HCPCS CODES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>S8092</td>
<td>Electron beam computed tomography (Ultrafast CT, cine CT)</td>
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Key References


Coronary Artery Disease Calcium Scoring (Cardiac CT Scan) to Assess Cardiovascular Risk, continued


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HEART TRANSPLANT: ADULT

Policy # 125
Implementation Date: 2/10/99
Review Dates: 1/4/00, 2/27/01, 5/13/02, 5/25/03, 4/22/04, 4/17/06, 5/17/07, 4/24/08, 4/23/09, 8/19/10, 9/15/11, 4/25/13, 2/20/14, 3/19/15, 2/16/17, 10/4/18, 10/15/19, 6/17/21
Revision Dates: 5/30/04, 1/28/10, 2/14/12, 2/16/16, 10/12/17, 10/8/18, 12/10/21

Description
Cardiac transplantation remains the treatment of choice for many patients with end-stage heart failure (HF) with severely impaired functional capacity, despite optimal medical therapy. Although barriers to long-term survival remain, the outcome among transplant recipients has improved over several decades as a result of careful recipient and donor selection, advances in immunosuppression, and the prevention and treatment of opportunistic infections.

In the most recent registry report, the median survival for heart transplants performed between 1982 and June 2015 was 11 years for adult recipients and 16 years for pediatric recipients. Patient survival has steadily improved since the 1980s, with one-year survival rates now exceeding 85 percent for adult patients and 90 percent for pediatric patients transplanted in the most current era (2009 through June 2015). The major survival gains are limited to the first 6 to 12 months, with a long-term attrition rate of 3.4 percent per year thereafter, remaining largely unchanged. The improvement is probably larger than it appears since the risk profile of recipients and the age of donors continue to increase.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers adult heart transplants for patients meeting the plan criteria for coverage as outlined below. Transplantation benefits and coverage will be determined only after the review of the work-up from the requesting transplant team has been completed. The work-up will be covered only for approved organ transplants.

To qualify for coverage, adult candidates for transplant must meet EITHER of the following criteria (A or B) (except for special cardiac conditions*):

A. Approved if recommended by Intermountain Transplant Services

OR

B. Must meet ALL the following criteria:

1. The patient has end-stage cardiac disease that is irreversible and progressive, with limited life expectancy, and with no available reasonable alternative medical or surgical therapy; and
2. NYHA Class III or Class IV cardiac dysfunction (see below for definition of NYHA functional classifications); and

3. Must have at least ONE of the following diagnoses:
   a. Coronary artery disease/ischemic cardiomyopathy
   b. Idiopathic dilated cardiomyopathy
   c. Valvular heart disease
   d. Myocarditis
   e. Restrictive cardiomyopathy
   f. Congenital heart disease
   g. Adriamycin cardiomyopathy
   h. Peripartum cardiomyopathy
   i. Hypertrophic cardiomyopathy
   j. Infiltrative cardiomyopathy—only if confined to heart (if not, it is an absolute contraindication)
   k. Chagas Disease
   l. *Unresectable Primary Cardiac Tumor
   m. *Intractable life-threatening arrhythmias
   n. *Severe cardiac allograft vasculopathy
   o. When pulmonary hypertension exists, pulmonary vascular resistance less than or equal to 5 wood units, with or without afterload reduction (e.g., Nitroprusside, etc.)

4. A reasonable expectation that the patient's quality of life, i.e., physical and social function suited to activities of daily living, will be improved

5. Strong motivation by the patient to undergo the procedure and a thorough understanding by the patient and family of the magnitude of the operation, its risks, and sequelae, including lifetime follow-up

6. Medical assessment that the patient will have a tolerance for immunosuppressive therapy and that no other major system disease or anomaly is present which would preclude surgery or a reasonable chance of survival

7. Medical and social assessment that the patient has sufficient social stability to provide assurance that they will cooperate with the long-term follow-up and the immunosuppressive program, which is required

8. No uncontrolled and/or untreated psychiatric disorder that would interfere with compliance to a treatment regimen
Cardiovascular Policies, Continued

Heart Transplant: Adult, continued

9. Age at time of transplant listing: > 18 and ≤ 70 years

*Peripheral vascular disease is a relative contraindication for transplantation when its presence limits rehabilitation and revascularization is not a viable option

Absolute Contraindications:

1. Severe, irreversible pulmonary hypertension

2. Pulmonary disease as listed below:
   a. Cystic fibrosis
   b. Obstructive pulmonary disease (FEV < 65% of predicted)
   c. Restrictive pulmonary disease (FVC < 50% of predicted)
   d. Unresolved pulmonary roentgenographic abnormalities of unclear etiology
   e. Unresolved pulmonary infarction

10. Vascular disease

11. Unresolved GI bleeding

12. Unresolved diverticulitis

13. Irreversible liver disease

14. Hepatitis B antigen positivity

15. Untreated positive Hepatitis C serology with severe pathology on liver biopsy and/or elevated transaminases

16. Active malignant disease

17. Active infection

18. Neuromuscular disorders with physical limitations impacting survival/QOL post-transplant

19. Acute psychiatric illness

20. Past alcohol or substance abuse unless successful counseling and follow-up documented along with documented abstinence (usually greater than 3 months)

21. History of medical non-compliance

Relative Contraindications:

22. History of psychiatric illness

23. Morbid obesity (Body Mass Index > 35 kg/m²)
24. Renal insufficiency as manifested a creatinine clearance below 30 mL/min. The concern in this setting is the superimposed nephrotoxicity of long-term cyclosporine therapy.

25. HIV positivity (can be considered if ALL the following):
   a. No active or prior opportunistic infections or CNS lymphoma, or visceral Kaposi sarcoma,
   b. Clinically stable and compliant on combination antiretroviral therapy (cART) for 3 months,
   c. Have undetectable HIV RNA and have CD4 counts > 200 cells/µl for > 3 months).

26. Advanced hepatic disease. Cirrhosis, for example, can limit survival and increase perioperative morbidity, particularly if a coagulopathy is present.

27. Diabetes mellitus with end-organ dysfunction (other than non-proliferative retinopathy), chronic infections, leg ulcers, or persistent poor glycemic control (HbA1C > 7.5% despite optimal effort)

Several other conditions increase the rate of perioperative complications or interact poorly with immunosuppressive agents. Included in this group are advanced peripheral vascular disease, morbid obesity, active peptic ulcer disease, cholelithiasis, and diverticulosis.

All cardiac transplantation candidates should undergo a complete psychosocial evaluation during the initial screening process. This may identify social and behavioral factors that cause difficulty during the waiting period, convalescence, and long-term post-operative management. The patient must understand that full cooperation and compliance are critical to the safe and effective use of immunosuppressive agents.

Finally, patients must be screened for the use and abuse of alcohol and other recreational drugs. Active drug or alcohol abuse should be considered an absolute contraindication for transplantation. Although post-transplant recidivism is a frequent occurrence in patients in "recovery," survival may not be reduced.

New York Heart Association (NYHA) Functional Cardiac Classifications:

28. Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.

29. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.

30. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.

31. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.
Cardiovascular Policies, Continued

Heart Transplant: Adult, continued

SelectHealth Advantage (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 SelectHealth 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

SelectHealth 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 SelectHealth 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

In 2001, the Clinical Practice Committee of the American Society of Transplantation published recommendations for considering transplantation in patients with cardiac conditions that have not responded to maximal medical management.

Improved survival should be the primary indication for cardiac transplantation and the primary selection task is to predict the prognosis in severe heart failure. Many predictors of poor prognosis have been identified, including NYHA functional class III or IV, reduced left ventricular ejection fraction (LVEF), and hyponatremia. However, there is sufficient overlap that these factors are of limited use in a particular individual. This is not surprising in view of the complexity of HF and the multiple neurohumoral, hemodynamic, and electrophysiological factors that may contribute to morbidity and mortality.

In general, the peak VO2 appears to provide the most objective assessment of functional capacity in patients with HF, and may be the best predictor of when to list an individual patient for cardiac transplantation. The 2002 task force of the ACC/AHA has given a class I recommendation to the use of exercise testing with ventilator gas analysis for this purpose.

The value of using the peak VO2 for this purpose is illustrated by a study of 114 consecutive ambulatory patients with advanced disease referred for possible cardiac transplantation. Three groups of patients were prospectively divided and had their outcomes compared based on their VO2 outcomes. They were comparable with regards to other clinical parameters of disease severity, including NYHA functional class, LVEF, and cardiac index. The 1-year survival of the healthier patients in group 2 was 94%, an outcome that was similar to that in transplanted patients in group 1. The prognosis was poorest in group 3, although survival varied with the peak VO2 in this group. Patients with a value less than or equal to 10 mL/kg per min had the lowest survival, while those between 10–14 mL/kg per min had an outcome that was only slightly worse than patients in group 1. Thus, patients with a profoundly reduced exercise capacity of 10 mL/kg per min are likely to experience the most pronounced improvement in survival with transplantation.

The small survival benefit seen for group 3 patients with a peak VO2 of 10–14 mL/kg per min illustrates the difficulty in selection of patients for transplantation. Many of these patients will benefit from transplantation, particularly those with a peak VO2 of 12 mL/kg per min. Patients in this intermediate range of peak VO2 who are initially considered too well for transplantation should have several measurements of exercise capacity over a period. Some will improve on repeated testing, but those with persistent values of 10–12 mL/kg per min and poor exercise tolerance should generally be considered for transplantation. Repeated hospitalization and/or the requirement for increasing medical therapy are additional indicators of likely benefit from transplantation.

It must be emphasized that these observations and recommendations for transplantation are applicable only if a severely reduced peak VO2 is caused by HF. Proper interpretation of the test requires that the patient achieve the anaerobic threshold, indicating that the level of exercise performed exceeded that
which can be supported by the cardiovascular system on an aerobic basis. Factors that can prematurely terminate the test must be excluded, including significant peripheral vascular disease, arthritis, or angina pectoris. The peak VO$_2$ should also be interpreted in light of the patient's age, lifestyle, and expectations. A peak VO$_2$ of 14 mL/kg per min may represent mild impairment to a 60-year-old patient, but marked impairment to a 20-year-old patient.

Although peak VO$_2$ is generally used to guide the selection of heart transplant candidates, a single variable cannot provide an optimal risk profile. As a result, several risk models have been developed that use factors identified in multivariable survival analysis to establish a risk score for prognosis in these patients.

One model that has been validated prospectively is the Heart Failure Survival Score (HFSS). This score was derived from a multivariable analysis of 268 ambulatory patients referred for consideration of cardiac transplantation and validated in 199 similar patients. Seven variables were used as predictors of survival in the HFSS. These include the presence or absence of coronary artery disease, resting heart rate, left ventricular ejection fraction, mean arterial blood pressure, presence or absence of an interventricular conduction delay on ECG, serum sodium, and peak VO$_2$. In an invasive version of the HFSS, pulmonary capillary wedge pressure is included as an eighth variable. The HFSS then stratifies patients into low-, medium-, and high-risk categories, based upon a sum of the variables above multiplied by defined coefficients. Among the patients in the validation sample, one-year survival rates without transplant for these three strata were 88%, 60%, and 35%, respectively. Other risk models exist and are used by various centers to assess patients' candidacy for heart transplantation.

Although the most common indication for heart transplantation is severe HF refractory to medical therapy, the operation may be recommended in other circumstances. These include severely limiting ischemia not amenable to interventional or surgical revascularization, recurrent symptomatic ventricular tachyarrhythmias refractory to medical therapy, an implantable cardioverter-defibrillator, surgery, and rarely, for the management of cardiac tumors.

Even the patient who meets the above requirements must be excluded from transplantation when one or more absolute contraindications are demonstrated by standard evaluation procedures. In addition, relative contraindications must be considered in judging whether a patient is likely to benefit from heart transplantation. Absolute contraindications include pulmonary vascular resistance (PVR) greater than 4–6 Wood units (320–480 dynes-sec/cm$^2$) (normal 1.5 Wood units [120 dynes-sec/cm$^2$]) or a transpulmonary gradient (mean pulmonary artery pressure minus mean pulmonary capillary wedge pressure) above 15 mmHg have an increased risk of right ventricular failure in the immediate postoperative period.

Patients whose PVR can be pharmacologically reduced to below 4 Wood units (320 dynes-sec/cm$^2$) are usually considered acceptable for transplantation. In one report, for example, the 3-month mortality rate was higher in patients whose PVR was above 2.5 Wood units compared to those with lower values (17.9% versus 6.9%). However, the 3-month mortality was only 3.8% in those with initially high values that were reduced by nitroprusside, compared to 41% and 28%, respectively, in those who were resistant to nitroprusside or who only responded at a dose that caused systemic hypotension. None of the patients with reversible pulmonary hypertension developed right ventricular failure after transplantation.

Two other absolute contraindications to transplantation are active infection and malignancy of any kind, both of which can be worsened by the immunosuppressive therapy given to prevent transplant rejection. Heart transplantation in patients with clinically important chronic viral infection remains a subject of active debate. Individuals with chronic hepatitis B or hepatitis C infections who undergo heart transplantation have an increased frequency of liver disease. However, it has been difficult to show that survival after heart transplantation is poorer in the presence of positive hepatitis B or C serology. As a result, practices of individual centers differ. Since the frequency of progressive liver disease appears to be more common with hepatitis B than with hepatitis C, many transplant programs will accept candidates who are anti-HCV antibody positive, but not those who are HBsAg positive.

HIV infection has been considered to be an absolute contraindication to heart transplantation, primarily because of concerns about the increased frequency of infectious and malignant complications and the previously poor survival of such patients. However, the advent of highly active antiretroviral therapy has changed the prognosis of HIV. As a result, the view has been expressed that HIV infection itself should not be sufficient reason to refuse transplantation.

Among the relative contraindications to cardiac transplantation, age has historically been a major factor. Many programs have routinely excluded patients over the age of 60–65. However, carefully selected...
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HIV infection has been considered to be an absolute contraindication to heart transplantation, primarily because of concerns about the increased frequency of infectious and malignant complications and the previously poor survival of such patients. However, the advent of highly active antiretroviral therapy has changed the prognosis of HIV. As a result, the view has been expressed that HIV infection itself should not be sufficient reason to refuse transplantation.

Among the relative contraindications to cardiac transplantation, age has historically been a major factor. Many programs have routinely excluded patients over the age of 60–65. However, carefully selected
Heart Transplant: Adult, continued

33945
Heart transplant, with or without recipient cardiectomy

HCPCS CODES

Not covered: Investigational/Experimental/Unproven for this indication

S2152 Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and post-transplant care in the global definition

S9975 Transplant related lodging, meals and transportation, per diem

Key References


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HEART TRANSPLANT: CHILDREN (UNDER AGE 18)

Policy # 126
Implementation Date: 2/10/99
Review Dates: 1/4/00, 2/27/01, 5/13/02, 6/25/03, 4/22/04, 4/19/05, 4/20/06, 8/23/07, 8/21/08, 8/13/09, 9/15/11, 10/24/13, 10/23/14, 10/15/15, 2/16/17, 2/15/18, 2/5/19, 2/13/20, 2/18/21, 1/13/22
Revision Dates: 9/15/06, 8/19/10, 2/16/16, 2/26/20, 1/27/22

Description
Worldwide, > 700 pediatric heart transplantation procedures are performed each year, representing about 12% of the total number of heart transplants performed. Most pediatric heart transplantation programs now have 5-year survival rates in excess of 80%.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers heart transplant in children under age 18 who meet EITHER of the following criteria (A or B).

A. Approved if recommended by Intermountain Healthcare Transplant Team;

OR

B. For services being requested outside of Intermountain Healthcare, guidelines for coverage include ALL the following:

1. The patient was evaluated and accepted for transplant by a paneled transplant team; and
2. The patient has end-stage cardiac disease, which is irreversible and progressive, a limited life expectancy or documented progressive (but partially reversible) pulmonary hypertension, or both, and no available reasonable alternative medical or surgical therapy; and
3. The patient suffers from New York Heart Association (NYHA) Class III or Class IV cardiac dysfunction - when criteria can be applied (see below for definition of NYHA Classes) despite maximal medical therapy; and
4. ONE of the following diagnoses:
   a. Cardiomyopathy
   b. Inoperable congenital heart disease, for which there is no reasonable corrective operation
Cardiovascular Policies, Continued

Heart Transplant Children: Under Age 18, continued

c. Myocarditis
d. Cardiac tumor

5. Pulmonary vascular resistance < 6 wood units with Nitroprusside or other vasodilators. (Does not apply to infancy); and

6. A reasonable expectation that the patient's quality of life, i.e., physical and social function suited to activities of daily living, will be improved; and

7. Strong motivation and emotional stability of parent/guardian, a thorough understanding by the patient and family of the magnitude of the operation and its sequelae, including lifetime follow-up; and

8. Medical assessment that the patient will have a tolerance for immunosuppressive therapy and that no other major system disease or anomaly is present which would preclude surgery or a reasonable survival; and

9. Medical and social assessment that the parent/guardian and child have sufficient social stability to provide assurance that he/she will cooperate with the long-term follow-up and the immunosuppressive program which is required; and

10. No uncontrolled and/or untreated psychiatric disorder that would interfere with compliance to a treatment regimen; and

11. Child is > 36 weeks gestational age and weight > 2.2 kilograms.

Absolute Contraindications

1. Severe pulmonary hypertension (PA pressure) or pulmonary vascular resistance (PVR) greater than 6 Wood units/m2, with inability of medications to reduce PVR and PA pressure to acceptable levels

2. Recent pulmonary infarct

3. Persistent acidosis with pH less than 7.1

4. Irreversible and severe renal, hepatic, CNS or pulmonary dysfunction.

5. Active/unresolved alcohol or drug abuse.

6. Active malignancy or history of malignancy with high rate of recurrence

Relative Contraindications

1. Psychosocial considerations as listed below:
   a. Strong history of parent/guardian alcohol and/or substance abuse.
   b. Documented parent/guardian child abuse or neglect.
   c. Family unable to support long-term medical needs of recipient.
   d. Parent/guardian with cognitive/psychiatric impairment severe enough to limit comprehension of medical regimen.
   e. Documented parent/guardian and/or patient noncompliance with previous medical care.

2. HIV positivity (transplant can be considered if ALL the following)
   a. No active or prior opportunistic infections or CNS lymphoma, or visceral Kaposi sarcoma,
   b. Clinically stable and compliant on combination antiretroviral therapy (cART)
   c. Have undetectable HIV RNA and have CD4 counts > 200 cells/μl for > 3 months.

3. Diabetes mellitus, with A1C levels > 8
Heart Transplant Children: Under Age 18, continued

**SelectHealth Advantage (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 SelectHealth 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&](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&) or the manual website.

**SelectHealth Community Care (Medicaid)**

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**Summary of Medical Information**

The 4 main etiologies leading to conditions that might require heart transplantation are errors in the formation of the heart, cardiac tumors, infections, and toxins (either endogenous or exogenous), leading to damage to the myocardium. Many of the congenital anomalies, including congenital cardiomyopathy, are now known to have specific chromosomal abnormalities associated with them.

Conditions considered for pediatric heart transplantation include the following:

- Cardiomyopathy (i.e., dilated, hypertrophic, restrictive)
- Anatomically uncorrectable congenital heart disease (e.g., HLHS, pulmonary atresia with intact ventricular septum plus sinusoids, congenitally corrected transposition of the great arteries with single ventricle and heart block, severely unbalanced atrioventricular septal defects)
- Congenital heart disease at high risk for repair (e.g., severe Shone complex, interrupted aortic arch and severe subaortic stenosis, critical aortic stenosis with severe endocardial fibroelastosis, Ebstein anomaly in a symptomatic newborn)
- Refractory heart failure
- Unresectable symptomatic cardiac neoplasms

**Billing/Coding Information**

**CPT CODES**

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<td>33940</td>
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<td></td>
<td>transplantation, including dissection of allograft from surrounding soft</td>
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<td></td>
<td>tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary</td>
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<td>artery, and left atrium for implantation</td>
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<tr>
<td>33945</td>
<td>Heart transplant, with or without recipient cardiectomy</td>
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**HCPCS CODES**

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<td>donor(s), procurement, transplantation, and related complications; including: drugs; supplies;</td>
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<td>hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and</td>
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<td></td>
<td>rehabilitative services; and the number of days of pre- and post-transplant care in the global</td>
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</table>
Cardiovascular Policies, Continued

Heart Transplant Children: Under Age 18, continued

Key References


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HEART-LUNG TRANSPLANT

Policy # 127

Implementation Date: 2/10/99

Review Dates: 1/4/00, 2/27/01, 5/21/01, 5/13/02, 6/25/03, 4/22/04, 4/22/05, 8/23/07, 8/21/08, 8/13/09, 8/19/10, 9/15/11, 7/18/13, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/13/19, 6/18/20, 3/15/22

Revision Dates: 9/15/06, 3/29/22

Description
Cardiopulmonary transplantation (heart and lung transplantation) is the simultaneous surgical replacement of the heart and lungs in patients with end-stage cardiac and pulmonary disease. This procedure remains a viable therapeutic alternative for patients in specific disease states, although the frequency of application has substantially diminished in recent years.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers heart-lung transplantation with limitations as outlined below (either A or B must be met).

A. Heart-Lung Transplantation will be approved if recommended by Intermountain Healthcare Cardiovascular Clinical Program, or

B. For clinicians outside of Intermountain Healthcare, all the following criteria must be met:
   1) Provided by In-Network Providers in an In-Network Facility* unless otherwise approved in writing in advance by SelectHealth; and
   2) Review of the transplant team demonstrates that patient has a significant and reasonable probability for improved health post-transplant; and
   3) Transplant is not being performed as part of an investigational trial; and
   4) Patient has severe cardiopulmonary disease which is refractory to standard-of-care therapy.

*This criterion does not apply to Idaho commercial plans. Members on Idaho commercial plans may use their out-of-network benefits with an out-of-network provider if all other criteria are met.
SelectHealth Advantage (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 SelectHealth 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.

SelectHealth 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 SelectHealth 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

The International Society Heart and Lung Transplantation (ISHLT) summarized the distribution of diagnoses leading to heart-lung transplantation from 1988 to 2019. The 3 leading indications were:

- Nonidiopathic pulmonary arterial hypertension due to congenital heart disease or cardiomyopathy: 38%: 32%
- Idiopathic pulmonary arterial hypertension: 28.4%
- Cystic fibrosis: 15%

Heart-lung transplantation may also be required in patients with end-stage parenchymal lung disease who also have severely compromised left ventricular function (e.g., sarcoidosis).

The updated joint guidelines from the American Thoracic Society/American Society for Transplant Physicians/European Respiratory Society and the ISHLT guidelines does not suggest an age limit for heart-lung transplantation. Among patients with severe lung disease, referral for heart-lung transplantation should be made if the patient is a New York Heart Association (NYHA) class III or IV heart failure despite optimal surgical and medical treatment. Malignant ventricular arrhythmias not amenable to pharmacologic or electrophysiologic interventions (including an implantable cardioverter-defibrillator) in patients with end-stage lung disease are rare indications for the combined procedure.

Patients with idiopathic pulmonary arterial hypertension with preserved left ventricular function are best treated with double-lung transplantation.

Combined heart-lung transplantation is the preferred procedure for patients with complex congenital heart disease with Eisenmenger syndrome, including those with single ventricle anatomy, unsuccessfully repaired or uncorrectable lesions, and/or severely depressed left ventricular function.

On the other hand, bilateral lung transplantation with repair of the congenital defect is the recommended procedure in patients with simple congenital heart disease. These lesions include:

- Atrial or ventricular septal defect
- Scimitar syndrome
- Pulmonary venous stenosis
- A functionally inadequate vascular bed as with multiple peripheral pulmonary arterial stenoses or pulmonary arteriovenous malformations.

Orthotopic heart transplantation alone has been performed in patients with congenital heart disease and a physiologic single lung (e.g., unilateral pulmonary venous stenosis, or due to previous aortopulmonary shunt procedure). Heart-lung transplant recipients receive an "en bloc" harvested heart and lung allograft and can be listed under both the lung and heart allocation systems. The lung allocation system in the United States was changed by United Network for Organ Sharing (UNOS) in 2018 (https://optn.transplant.hrsa.gov/policies-bylaws/policies/).
### Cardiovascular Policies, Continued

#### Heart-Lung Transplant, continued

**Billing/Coding Information**

**CPT CODES**

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<td>33930</td>
<td>Donor cardiectomy-pneumonectomy (including cold preservation)</td>
</tr>
<tr>
<td>33933</td>
<td>Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation</td>
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<tr>
<td>33935</td>
<td>Heart-lung transplant with recipient cardiectomy-pneumonectomy</td>
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<tr>
<td>33940</td>
<td>Donor cardiectomy (including cold preservation)</td>
</tr>
<tr>
<td>33944</td>
<td>Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation</td>
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<tr>
<td>33945</td>
<td>Heart transplant, with or without recipient cardiectomy</td>
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**HCPCS CODES**

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<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>S2054</td>
<td>Transplantation of multisviseral organs</td>
</tr>
<tr>
<td>S2055</td>
<td>Harvesting of donor multisviseral organs, with preparation and maintenance of allografts; from cadaver donor</td>
</tr>
<tr>
<td>S2060</td>
<td>Lobar lung transplantation</td>
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<tr>
<td>S2061</td>
<td>Donor lobectomy (lung) for transplantation, living donor</td>
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<td>S2152</td>
<td>Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and post-transplant care in the global definition</td>
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**Key References**


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Description
The implantable loop recorder (ILR) is an implantable, self-sensing, and/or patient-activated monitoring system that records electrocardiography data. It is designed to diagnose a cardiac cause of syncope when the standard work-up, including non-invasive tests, is not diagnostic. Electrodes in the device sense the heart's activity through human tissue, so there is no need for any intravenous leads. When symptoms occur, the patient uses an external activator device to record electrocardiogram (ECG) data for analysis by a physician; the Reveal® Plus device has an autosensing feature that can be programmed to automatically begin recording when it senses an arrhythmia. The monitor can store up to 40 minutes of preceding signals after an episode of spontaneous syncope. The device is removed after the battery has failed, or earlier, if a definitive diagnosis has been established.

The ILR is implanted subcutaneously under local anesthetic in a single incision procedure in a left pectoral or mammary location. The projected life of the battery is approximately 24 to 36 months. The manufacturer recommends that the device be explanted (removed) when it is no longer clinically necessary, or when the battery is depleted. The electrodes are self-contained within the recorder. The ILR system consists of the following elements:

1. A subcutaneously placed, programmable cardiac event recorder with looping memory.
2. A handheld telemetry unit; which is used by the patient to activate electrocardiographic storage.
3. A programmer; which is used to program the event recorder and retrieve, display, and print stored data.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)
SelectHealth covers implantable loop recorders.

SelectHealth Advantage (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 SelectHealth 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.
Cardiovascular Policies, Continued

Implantable Loop Recorder (ILR), continued

SelectHealth Community Care (Medicaid)

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Summary of Medical Information

Syncope is the abrupt and transient loss of consciousness associated with absence of postural tone, followed by a rapid and usually complete recovery. This symptom is alarming for the individual, witnesses, family, and physicians. Although syncope can be a harbinger of a multitude of disease processes and can mimic the appearance of a cardiac arrest, it is most often benign and self-limited. Nevertheless, injuries associated with syncopal attacks occur in 35% of patients, and recurrent episodes can be psychologically devastating. In addition, syncope can be a premonitory sign of sudden cardiac death, especially in patients with organic heart disease.

The common pathway of all forms of syncope is a sudden decrease or brief cessation of cerebral blood flow. The causes can be classified into 7 main groups: unknown origin (estimated 34% of total), neurally-mediated (24%), cardiac (18%), neurological (10%), orthostatic hypotension (8%), medication-related (3%), and psychiatric disorders (2%). Since a syncopal episode can occur without warning, it sometimes causes injuries due to falls and other accidents.

Syncope is common and accounts for around 6% of all hospital admissions and 3% of emergency room visits. Forty-three percent of patients experience recurrent syncope with an approximate 5% first year mortality in patients with unexplained syncope. Moreover, it does not always have a benign course, with mortality rates up to 33% at one year in patients with a structural cardiac disorder. In addition, costs for investigation for syncope ("diagnostic odysseys") are substantial, and about 25% of all patients remain undiagnosed.

A major problem in the diagnosis of the underlying cause is that syncope is a transient symptom and not a disease. Typically, patients are asymptomatic at the time of assessment, and thus, the likelihood of capturing a spontaneous event during diagnostic testing is low. The cause of syncope is not determined after history, physical examination, or surface ECG, in 38–47% of patients. Even after further referral for tilt-table and electrophysiological testing, 10%–26% of patients will remain undiagnosed. Other tests that can be employed include 24–48-hour halter or prolonged cardiac monitoring.

Ambulatory event monitors (AEMs) were developed to provide longer periods of monitoring and may be useful when the initial evaluation is non-diagnostic or when symptoms are infrequent. Ambulatory event monitors (AEMs) are intermittent recorders that can be used for longer periods (weeks to months) of monitoring to provide briefer, intermittent recordings to investigate events that occur infrequently. Intermittent recorders can be worn continuously or be attached by the patient when symptoms occur. They are activated after the onset of symptoms. Some recorders are implanted under the skin for long-term recordings (Medtronic's Reveal implantable loop recorder). Ambulatory event monitors are useful if symptoms are quite brief, or if symptoms include only very brief or no patient incapacitations, so that the patient, or a companion, can activate the recorder. These devices are often capable of downloading data trans-telephonically.

There are several types of AEMs available:

1. Noncontinuous devices with memory. These devices are carried by the patient and applied to the precordial area when symptoms occur (e.g., HeartCard Cardiac Event Recorder). The limitations are that an arrhythmia may be of short duration and not captured by the device or the patient may be incapacitated and unable to apply the device while symptomatic.

2. Continuous memory loop devices. These devices are worn continuously and can continuously store EKG data so that when symptoms occur, the patient activates the device, and the EKG is recorded from the memory loop for the preceding 30–90 seconds and approximately 1 minute after.

3. Implantable continuous memory loop devices. These devices are inserted under the skin in the chest area during an outpatient surgical procedure. When symptoms occur, the patient activates the handheld activator over the recorder to activate the storage of cardiac rhythms; the newest
Implantable Loop Recorder (ILR), continued

The current generation of this device (Medtronic's Reveal Plus) also has an autosensing feature. The device may be used for more than 1 year's duration and has a projected battery life of 14 months, at which time the device must be surgically removed.

Current published evidence consists of numerous case series and studies and several controlled trials; and at least 1 economic study. Additionally, there is an abstract of a relatively large (n = 201) randomized trial (EaSyAS) reported at the European Society of Cardiology annual meeting in 2002.

With the exception of the EaSyAS trial, virtually all of the biggest available trials and several smaller series, including the economic trial, were sponsored by the manufacturer (Medtronic) and the authors are part of the (Medtronic) Reveal Investigators group. Additionally, these studies are not without flaws. That being said, both the RCTs and case studies consistently demonstrate substantial improvements in diagnostic yield (i.e., of recurrent, unexplained syncope), in an assortment of patient populations. However, both the Krahn randomized trial and the EaSyAS trial demonstrated no difference in patient outcomes and the EaSyAS trial also demonstrated increased treatment costs (without a significant difference in outcomes). Krahn et al. demonstrated dramatic improvements in costs per diagnosis; however, this trial must be interpreted with caution due to the authors' affiliations with Medtronic. The EaSyAS trial demonstrated increased costs for treatment in the ILR group vs. conventional work-up of a recurrent, unexplained syncope population. Thus, there are probable substantial improvements in diagnostic yield, possible reductions in diagnostic costs in, as yet, ill-defined patient populations; but little direct evidence of improved patient outcomes and some evidence of increased costs for treatment (without improvements in patient outcomes). Many questions remain, however, about just who these patients are, and which of them would benefit from a diagnosis. As Noll stated in Internal Medicine News: "We have a diagnosis in these patients, but we are not able to treat them appropriately. This raises the question, then, of whether we really need to diagnose these patients if there are no good methods to influence outcome."

Billing/Coding Information

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<td>93291</td>
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<td>93298</td>
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<td>93299</td>
<td>Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results</td>
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<td>E0616</td>
<td>Implantable cardiac event recorder with memory, activator, and programmer</td>
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</table>

**Key References**

Implantable Loop Recorder (ILR), continued


22. Sulke N. Eastbourne Syncope Assessment Study (EASYAS). European Society of Cardiology XXIV Annual Meeting. Berlin, 8/31 - 9/4/02

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INTIMA-MEDIA THICKNESS (IMT) TESTING FOR THE ASSESSMENT OF HEART DISEASE RISK (HEART SCAN)

Policy # 238
Implementation Date: 9/14/04
Review Dates: 10/18/05, 10/19/06, 10/19/07, 12/18/08, 12/17/09, 12/16/10, 12/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/13/19, 6/18/20, 6/17/21

Description
Intima-media testing involves the application of B-mode ultrasound to the carotid artery to determine quantitative arterial intima-media wall thickness (IMT) of the artery. This is used as a surrogate to estimate intima-media wall-thickening in the coronary arteries. A relationship between common carotid artery intima-media thickness and angiographic presence and extent of coronary artery disease has been reported in several studies. These studies suggest that patients at high risk for an adverse coronary event can be identified early, before the patient is symptomatic through use of these surrogate markers. Data from a National Heart Lung and Blood Institute study indicates that carotid arterial IMT incorporates additional, independent information on prediction of coronary events beyond angiographic measurements of lumen narrowing.

Commercial Plan Policy/CHIP (Children's Health Insurance Program)
SelectHealth does NOT cover intima-media thickness (IMT) testing to assess cardiovascular risk in any population. This meets the plan’s definition of experimental/investigational.

SelectHealth Advantage (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 SelectHealth 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.

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Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for SelectHealth Commercial, SelectHealth Advantage (Medicare/CMS), and SelectHealth Community Care (Medicaid/CHIP) plans. Refer to the “Policy” section for more information.
Summary of Medical Information

The current state of the literature has clearly established that carotid IMT, with its numerous methods and sub sites (e.g., common, internal, bifurcation, maximal, mean/average), is highly correlated with a variety of traditional risk factors for coronary artery disease (CAD) as well as for CAD-related events (i.e., MI, stroke). The evidence supporting the belief that carotid IMT provides additional predictive capability beyond traditional risk factors is mixed; however, the weight of the evidence seems to suggest that indeed carotid IMT does provide some additional predictive capability beyond traditional risk factor assessment. One report suggests that IMT is equal in weight/value to nine separate traditional risk factors.

However, the predictive ability of carotid IMT seems to vary widely between subpopulations of people at elevated risk for CAD without a history of CAD-related events as a function of age, gender, and the presence and degree of other risk factors. Additionally, it is not clear whether the additional predictive capacity of carotid IMT would persist when adjusted for the entire risk factor profile now being proposed by Intermountain’s Cardiovascular Services group (which includes C-reactive protein and serum homocysteine in addition to the more traditional Framingham risk factors). To date, there have been no studies that have prospectively followed appropriate patient groups to determine whether the addition of carotid IMT to a standard and complete battery of risk factors (comparable to the profile now being advocated by Intermountain’s CV Services) changes treatment decisions and/or leads to meaningful improvements in patient outcomes.

Current literature evaluates IMT as a risk factor. However, no studies are available to assess IMT and treatment outcomes to reduce coronary cerebrovascular events or death from atherosclerosis.

Additional concerns/issues include:

- IMT “... is complex and expensive ...” (Nichols et al., 1999)
- “The differences in carotid-artery intima-media thickness between patients at high risk and those at low risk are too small for common clinical use (Nichols et al., 1999).”
- There seems to be consensus suggesting that carotid IMT is an early-to-intermediate or late-intermediate marker when atherosclerosis is still limited to the arterial wall, whereas coronary angiography measures atherosclerosis in its late stages. Traditional risk factors generally are measures (albeit indirect and sometimes weak) of the numerous factors at play throughout the process but their predictive capacity may diminish with age and advanced disease. Thus, the value of carotid IMT may be at its highest during the early-to-late “intermediate” period of atherosclerosis and less useful in the earliest and possibly latest stages of disease.
- “The association between IMT and risk of MI did not show a clearly linear pattern (Bots et al., Circulation 1997).” Thus, use of a linear algorithm may not be valid for this indication.
- IMT measurement protocols have yet to be standardized and concerns remain about quality control of IMT facilities outside of tightly-controlled clinical trials.
- Atherosclerosis is a focal, patchy disease, thus, measures of carotid IMT may not reflect the process in other vessels.
- “Whether increased common carotid intima-media thickness itself reflects local atherosclerosis is still a subject of debate. It may merely reflect an adaptive response of the vessel wall to changes in sheer stress, tensile stress, and blood flow and subsequent changes in lumen diameter (Bots et al., Circulation 1997).”
- “We believe that the primary ill effect is not the increase in carotid-artery thickness in itself, but rather the increase in the stiffness of the vessel that results from increased wall thickness and content (Nichols et al., 1999).”

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

0126T Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment

HCPCS CODES
INtima Media Thickness (IMT) Testing for the Assessment of Heart Disease Risk (Heart Scan), continued

No specific codes identified

Key References

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Description
There are many types of vascular diseases, and about 79 million Americans have one or more of them. One form of vascular disease is coronary artery disease (CAD) which affects about 14 million men and women in the United States. Peripheral vascular disease (PVD) refers to diseases of blood vessels outside the heart and brain. It’s often a narrowing of vessels that carry blood to the legs, arms, stomach, or kidneys. PVD can arise from a variety of problems such as chronic venous insufficiency or atherosclerosis. Peripheral artery disease (PAD) is a subset of organic PVD and the terms are sometimes used interchangeably. Estimates indicate that 8−10 million Americans (2.6%−3.2%) are affected by PAD.

A variety of invasive and noninvasive techniques may be used in determining the severity of CAD and PVD. Cardiac angiography (ICA), also known as cardiac catheterization is an invasive procedure, and is the gold standard for diagnosing CAD and is the primary method used to help delineate coronary anatomy. Other invasive tests include computed tomography (CT) angiography, cardiac MRI, angiography, and venography. Less invasive tests include cardiac MRI and nuclear imaging studies such as SPECT or PET.

The clinical evaluation for PAD is noninvasive and can be done in the office setting using the ankle-brachial index (ABI), a comparison of the systolic blood pressure (SBP) in the dorsalis pedis and posterior tibial arteries in the leg with the brachial artery of the arm. Other noninvasive tests include Doppler ultrasound, CT, and MRI. More invasive tests comprise of CT angiography (CTA) and MR angiography (MRA).

Intravascular ultrasonography (IVUS) is an invasive, catheter-based imaging procedure that uses sound waves to see inside the vessels within the body. IVUS provides a standard sonographic image to assess the lumen, the vessel wall, and the atherosclerotic process within the wall simultaneously. Ultrasound transmitted from the transducer will “bounce” back whenever it encounters an interface of different acoustic impedance. Acoustic impedance is primarily dependent upon the density of the tissue. Therefore, ultrasound emitted from the transducer will traverse the blood with minimal reflection but will be highly reflected when it meets the intima of the blood vessel. IVUS is useful in the catheterization laboratory when angiography alone cannot clarify the anatomy or the status after percutaneous vascular intervention adequately. It can also be used in the baseline assessment of a target lesion before a percutaneous vascular intervention. The most common way IVUS is used is to assess the adequacy of deployment of coronary stents, including the extent of the stent apposition and determination of the minimum luminal diameter within the stent.

Optical coherence tomography (OCT) is an imaging technique that uses near-infrared light to image the coronary arteries. Potential applications in cardiology include evaluating the characteristics of coronary artery plaques for the purpose of risk stratification and following coronary stenting to determine the success of the procedure.
Optical coherence tomography (OCT) has important similarities to intravascular ultrasound (IVUS), and also important differences. Ultrasound (US) uses acoustic waves for imaging, while OCT uses near-infrared electromagnetic light waves. OCT generates cross-sectional images by using the time delay and intensity of light reflected from internal tissue structures. The main obstacle to OCT is the difficulty of imaging through blood, necessitating saline flushes or occlusion techniques to obtain images. Frequency-domain OCT (FD-OCT) is a newer generation device that partially alleviates this problem by allowing faster scanning and less need for blood clearing.

Optical coherence tomography (OCT) is intended as an alternative to intravascular ultrasound (IVUS) for imaging the coronary arteries. Therefore, the most relevant type of studies in evaluating the utility of OCT includes a head-to-head comparison between OCT and IVUS. These studies are limited by the lack of a true gold standard for intravascular imaging but nevertheless can compare the frequency and type of findings between the two types of imaging. Single-arm case series of OCT provide less useful information. Results from case series can characterize the findings that are obtained from OCT, use these findings to predict future events, and then provide important information on adverse events. However, case series provide limited data on the comparative efficacy of OCT and IVUS.

### Commercial Plan Policy (No Preauthorization Required but criteria must be met)

SelectHealth covers intravascular imaging, such as intravascular ultrasound (IVUS) and optical coherence tomography (OCT) in coronary arteries as an adjunct to coronary angiography in limited circumstances.

#### Clinical circumstances in which IVUS and OCT is covered:

- As a method for both guidance of placement of endoluminal devices and immediate assessment of the results of intracoronary interventional procedures (e.g., angioplasty, atherectomy, stenting); including those performed on coronary grafts
- Assess anomalous coronary anatomy;
- As a conclusive study to assess suspected left main stem coronary artery disease not revealed by coronary angiogram

SelectHealth covers intravascular imaging for peripheral arterial and venous disease (non-coronary) as an adjunct to peripheral angiography, angioplasty with and without stent placement, and to guide the placement of intravascular vena cava filters.

SelectHealth does NOT cover intravascular imaging for screening of coronary artery disease, diagnosing coronary vulnerable plaques, and its use in other coronary procedures. This meets the plan’s definition of investigational/experimental.

### SelectHealth Advantage (Medicare/CMS) (No Preauthorization Required but criteria may apply if appropriate)

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Intravascular Imaging (i.e., Intravascular Ultrasound [IVUS] and Optical Coherence Tomography [OCT]), continued

SelectHealth Community Care (Medicaid/CHIP) (No Preauthorization Required but criteria may apply if appropriate)

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Although intravascular ultrasound devices have only been available for a relatively short time, an array of studies demonstrating numerous diagnostic and therapeutic applications in interventional cardiology has been reported. Numerous studies support IVUS as a safe, accurate, and reproducible method of detecting coronary vessel wall structure and disease and visualizing the dynamic changes before, during and after PCI. IVUS can differentiate coronary vessel wall components and types of atherosclerotic plaque which aids in determining what any treatment is indicated. This is especially helpful when angiography results are ambiguous. The maturity of the technology is such that IVUS currently has a place as a clinical decision-making tool in patients with symptoms and intermediate lesions, as a provisional study to assess left main stem disease suspected but not disclosed by coronary angiography, and as a method for both guidance of endoluminal devices and immediate assessment of the results of therapeutic techniques, including balloon angioplasty, atherectomy, and intravascular stent deployment.

Wellons et al. stated that reports have demonstrated the benefit of prophylactic inferior vena cava filter (IVCF) placement to prevent pulmonary embolism. This study evaluated the potential for the bedside placement of a removable IVCF under "real-time" IVUS guidance. A total of 20 trauma patients underwent intensive care unit placement of a removable IVCF with IVUS guidance. All patients had ultrasonography of the femoral veins after placement to rule out post-procedure femoral vein thrombosis and radiographs to identify filter location. Nineteen of 20 IVCFs were placed at approximately the L2 level as verified by radiography. One patient had a large IVC (34 mm) and underwent bilateral common iliac IVCF placement under IVUS. Within 3 weeks of placement, 12 IVCFs were retrieved. Of the remaining 8 patients, 6 had indications for permanent implantation, 2 had contralateral deep venous thrombosis, and 1 had ipsilateral deep venous thrombosis. The authors concluded that bedside insertion of a removable IVCF with IVUS guidance and its removal are simple, safe, and accurate. Fassman et al. stated that bedside placement of ICVF by using either trans-abdominal duplex ultrasonography or IVUS has been shown to be safe and effective. The authors reviewed techniques for bedside filter placement with trans-abdominal duplex ultrasonography, IVUS with dual venous access, and IVUS with single venous access. They noted that trans-abdominal duplex ultrasonography and IVUS remain their preferred techniques for filter placement when feasible, especially in critically ill and immobilized patients.

de Ribamar Costa et al. found the drug-eluting stent (DES) era, stent expansion remains an important predictor of re-stenosis and sub-acute thrombosis. Compliance charts are developed to predict final minimum stent diameter (MSD) and area (MSA). The objectives of the study were 2-fold: (i) to evaluate DES expansion by comparing IVUS-measured MSD and MSA against the values predicted by compliance charts and (ii) to compare each DES against its bare-metal stent (BMS) equivalent. These researchers enrolled 200 patients with de novo coronary lesions treated with single, greater than 2.5-mm Cypher (Cordis, Johnson & Johnson, Miami Lakes, FL) (sirolimus-eluting stent [SES], n = 133) or Taxus (Boston Scientific, Natick, MA) (paclitaxel-eluting stent [PES], n = 67) stent under IVUS guidance without another post-dilation balloon. They used a comparison cohort of 65 equivalent BMS (Express 2 [Boston Scientific], n = 37; Bx Velocity [Cordis, Johnson & Johnson], n = 28) deployed under similar conditions. The DES achieved only 7 % +/- 10% of predicted MSD and 66% +/- 17% of predicted MSA; this was similar for SES and PES. Furthermore, 24% of SES and 28% of PES did not achieve a final MSA of 5 mm² a consistent predictor of DES failure. The SES achieved 75% +/- 10% of predicted MSA vs. 75% +/- 9% for Bx Velocity (p = 0.9). The PES achieved 79.9% +/- 14% of predicted MSA vs. 79% +/- 10% for Express 2 (p = 0.8). Lesion morphology, arc and length of calcium, stent diameter and length, and implantation pressures did not affect expansion. The authors concluded that compliance charts fail to predict final MSD and MSA. A considerable percentage of DES does not achieve minimum standards of stent expansion. The DES and PES achieve similar expansion to their BMS platform, indicating that the polymer coating does not affect DES expansion in vivo. However, stent expansion cannot be predicted from pre-intervention IVUS lesion assessment.
The randomized TAXUS II trial evaluates the polymer-based paclitaxel-eluting Taxus stent in slow- and moderate-release formulations. Tsuchida et al. examined the consistency between angiographic and IVUS outcomes of late lumen loss (late loss) and neointimal growth to measure restenotic plaque load in Taxus and BMS. Serial angiographic and IVUS analyses were available in 155 event-free patients (BMS, n = 74; Taxus stent, n = 81) after the procedure, at 6 months, and at 2 years. For this sub-analysis, quantitative coronary angiographic (QCA) and IVUS measurements were used to derive late loss and neointimal volume. From after the procedure to 6 months, QCA and IVUS showed matching results for the 2 groups with significant decreases in late loss and neointimal volume in the Taxus versus the control group. From 6 months to 2 years, QCA and IVUS measurements also showed results similar to those in the control group, demonstrating neointimal compaction over time. However, in the Taxus group, QCA late loss showed a non-significant decrease from 6 months to 2 years, whereas IVUS neointimal volume increased. The authors concluded that although QCA and IVUS results were similar over the first 6 months, long-term assessment of changes in re-stenotic plaque load showed discrepant findings for the Taxus stent. These findings suggest the need for critical re-evaluation of current end points and the use of more precise techniques to detect lumen and stent boundaries.

Hoffmann and colleagues identified the impact of incomplete stent apposition (ISA) after drug-eluting stent implantation determined by IVUS on late clinical events is not well-defined. These researchers assessed the clinical impact of ISA after sirolimus-eluting stent (SES) placement during a follow-up period of 4 years. Intravascular ultrasound at angiographic follow-up was available in 325 patients (SES, n = 180; BMS, n = 145); IVUS images were reviewed for the presence of ISA defined as one or more unopposed stent struts. Frequency, predictors and clinical sequel of ISA at follow-up after SES and BMS implantation were determined. Incomplete stent apposition at follow-up was more common after SES (n = 45 [25%]) than after BMS (n = 12 [8.3%], p < 0.001). Canadian Cardiology Society class III or IV angina at stent implantation (odds ratio (OR) = 4.69, 95% CI 2.15 to 10.23, p < 0.001) and absence of diabetes (OR = 3.42, 95% CI 1.05 to 11.1, p = 0.041) were predictors of ISA at follow-up after SES placement. Rate of myocardial infarction tended to be slightly higher for ISA than for non-ISA patients. When only SES patients were considered, major adverse cardiac event free survival at 4 years was identical for those with and without ISA at follow-up (11.1% vs. 16.3%, p = 0.48). The authors concluded that ISA at follow-up is more common after SES implantation than after BMS implantation. Considering the current very sensitive IVUS definition, ISA appears to be an IVUS finding without significant impact on the incidence of major adverse cardiac events even during long-term follow-up.

Garcia-Garcia et al. stated that detection of coronary vulnerable plaques in vivo is essential for studying their natural history and assessing potential treatment modalities and, therefore, may have an important impact on the prevention of acute myocardial infarction and death. Currently, conventional grayscale IVUS, IVUS-virtual histology (IVUS-VH) and paleography data are being collected with the same catheter during the same pullback. A combination of this catheter with either thermography capability or additional imaging, such as optical coherence tomography or spectroscopy, would be an exciting development. Intravascular magnetic resonance imaging also holds much promise. To date, none of the techniques described above have been sufficiently validated and, most importantly, their predictive value for adverse cardiac events remains elusive. The authors noted that very rigorous and well-designed studies are needed for defining the role of each diagnostic modality. In this regard, Ibañez and colleagues consider IVUS as an investigational technique for the visualization as well as the compositional characterization of atheromatous plaques.

Clementi et al. noted that plaque reduction with the use of pioglitazone and statin combination therapy has been observed in carotid plaque. These researchers examined the effect of combination therapy with statins and pioglitazone on coronary plaque regression and composition with the use of IVUS and IVUS-VH. These investigators analyzed 29 plaques in 25 diabetic patients with angiographic evidence of non-significant coronary lesions with IVUS-VH. Patients were treated with 80 mg of atorvastatin and 30 mg of pioglitazone daily for 6 months. After 6 months of therapy, IVUS-VH of each lesion was re-acquired. Mean elastic external membrane volume was significantly reduced between baseline and follow-up (343.0 mm vs. 320.5 mm; p < 0.05) as was mean total atheroma volume (179.3 mm vs. 166.6 mm; p < 0.05). Change in total atheroma volume showed a 6.3% mean reduction. Areas of fibrous tissue, fibro-lipidic tissue and calcium decreased over the 6 months of follow-up, although not significantly. On the other hand, the necrotic core increased from 9% to 14% (p < 0.05). The authors concluded that these findings demonstrated that atorvastatin/pioglitazone association is able to induce significant regression of coronary atherosclerosis, acting on plaque composition. Moreover, they noted that their findings are preliminary results and will be confirmed in an ongoing randomized placebo-controlled multi-center trial.
Intravascular Imaging (i.e., Intravascular Ultrasound [IVUS] and Optical Coherence Tomography [OCT]), continued

An assessment prepared for the Agency for Healthcare Research and Quality concluded that currently, neither IVUS nor other imaging technologies can reliably identify vulnerable plaque prospectively, i.e., before rupture.

A Medical Technology Assessment performed in April 2012 focused on IVUS for peripheral vascular disease. The quantity and quality of literature detailing IVUS in peripheral vascular disease is limited compared with the use of IVUS in coronary artery disease.

Only 1 systematic review on IVUS in PVD was identified. This review from Australian Medical Services Advisory Committee published in 2002 combined data from coronary and peripheral IVUS. They concluded that despite being safe the cost effectiveness for IVUS had not been established.

Assessment of the literature found that IVUS in non-coronary PVD can be utilized in venous occlusion, placement of IVC filter, aortic dissection, aortic aneurysms, medium and small PVD and in totally occluded arterial vessels.

The most robust literature supporting IVUS has been published by Buckley et al. Between 1992-1995 52 patients with 71 limb procedures involving the iliac artery participated in a non-randomized study and followed prospectively. The mean time of follow up was 62 months for IVUS patients and 58 months for patients treated without IVUS. Patency rates were 100% at 3 and 6 years in the IVUS group and 82% and 69% respectively in the non-IVUS group. Also 23% of patients in the non-IVUS group required another procedure due to re-stenosis.

Other articles have shown a 1−4 mm underestimation by angiography compared with IVUS representing 62% of the patients studied. Forty percent of the stents used would have been under deployed if angiography were used alone. Many believe this scenario leads to failure of the endovascular intervention and re-stenosis within the follow-up period.

Additional benefits for IVUS may: 1) Limit radiation exposure; 2) Reduce the risk of acute renal failure in predisposed patients with CKD 2-4; 3) Avoid contrast in contrast-allergic patients; 4) Define vessel anatomy and pathology compared with angiography to enhance more accurate stent placement thus decreasing stent re-stenosis rates; 5) Assist the identification of the true lumen in aortic dissection. Many of these claims have not been documented in randomized controlled studies.

Countering the benefits of IVUS expressed by Kawasaki et al., and Dangas et al. other experts express caution with IVUS. Their concerns are the limited data supporting improved outcomes and the additional expense and time during the procedure when IVUS is utilized.

The literature demonstrates stent placement using IVUS guidance results in a statistically significant reduction in the number of patients that will require revision surgeries for ill-fitting or misplaced stents in the peripheral vascular system in comparison to patients in whom stents were placed using CTA. IVUS is able to more accurately demonstrate the extent of lesions in peripheral vessels than CTA and it appears to have good sensitivity and specificity for detection of plaque dissections and media rupture but lower sensitivity for the detection of plaque rupture or thrombus formation.

A smaller number of studies evaluate the clinical utility of OCT for follow-up evaluation post-stenting. Capodanno et al. (2009) compared OCT with IVUS for stent evaluation in 20 patients who had stent implantation 6 months prior. The parameters that were compared included stent length, vessel luminal area, stent area, and the percent of stent coverage with neoendothelial cells. The measurement of stent length was similar between IVUS and OCT (16.3 ± 3.0 mm vs. 16.2 ± 3.8 mm, p=0.82). However, the other measured parameters differed between groups. Vessel luminal area was significantly lower by OCT compared to IVUS (3.83 ± 1.60 mm² vs. 4.05 ± 1.44 mm², p=0.82), while stent area was significantly higher with OCT (6.61 mm²± 1.39 vs. 6.17 ± 1.07 mm², p<0.001). The percentage of tissue coverage was also higher with OCT (43.4 ± 16.1% vs. 35.5 ± 16.4%), suggesting that IVUS underestimates stent coverage compared with OCT.

Inoue et al. (2011) used OCT to evaluate 25 patients who had previously undergone PCI with drug-eluting stents. OCT was performed at a mean of 236 ± 39 days post-PCI. OCT identified neointimal coverage of the stent in 98.4% of cases. In 0.52%, there was evidence of stent malposition and a lack of neointimal coverage. Full neointimal coverage was evident in 37% of patients. In 7.2% of patients, there was evidence of a low-intensity area surrounding the struts, which is thought to be indicative of abnormal neointimal maturation. There were no intra-stent thrombi identified and no major complications of the procedure.

The use of OCT as a follow-up to stenting can determine the extent of neoendothelial covering within the first year of stenting. This parameter is predictive of future stent-related events and has been used as an
Intravascular Imaging (i.e., Intravascular Ultrasound [IVUS] and Optical Coherence Tomography [OCT]), continued

intermediate outcome in stenting trials. However, the clinical relevance of measuring stent neo-
endothelialization has not been demonstrated. While this might provide prognostic information, it is not
clear how management would be changed, or health outcomes improved.

As an adjunct to PCI, OCT may improve upon the ability of IVUS to pick up clinically relevant
abnormalities, and this may lead to changes in management. A single small RCT did not report any
advantage of OCT over IVUS for achieving optimal stent placement. Overall, the current evidence is
limited and includes relatively small numbers of patients who have been evaluated by OCT. As a result, it
is not possible to determine the degree of improvement with OCT, or the clinical significance of this
improvement. Therefore, the use of OCT as an adjunct to PCI is considered investigational.

For the indications of risk stratification of coronary plaques and follow-up of stenting, OCT may also be
more accurate than IVUS for imaging of superficial structures. However, the clinical utility of IVUS has not
been demonstrated for these indications, since test results do not lead to changes in management that
improve outcomes. Therefore, clinical utility has not been demonstrated for OCT for the same reasons.
As a result, OCT is considered investigational for risk stratification of coronary plaques and for follow-up
post-stent implantation.

Blackham et al (2015) noted that OCT is a modern intra-vascular imaging modality that has the capability
to provide detailed, in-vivo characterization of the arterial wall and atherosclerotic plaque. The current
understanding of the appearance of atherosclerotic plaque via OCT is largely based on coronary arterial
studies where OCT information has been employed to guide therapeutic management and permits the
immediate evaluation of PCI. The clinical success of OCT in the coronary arteries has laid the foundation
for investigation of the carotid artery and thus, stroke risk assessment. The authors reported the novel
use of OCT for tissue characterization of severe stenosis subsequent to carotid artery stenting, both
before and after treatment with cutting balloon angioplasty.

An UpToDate review on “Evaluation of carotid artery stenosis” (Furie, 2015) does not mention optical
coherence tomography as a diagnostic tool.

Hoffmann et al (2016) stated that rupture risk assessment of an intracranial aneurysm (IA) is an important
factor for indication of therapy. Until today, there is no suitable objective prediction method. Conventional
imaging modalities cannot assess the IA’s vessel wall. These researchers investigated the ability of intra-
vascular OCT as a new tool for the characterization and evaluation of IAs. An experimental set-up for
acquisition of geometrical aneurysm parameters was developed. Object of basic investigation was a
silicone phantom with 6 IAs from patient data. For structural information, 3 circles of Willis were dissected
and imaged post-mortem. All image data were post-processed by medical imaging software. Geometrical
image data of a phantom with 6 different IAs were acquired. The geometrical image data showed a signal
loss, e.g., in aneurysms with a high bottle-neck ratio. Imaging data of vessel specimens were evaluated
with respect to structural information that is valuable for the characterization of IAs. Those included thin
structures (intimal flaps), changes of the vessel wall morphology (intimal thickening, layers), adjacent
vessels, small vessel outlets, arterial branches and histological information. The authors concluded that
intra-vascular OCT provides new possibilities for diagnosis and rupture assessment of IAs. However,
currently used imaging system parameters have to be adapted and new catheter techniques have to be
developed for a complete assessment of the morphology of IAs.

Kimura et al (2015) stated that periprocedural myocardial injury (PMI) is not an uncommon complication
and is related to adverse cardiac events after PCI. These researchers investigated the predictors of PMI
in patients with stable angina pectoris (SAP) on intra-vascular imaging. They enrolled 193 SAP patients
who underwent pre-PCI IVUS and OCT. Clinical characteristics, lesion morphology, and long-term follow-
up data were compared between patients with and without PMI, defined as post-PCI elevation of high-
sensitivity cardiac troponin-T. Periprocedural myocardial injuries were observed in 79 patients (40.9%).
Estimated glomerular filtration rate (OR, 0.973; 95% CI: 0.950 to 0.996; p = 0.020), greater than or equal
to 2 stents (OR, 3.100; 95% CI: 1.334 to 7.205; p = 0.009), final myocardial blush grade 0 to 2 (OR,
4.077; 95% CI: 1.295 to 12.839; p = 0.016), and IVUS-identified echo-attenuated plaque (EA; OR, 3.623;
95% CI: 1.700 to 7.721; p < 0.001) and OCT-TCFA (OR, 3.406; 95% CI: 1.307 to 8.872; p = 0.012) were
independent predictors of PMI on multi-variate logistic regression analysis. A combination of EA and
OCT-TCFA had an 82.4% positive predictive value (PPV) for PMI. On Cox proportional hazards analysis,
PMI was an independent predictor of adverse cardiac events during 1-year follow-up (hazard ratio [HR],
2.984; 95% CI: 1.209 to 7.361; p = 0.018). The authors concluded that plaque morphology assessment
using pre-PCI IVUS and OCT may be useful for predicting PMI in SAP patients.
Losif and co-workers (2016) stated that due to its high spatial resolution, intravascular OCT has been used as a valid method for in-vivo evaluation of several types of coronary stents at straight lumen and bifurcation sites. These researchers evaluated its effectiveness for flow diverting stents deployed in arterial bifurcation sites involving jailing of a side branch. A total of 4 large white swine were stented with flow diverting stents covering the right common carotid artery-ascending pharyngeal artery bifurcation. After 12 weeks of follow-up the animals were evaluated by digital subtraction angiography and intravascular OCT and subsequently sacrificed. Neointimal thickness on the parent arteries and the free segments of the stent were measured. The stented arteries were harvested and underwent scanning electron microscopy (SEM) imaging. Ostia surface values were measured with OCT three-dimensional (3D) reconstructions and SEM images. All endovascular procedures and OCT pullback runs were feasible. Stent apposition was satisfactory on the immediate post-stent OCT reconstructions. At 12-week controls, all stents and jailed branches were patent. Mean neointimal thickness was 0.11 ± 0.04 mm on the free segments of the stent. The mean ostia surface at 12 weeks was 319,750 ± 345,533 μm² with 3D-OCT reconstructions and 351,198 ± 396,355 μm² with SEM image-derived calculations. Good correlation was found for ostia surface values between the 2 techniques; the values did not differ significantly in this preliminary study. The authors concluded that intravascular OCT appeared to be a promising technique for immediate and follow-up assessment of the orifice of arterial branches covered by flow diverting stents.

In conclusion, Optical coherence tomography (OCT) is an imaging technique that has some advantages over intravascular ultrasound (IVUS) for imaging coronary arteries. It has a higher resolution and provides greater detail for accessible structures compared to IVUS. Case series have demonstrated that OCT can be performed with a high success rate and few complications. Head-to-head comparisons of OCT and IVUS report that OCT picks up additional abnormalities that are not detected by IVUS, implying that OCT is a more sensitive test compared to IVUS.
Intravascular Imaging (i.e., Intravascular Ultrasound [IVUS] and Optical Coherence Tomography [OCT]), continued


Intravascular Imaging (i.e., Intravascular Ultrasound [IVUS] and Optical Coherence Tomography [OCT]), continued


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Cardiovascular Policies, Continued

Intravascular Imaging (i.e., Intravascular Ultrasound [IVUS] and Optical Coherence Tomography [OCT]), continued

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INTRAVASCULAR LITHOTRIPSY (IVL)

Policy # 647
Implementation Date: 4/23/21
Review Dates:
Revision Dates:

Description
Intravascular lithotripsy (IVL) is a technology derived from renal lithotripsy, in which multiple emitters mounted on a traditional balloon catheter provide circumferential pulsatile energy to disrupt calcified plaque and improve acute gain while minimizing vessel injury. Over the last 40 years, despite multiple advancements in percutaneous coronary interventions, calcified lesions remain a challenge for even the most experienced operators leading to an increase in morbidity and mortality. Most recently, intravascular lithotripsy (IVL) has been shown to be an innovative technology that is designed to address heavily calcified lesions.

The Shockwave Medical Peripheral IVL System (Shockwave Medical, Fremont, CA) received U.S. Food and Drug Administration (FDA) approval in 2016. This system is a single-use sterile disposable catheter that contains multiple lithotripsy emitters enclosed in an integrated balloon. The emitters create sonic pressure waves in the shape of a sphere, creating a field effect to treat circumferential vascular calcium. These sonic pressure waves selectively disrupt and fracture calcium in situ, altering vessel compliance, while minimizing injury and maintaining the integrity of the fibro-elastic components of the vessel wall.

Commercial Plan Policy/CHIP (Children's Health Insurance Program)
Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

SelectHealth covers Intravascular Lithotripsy (IVL) for patients undergoing transfemoral aortic valve replacement (TAVR) with calcified peripheral arterial disease; all other indications of IVL are considered investigational/experimental.

SelectHealth Advantage (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 SelectHealth 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.
Intravascular Lithotripsy (IVL), continued

**SelectHealth 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 SelectHealth 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](http://health.utah.gov/medicaid/manuals/directory.php) or the Utah Medicaid code Look-Up tool.

**Summary of Medical Information**

IVL, by disrupting intimal and medial calcification, alters vessel compliance to allow for the safe passage of large-bore delivery sheaths. This expands the patient cohort that could be eligible for transfemoral access for TAVR procedures. IVL-enabled transfemoral access offers several advantages. First, it preserves the established benefits of TAVR: decreased morbidity and mortality, fewer hospital days, and reduced cost. Second, although alternative access options exist, they are more invasive and have a significant learning curve (1,5). IVL leverages the familiarity of a balloon-based intervention, minimizing the learning curve, regardless of a center’s volume.

IVL may represent a straightforward technique to preserve the benefits of reduced morbidity and mortality of transfemoral TAVR in patients with calcified peripheral arterial disease.

**Billing/Coding Information**

**CPT CODES**

- **C9764** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
- **C9765** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
- **C9766** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
- **C9767** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed
- **C9772** Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
- **C9773** Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
- **C9774** Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
- **C9775** Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with the intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within same vessel(s), when performed

**Key References**

Intravascular Lithotripsy (IVL), continued


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Description
Heart disease is the number one cause of morbidity and mortality in the adult US population. Lowering total and LDL cholesterol has been shown to reduce the development and recurrence of heart disease. Consequently, great emphasis is placed on the treatment of elevated total and LDL cholesterol by many physicians. Treatment including diet and multiple medications are used to reach goals published by the National Cholesterol Education Program (NCEP). However, some patients, primarily those with familial hypercholesterolemia (FH), may require additional therapy.

The dextran sulfate cellulose adsorption system (LipoSorber) uses columns containing dextran sulfate immobilized on cellulose beads to remove LDL from the plasma. Typically, there are 2 such columns in the plasma circuit, which are regenerated automatically during LDL apheresis. The system has a high selectivity for the removal of apolipoprotein B (apo B)-containing lipoproteins, removing LDL, very low-density lipoprotein, and lipoprotein (a). Binding of LDL appears to depend on electrostatic interaction between dextran sulfate and apo B and is inhibited by acetylation of LDL. Interestingly, dextran sulfate columns can remove LDL of patients with familial defective apo B-100 with equal efficacy. Although some molecules with similar properties are absorbed to the column, this is not associated with any adverse clinical consequences. The columns are discarded after each apheresis procedure, and this contributes to the high running costs of this system.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers LDL apheresis in limited circumstances when certain criteria have been met.

Patients must meet ONE of the following criteria:

1. Patient has one of the following diagnoses and associated LDL Cholesterol levels:
   a. Patients with homozygous FH and LDL-chol > 500mg/dl;
   b. Patients with heterozygous FH with an LDL-chol > 300mg/dl;
   c. Patients with heterozygous FH with an LDL-chol > 200mg/dl and failed to reach NCEP targets on maximal medical therapy.

2. Patient has documented medical nutritional therapy consultation and has shown active efforts at appropriate lifestyle modifications.
3. Supporting documentation demonstrates the patient to have attempted or is currently on maximal medical therapy. Maximal medical therapy is defined as the following:
   a. Maximal doses of high-potency HMG-CoA reductase inhibitor (statin) therapy (unless intolerant or detrimental side effects are documented) with ezetimibe and a PCSK-9 agent with compliance to that therapy.

   In addition to the above criteria, the following will apply:
   a. Patients with familial heterozygous traits with LDL cholesterol > 200 must have documented atherosclerosis. The patient should have known coronary artery disease, cerebrovascular disease, or peripheral vascular disease documented prior to apheresis therapy.
   b. Discontinuation/avoidance of ACE inhibitor medications (due to the greater risk of hypotension induced by bradykinin release).
   c. Avoidance of smoking for > 6 months prior to the start of apheresis therapy.
   d. Absence of other severe co-morbid conditions such as end-stage renal disease, emphysema, or other life-threatening conditions.
   e. LDL apheresis is to be performed on an FDA approved device.
   f. The patient is in active case management with SelectHealth and demonstrates compliance with therapies.
   g. The therapy must be performed by a board-certified Lipidologist at a formal Lipid management clinic.

SelectHealth Advantage (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 SelectHealth 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.

SelectHealth Community Care (Medicaid)

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Summary of Medical Information

The evidence permits the conclusion that lipid apheresis consistently reduces total cholesterol and LDL cholesterol. Three randomized, controlled trials (RCTs) report that the reductions in LDL cholesterol are clinically and statistically significantly greater than those achieved by medication alone for patients with refractory hypercholesterolemia. The evidence suggests that lipid apheresis may reduce arterial morphologic change and improve hemodynamic flow in diseased arteries; however, this has not been consistently demonstrated in RCTs. The RCTs are insufficient to provide direct evidence that lipid apheresis reduces adverse cardiovascular events as compared to maximal medical management. The results of these RCTs are also limited by the fact that 2 of the 3 trials included some patients who may have been responsive to medical management, rather than limiting the population to those patients who are truly refractory to maximal medical management.

In most of the nonrandomized studies, the patients had failed diet and drug therapy, and correspond more closely to the target group of refractory patients. The efficacy of LDL lowering is of similar
magnitude in these studies as compared to the RCTs. In uncontrolled studies using pre-and post-treatment coronary angiography, the reductions in cholesterol appear to be associated with non-progression of atherosclerosis. Therefore, the evidence supports the effectiveness of lipid apheresis for providing a long-term lipid-lowering benefit and suggests that lipid apheresis may be associated with non-progression of coronary artery disease. Given the established causal relationship between LDL cholesterol and cardiac events, it is likely that lipid apheresis will reduce cardiovascular events for patients with hypercholesterolemia who are refractory or intolerant to maximal drug therapy.

Lipid apheresis improves health outcomes by lowering cholesterol in patients with refractory hypercholesterolemia, leading to a reduction in adverse cardiovascular events. However, the available evidence has not quantified the magnitude of this benefit. Given that the magnitude of LDL lowering by apheresis is large, 50%–70% or greater, the magnitude of reduction in adverse cardiovascular events is also likely to be clinically meaningful.

Lipid apheresis is a relatively safe treatment, although it occasionally may be associated with significant hypotension and anaphylactic reactions. Most adverse effects are minor. Hypotension may be more likely with dextran sulfate chemo adsorption, especially in patients receiving concomitant angiotensin-converting enzyme (ACE) inhibitors. There are no adequate trials of direct comparison of the techniques to quantitatively determine treatment or safety advantages. All 3 techniques are relatively selective for LDL cholesterol but may remove some other molecules non-selectively. The clinical effect of removal of other factors such as HDL, fibrinogen, and bradykinin are unclear at this time, but there is no evidence to suggest that adverse effects have resulted from this phenomenon.

For the indicated patient group with refractory hypercholesterolemia despite maximal medical therapy, the alternatives are very limited. Radical treatments such as portocaval shunt or liver transplantation have been tried but are not yet established in clinical practice. Intensification of medical therapy is an option as newer and more potent cholesterol lowering agents are introduced, but only a minority of patients will remain refractory. Lipid apheresis is likely the best option for many of these patients.

Billing/Coding Information

**Covered: For the conditions outlined above**

**CPT CODES**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>0342T</td>
<td>Therapeutic apheresis with selective HDL delipidation and plasma reinfusion</td>
</tr>
<tr>
<td>36516</td>
<td>Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion</td>
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</tbody>
</table>

**HCPCS CODES**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2120</td>
<td>Low density lipoprotein (LDL) apheresis using heparin-induced extracorporeal LDL precipitation</td>
</tr>
<tr>
<td>E88.89</td>
<td>Other specified metabolic disorders</td>
</tr>
</tbody>
</table>

Key References

4. BCBS TEC — Lipid apheresis in the treatment of patients with severe, refractory hypercholesterolemia. 4/1999.
Cardiovascular Policies, Continued

Acute Inpatient Rehabilitation LDL Apheresis (Liposorber Device, Help System), continued


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Atrial fibrillation (AF) is a common dysrhythmia. It is characterized as paroxysmal if the duration is less than one week, persistent if the duration is between 7 days and 1 year, and permanent if greater than one year in duration with failure of conversion. AF can have adverse consequences related to a reduction in cardiac output and thrombus formation that can lead to systemic embolization and strokes.

Most embolized thrombi are felt to develop in the left atrial appendage (LAA). In patients with atrial fibrillation, blood tends to pool and form clots in this appendage. To prevent clot formation and subsequent embolization in patients with AF, current guidelines recommend anticoagulation with warfarin. Management of anticoagulation with warfarin is cumbersome due to the need for frequent monitoring as warfarin is subject to significant drug-drug and drug-food interactions which can result in excessive or inadequate anticoagulation. Though warfarin is the long-term oral antithrombotic of choice in patients at high risk of embolism in association with non-valvular atrial fibrillation, especially after an ischemic cerebrovascular event, many patients cannot achieve anticoagulation targets. It is estimated that therapeutic INRs are reached less than 60% of the time, and only 50% of high-risk atrial fibrillation patients are treated with warfarin. In some of these instances, alternative treatments with medications such as aspirin or clopidogrel are used, though, studies have shown these therapies to be inferior to warfarin.

To overcome many of the alternative issues surrounding anticoagulation therapy, the WATCHMAN LAA Closure Technology (Boston Scientific Corporation, Maple Grove, MN) consists of a delivery catheter and a device that is permanently implanted in the left atrial appendage (LAA) of the heart. The device, often referred to as the WATCHMAN, which received FDA approval on March 13, 2015, prevents LAA blood clots from entering the bloodstream and potentially causing a stroke. It is made of a self-expanding, nickel-titanium (Nitinol) frame with an attached woven plastic cap. The physician inserts the delivery catheter into the body through a vein in the leg. The catheter is advanced through the bloodstream until it reaches the upper right chamber of the heart (right atrium). The physician makes a small hole through the wall between the two upper chambers of the heart (atrial septum) so that the catheter reaches the LAA. The physician then pushes the WATCHMAN through the delivery catheter into the LAA where it opens like an umbrella and is permanently implanted. Once the WATCHMAN is in place, a thin layer of tissue grows over it in about 45 days. This keeps blood clots in the LAA from entering the bloodstream.

The Amplatzer Amulet Left Atrial Appendage Occluder (LAAO) is a permanent implant that is placed in the patient’s left atrial appendage, which is a pouch-like part of the heart. The device is intended to prevent blood clots formed in the LAA from entering the bloodstream and potentially causing a stroke. The device is made of a Nitinol (nickel-titanium) mesh with polyester fabric cover.

Percutaneous LAA closure with Watchman or Amulet may reduce the risk of stroke in some patients with AF and high risk of stroke with contraindications to oral anticoagulation (OAC) or unwillingness to adhere to long-term OAC therapy.
Cardiovascular Policies, Continued

Left Atrial Appendage Closure (LAAC) Devices (e.g., Watchman®), continued

### Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers left atrial appendage closure with an FDA approved device (e.g., Watchman or Amulet) in limited circumstances as outlined below. SelectHealth covers this procedure when either A or B are met.

A. Will be approved if recommended by Intermountain Healthcare Cardiovascular Clinical Program,

OR

B. For all other clinicians, criteria for coverage must be met (Must meet 1 and 2 AND either 3, 4, or 5).

1. Patients with CHA2DS:VAsc ≥ 2 who have contraindications to anticoagulation therapy.
2. Patient does not have rheumatic mitral stenosis.
3. Patients are unable to take long-term oral anticoagulation occupational or intolerance of anticoagulation due to side effects or prior bleeding experience.
4. Patients in whom administering oral anticoagulation long-term is deemed clinically high risk, or contraindicated, because of fall-risk or other predisposition to bleeding complications.
5. Patients in need of secondary prevention who had a therapeutic INR or verified medication compliance with novel oral anticoagulation (NOAC) medications at the time of their embolic event.

### SelectHealth Advantage (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 SelectHealth 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](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp) or the manual website.

### SelectHealth Community Care (Medicaid)

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### Summary of Medical Information

The WATCHMAN was evaluated in four clinical studies, in which two studies compared the WATCHMAN to warfarin. Many patients with atrial fibrillation take warfarin or other FDA approved blood thinning...
Left Atrial Appendage Closure (LAAC) Devices (e.g., Watchman®), continued

medicines to prevent a stroke caused by a blood clot in the brain. However, warfarin can increase the risk of bleeding anywhere in the body. If bleeding happens in the brain, this can also cause a stroke.

These two clinical studies suggested that warfarin was better than the WATCHMAN in preventing strokes caused by a blocked blood vessel in the brain. However, the number of strokes caused by bleeding in the brain was lower in the WATCHMAN patients compared to the warfarin patients.

The overall rate of serious bleeding was similar in the WATCHMAN and warfarin patients. Within several months after the device was implanted, the rate of serious bleeding was higher in the WATCHMAN patients compared to warfarin patients. However, beginning six months after the device implant procedure, the rate of serious bleeding was lower in WATCHMAN patients.

In one of the clinical studies that evaluated the WATCHMAN, 226 out of 246 WATCHMAN patients (approximately 92%) were able to stop taking their warfarin 45 days after the device was implanted. Within a year after the implant procedure, 231 out of 234 patients remaining in the study (over 99%) were able to stop taking warfarin.

To prevent strokes, most atrial fibrillation patients can safely take blood thinning medicines (like warfarin) without serious side effects. However, in some patients, blood thinning medicines can be difficult to use due to bleeding concerns. In choosing a treatment, physicians should consider the risks and benefits of blood thinning medicines compared to the WATCHMAN or Amulet for each individual patient. This includes the risk that either kind of stroke (caused by a blocked blood vessel or by bleeding) might occur.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

33340
Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

HCPCS CODES

No specific codes identified

Key References


Cardiovascular Policies, Continued

Left Atrial Appendage Closure (LAAC) Devices (e.g., Watchman), continued


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MAGNETIC RESONANCE IMAGING (MRI) FOR CARDIOVASCULAR INDICATIONS

Policy # 154

Implementation Date: 4/20/03
Review Dates: 10/23/03, 4/18/05, 4/27/06, 5/17/07, 6/23/08, 4/21/11, 6/21/12, 8/15/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/18/19, 7/12/21
Revision Dates: 5/1/04, 4/28/09, 4/22/10, 1/16/15, 8/1/19, 6/30/22

Related Medical Policies:
#528 PET Scans for Cardiac Indications

Description
Magnetic resonance imaging (MRI) is a non-invasive imaging procedure used to study various organs including the brain, spine, bones, heart, and other soft tissues. MRI uses pulsed radiofrequency waves in the presence of a high magnetic field to produce high-quality images in any plane. These studies are performed with or without IV contrast.

MRI use in the field of cardiology has evolved into a mature modality. However, echocardiography, i.e., transthoracic (TTE) remains the generally accepted modality to evaluate cardiac anatomy and function for many routine applications, given its greater ease of application and interpretation, lower cost, and real-time interpretation. However, 20–30% of the population cannot be adequately imaged with an echocardiogram or have adequate diagnostic information provided. Additionally, the details provided by MRIs are of greater utility for preoperative planning.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers cardiac MRI in limited conditions.

Coverage is allowed in the following situations:
- Congenital or acquired disease of the thoracic aorta
- Tumor staging of the organs of the chest
- Congenital heart disease
- Constrictive pericarditis
- Evaluation of anomalous coronary arteries
- Aortic and pulmonary artery disease: To define the dimensions and extent of aortic aneurysms, false aneurysms, dissection flaps, periaortic abscess, aortic arch abnormalities, coarctation, valvular and supravalvular aortic stenosis, or abnormalities of the pulmonary artery and great neck vessels
- Cardiac masses: MRI is useful in the assessment of cardiac tumors and paracardiac masses (to assess for cardiac invasion)
Cardiovascular Policies, Continued

Magnetic Resonance Imaging (MRI) for Cardiovascular Indications, continued

- As planning for patients undergoing ablative procedures for atrial fibrillation, supraventricular tachycardia, or other dysrhythmias found to be amenable to ablative therapies
- For post-ablative follow-up of cardiac dysrhythmia involving the pulmonary vein or right ventricular (RV) outflow tract (limited to once in the first 6 months post-ablation for asymptomatic patients)

**Coverage is allowed in any of the following situations when standard cardiovascular testing has been done and is felt to be inadequate to determine appropriate management by the ordering physician:**

- Ischemic heart disease and post-myocardial infarction status
- Measurement of left and right ventricular function and volumes
- Assess mitral regurgitation and ventricular septal defects (mechanical complications of acute MI)
- Assess thrombus formation
- Assess left ventricular aneurysm
- Detect regional wall motion abnormalities
- Initial and serial evaluations of pericardial disease, including pericarditis, pericardial effusions, and pericardial masses
- Assess viability of the infarcted myocardium utilizing delayed hyperenhancement (contrast studies)
- Assess perfusion, function, and viability when all 3 parameters are required for predictive or decision-making purposes:
  - Evaluate patients with suspected anomalous coronary arteries
  - Assess microvascular angina (Syndrome X) in patients without epicardial coronary artery occlusive disease
- Known, suspected, or genetic carrier for cardiomyopathy:
  - Dilated
  - Hypertrophic
  - Infiltrative or restrictive
  - Myocarditis
- As an initial assessment of cardiac dysrhythmias to discern potential etiology including atrial fibrillation, supraventricular tachycardia, or other dysrhythmias
- Assess regional wall-thickening and tissue classification in variants of hypertrophic cardiomyopathy
- Diagnosis of infiltrative cardiomyopathies such as those associated with hemachromatosis, sarcoidosis, and amyloidosis
- Distinguish between restrictive and constrictive disease
- Serial assessment of volumes and function during medical or surgical therapy when more precise, reproducible values are clinically required than provided by echocardiography
- Valvular heart disease: To assess valvular regurgitation or stenosis when echocardiographic studies are technically inadequate
- Right ventricular lesions to evaluate for the presence of arrhythmogenic right ventricular cardiomyopathy (ARVC) and for other right ventricular diseases when echocardiographic studies are technically inadequate
- To evaluate cardiotoxicity in members who are undergoing treatment with cardiotoxic medications
SelectHealth does NOT cover MRI of the cardiovascular system, particularly of the coronary arteries, when used as a screening study in asymptomatic individuals.

**SelectHealth Advantage (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 SelectHealth 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&](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&) or the manual website

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**Summary of Medical Information**

Magnetic resonance imaging (MRI) is a non-invasive imaging procedure used frequently for studying intracranial and intraspinal pathology, and for evaluating abnormalities of the musculoskeletal system, the heart, and pelvis. It is also used to evaluate abdominal visceral problems.

Magnetic resonance imaging uses a pulsed radiofrequency wave in the presence of a high magnetic field to produce high-quality images of the body in any plane. Magnetic resonance imaging may be preferred to a CT scan because of its established capability to depict soft tissue, often without the need for contrast material and absence of ionizing radiation.

During a MRI examination, the patient is placed inside a very strong hollow magnet. A fraction of the hydrogen atoms within the patient's body align themselves with the magnetic field. The body area being examined is exposed to radio waves that are first absorbed and then emitted.

The emitted waves become the MRI signal. The signal is analyzed by computer and processed into images of the body. The images are usually in the form of slices through the body. The slices can be taken in any plane. Magnetic resonance imaging also has the ability to acquire 2-, 3- or 4-dimensional data. Images with high-signals appear white (e.g., fat) and those with low-signals appear black (e.g., air in the lungs).

Magnetic resonance imaging is sometimes performed with the use of contrast agents for specific indications in order to achieve a desired image. Contrast enhancement agents approved by the Federal Drug Administration (FDA) for use with MRI include Magnevist, (gadopentetate dimeglumine), ProHance, (gadoteritol), Omniscan, (gadodiamide), Ultravist, (iopromide), and Ferumoxsil (feroxide).

Magnetic resonance imaging has been shown to have several technical advantages in comparison to other standard diagnostic testing procedures such as CT scan and X-ray. Magnetic resonance imaging is a non-invasive technique that uses no ionizing radiation, and according to available literature, there are no known clinically significant side effects. The literature indicates magnetic resonance imaging can be used during the first trimester of pregnancy when it has been shown to offer an advantage over other modalities. Magnetic resonance imaging does not always require contrast agents in order to achieve a high degree of resolution. The literature indicates there is some increased risk of administering MRI contrast agents to patients with asthma or iodine allergy, but administration of these agents is still performed with caution. Magnetic resonance imaging soft tissue contrast has been shown to be superior to that of other imaging modalities, and there are no image artifacts from bone. The literature indicates magnetic resonance imaging has greater inherent contrast between different types of normal body tissues and between pathological tissues and normal tissues. Magnetic resonance imaging clarity is equal in any
view: axial, sagittal, coronal, or oblique. Magnetic resonance imaging also has the ability to acquire two dimensional, three-dimensional, and four-dimensional data.

Magnetic resonance imaging has been shown to have several disadvantages. It requires more patient cooperation than other tests. Imaging time is longer than CT or x-ray. Exposure time of MRI is between 100 and 1,000 times as long as the time required for a CT slice. Installation and operation of MRI equipment is costly. It has limitations in the acute trauma setting due to its incompatibility with various medical and life-support devices. Transient biological effects have been noted, such as cardiac T-wave changes. Overheating may result from the alternating magnetic transmissions of the radiofrequency coils. The literature indicates that care should be exercised when using MRI with infants, elderly patients, and hyper-pyrexic individuals. There is a forceful attraction of ferromagnetic objects to the magnet. Many aneurysm clips, intracranial or intraocular metal, shrapnel, cardiac pacemakers or pacemaker wires and cochlear implants are absolute or relative contraindications for MRI. Magnetic resonance imaging has somewhat less spatial resolution than CT scan. According to the literature, incidental anatomic discrepancies, such as non-specific white matter abnormalities, may be misinterpreted as causing the patient's symptoms.

Magnetic resonance imaging in the field of cardiology has evolved at a rapid pace. However, echocardiography, i.e., transthoracic (TTE) and transesophageal echocardiogram (TEE) remains the generally accepted modality for the evaluation of cardiac anatomy and functions, most of the time, because of greater ease of acquisition, lower cost, and real-time imaging. According to the literature, 20–30% of the population cannot be adequately imaged with an echocardiogram or get adequate diagnostic information. For these patients, MRI has been shown to be particularly important. Magnetic resonance imaging has the following important attributes that make it effective for the evaluation of the cardiovascular system:

- It can produce high-resolution images of the cardiac chambers and large vessels without the need of contrast agents;
- It is a three-dimensional imaging technique;
- It produces images of cardiovascular structures without the interference from adjacent bone or air;
- Fast gradient echo techniques can be used to assess global and regional ventricular contractile function;
- Velocity-encoded techniques permit measurement of blood flow;
- It has high tissue contrast;
- It does not have the weakness of geometric assumptions as does angiography and echocardiography in the assessment of ventricular volumes; and
- It does not have difficulties in evaluating right ventricular function.

Since MRI can usually not be brought to the bedside like the TEE, it usually is not the first test used in an emergency situation, but it may be used later to better define the diagnosis. Under established guidelines, magnetic resonance imaging is used as the diagnostic test for the following indications: diseases of the aorta, diseases of the pericardium, external and internal masses, pathology involving surrounding structures, congenital heart disease, and ventricular dysplasia. Magnetic resonance imaging is increasingly being used in the assessment of cardiac function, morphology, structure, perfusion, and viability. When echocardiography does not provide enough information, in these circumstances, the literature suggests MRI may be warranted.

A February 2009 Medical Technology review found that MRI is equivalent, and in some cases superior, to alternative procedures for measuring cardiac parameters. Indeed, in some cases, cardiac MRI appears to have become the gold standard of care such as in the case for diagnosing cardiomyopathy or for estimating ejection fraction. No studies could be located that estimated the cost-effectiveness of CMRI relative to standard diagnostic tests, which remains an important limitation in the literature. Moreover, the validity of testing in individuals with a low probability of heart disease is poorly understood. Thus, its use as a screening test is not supported in the literature. However, for diagnosing heart conditions in patients in whom such conditions are likely to be present, CMRI appears to be a useful test.

A literature reviewed performed in June 2012 identified a British trial Clinical evaluation of Magnetic Resonance imaging in Coronary heart disease (CE MARC) representing a 2012 update in use of CMR for stress perfusion testing. In this prospective trial, 752 patients with suspected angina underwent adenosine stress CMR, adenosine SPECT (radionucleotide) and x-ray coronary angiography testing. By
coronary angiography, 39% had significant CAD. The sensitivity (87% vs. 67%) and negative predictive value (91% vs. 79%) differed in favor of CMR vs. SPECT (p < 0.001) whereas specificity (83% vs. 83%) and positive predictive value (77% vs. 71%) were similar. These results argue for broader application of stress CMR in the investigation of CAD.

The diagnostic and prognostic utility of myocardial delayed (late) gadolinium enhancement (MDE) as a marker of myocardial scar/fibrosis continues to build. MDE has well-established prognostic value after MI, and to determine reproducibility of with revascularization (viability) in hypertrophic cardiomyopathy, the degree of MDE contributes to the risk of sudden death and may be considered in resolving decision-making for implantation of an implantable defibrillator.

Additional emerging applications of MDE include atrial fibrosis and stroke risk midwall fibrosis and cardiomyopathy risk, RV fibrosis, and arrhythmic RV cardiomyopathy diagnosis, detection of silent MI and prognosis in constrictive pericarditis. Increasingly, CMR is recognized as an ideal one-stop-shop for non-invasive assessment of complex cardiac conditions.

Billing/Coding Information

CPT CODES
75557  Cardiac magnetic resonance imaging for morphology and function without contrast material;
75559  ; with stress imaging
75561  Cardiac magnetic resonance imaging for morphology and function without contrast material(s) followed by contrast material(s) and further sequences;
75563  ; with stress imaging
75565  Cardiac magnetic resonance imaging for velocity flow mapping (List separately in addition to code for primary procedure)

HCPCS CODES
A9576  Injection, gadoteridol, (ProHance multipack), per ml
A9577  Injection, gadobenate dimeglumine (MultiHance), per ml
A9578  Injection, gadobenate dimeglumine (MultiHance multipack), per ml
A9579  Injection, gadolinium-based magnetic resonance contrast agent, not otherwise specified (NOS), per ml
A9581  Injection, gadoxetate disodium, 1 ml
Q9953  Injection, iron-based magnetic resonance contrast agent, per ml
Q9954  Oral magnetic resonance contrast agent, per 100 ml

Key References
Magnetic Resonance Imaging (MRI) for Cardiovascular Indications, continued


Magnetic Resonance Imaging (MRI) for Cardiovascular Indications, continued


Cardiovascular Resonance Imaging (MRI) for Cardiovascular Indications, continued


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NON-INVASIVE FRACTIONAL FLOW RESERVE USING CT ANGIOGRAPHY

Policy # 617
Implementation Date: 8/1/17
Review Dates: 7/25/18, 6/13/19, 6/18/20, 6/17/21
Revision Dates:

Description
Invasively measured fractional flow reserve (FFR) evaluates the severity of ischemia caused by coronary artery obstructions and can predict when revascularization is beneficial. FFR is not a diagnostic test for ischemic heart disease, but evaluates ischemia resulting from a stenosis. It is now possible to obtain FFR noninvasively, using computed tomography angiography (CTA), also called FFR-CT (HeartFlow software termed FFRCT; Siemens cFFR) using routinely collected CTA imaging data. The process involves constructing a digital model of coronary anatomy and calculating FFR across the entire vascular tree using computational fluid dynamics. FFR-CT can also be used for “virtual stenting” to simulate how stent placement would be predicted to improve vessel flow.

Only the HeartFlow FFR-CT software has been cleared by the U.S. Food and Drug Administration. Imaging analyses require transmitting data to a central location, taking 1 to 3 days to complete. Other prototype software is workstation-based with onsite analyses. FFR-CT cannot be calculated when images lack sufficient quality (11% to 13% in recent studies); for example, in obese individuals (e.g., body mass index, > 35 kg/m2).

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

SelectHealth does NOT cover noninvasive fractional flow reserve testing using computed tomography angiography (FFR-CT) preceding invasive coronary angiography in patients with suspected stable ischemic heart disease; it is considered investigational.

SelectHealth Advantage (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 SelectHealth 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.

SelectHealth 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 SelectHealth Commercial criteria will apply. For the most up-to-date Medicaid policies and
Non-Invasive Fractional Flow Reserve Using CT Angiography, continued

Summary of Medical Information
For individuals who have suspected stable ischemic heart disease and planned invasive coronary angiography (ICA) who receive fractional flow reserve using computed tomography angiography (FFR-CT), the evidence includes studies on test technical performance, meta-analyses of diagnostic accuracy, and 2 studies of patient outcomes [one non-randomized study and one retrospective cohort study (Phase III), with no post-adoption use/safety studies (Phase IV) identified]. Relevant outcomes are test accuracy and validity, morbid events, quality of life, resource utilization, and treatment-related mortality and morbidity.

Randomized controlled trials and observational studies have demonstrated that FFR-guided revascularization can improve cardiovascular outcomes, reduce revascularizations, and decrease costs. For example, the Fractional Flow Reserve versus Angiography for Multivessel Evaluation (FAME) trial randomized 1,005 patients with multivessel disease and planned percutaneous coronary intervention (PCI). At 1 year, compared with PCI guided by angiography alone, FFR-guided PCI reduced the number of stents placed by approximately 30%, followed by lower rates (13.2% vs 18.3%) of major cardiovascular adverse events (myocardial infarction, death, repeat revascularization) and at a lower cost. The clinical benefit persisted through 2 years, although by 5 years, event rates were similar between groups.

European guidelines for stable coronary artery disease recommend FFR be used: “… to identify hemodynamically relevant coronary lesion(s) when evidence of ischemia is not available” (class 1A), and “[r]evascularization of stenoses with FFR < 0.80 is recommended in patients with angina symptoms or a positive stress test.” Guidelines also recommend using: “FFR to identify hemodynamically relevant coronary lesion(s) in stable patients when evidence of ischemia is not available” (class 1A recommendation). U.S guidelines state that an FFR of 0.80 or less provides level 1A evidence for revascularization for significant stenosis amenable to revascularization and unacceptable angina despite guideline-directed medical therapy.

FFR-CT may offer an effective means to reduce unnecessary ICA with a rationale for a potential role in decision making. Test performance characteristics are consistent with a negative test reducing the probability of significant obstructive disease (e.g., vessels with FFR < 0.80) and potentially altering a decision to perform ICA. However, outcome data are limited and obtained entirely from non-randomized studies with comparisons only to usual care. Limitations and uncertainties in body of evidence examining FFR-CT prevent conclusions concerning the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding Information
CPT CODES
93799 Unlisted cardiovascular service or procedure

Effective 1/1/18

0501T Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report

0502T data preparation and transmission

0503T analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model

0504T anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report

(Report 0501T, 0502T, 0503T, 0504T one time per coronary CT angiogram)
(Do not report 0501T in conjunction with 0502T, 0503T, 0504T)
Non-Invasive Fractional Flow Reserve Using CT Angiography, continued

**HCPSC CODES**

No specific codes identified

**Key References**


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PECTUS EXCAVATUM SURGERY

Policy # 160

Implementation Date: 4/22/02

Review Dates: 6/25/03, 6/24/04, 5/20/05, 5/4/06, 7/12/07, 6/19/08, 6/11/09, 5/19/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 6/21/18, 6/19/19, 6/18/20, 10/15/21, 6/19/22

Revision Dates: 4/22/02, 7/24/06, 1/12/10, 11/17/21, 6/30/22

Description

Pectus excavatum deformity is a congenitally acquired deformity of the front portion of the chest wall caused by the backward displacement of the xiphoid cartilage. In this condition, the anterior chest wall cartilages develop abnormally, leaving a "dent" in the chest wall. Though it causes a cosmetic deformity, it can also cause reduced function of an individual if the depression in the chest wall impairs the ability of the lungs or heart to work normally. Surgery can be done to correct the deformity while the child is still growing. Surgery is usually done prior to puberty with its associated bone growth and maturing of the child's skeletal structure.

The degree of anticipated functional impairment a patient with pectus excavatum deformity may expect is measured indirectly with the Haller Index. This value reflects the ratio of the transverse diameter (the horizontal distance of the inside of the ribcage) to the anterior-posterior diameter (the shortest distance between the vertebral body and sternum) of the chest and is calculated from a single CT scan of the chest performed through the deepest portion of a pectus excavatum deformity.

Haller Index

The Haller index (HI), also known as the pectus index, is a simple mathematical way to assess and describe the chest cage on CT of the thorax and is used in the detection and pre/postoperative assessment of pectus excavatum.

The Haller index is calculated by dividing the transverse diameter of the chest by the anterior-posterior distance on CT of the chest on the axial slice that demonstrates the smallest distance between the anterior surface of the vertebral body and the posterior surface of the sternum. Some authors have found that both radiographic- and CT-calculated Haller indices are strongly correlated and thus recommend the use of chest radiography instead of CT to minimize the radiation exposure.

The Haller index is affected by the vertebral level at which it is measured and is largest cranially. For consistency, therefore, it is recommended to calculate the largest Haller index in pectus excavatum patients by obtaining the AP diameter at the deepest point of the sternum.

The following values are used:

- normal chest: < 2.0
- mild excavatum: 2.0-3.2
- moderate excavatum: 3.2-3.5
- severe excavatum: > 3.5

Corrective pectus excavatum surgery is considered with a Haller index ≥ 3.25.

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for SelectHealth Commercial, SelectHealth Advantage (Medicare/CMS), and SelectHealth Community Care (Medicaid/CHIP) plans. Refer to the “Policy” section for more information.
Correction Index

To assess a correction index (CI), a virtual correction of the pectus is performed, and a horizontal line is drawn across the posterior aspect of the corrected sternum. CIs are calculated by measuring the distance between the posterior aspect of the corrected sternum and anterior aspect of the vertebra. This number is subtracted by the distance between the posterior aspect of the sternum at the site of deepest depression and anterior vertebra. This difference is divided by the first measurement and multiplied by 100 to represent the percentage of chest depression and, therefore, potential correction.

The CI provides an accurate assessment of pectus severity, and by the nature of the measurement, reflects the potential degree of operative repair. The Haller index correlates well with the correction index in pectus patients with standard chest wall dimensions, but is quite discrepant in the nonstandard chest. We recommend operative repair for pectus excavatum with a correction index of 28% or more, because this value correlates with the long-accepted standard (Haller index ≥ 3.25) and this index remains accurate even in nonstandard chest morphologies.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers repair of pectus excavatum deformities when the following criteria are met:

1. Patient is > 7 years of age; AND one of the following:
   2. Haller index ≥ 3.25 or correction index ≥ 28% by non-contrast chest CT; OR
   3. Serial PA and lateral chest x-rays taken at mid-respiration and at least 6 months apart revealing a persistent ratio of the external skeletal AP diameter of the chest at the angle of Lewis compared to the distance between the anterior surface of the vertebral body and the gladiolar-xiphoid junction is < 0.3; OR
   4. Serial PA and lateral chest x-rays taken at mid-respiration and at least 6 months apart revealing a persistent ratio of the external skeletal AP diameter of the chest at the angle of Lewis compared to the distance between the anterior surface of the vertebral body and the gladiolar-xiphoid junction is < 0.5 and > 0.3, AND either of the following:
      a) Pulmonary function tests consistent with restrictive lung disease without other underlying lung disease which explains the abnormalities; OR
      b) An echocardiogram performed within the last 3 months reveals reduced cardiovascular function attributable to the chest wall deformity.

SelectHealth Advantage (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 SelectHealth 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.
Cardiovascular Policies, Continued

Pectus Excavatum Surgery, continued

**SelectHealth 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 SelectHealth 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](http://health.utah.gov/medicaid/manuals/directory.php) or the Utah Medicaid code Look-Up tool.

**Summary of Medical Information**

Patients with chest wall deformities often have poor body image and self-esteem. Some individuals attempt to cover the defect with clothing and avoid activities that may require exposure of the chest. Indications for surgical correction are controversial and vary widely. Surgical repair is offered primarily as a method of improving cosmesis and psychological factors but may be necessary to improve cardiopulmonary function in some patients, as the disfigurement may be accompanied by physiologic impairment.

The scientific literature is controversial as to whether pectus excavatum is primarily cosmetic or whether it results in actual physiological impairment of function. Patients with mild pectus excavatum deformity may be treated with posture and exercise. Most surgical corrections are performed for cosmetic reasons, and in some cases to improve functional impairment. Authors agree that if patients with severe deformities do not undergo surgical repair in childhood, their symptoms worsen in adulthood.

If surgical repair is performed at an early age it has been reported there is a high recurrence rate due to periods of rapid bone growth. While the optimal age for surgical repair is generally between the ages of 11 and 18 years, each case must be reviewed individually for the presence of impaired cardiopulmonary symptoms. In some cases, surgery may be performed in adults to correct pectus deformities. Adults who have uncorrected pectus excavatum deformity and experience symptoms of activity limitation may undergo surgical repair with low morbidity, short-term limitation of activities, and improvement of symptoms.

Surgery for pectus excavatum may be performed using any of several techniques, including a sternal osteotomy (i.e., a modified osteotomy that involves supporting, removing and repositioning the sternum) or implantation of a Silastic mold in the subcutaneous space to fill the defect without altering the thoracic cage. Surgical correction often employs a metal bar behind the sternum; the bar may be removed in 1 to 2 years, after remodeling has occurred. The standard surgical procedure is the open Ravitch procedure, which involves extensive dissection, cartilage resection, and sternal osteotomy. More recently, minimally invasive techniques, including the Nuss procedure (i.e., a minimally invasive repair of pectus excavatum [MIRpectus excavatum]), have been utilized that involve the insertion of a convex steel bar beneath the sternum through small thoracic incisions. These recently developed minimally invasive methods do not require cartilage resection or osteotomy.

**Billing/Coding Information**

**CPT CODES**

- 21740: Reconstructive repair of pectus excavatum or carinatum; open
- 21742: ; minimally invasive approach (Nuss procedure), without thoraoscopy
- 21743: ; minimally invasive approach (Nuss procedure), with thoracoscopy

**HCPCS CODES**

No specific codes identified

**Key References**


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PERCUTANEOUS MITRAL VALVE REPAIR (MITRACLIP)

Policy # 464
Implementation Date: 10/19/10
Review Dates: 12/15/11, 10/20/16, 10/19/17, 10/3/18, 10/15/19, 10/19/21, 11/25/21
Revision Dates: 5/30/13, 1/10/14, 1/23/14, 12/13/21, 1/10/22

Description
The mitral valve insufficiency occurs when the mitral valve fails to close properly causing blood to flow backward into the atrium (regurgitation), leaving the left ventricle, the heart’s primary pumping chamber, with too little blood. To compensate, the ventricle stretches and overworks. Over time, it becomes enlarged, distorted, and weak.

Historically, 3 options have been available to treat symptomatic mitral valve regurgitation: medications (such as diuretics to alleviate fluid retention), valve repair, and valve replacement. Valve surgery is a highly invasive procedure which many fragile patients may not be able to undertake due to their associated comorbidities. Consequently, new approaches to mitral valve repair/replacement are under development.

One such development is the MitraClip (Abbott Laboratories, Chicago, IL). The MitraClip procedure is performed in a cardiac catheterization laboratory with the patient under general anesthesia. A thin catheter is inserted through a small incision in the groin and guided through the femoral vein to the affected area of the heart. A smaller catheter holding the clip is slipped through the first catheter. After the clip is attached to the valve leaflets, the catheters are removed. The patient is released from the hospital within a day or two. If the clip is not placed ideally on the first attempt, it can be reset. If it does not sufficiently correct the regurgitation, surgical repair or replacement of the valve remains an option.

The MitraClip system received FDA approval on October 24, 2013, for use in the United States. The FDA approved indication is for the percutaneous reduction of significant symptomatic mitral regurgitation (MR) is for the percutaneous reduction of significant symptomatic mitral regurgitation (> 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at a prohibitive risk for mitral valve surgery by a heart team. This team includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and this procedure is intended for patients in whom existing comorbidities would not preclude the expected benefit from the reduction of the mitral regurgitation.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers percutaneous mitral valve repair (MitraClip) for patients who have been determined to be at a prohibitive risk for mitral valve surgery and meet other specific coverage criteria.
Percutaneous Mitral Valve Repair (Mitraclip®), continued

Coverage criteria:

A. Must meet BOTH of the following:

1. Symptomatic* mitral regurgitation is > 3+ on echocardiography or cardiac catheterization

   AND

2. Mitral regurgitation is due to degenerative** mitral valve disease OR for patients with normal mitral valves who develop heart failure symptoms and moderate-to-severe or severe mitral regurgitation because of diminished left heart function (commonly known as secondary or functional mitral regurgitation) despite being treated with optimal medical therapy

*Symptomatic is defined as patients experiencing chest pain, shortness of breath at rest or with exertion, orthopnea or PND requiring medical intervention and directly related to the mitral regurgitation.

**Degenerative mitral valve disease is classified as degeneration of the mitral valve due to changes in the connective tissue of the valve or mitral chordae causing weakness and redundancy of the leaflets and their supporting structures. Degenerative mitral valve disease does not include infective causes, or mitral regurgitation due to ischemia or problems intrinsic with the left ventricle causing the mitral annulus to dilate and creating the mitral insufficiency. The most common finding in patients with degenerative valve disease is leaflet prolapse due to elongation or rupture of the chordal apparatus.

**SelectHealth Advantage (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 SelectHealth 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&](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&) or the manual website.

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**Summary of Medical Information**

In December 2013, an updated review of this technology was undertaken. This review identified one systematic review and 41 primary literature articles which met the inclusion criteria for review. Most of the authors conducted and published their results after the EVEREST I Trial, EVEREST II RCT, EVEREST II HRR, and REALISM HR trials were completed. The only systematic review included only 12 studies and stated that no RCTs comparing MitraClip to non-surgical therapies were identified. This is the same finding illustrated in this report. They also noted that only one paper published between 2000 and 2013 reported outcomes beyond 12 months; however, 11 papers identified for this review followed-up with patients after 12 months between only 2010 and 2013; with regards to the primary literature articles, 5,575 patients have been enrolled in published studies in the last three years. Outcomes from the studies showed successful implantation ranging from 85% to 100% with reduction in mitral regurgitation ranging from a low 41.4% to 65%. These studies also showed improvement in NYHA categorization of at least 1 grade, ranging from 34.4% to 66.7%. In the 9 studies which assessed patients out to at least 12 months post-procedure, survival ranged from 71.1% to 87.5%. Similar to the findings reported in the systematic review, the average follow-up time was just over a year in the primary literature. Dissimilar to that review, however, 5 papers followed patients for 2 years and one paper followed patients out to 4 years.
An important observation from the studies relates to the number of MitraClips used. 11 of the 41 studies used either more than 2 clips or no clip at all in each procedure. Paramskaya et al., for example, reported that 19 patients (22.3%) received 3 clips, 4 patients (4.7%) received 4 clips, and 1 patient (1.2%) received 5 clips. For studies where clips had to be removed because of perioperative complications, the authors reported that zero clips were used. Also, some of the 11 studies did not report what number of clips over 2 were used during the procedure so it is difficult to estimate what number of procedures used 3, 4, or 5 clips.

Feldman et al. and Mauri et al. were the only two to have randomized their surgical repair patients from their MitraClip patients. This is important to note as the remaining three studies explicitly note that MitraClip patients were significantly older, had lower LVEF, had a higher EuroSCORE I, had higher LV diameter, and had more comorbidities in general.

Five studies compared MitraClip surgery to standard valvular surgery. Feldman et al. and Mauri et al. were the only two to have randomized their surgical repair patients from their MitraClip patients. This is important to note, as the remaining three studies explicitly note that MitraClip patients were significantly older, had lower LVEF, had a higher EuroSCORE I, had higher LV diameter, and had more comorbidities in general. These studies did not demonstrate a statistically significant difference between percutaneous MitraClip procedures to valvular surgery for endpoints which included 30-day survival, longer term mortality, and improvement in cardiovascular function.

In conclusion, the current body of evidence regarding MitraClip demonstrates that MitraClip may reasonably improve patient outcomes, especially for patients who otherwise could not undergo surgery. Though only a few papers thoroughly examine patient outcomes in the long-term (> 2 years), what evidence does exist, shows similar outcomes as compared to standard surgical methods in appropriately selected patients. (GRADE 1B).

Billing/Coding Information

CPT CODES

0483T Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed

0484T Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)

33418 Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis

33419 ; additional prosthesis (es) during the same session (List separately in addition to code for primary procedure)

Not Covered/Considered investigational:

93590 Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve

93592 Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)

HCPCS CODES

No specific codes identified

Key References

1. Alegria-Barrero, E, Chan, PH, Foin, N, et al. (2013). Concept of the central clip: when to use one or two MitraClips(R). EuroIntervention


Percutaneous Mitral Valve Repair (Mitraclip®), continued


Percutaneous Mitral Valve Repair (Mitraclip™), continued


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PERCUTANEOUS TRANSCATHETER CLOSURE FOR THE TREATMENT OF ATRIAL SEPTAL DEFECTS (ASD) AND PATENT FORAMEN OVALE (PFO)

Policy # 174
Implementation Date: 4/21/02
Revision Dates: 11/18/04, 8/4/06, 10/31/06, 2/5/07, 6/30/07, 12/5/11, 8/14/18, 5/13/22

Description
Atrial septal defect (ASD) is the most common congenital lesion in adults after bicuspid aortic valve. Although the defect is often asymptomatic until adulthood, potential complications of an undetected ASD include right ventricular failure, atrial arrhythmias, paradoxical embolization, cerebral abscess, and pulmonary hypertension that can become irreversible and lead to right-to-left shunting (Eisenmenger syndrome).

In approximately 70% of individuals, the primum and secundum septa fuse after birth, creating an intact interatrial septum. However, in a significant proportion of the population, the septae do not fuse. If the foramen ovale is completely covered but not sealed, it is called a "probe patent" or simply "patent" foramen ovale (PFO), indicating that the foramen can be opened by a reversal of the interatrial pressure gradient or by an intracardiac catheter. Less commonly, an open communication persists between the atria after septation. Such a communication is called an atrial septal defect (ASD).

The various types of ASDs are classified according to their location and the nature of the embryologic defect. Isolated ASDs include: PFO, ASD at the fossa ovalis (secundum ASD), a defect superior to the fossa ovalis (superior sinus venosus type ASD, superior vena caval defect), a defect inferior to the fossa ovalis (inferior sinus venosus type ASD, inferior vena caval defect), and coronary sinus defects.

The standard of care for the treatment of significant or symptomatic ASDs is percutaneous closure using several FDA-approved devices. Recently, this same therapy has been investigated for closure of physiologically significant PFOs. No devices are currently FDA approved that are specific to PFO-closure, however, this therapy is being performed using devices that are FDA approved for ASD-closure in patients with cryptogenic stroke. PFO-closure is also being investigated as a treatment of migraine headaches.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers percutaneous transcatheter closure of symptomatic atrial septal defect (ASD) in secundum position or for the closure of the fenestration in individuals who have undergone a fenestrated Fontan procedure. These procedures are considered medically necessary when using a device that has been FDA approved for that purpose and used according to the labeled indications.
SelectHealth covers percutaneous transcatheter closure of patent foramen ovale (PFO) using FDA approved closure devices in limited circumstances.

Criteria for coverage:
1. Patient has a documented history of recurrent, cryptogenic, clinically-evident transient ischemic episode or stroke, which has been verified by an independent, qualified neurologic specialist.
2. Patient has demonstrated the PFO to be hemodynamically significant as defined by EITHER one of the following:
   a. Right-sided pressure or volume overload changes on imaging studies along with evidence of a large shunt (typically permanent right-to-left shunt); or
   b. Documented orthodeoxia-platypnea (resting or exercise induced)

SelectHealth does NOT cover percutaneous transcatheter closure of PFO for migraine prophylaxis or for any other indications because its effectiveness for these indications has not been established. It is considered experimental and investigational in these circumstances.

SelectHealth Advantage (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 SelectHealth 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.

SelectHealth Community Care (Medicaid)

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Summary of Medical Information

There are several devices approved by the FDA for closure of ASDs. These include the AMPLATZER Septal Occluder, HELEX Septal Occluder, and the NMT Medical CardioSEAL STARFlex Septal Occlusion System. All these devices are inserted via a catheter in collapsed form, then once at the defect, the device opens, and occludes the defect.

Prior to October 31, 2006, the FDA approved 2 catheter systems under the Human Device Exemption (HDE) for patients with patent foramen ovale (PFO) and cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy. The previously approved devices were the NMT Medical CardioSEAL STARFlex Septal Occlusion System and the AGA Medical Amplatzer PFO Occluder. As it was felt that these devices no longer met the criteria for the HDE exemption and needed to prove their efficacy through the PMA approval process, both manufacturers agreed to cease marketing their devices effective October 31, 2006.

Though no randomized, controlled trials have proven the PFO specific percutaneous devices to be safe and effective, the literature suggests that currently approved FDA devices are effective in closing both ASD and PFO. Anzola et al., for example, studied 140 patients who underwent percutaneous closure for PFO. At the 12-month follow-up, 91% had not detectable right-to-left shunt and only one CVA-like event.
Percutaneous Transcatheter Closure for the Treatment of Atrial Septal Defects (ASD) and Patent Foramen Ovale (PFO), continued

had occurred. Bruch et al. reported on 66 patients with ASD, none of whom had residual shunting after 12 months. No evidence of recurrent thromboembolic events was observed in this population.

A 2004 study of 28 patients with ASD by Khositseth et al. found a 7% residual shunt rate at 12 months. A 3.6% recurrence rate for recurrent thromboembolic events was observed at 23 months. Yew et al. reported 5-year data on patients who underwent percutaneous ASD-closure. All patients experienced complete closure.

Subsequently, as the questions around the similarity between PFO and ASD physiology have been addressed in the above literature, one may be able to extrapolate that use of ASD-closure approved devices will be effective in PFOs. Supporting this supposition, several conference abstracts provide additional support for ASD-closure devices for treating PFO. In 58 patients, closed with either the Amplatzer PFO device or the Amplatzer Septal Occluder, residual shunt at 3 months was lower in the latter group. In 1000 patients treated with either device, serious adverse events were uncommon and the relative risk of CVA was 0.15 compared with historical controls.

It was noted that a Hayes Directory published in 2002 gave percutaneous closure of PFO and ASD a ‘B’ rating indicating a device with some proven benefit (i.e., use of the technology is supported by a moderate level of published evidence but further research is required to fully clarify clinical indications, contraindications, treatment parameters, comparison with other technologies, and/or impact on health outcomes). The report cited a lack of long-term follow-up data as a weakness in the literature.

These data suggest that ASD devices are effective at closing PFO and reducing risk for recurrent stroke, at least in the short-term. Long-term data are still lacking as well as comparative trials to examine the relative efficacy between percutaneous devices and medical therapy on stroke outcomes. Ongoing clinical trials may provide additional insight pertinent to this question.

In 2011, a literature review was performed, and guidelines provided by the Intermountain Medical Center Heart Institute identified a science advisory from the American College of Cardiology Foundation (ACCF), American Heart Association (AHA), American Stroke Association (ASA), and the American Academy of Neurology published in 2010. The advisory concluded the optimal therapy for prevention of recurrent stroke or transient ischemic attack in patients with cryptogenic stroke and PFO has not been defined. Although numerous observational studies have suggested a strong association between PFO and cryptogenic stroke, a causal relationship has not been convincingly established for the majority of affected patients. Treatment choices include medical therapy with antiplatelet agents or vitamin K antagonists, percutaneous device closure, or open surgical repair. Whereas suture closure of an incidental PFO is performed routinely during an operation undertaken for another indication, primary surgical repair is rarely advocated in the current era. The choice between medical therapy and percutaneous device closure has been the subject of intense debate over the past several years, albeit one that has not been adequately informed by randomized, prospective clinical trial data to permit an objective comparison of the relative safety and efficacy of these respective approaches. Enrollment in clinical trials has lagged considerably despite frequent calls for participation from the US Food and Drug Administration and major professional societies. Completion and peer review of ongoing trials are critical steps to establish an evidence base from which clinicians can make informed decisions regarding the best therapy for individual patients. The present advisory strongly encourages all clinicians involved in the care of appropriate patients with cryptogenic stroke and patent foramen ovale—cardiologists, neurologists, internists, radiologists, and surgeons—to consider referral for enrollment in these landmark trials to expedite their completion and help resolve the uncertainty regarding optimal care for this condition.

Based on a guideline for healthcare professionals from the American Heart Association/American Stroke Association published in 2011, the importance of PFO with or without atrial septal aneurysm for a first stroke or recurrent cryptogenic stroke, remains in question. No randomized controlled clinical trials comparing different medical therapies, medical versus surgical closure, or medical versus transcatheter closure, have been reported, although several studies are ongoing. Non-randomized comparisons of various closure techniques with medical therapy have generally shown reasonable complication rates and recurrence risk with closure at or below those reported with medical therapy. One study suggested a particular benefit in patients with > 1 stroke at baseline.

There is still debate on the possible mechanism of formation of WMLs in migraine. Subjects with migraine with aura (MA) have a two-fold risk of being a carrier of a cardiac right-to-left shunt (RILES) due to PFO compared with the general population. Patent foramen ovale, which can be detected by transcranial Doppler (TCD), is a risk factor for cryptogenic ischemic stroke in young patients, and its prevalence in patients with MA is about 45%.
In 2010, Ueno et al. assessed the contribution of embolic etiologies, PFO and atrial septal aneurysm (ASA), to cerebral white matter lesions (WMLs) in ischemic stroke patients. They enrolled 115 patients (age, 69 +/- 11 years; 41 females); 49 (43%) were in the PFO group, 4 (3%) were in the ASA group, 23 (20%) were in the PFO-ASA group, and 39 (34%) were in the non-SA group. The PFO-ASA group had significantly increased WMLs compared to the other three groups (p = 0.004). On multiple logistic regression analysis, the coexistence of PFO and ASA was significantly associated with the degree of WMLs (odds ratio: 2.40; 95% confidence interval: 1.11-5.17; p = 0.026) when the PFO-ASA and non-SA groups were compared. They concluded that coexistence of PFO with ASA could play an important pathogenic role in WML severity.

Adami et al. performed the Shunt Associated Migraine (SAM) study. One hundred eighty-five patients (77% women) underwent a standardized headache and vascular risk factors questionnaire, contrast-enhanced transcranial Doppler, blood coagulation tests, and brain MRI. RLS was categorized into four grades: no shunt, < 10 microbubbles (mb), > 10 mb single spikes pattern, and > 10 mb shower/curtain pattern. Standard and fluid-attenuated inversion recovery T2-weighted MRI sequences were inspected for WMLs by three independent raters blinded to RLS grade. WML load was scored in the periventricular areas (PV-WMLs) with the Fazekas scale and in the deep white matter (D-WMLs) with the Scheltens scale. Interobserver agreement was good to excellent (k = 0.64 to 0.96, p < 0.0001). WML load was then correlated between patients with and without RLS. They concluded that the presence of right-to-left shunt does not increase white matter lesion load in patients who have migraine with aura.

In summary, these studies provide new information on options for closure of PFO and generally indicate that short-term complications with these procedures are rare and for the most part minor. Unfortunately, long-term follow-up is lacking. Event rates over 1–2 years after transcatheter closure ranged from 0%–3.4%. Studies in which closure was compared with medical treatment alone indicate trends toward better outcomes with closure. Windecker et al. reported a very high 3-year event rate of 33.2% in 44 medically treated patients compared with 7.3% in 59 similar patients treated with PFO-closure. The generally low rates of stroke in the closure series, the lack of robust outcome differences in the 3 non-randomized comparison studies, and the overall absence of controlled comparisons of closure strategies with medical treatment alone, reinforce the need to complete randomized clinical trials comparing closure with medical therapy. A 2009 statement from the AHA/ASA/ACC strongly encourages all clinicians involved in the care of appropriate patients with cryptogenic stroke and PFO-cardiologists, neurologists, internists, radiologists, and surgeons, to consider referral for enrollment in these landmark trials to expedite their completion and help resolve the uncertainty regarding optimal care for this condition.

Billing/Coding Information

CPT CODES

Covered: For the indications outlined above

93580 Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant

HCPCS CODES

C1760 Closure device, vascular (implantable/insertable)

C1817 Septal defect implant system, intracardiac

Key References

Percutaneous Transcatheter Closure for the Treatment of Atrial Septal Defects (ASD) and Patent Foramen Ovale (PFO), continued


Percutaneous Transcatheter Closure for the Treatment of Atrial Septal Defects (ASD) and Patent Foramen Ovale (PFO), continued


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Cardiovascular Policies, Continued

Percutaneous Transcatheter Closure for the Treatment of Atrial Septal Defects (ASD) and Patent Foramen Ovale (PFO), continued

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PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY STENTING (PTAS) FOR THE TREATMENT OF INTRACEREBRAL DISEASE

Policy # 495
Implementation Date: 12/5/11
Review Dates: 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/18/18, 8/7/19
Revision Dates:

**Description**
Cerebrovascular disease (CVD) refers to a group of conditions that affect the circulation of blood to the brain, potentially limiting blood flow to affected areas of the brain. This can manifest itself as either a stroke or transient ischemic attack (TIA).

Standard therapy for patients with atherosclerotic disease is antiplatelet therapy with aspirin or other antiplatelet agents and control of other risk factors. Intracerebral stenting of identified atherosclerotic lesions is also offered to some patients. The stent and delivery catheter consist of an expandable stainless-steel device that provides structural support for a blood vessel, helping to keep it open. The stent is a self-expanding, metal (nitinol) mesh in the shape of a tube. It is intended for use in the treatment of patients with recurrent intracranial stroke due to atherosclerotic disease who did not respond to medical therapy.

**Commercial Plan Policy**
SelectHealth does NOT cover percutaneous transluminal angioplasty stenting (PTAS) in the treatment of intracranial disease. The current evidence has not demonstrated this treatment as a clinical benefit for the initial therapy of intracerebral atherosclerotic disease.

SelectHealth Advantage (Medicare/CMS) (No Preauthorization Required but criteria may apply if appropriate)

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SelectHealth Community Care (Medicaid/CHIP) (No Preauthorization Required but criteria may apply if appropriate)

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Summary of Medical Information
A Medical Technology Assessment performed in October 2011 identified 4 systematic reviews. All systematic reviews were published in 2006 or 2007 and no updates are available and long-term outcomes were not presented. Questions concerning durability and success of 2 different stents were raised. All concluded that current evidence at the time of their reviews was insufficient to warrant broad coverage outside an investigational setting.

Seventeen peer-reviewed papers studying PTAS were identified. These studies were small in size and supported the use of stenting in patients with > 50% atherosclerotic narrowing of any intracerebral vessel with significant success and relatively low risk of complications. For example, the largest study by Jiang, involved 637 patients and 670 lesions. It was a retrospective study comparing 2 different stents. A relatively low risk of complications, 6.1% within 30 days of the procedure was demonstrated. This study’s limitations include the short duration of follow-up (1 month), and the lack of randomization or blinding.

The most recent article on this topic was a randomized controlled multi-centered study published in September 2011 by Chimowitz et al. This study compared percutaneous transluminal angioplasty and stenting (PTAS) with aggressive medial management in patients with 70%–99% narrowing. The 2 groups had similar initial clinical findings, and both achieved similar outcomes to medical management including improved blood pressure control, LDL reduction, and diabetic control. Aspirin and clopidogrel were used. The interventional group developed a much higher rate of complications including hemorrhagic stroke and death within the first 30 days. The medical group also achieved a lower rate of stroke reduction than what was expected compared with previous studies evaluating the role of medical therapy in the prevention of recurrent stroke. “The 30-day rate of stroke or death in the PTAS group (14.7) is substantially higher than the rates previously reported with the use of the Wingspan stent in the Phase I trial and in 2 registries (rates ranging from 4.4-9.6).” The rate of stroke was much lower at 5.5% with expected rate of 10.7%. The expected 1-year rate of stroke or death was 25% and realized rate in this study was 12.2%. These results were carefully analyzed to attempt to explain the difference in realized and expected outcomes.

Despite experienced interventional radiologists, similar initial clinical parameters, and similar results in aggressive medical management between the 2 groups, the much higher complication rate within the first 30 days of the procedure which included stroke and death led to the early suspension of this trial.

Also discouraging was that 4% of patients (total of 9) who crossed over from the medical group to the PTAS group due to recurrent strokes also had a high rate of complications. Three of the 9 patients suffered a stroke after PTAS within 30 days. Despite attempts from stent manufacturers to minimize restenosis the rate of restenosis occurs “23%-30% within 6 months after intracranial PTAS and could also lead to later stroke.”

In conclusion, the most recent large clinical trial, Stenting and Aggressive Medical Management for Preventing Recurrent stroke in Intracranial Stenosis (SAMMPRIS), 14% of patients treated with angioplasty combined with stenting experienced a stroke or died within the first 30 days after enrollment compared with 5.8% of patients treated with medical therapy alone. Even though there have been many studies dating back to 2002, the literature has shown for patients with intracranial arterial stenosis, aggressive medical management was superior to PTAS with the use of either the Wingspan™ or the Neurolink® stent systems. The risks of early stroke after PTAS were high and the risk of stroke with aggressive medical therapy alone was lower than expected. Therefore, the use of PTAS with or without medical management does not seem to be a reliable form of treatment for intracranial stroke.

Billing/Coding Information
Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES
61635 Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed

HCPCS CODES
C1874 Stent, coated/covered, with delivery system
C1875 Stent, coated/covered, without delivery system
C1876 Stent, non-coated/non-covered, with delivery system

C1877 Stent, non-coated/non-covered, without delivery system

Key References
Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research. Circulation 119.16: 2235-49.


Cardiovascular Policies, Continued

MEDICAL POLICY

SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR

Policy # 535
Implementation Date: 8/9/13
Review Dates: 8/28/14, 8/20/15, 8/25/16, 8/17/17, 7/25/18, 6/13/19, 6/18/20, 8/11/21
Revision Dates: 8/23/21

Description
Tachyarrhythmias are broadly characterized as supraventricular tachycardia (SVT), defined as a tachycardia in which the driving circuit or focus originates, at least in part, in tissue above the level of the ventricle (i.e., sinus node, atria, AV node, or the bundle of His) and ventricular tachycardia (VT), defined as a tachycardia in which the driving circuit or focus solely originates in ventricular tissue or Purkinje fibers. Sustained arrhythmias are an important cause of sudden death. Ventricular arrhythmias that occur in the absence of structural heart disease or a defined ion channel abnormality are referred to as *idiopathic* and are usually benign. Ventricular arrhythmias are responsible for most of the 150,000 to 350,000 sudden deaths that occur annually in the United States and account for approximately 13% of all mortality. Without immediate action, ventricular tachycardia can degenerate to ventricular fibrillation and lead to sudden death. Short-term goals of treatment are to stabilize hemodynamically unstable patients, transfer them to a hospital immediately, and stop ventricular tachycardia.

Transvenous implantable cardiac defibrillators (ICDs) have been used for years and are designed to detect a life-threatening, rapid heartbeat emanating from the lower chamber of the heart, and then deliver an electrical discharge intended to terminate the rhythm so that it is converted back to normal. Conventional ICDs consist of a generator, which is usually implanted in a pocket in the pectoral region below the left shoulder. The transvenous right ventricular lead contains the shock coils and pacing electrode. Additional leads may be connected for right atrial or left ventricular pacing, sensing, and defibrillation. The ICD can be implanted under local anesthesia with the leads inserted through an incision into a vein and guided to the heart under fluoroscopy. The lead is attached to the heart muscle, while the other end of the lead is attached to the pulse generator.

Subcutaneous implantable defibrillators (S-ICD) have recently been approved in an effort to reduce morbidity and procedure-related complications. The S-ICD consists of an electrically active pulse generator, which is implanted near the left mid-axillary line and a subcutaneous lead, consisting of sensing electrodes and a shocking coil, which is tunneled 1 to 2 cm to the left of the mid-sternal line. The current FDA approved S-ICD weighs 145 grams and has a lithium battery with a projected life of 5 years; therapy consists of 80-Joule biphasic transthoracic shocks and 30 seconds of post-shock pacing.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

SelectHealth covers subcutaneous implantable defibrillator for members 10 years of age and older who would require a transvenous cardiac defibrillator for ventricular tachyarrhythmias for the treatment of life-threatening ventricular tachyarrhythmias.

SelectHealth does not cover subcutaneous implantable defibrillators for patients who have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with antitachycardia pacing.
SelectHealth Advantage (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 SelectHealth 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.

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Summary of Medical Information

A recent review of subcutaneous implantable cardiac defibrillators (S-ICDs) identified eight peer-reviewed published studies that met inclusion criteria for this report. No systematic reviews on the safety, efficacy, or cost-effectiveness of subcutaneous implantable defibrillators have been published. These studies had a mean duration ranging from 7.2 to 22.3 months. The studies documented efficacy of 89.6% to 100% in aborting dysrhythmias. These studies also identified inappropriate shocks occurring from 0% to 22% of the time. These numbers compare favorably to historical rates for efficacy and inappropriate shocks for transvenous ICDs which have demonstrated inappropriate shock rates as high as 30%.

In general, single shocks, whether preceded by symptoms or not, are most often caused by the appropriate detection and treatment of a ventricular tachyarrhythmia. Conversely, multiple transvenous ICD discharges often result from the detection of other arrhythmias or signals that are inaccurately classified as a ventricular tachyarrhythmia. Thus, transvenous ICD therapy often is inappropriately delivered for sinus tachycardia, or other supraventricular tachycardias with rapid AV conduction. To this point, Jarman et al., Kobe et al., and Olde Nordkamp et al., all noted that inappropriate shocks (5.6% of all shocks) were associated with T-wave oversensing in patients with S-ICDs. During the MADIT II Trial of transvenous ICDs, Daubert et al. found that one or more inappropriate shocks occurred in 11.5% of the 719 patients enrolled.

No cost-effectiveness studies have been completed comparing S-ICD to either transvenous ICD or to medical treatment.

Using the Grade evidence system, which rates the body of evidence as either Grade 1−3, with additional ranking of A–C, the current body of evidence has a Grade evidence level of 2B. This is primarily due to the limitations in evidence, where risks and magnitude of benefits appear to be finely balanced in comparison to medical treatment or conventional ICD placement and where the quality of evidence is moderate (cohort studies with short follow-up times).

Billing/Coding Information

CPT CODES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>33240</td>
<td>Insertion of implantable defibrillator pulse generator only; with existing single lead</td>
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<tr>
<td>33241</td>
<td>Removal of implantable defibrillator pulse generator only</td>
</tr>
<tr>
<td>33262</td>
<td>Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system</td>
</tr>
<tr>
<td>33263</td>
<td>Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system</td>
</tr>
<tr>
<td>33264</td>
<td>Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system</td>
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</tbody>
</table>
Cardiovascular Policies, Continued

Subcutaneous Implantable Defibrillator, continued

33270  Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed

33271  Insertion of subcutaneous implantable defibrillator electrode

33272  Removal of subcutaneous implantable defibrillator electrode

33273  Repositioning of previously implanted subcutaneous implantable defibrillator electrode

93260  Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system

93261  Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system

HCPCS CODES

C1721  Cardioverter-defibrillator, dual chamber (implantable)

C1722  Cardioverter-defibrillator, single chamber (implantable)

C1882  Cardioverter-defibrillator, other than single or dual chamber (implantable)

C1899  Lead, pacemaker/cardioverter-defibrillator combination (implantable)

G0448  Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

Key References


Subcutaneous Implantable Defibrillator, continued


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Cardiovascular Policies, Continued

TOTAL ARTIFICIAL HEART

Policy # 436
Implementation Date: 3/22/10
Review Dates: 8/16/11, 8/15/13, 8/28/14, 8/20/15, 8/25/16, 12/15/16, 8/17/17, 7/20/18, 6/13/19, 6/18/20
Revision Dates: 8/16/12, 10/19/15

Description
Heart failure (HF) is a common complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood.

Heart failure is classified based upon the history, including assessment of New York Heart Association (NYHA) functional class, and physical examination in conjunction with certain diagnostic tests. Both establish the primary cause of the heart failure and provide a reasonable estimate of its severity. The NYHA classification system most commonly used to quantify the degree of functional limitation imposed by HF was first developed by the New York Heart Association (NYHA). This system assigns patients to one of four functional classes, depending on the degree of effort needed to elicit symptoms.

• Class I - symptoms of HF only at activity levels that would limit normal individuals
• Class II - symptoms of HF with ordinary exertion
• Class III - symptoms of HF with less than ordinary exertion
• Class IV - symptoms of HF at rest

Additionally, heart failure has 4 stages (Stage A – Stage D) that reflect the development and progression of the condition. Treatment depends on the stage of heart failure. The first 2 stages (Stage A and B) are technically not heart failure but indicate that a patient is at high risk for developing it. Lifestyle and risk factor modification are the key components to the treatment of these stages.

Patients with Stage C heart failure have a structural abnormality and current or previous symptoms of heart failure, including shortness of breath, fatigue, and difficulty exercising. In addition to the treatment undertaken for Stage A and B, these patients may be placed on a number of additional treatments, medications, or procedures.

In addition to left ventricular assist devices, total artificial heart transplants (TAH-t) are used in patients with end-stage heart disease who need a heart transplant, who have failed optimal medical therapy, and for who no other reasonable medical or surgical treatment options are available. TAH-t is typically chosen in patients with biventricular failure rather than left ventricular failure only or who are ineligible for other ventricular devices when a donor organ is not immediately available. Total artificial hearts have been used as a bridge to transplant (temporary) or as a destination therapy (permanent).

The SynCardia™ Total Artificial Heart (SynCardia Systems Inc., Tucson, AZ) is a pulsating bi-ventricular device that is implanted into the chest to replace the lower portion of the patient’s heart. Patients are connected by tubes from the heart through their chest wall to a large power-generating console, which operates and monitors the device. A smaller portable controller, the Freedom Driver, is available through clinical trial and patients may be discharged to home while waiting for transplantation.

The AbioCor® Implantable Replacement Heart (Abiomed, Inc., Danvers, MA) is an electrically powered pump (pulsatile electrohydraulic device) used to replace the main pumping chambers (the ventricles) of the human heart. The device consists of a “Thoracic Unit” containing 2 sealed blood pumps, separated by an energy converter. After the lower chambers are removed, the unit is connected to the heart’s 2 upper collecting chambers. The energy converter moves hydraulic fluid from one side of the device to the other.

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for SelectHealth Commercial, SelectHealth Advantage (Medicare/CMS), and SelectHealth Community Care (Medicaid/CHIP) plans. Refer to the “Policy” section for more information.
squeezing a sac containing the blood in one side of the pump to force the blood through the connected outgoing vessel. Simultaneously, blood is actively drawn into the pump on the opposite side, filling it for the next cycle, which will discharge blood to the other outgoing vessel. This device is totally implanted, including a regulator and an externally rechargeable battery.

Both artificial hearts continue to be studied extensively, as both a bridge to transplant and a destination therapy in patients with intractable (stage 4) heart failure, failing on medication therapy alone.

**Commercial Plan Policy (Preauthorization Required)**

SelectHealth covers the SynCardia™ total artificial heart as a bridge to transplant in *limited circumstances*.

Members must meet ALL the following criteria:

1. Intractable biventricular failure unresponsive to maximal medical therapy; **AND**
2. Member is an approved candidate for donor heart transplantation and has been registered as a transplant candidate; **AND**
3. Member is NOT a candidate for left ventricular assist device (LVAD) implantation; **AND**
4. Member has adequate space in the chest area where the ventricles will be removed. This is generally defined as a body surface area (BSA) > 1.7 m² and a distance between the sternum and the 10th anterior vertebral body measured by CT is > or = 10 cm.

SelectHealth does NOT cover any other total artificial heart device (e.g., AbioCor®). The lack of evidence does not support adequate safety or efficacy. This meets the plan’s definition of investigational/experimental.

SelectHealth does NOT cover ANY total artificial heart device as destination therapy. The lack of evidence does not support adequate safety or efficacy. This meets the plan’s definition of investigational/experimental.

**SelectHealth Advantage (Medicare/CMS) (Preauthorization Required)**

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**SelectHealth Community Care (Medicaid/CHIP)**

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 SelectHealth 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](http://health.utah.gov/medicaid/manuals/directory.php) or the Utah Medicaid code Look-Up tool.

**Summary of Medical Information**

The number of studies available assessing total artificial heart transplant (TAH-t) as a bridge to transplant or destination therapy is quite limited. Only 3 studies met the inclusion criteria for review and none were randomized to include an arm comparing the efficacy and safety of TAH-t to left ventricular assist device (LVAD) implantation. None of the reviews assessed the AbioCor device.
These studies, as expected, tended to have small study numbers, though, the largest by Platis et al. published in 2009 assessed the outcomes of 715 SynCardia transplants over 16 years. Overall, the studies demonstrated improved mortality as compared to watchful waiting but also demonstrated significant complications. From the studies included in this report, the table below provides a parallel comparison of the various trials and the outcomes as they compare to LVAD used as a bridge to transplant.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total Artificial Heart Device</th>
<th>Left Ventricular Assist Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival to transplant post-implantation</td>
<td>71.5%–79%</td>
<td>69%–86.9%</td>
</tr>
<tr>
<td>1-year survival post donor heart transplant</td>
<td>57%–90%</td>
<td>63%–66.6%</td>
</tr>
<tr>
<td>5-year survival post donor heart transplant</td>
<td>34%–81%</td>
<td></td>
</tr>
<tr>
<td>Re-exploration for bleeding</td>
<td>47%</td>
<td>15.6%–33.3%</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>4.7%–44%</td>
<td></td>
</tr>
<tr>
<td>Renal failure requiring temporary dialysis</td>
<td>40%</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>33%–85%</td>
<td>8%–19%</td>
</tr>
<tr>
<td>Neurological event</td>
<td>7%–16%</td>
<td>4.8%–8.0%</td>
</tr>
<tr>
<td>GI bleeding</td>
<td>33%</td>
<td>8%–19%</td>
</tr>
<tr>
<td>Device failure</td>
<td>2.3%</td>
<td>0%–3.1%</td>
</tr>
</tbody>
</table>

Though difficult to directly compare, parallel analysis of LVAD to TAH-t therapy suggests similar outcomes in appropriately selected patients.

**Billing/Coding Information**

**Covered: For the conditions outlined above**

**CPT CODES**

- **33927** Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
- **33928** Removal and replacement of total replacement heart system (artificial heart)
- **33929** Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)

**HCPCS CODES**

No specific codes identified

**Key References**


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**TRANSCATHETER AORTIC VALVE IMPLANT (TAVI)**
**TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)**

**Policy # 444**

**Implementation Date:** 5/26/10  
**Review Dates:** 4/21/11, 12/18/14, 10/20/16, 9/19/18, 12/1/18, 12/23/20, 12/18/21  
**Revision Dates:** 8/5/13, 11/06/13, 4/3/15, 7/10/15, 12/9/16, 1/20/17, 12/21/17, 9/24/18, 8/23/19, 1/4/22

**Description**

There are 3 primary causes of valvular aortic stenosis (AS): a congenitally abnormal valve with superimposed calcification (unicuspid or bicuspid), calcific disease of a trileaflet valve, and rheumatic valve disease. In North America and Europe, aortic valve disease is primarily due to calcific disease of a native trileaflet or a congenital bicuspid valve. Worldwide, rheumatic valve disease is most common; mitral valve involvement invariably accompanies rheumatic aortic valve disease.

Many patients do not develop symptoms until severe valve obstruction (valve area < 1.0 cm²) is present, while some patients become symptomatic when the stenosis is less severe (1.5–2.0 cm²), particularly, if there is coexisting aortic regurgitation. Replacement of the aortic valve is the only effective treatment for severe AS. Standard aortic valve replacement surgery involves the patient undergoing a sternotomy and being placed on cardiopulmonary bypass. Not all patients can tolerate such an extensive procedure.

Less invasive transcatheter techniques for aortic valve replacements have been developed. Currently, FDA approved transcatheter valves include the balloon expandable Sapien® valve and self-expandable CoreValve® systems. Both Sapien and CoreValve consist of metal frames which support tissue valves. In June 2015, the first repositionable transcatheter valve, the CoreValve Evolut R™ received FDA approval. This is the first valve which can be repositioned after initial deployment, so as to reduce valve leakage or other issues.

Approaches to transcatheter aortic valve replacement include retrograde delivery with transfemoral, transaortic, and subclavian access, as well as antegrade delivery with the transapical approach.

**Commercial Plan Policy/CHIP (Children’s Health Insurance Program)**

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

SelectHealth covers FDA approved transcatheter aortic valve implants/replacements when EITHER of the following criteria are met (A or B).

A. TAVR will be approved If recommended by Intermountain Healthcare Cardiovascular Clinical Program,

OR

B. For all other clinicians, TAVR will be approved when ALL the following criteria are met:

**Disclaimer:**
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for SelectHealth Commercial, SelectHealth Advantage (Medicare/CMS) and SelectHealth Community Care (Medicaid/CHIP) plans. Refer to the “Policy” section for more information.
Criteria for Coverage (Must meet ALL):

1. Device has been approved by the FDA [PMA or 510(k)]

2. Patient has one of the following conditions:
   a. Severe native calcific aortic stenosis demonstrated by at least 1 of the following:
      1) An aortic valve area ≤ 1.0cm²
      2) A mean aortic valve gradient greater than 40mmHg
      3) A jet velocity greater than 4.0m/sec
   b. Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve
   c. Severe aortic regurgitation with justification from a cardiothoracic surgeon

3. Patient has documented New York Heart Association (NYHA) functional class II or greater

4. Patient has been evaluated face-to-face for open heart surgery by at least 1 cardiologist and 1 cardiothoracic surgeon, with full documentation, and determined to be a candidate for TAVR

5. Patient does not have a life expectancy < 12 months due to non-cardiac co-morbid conditions

SelectHealth Advantage (Medicare/CMS)

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Summary of Medical Information

TAVR for Aortic Stenosis: A May 2010 Medical Technology Assessment found the published literature available on this topic was limited. Only 1 technology assessment and 4 primary studies were identified. However, it is important to note the 1 technology assessment was published in June 2006 and was performed by a highly respected organization—the National Institute for Health and Clinical Excellence (NICE) out of the U.K. This technology assessment aimed to provide conclusions concerning current evidence of transcatheter aortic valve implantation. Aortic regurgitation and transvalvular gradient both appeared to decrease significantly in postoperative follow-up. Most of the literature focused on the implementation of these 2 devices. These are 2 major indicators/complications associated with diseased aortic valves.

A Medical Technology Assessment performed in June 2012 identified 23 new papers published since the last review in 2010, reflecting data at least 2 years post-procedure. In February 2012, Bleiziffer et al. reported 2-year results in 227 patients who received TAVI/TAVR. Clinical and echocardiographic investigations were performed at 6 months, 1 year, and 2 years. Survival was 89.5% at 30 days, 75.9% at 6 months, 74.5% at 1 year, and 64.4% at 2 years. Patients improved significantly in New York Heart Association class after 6 months (from 3.2 +/- 0.5 to 1.7 +/- 0.7, p < .001) and up to 2 years (1.9 +/- 0.7). Cumulative incidences of myocardial infarction, stroke, and life-threatening or major bleeding were 2.7%, 5.4%, and 3.8%, respectively.
6.2%, and 16.2% at 2 years, respectively. Moderate or severe prosthetic regurgitation was present in 8% of patients at 2 years. In 6% of patients, the paravalvular or valvular regurgitation grade increased significantly over time. They concluded transcatheter aortic valve implantation may be considered the treatment of choice for aortic valve stenosis in elderly patients with an increased risk for surgery with a heart-lung machine.

A prospective multicenter observational study published in 2011 by D’Onofrio et al. assessed early and 2-year outcomes after TAVI/TAVR in 179 patients. Patients underwent clinical and echocardiographic follow-up visits at hospital discharge, 3 and 6 months after TAVI/TAVR, and every 6 months thereafter. Seventeen severe intraoperative complications occurred in 13 (7.3%) patients. Thirty-day mortality was 3.9% (7 patients). Mean follow-up was 9.2 +/- 6.5 months. Late mortality occurred in 9 patients. Two-year survival was 88% +/- 3%. An intraoperative severe complication was identified as the only significant independent predictor of 1-year mortality. A significant benefit was found when comparing 2-year survival of the second versus the first 50% patients at each center (93% +/- 2% vs. 84% +/- 3%; p = 0.046). A significant reduction of both mean and peak gradients from the preoperative to the postoperative period, which remained stable during follow-up, was found.

In May 2012, the Centers for Medicare and Medicaid (CMS) issued a national coverage determination (NCD) outlining criteria under which it would provide coverage of TAVR/TAVI. Current evidence demonstrates improved mortality for patients who are ineligible for standard AVR, though, some increased morbidity risks exist especially for early stroke problems. Nonetheless, several studies identify this therapy to meet current standards for cost-effectiveness as defined by QALY’s.


Kapadia and colleagues focused on 358 patients with severe aortic stenosis (mean age, 83; mean Society of Thoracic Surgeons estimated risk of 30-day mortality after operative AVR [STS], 11.7%; women, 54%) who were deemed inoperable because of mortality risk or anatomical factors. Individuals were randomized to TAVR or nonoperative standard therapy. At 5 years, mortality was 71.8% in the TAVR group and 93.6% in the standard therapy group. There were six standard-therapy survivors with follow-up data; five received AVR outside the study. Of 49 survivors in the TAVR group, 86% had modest symptom burden (New York Heart Association class I or II symptoms). Prosthetic valve deterioration was not evident in the TAVR group.

Mack and colleagues followed 699 patients with severe aortic stenosis (mean age, 84; mean STS score, 11.7%; women, 43%) who were considered at high but not prohibitive risk for surgery. Individuals were randomized to TAVR or surgical AVR (SAVR). At 5 years, the two groups had statistically similar mortality—67.8% with TAVR and 62.4% with SAVR. No postprocedural events requiring repeat valve replacement were reported. Moderate-to-severe aortic regurgitation 30 days after the procedure occurred in 14% of the TAVR group and 1% of the SAVR group (P < 0.0001) and was identified as a risk factor for death.

Aortic Stenosis with Aortic Insufficiency: A literature review completed in November 2016 reviewed the evidence as it relates to TAVR use in aortic insufficiency. This review identified one systematic review and 3 primary studies were identified which met inclusion criteria. In all, 159 patients were studied, of which, 92 (57.9%) received TAVR for aortic insufficiency. The systematic review by Phan et al., though, specific to AI, investigated the use of TAVR in patients with a left ventricular assist device. Though the report showed promise for the procedure, it does not generally address the question of the procedure’s clinical utility in most patients with traditional AI symptoms.

The 3 primary studies were all published since 2013. They consist of multi-center, prospective, or retrospective patient populations. No long-term data has been published to date on the use of this intervention for the treatment of AI. Only 1 of the 3 (33%, Wilder et al.) compared outcomes to other surgical methods. Survival outcomes from studies by Roy et al. and Testa et al. varied widely even with use of the same device (CoreValve) likely due to differing patient populations and inclusion criteria. Mortality from AI/AR in symptomatic patients is > 10% per year. The assessed studies show greater than double the mortality rate in patients treated with TAVR for AI than previously published outcomes from patients not undergoing surgical management for the treatment of AI. One obvious limitation of this
conclusion is the lack of randomized, controlled published data regarding TAVR in patients with primary symptomatic AI.

Though the evidence regarding TAVR in aortic insufficiency is weak, it demonstrates net benefit in high-risk patients who are otherwise not surgical candidates. In addition, the FDA has approved the Edwards Sapien XT for use in aortic insufficiency in patients with a bioprosthetic valve (valve-in-valve procedure).

As experience with TAVR continues to grow, potential candidates for TAVR continue to be explored. Whereas initial candidates were either ineligible for surgery or have serious surgery risk for post-operative morbidity or mortality. A body of literature has been published related to performing TAVR in patients with intermediate surgical risk (STS score ≥ 3 and ≤ 10). A review of the published literature recently completed identified four systematic reviews and 14 primary studies related to patients with intermediate surgical risk undergoing TAVR. All 4 systematic reviews were published in 2016 and the primary studies have all been published since 2012. These studies represent assessment of > 17,000 intermediate risk patients, of which, > 8,800 received TAVR.

The four systematic reviews by Arora et al., Khan et al., Siemieniuk et al., and Zhou et al., reached similar conclusions that all-cause mortality rates did not differ to a statistically significant degree between SAVR and TAVR-treated intermediate-risk patients. From the primary literature studies by Abdul-Jawad Altisent et al., D’Errigo et al., Fanning et al., Kodali et al., Leon et al., and Thourani et al., it was also suggested the rate of stroke was lower in TAVR than in SAVR.

One concern noted from the studies was related to the need for permanent cardiac pacemaker placement. Nine of the primary studies and the four systematic reviews reported on pacemaker implantation. All the systematic reviews reported an increased incidence of pacemaker implantation in TAVR vs. SAVR patients. This rate varied in the studies, from 2 to 15 times the incidence of pacemaker placement TAVR compared to SAVR.

Conclusions drawn from the recently published data on TAVR for intermediate risk patients from 2012 has illustrated mortality and pacemaker implantation rates in nearly 8,000 patients. Most of the literature compared TAVR to SAVR and illustrated comparable mortality rates at follow-up periods between 1 and 24 months. However, substantially more pacemakers are implanted in TAVR patients than in those receiving standard surgical treatment.

Billing/Coding Information
Covered: For the circumstances outlined above:

CPT CODES

<table>
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<th>CPT CODE</th>
<th>Description</th>
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<td>33361</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach</td>
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<tr>
<td>33362</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach</td>
</tr>
<tr>
<td>33363</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach</td>
</tr>
<tr>
<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
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<tr>
<td>33365</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)</td>
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<tr>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)</td>
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<tr>
<td>33367</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>33368</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>
Transcatheter Aortic Valve Implant (TAVI), Transcatheter Aortic Valve Replacement (TAVR), continued

33369  Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)

33405  Replacement, aortic valve, with cardiopulmonary bypass; with prosthetic valve other than homograft or stentless valve

93355  Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D

Not Covered: Considered investigational:

933591  Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve

HCPCS CODES

No specific codes identified

Key References
regurgitation in adults?source=search_result&search=aortic%20regurgitation%20treatment&selectedTitle=1~150#H1411845277.
Transcatheter Aortic Valve Implant (TAVI), Transcatheter Aortic Valve Replacement (TAVR), continued


Intermediate Risk References


Transcatheter Aortic Valve Implant (TAVI), Transcatheter Aortic Valve Replacement (TAVR), continued


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TRANSCATHETER PULMONARY VALVE REPLACEMENT

Policy # 483
Implementation Date: 4/11/11
Revision Dates: 5/21/16, 2/13/20, 6/17/21

DESCRIPTION

The pulmonary valve is made up of 3 thin pieces of tissue called leaflets that are arranged in a circle, much like a 3-piece pie. With each heartbeat, the valve opens in the direction of blood flow, into the pulmonary artery and continuing to the lungs, and then closes to prevent blood from flowing backward into the right ventricle of the heart. In pulmonary valve stenosis, 1 or more of the leaflets may be defective or too thick, or the leaflets may not separate from each other properly. If this happens, the valve doesn't open correctly, restricting blood flow. Pulmonary valve stenosis usually occurs when the pulmonary valve doesn't grow properly during fetal development. It's not known what causes the valve to develop abnormally. Adults occasionally have the condition as a complication of another illness, but most of the time pulmonary valve stenosis develops before birth.

As the condition advances, patients may develop symptoms of shortness of breath or fluid retention. In these instances, medications may be prescribed to control shortness of breath, reduce the heart's workload, or regulate the heart's rhythm. For most people, medication alone cannot slow the progression of pulmonary valve disease. Once severe or moderately severe stenosis develops, patients will often require surgical intervention. The 2006 ACC/AHA guidelines recommend balloon valvotomy in symptomatic patients with a peak systolic gradient > 30 mmHg and in asymptomatic patients with peak systolic gradient > 40 mmHg (moderate-to-severe disease). Standard surgery involves open sternotomy with inherent risks to cardiovascular, pulmonary, and infectious complications.

A newer approach has been developed which avoids the necessity of open-heart surgery. Transcatheter valve implantation involves placement of an artificial valve in the affected valve via a catheter inserted through a vein such as the femoral vein or jugular vein. Currently, only two valves have obtained FDA approval, the Medtronic Melody® Transcatheter Pulmonary Valve (Medtronic, Inc., Santa Ana, CA) and the Edwards SAPIEN XT Transcatheter Heart Valve (Edwards Lifesciences Corporation Irvine, CA). With both these valves, the heart valve is first crimped down onto the catheter’s balloon and then is fished through a vein in the groin and into the right side of the heart where it is placed into position within the pulmonary valve. The small balloon is then inflated to open the valve into position, the catheter is removed from the body, and then immediately becomes the new pulmonary valve.

Harmony™ TPV is the first FDA-approved transcatheter valve system specifically designed to treat severe pulmonary regurgitation in patients with a native or surgically-repaired right ventricular outflow tract (RVOT) — offering your patients a minimally invasive treatment option.

The Harmony TPV was designed in an effort to offer a treatment alternative for patients with Congenital Heart Disease (CHD), specifically the 80 percent of CHD patients born with right ventricular outflow tract anomalies who undergo a surgical repair early in life. For these patients, the Harmony TPV provides a less invasive option to restore normal valve function later in life. The minimally invasive TPV therapy builds off of the proven Melody TPV technology, the first transcatheter heart valve available anywhere in the world, which has been implanted in more than 10,000 patients worldwide.
Transcatheter Pulmonary Valve Replacement, continued

**Commercial Plan Policy/CHIP (Children’s Health Insurance Program)**

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

SelectHealth covers Transcatheter Pulmonary Valve Replacement with an FDA approved device when either A or B are met:

A. Will be approved if recommended by Intermountain Healthcare Cardiovascular Clinical Program,

OR

B. For all other clinicians, will be approved when **EITHER of** the following criteria are met:

1. SelectHealth covers Transcatheter Pulmonary Valve Replacement with an FDA approved device (e.g., Harmony valve) for pediatric and adult patients who meet the following conditions:
   i) Severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction ≥ 30% as determined by cardiac magnetic resonance imaging)
   ii) Who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement; **or**

2. SelectHealth covers Transcatheter Pulmonary Valve Replacement with an FDA approved device (e.g., Melody® Transcatheter Pulmonary Valve or Sapien XT) for the management of pediatric and adult patients with prior surgical valve replacement when the following criteria are met:

   i) Dysfunctional RVOT conduits with a clinical indication for intervention, **and** either of the following:

   a) ≥ Moderate pulmonary stenosis, **or**

   b) ≥ Moderate pulmonary regurgitation

**SelectHealth Advantage (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 SelectHealth 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](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp) or the manual website.
SelectHealth 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 SelectHealth 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
A Medical Technology Assessment performed in March 2011 identified 3 systematic reviews and 8 peer-reviewed journal articles related to percutaneous transcatheter pulmonary valve implantation. Notable is the fact that the 3 systematic reviews were completed by well-respected organizations: Hayes, NICE, and the Australia and New Zealand Horizon Scanning Network.

Though the Hayes systematic review completed in 2010 was a “Prognosis Notes” rather than a “Directory Report,” this reflects the limited evidence currently available on the Melody device; it provided insight into the current state of the evidence, specifically regarding the Melody device. It reported: “PPVi with the Melody Valve system is feasible and may delay open heart surgery in selected patients with failing RVOT conduits, but the long-term efficacy of this intervention to reduce the lifetime risk for exposure to multiple pulmonary valve surgeries is still being evaluated.” It also noted, importantly, that long-term durability remains unknown and the appropriate patient selection criteria remain undefined.

The NICE guidance, though completed in 2007, holds remarkably similar findings to that of Hayes’ “Prognosis Notes.” It notes most of the evidence was derived from a small number of patients, but short-term efficacy was good. It too, noted little evidence related to long-term efficacy; safety was also noted to not be a concern.

The Australia and New Zealand Horizon Scanning Network compared bare-metal stenting (BMS) to percutaneous pulmonary valve implantation (PPVi). Though use of BMS to treat pulmonary stenosis is not commonly performed in the US, this review noted no major complications for BMS or PPVi in the perioperative period, and a complication rate of 9% over the median 28.4-month follow-up period. Additionally, it observed the mean pulmonary artery diastolic pressure increased significantly after PPVi compared to BMS, indicating that pulmonary valvular competence was restored (9 mmHg before BMS vs. 11 mmHg after PPVi; p = 0.048). Pulmonary regurgitation was virtually eliminated following PPVi as indicated by measurements of pulmonary regurgitation fraction (41.4% after BMS vs. 3.6% after PPVi; p < 0.001). Right ventricular end diastolic volume was also significantly lower (98.3 mL/m² vs. 85.3 mL/m², p = 0.021) and there was a significant improvement in effective right ventricular stroke volume after PPVi, compared with the post-BMS state (32.6 mL/m² vs. 41.0 mL/m²; p = 0.004). All indications were for correction of the underlying hemodynamic issues related to the pulmonary valve stenosis. Again, a lack of long-term outcomes was noted.

Seven of these were considered major complications: device instability in 5 patients, which included dislodgement of the device (n = 2) and homograft rupture (n = 3); compression of the left main coronary artery (n = 1); and obstruction of the origin of the right pulmonary artery (n = 1). Five of the patients with major complications required surgical RVOT revision. During the follow-up period, 5 patients were diagnosed with endocarditis, a median 4.9 months after PPVi, which led to valve removal in 3 patients. A stent fracture led to stent embolization in the right pulmonary valve in 1 patient, requiring surgical removal of the Melody valve.

BMS achieved significant reduction in mean right ventricular systolic pressure, mean pulmonary artery to right ventricular pullback gradient, and the mean ratio of right ventricular to systemic pressure. However, PPVi did not produce any statistically significant changes in these measurements.

The primary studies, as could be imagined (as they are the basis for the systematic reviews), demonstrate the same outcomes. They show adequate safety and good short-term efficacy. These studies all suffer from the lack of randomization and short-term endpoints, and for the most part, are small in size. One large case series study indicated that PPVi is a feasible procedure (in a select group of patients) and that most patients who underwent PPVi avoided surgical RVOT revision. Nevertheless, the proportion of patients who required re-do procedures (surgical or transcatheter) was quite substantial and increased over time. The results also indicated that patient outcomes improved substantially with operator experience.
Transcatheter Pulmonary Valve Replacement, continued

In conclusion, current evidence supports transcatheter pulmonary valve implantation to be safe and efficacious, at least in the short-term. Long-term evidence is lacking related to efficacy and durability of the procedure and the optimal patient candidates are poorly defined.

Billing/Coding Information

Covered: For the indications outlined above

CPT CODES

33477  Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

HCPCS CODES

No specific codes identified

Key References


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Transcatheter Pulmonary Valve Replacement, continued

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TRANSTHORACIC ELECTRICAL BIOIMPEDANCE (TEB) TESTING

Policy # 335

Implementation Date: 12/21/06
Review Dates: 12/20/07, 12/19/08, 12/16/10, 12/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/13/19, 6/18/20
Revision Dates: 1/17/14

Description
Transthoracic electrical bioimpedance (TEB), also referred to as plethysmography or bioimpedance cardiography, has been investigated as a non-invasive method for the determination of cardiac output. TEB relies on the conductivity of blood and the fact that resistance to electrical current in the thorax varies in relation to the amount of blood in the aorta. Blood pumped into the aorta causes a decrease in electrical impedance (resistance) that is inversely proportional to the volume of blood pumped.

Transthoracic electrical bioimpedance measures cardiac output by introducing a low voltage alternating current between 2 sets of electrodes placed on the skin over the thorax. The outer sensors, attached to the neck and chest, transmit a high-frequency, low-amplitude electric current through the thoracic cavity. The inner sensors, placed adjacent to the first set, detect impedance of the electric current in the thoracic cavity. The difference between the initial voltage and that which the device senses moving through the thorax provides a measure of electrical impedance. The magnitude of the decrease in impedance in conjunction with electrocardiographic results allows stroke volume to be estimated, which can be used to calculate cardiac output.

Multiple uses for TEB have been proposed: these include non-invasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease, differentiation of cardiogenic from pulmonary causes of acute dyspnea, optimization of atrioventricular interval for patients with A/V sequential cardiac pacemakers, patients with need of determination for intravenous inotropic therapy, early identification of rejection in post-heart transplant myocardial biopsy patients, cardiac patients with a need for fluid management (excluding patients on dialysis and with cirrhosis of the liver), and management of hypertension.

Commercial Plan Policy

SelectHealth does NOT cover transthoracic electrical bioimpedance (TEB) testing. This testing is not found to be medically necessary to manage patients with various cardiac conditions in an outpatient setting.

SelectHealth Advantage (Medicare/CMS) (No Preauthorization Required but criteria may apply if appropriate)

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 SelectHealth Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-
Transthoracic Electrical Bioimpedance (TEB) Testing, continued

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 SelectHealth 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](http://health.utah.gov/medicaid/manuals/directory.php) or the [Utah Medicaid code Look-Up tool](http://health.utah.gov/medicaid/manuals/directory.php).

Summary of Medical Information

In a 2003 Hayes Review, Thoracic Electrical Bioimpedance was given a rating of ‘C,’ reflecting a technology with potential but unproven benefit. The review concluded that the literature suggests that TEB provides accurate measurement of cardiac output in properly selected patients, but that the appropriate clinical role of cardiac output measurement in patient management and its impact on clinical outcomes were poorly defined. Similarly, the Agency for Healthcare Research and Quality’s (AHRQ) 2002 review concluded that TEB may have potential value in patient care. However, the accuracy of TEB relative to other measures of hemodynamic parameters could not be evaluated because limited literature and that a focus on clinical outcomes of TEB measurement was needed to evaluate its role in clinical care. The literature published since 2003 is fairly consistent with the observations made in these two reviews, and TEB measurements of hemodynamic parameters also correlate fairly well with those from other invasive or noninvasive techniques, though one study by Leslie et al., found poor agreement between TEB and thermodilution on measures of cardiac output.

A few studies provide some data to address the question of the clinical role of TEB and the impact of measuring cardiac output on changing patient outcomes. Several of these have application to outpatient uses. In Packer et al. for example, 212 patients with chronic heart failure attributable to an ischemic or non-ischemic cause underwent clinical assessment and TEB every 2 weeks for 26 weeks. Three clinical variables (patient visual analog rating of symptoms, NYHA functional class, and systolic blood pressure) and three TEB parameters (thoracic fluid content index, velocity index, and left ventricular ejection time) were independently associated with the occurrence of a heart failure event within 14 days following their measurement. A composite ICG score based on these 3 variables grouped patients into low- (0–3), intermediate- (4–6), and high-risk categories (7–10). Patients in the high-risk group had an 8.4% event rate compared with vs. 3.5% and 1.0% for intermediate- and low-risk patients, respectively. High-risk patients accounted for 41.6% of heart-failure events. While the study suggests that TEB may provide some prognostic information pertinent to treatment planning in this population, the authors caution that TEB parameters should not be used to titrate therapeutic agents or to monitor therapy. Moreover, they noted that the study could not determine whether TEB contributed any unique information to the clinical data already available to clinicians. They indicate that large-scale trials are needed to evaluate whether treatment guided by TEB would have any impact on clinical outcomes.

Peacock et al. examined the use of TEB with patients presenting with dyspnea to an emergency department. After conducting their routine history and physical, and indicating their working diagnosis, physicians reviewed each patient’s TEB data and reconsidered their working diagnosis. Of the 89 patients evaluated, the initial diagnosis for 12 (13%) was changed after the physician had reviewed the TEB data. Physicians made changes to the medication plan in 35 patients (39%) after the initial assessment and review of TEB.

A 2004 study by Sharman et al. enrolled 21 patients with uncontrolled hypertension on a treatment protocol that was guided by TEB measurements of hemodynamic parameters. After 215 ± 85 days, average blood pressure had declined from approximately 157/78 mmHg to 142/77 mmHg. Moreover, 57% of participants achieved sustained blood pressure control. A prospective randomized controlled trial in 2006 by Smith et al. also evaluated use of TEB to inform treatment in patients with essential hypertension. Patients (n = 164) underwent a 2-week anti-hypertensive medication washout period and were randomized to a standard care or TEB-informed treatment group. Physicians treating patients in the standard group prescribed anti-hypertensives according to published guidelines, usual practice patterns, and patient characteristics. Physicians treating patients in the TEB-informed group were also provided...
Transthoracic Electrical Bioimpedance (TEB) Testing, continued

TEB measurements about their patients and were encouraged to use a hemodynamic treatment algorithm to guide decisions about pharmacologic agents and dosing. Compared with standard care, patients in the TEB group were more likely to achieve blood pressure reduction at or below the target goal of < 140/90 mmHg (77% vs. 57%). A greater percentage of TEB patients also achieved reductions below 130/85mmHg (55% vs. 27%).

These studies suggest some novel clinical applications for TEB in the outpatient setting and that TEB may impact physicians' treatment decisions. However, small sample sizes and lack of replication suggest that these findings should be considered preliminary. Future research is needed to define specific TEB-informed treatment protocols in addition to replicating these findings in larger patient samples.

Literature reviews performed in December 2008, 2009, and 2010 did not identify any new information.

Billing/Coding Information
Not Covered: Investigational/Experimental/Unproven for this indication

CPT CODES
93701  Bioimpedance-derived physiologic cardiovascular analysis

HCPCS CODES
No specific codes identified

Key References


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VENTRICULAR ASSIST DEVICES

Policy # 187

Implementation Date: 7/98

Review Dates:
1/4/00, 2/27/01, 4/16/02, 10/23/03, 11/18/04, 3/25/05, 4/20/06, 10/18/07,
10/22/09, 10/22/10, 2/16/12, 4/25/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18,
2/5/19, 2/11/20, 2/18/21

Revision Dates: 8/22/06, 10/30/06, 10/23/08

Description
A ventricular assist device (VAD) is a mechanical pump that relieves the native left ventricle by pumping blood through the body. The VAD requires a control system and a power source that are maintained outside the body. The VAD pump may be placed internally or externally but the control system and power source are maintained outside the body. Sometimes called, “bridge-to-transplant” (BTT), VADs were originally intended for use in patients awaiting heart transplant who required additional assistance for survival. As VAD technology has improved and the supply of transplantable hearts remains limited, VADs are now sometimes used for long-term (destination) therapy in severe heart-failure patients.

The first FDA approval of a VAD for this indication was in 1994. A variety of devices have received approval from the U.S. Food and Drug Administration (FDA), encompassing both biventricular and left ventricular devices, as well as devices that are intended to be used in the hospital setting alone and those that can be used as an outpatient. Devices that can be used in an outpatient setting while the patient awaits a human donor heart include Thoratec’s HeartMate XVE, HeartMate II LVAS, and the Ventricular Assist Device (VAD) System. In these systems, the device is surgically placed entirely within the thoracic and abdominal cavity and connected to the power source by a percutaneous drive line.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers all FDA approved* ventricular assist devices in the following limited circumstances.

1. Members with post-cardiotomy ventricular dysfunction on maximum inotropic volume and support and intra-aortic balloon pump where indicated; or
2. As a bridge to transplant for members who are awaiting heart transplantation; or
3. As destination therapy for members with severe (NYHA Class IV) heart failure, and who are ineligible for heart transplantation due to age or co-morbidities.

*FDA approved is defined as devices that have been granted approval through a Pre-Marketing Approval (PMA) process or have gained FDA approval as Investigational Exempt Devices (IDE) and are categorized as Category “B” devices by the FDA.
SelectHealth Advantage (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 SelectHealth 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.

SelectHealth Community Care (Medicaid)

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Summary of Medical Information

Destination Therapy Support

The Thoratec HeartMate XVE LVAS is also FDA approved for use as a long-term permanent implant, (i.e., for destination therapy) as an alternative to optimal medical therapy for end-stage HF patients who are not eligible for cardiac transplantation (patients with NYHA Class IV end-stage left ventricular failure who have received optimal medical therapy for at least 60 of the last 90 days, have a life expectancy of < 2 years, and are not eligible for cardiac transplantation). The device system is approved for use both inside and outside of the hospital. FDA approval of this device system is based on the results of the REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) trial, which compared the experience of patients supported by the HeartMate SNAP VE LVAS with those being treated with optical medical management.

The Thoratec HeartMate II LVAS is approved by the FDA for use in a DT clinical trial evaluating efficacy as an alternative to optimal medical therapy for end-stage heart failure patients not eligible for cardiac transplantation.

The basic design of available VADs is similar. Usually, the pump is implanted into the upper part of the abdominal wall or the peritoneal lining, and, for left ventricular assist devices (LVADs), a tube from the pump fits into the left ventricle, draining blood from the ventricle into the pump, which then sends the blood into the aorta. Another tube from the implanted pump extends outside the body through the skin and is attached to a beeper-sized control system that is worn on a belt; the computerized control unit is powered by a console or battery pack that is worn on a shoulder holster or belt. For right ventricular assist devices (RVADs), a tube shunts blood from the right ventricle through the pump and into the pulmonary artery. VADs have activity sensors to increase the pump output when activity increases, and backup mechanisms are available in case of pump failure. Patients who receive VADs with a wearable power source can be fully ambulatory after implantation, and, if their condition permits, live at home, although a 24-hour companion is necessary in the event of equipment malfunction.

There are several different types of VADs currently in use; the devices can be broadly subdivided into continuous flow/centrifugal or pulsatile pumps. Continuous flow/centrifugal pumps operate on the principle of a cyclone. Blood is diverted through cannulae placed in the right or left heart to an external chamber with a centrifugal pump. Continuous flow/centrifugal pumps include the Thoratec HeartMate II LVAS, Biopump, the Sarns-3M, and the Hemopump.

Pulsatile pumps are subdivided into pneumatic and electromechanical types. Each type can be operated in several different modes including a synchronous mode triggered by the EKG (similar to an intra-aortic balloon pump) and an asynchronous mode. Placement of the inflow and outflow cannulae is variable. Pulsatile pumps include the Abiomed, Thoratec (Pierce Donachy), Novacor, and HeartMate XVE devices.

Bridge to Transplant (BTT) Support:

VADs have also been used as a bridge to transplant. Several clinical studies have demonstrated the success of VADs in improving survival rates to heart transplantation. In addition, VADs have been shown to significantly improve patients’ functional status prior to heart transplantation such that patients are
overall better surgical candidates. More than 5 million people in the United States live with heart failure, and the incidence of heart failure continues to increase, due in part to the expanded aging population and advances in therapeutic management of cardiovascular disease. Transplantation has become the standard treatment for eligible patients with irreversible severe biventricular failure unresponsive to medical or surgical treatment. The supply of donor hearts has decreased in recent years, however, while the demand has increased, as patients become more hemodynamically compromised, there is an increased risk of death prior to transplantation, as well as a less favorable outcomes following transplantation. Timely VAD use may restore hemodynamic stability and end-organ function, and allow nutritional support and rehabilitation prior to transplantation.

VAD implant surgery carries risks of severe complications, including bleeding, development of blood clots, the most common causes of early morbidity and mortality after placement of a VAD have been bleeding, right-sided heart failure, air embolism, and progressive multisystem organ failure. In the late postoperative period, the most common complications have been infection, thromboembolism, and failure of the device. Early investigators reported that approximately 50% of patients required reoperation for bleeding; however, the risk of major hemorrhage decreased to approximately 30% with the use of aprotinin. In patients who do not have major bleeding in the perioperative period, right-sided HF rarely develops. Additionally, the use of textured blood-contacting surfaces (e.g., in the HeartMate LVAD) has decreased the incidence of thromboembolic events.

The REMATCH trial, a multicenter randomized controlled clinical trial, involved 129 adults with end-stage heart failure who were not eligible for a heart transplant. Participants had NYHA class IV heart failure for at least 90 days despite attempted therapy with an ACE inhibitor, diuretics, and digoxin; an ejection fraction ≤ 25%; and an exercise peak \( O_2 \) uptake ≤ 14 mL/kg per minute or a continued need for intravenous inotropic therapy because of symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion. After 18 months of enrollment, entry criteria were relaxed to include patients with symptoms of NYHA class III or IV heart failure for 28 days and 14 days of support with an intra-aortic balloon pump or with a dependence on intravenous inotropic agents with 2 failed weaning attempts. 61 patients received optimal medical management, including intravenous inotropic therapy, and 68 patients received LVADs. Survival at 1 year was significantly improved from 25% at 1 year in the medical therapy group to 52% in the LVAD group (relative risk, 0.52 (95% confidence interval 0.34–0.78)). Median length of survival for patients implanted with the HeartMate LVAD was 408 days compared to 108 days for patients in the medical therapy group. At 2 years, 23% of LVAD patients had survived compared to 8% in the medical group (p = 0.09). Serious adverse events were 2.35 times as frequent in the LVAD group, predominately caused by infection, bleeding, neurological dysfunction, and device malfunction.

A 2005 Hayes review concluded the following regarding Ventricular Assist Devices: There is substantial evidence that LVADs can provide effective circulatory support for patients with end-stage HF, and that the improved hemodynamics that these devices provide, can help to stabilize and possibly reverse damage to myocardial tissue and secondary organs in patients waiting for transplantation, improving survival, both before, and after transplantation. There also is evidence to support the use of LVADs as intermediate-term support for HF patients who may subsequently recover sufficient function of the native heart to allow explantation. In addition, there is recent evidence to support the use of LVADs as permanent, or destination, therapy for end-stage HF patients who are not suitable candidates for transplantation. Additional research is necessary to determine optimal timing for implantation, to define criteria for weaning and explantation in patients with reversible cardiac dysfunction, and to determine methods of reducing the occurrence of complications such as bleeding and sepsis. Therefore, the following Hayes Ratings have been assigned: A for LVAD use as a bridge to cardiac transplantation in patients with end-stage HF; B for LVAD use as a bridge to recovery for those patients meeting hemodynamic criteria who have potentially reversible left ventricular dysfunction; B for LVAD use as destination therapy for patients who are not eligible for transplantation and in whom no return of cardiac function is anticipated. A rating of D has been assigned for LVAD use in patients with specific contraindications, including irreversible multiple organ dysfunction, HIV seropositivity, age > 70, stroke, systemic infection, cancer, severely restricted pulmonary function, major neurological deficit, blood clotting disorders, or long-term high-dose corticosteroid use. This rating reflects the lack of evidence that LVAD use improves outcomes in patients with these conditions. A 2007 Update Search showed efficacy and safety remained the same.

In 2007, the HeartMate II BTT Pivotal trial reported that principal outcomes occurred in 75% of patients; the median duration of support was 126 days. The survival rate during support was 75% at 6 months and 68% at 12 months. At 23 months, therapy was associated with significant improvement in functional status and in quality of life. The trial concluded that a continuous flow left VAD can provide effective
hemodynamic support for a period of at least 6 months in patients awaiting heart transplantation with improved functional status and quality of life.

A Hayes review published in August 2010 concluded in their analyses of several moderate-size to large groups of patients implanted with ventricular assist devices (VADs) for bridge to transplantation (BTT) suggested that most patients survive until transplantation, but the lack of comparative data for patients treated with optimal medical management (OMM) precludes any conclusion regarding the causal effect of VADs on survival to transplantation. A large volume of comparative evidence strongly suggests that patients supported by VAD as BTT have survival following cardiac transplant similar to that of patients supported with OMM while waiting for transplant. Evidence pertaining to overall survival from the time of left ventricular assist device (LVAD) implantation for BTT until death is sparse and comparisons with OMM groups reported conflicting results. Evidence pertaining to the impact of LVADs BTT on quality of life (QoL) and function was insufficient to allow conclusions. A small percentage of patients implanted with LVAD as BTT can be expected to recover, but patient characteristics associated with bridge to recovery (BTR) have not been identified. A single randomized controlled trial and a nonrandomized trial have demonstrated that LVADs as destination therapy (DT) substantially improve survival and disease-related functional status and have modest positive effects on QoL. Serious adverse events in patients who have an implanted LVAD are common; LVAD has been shown to cause an increase in nonfatal adverse events when used as DT, but the causal link between LVAD and adverse events when the device is used as BTT is unknown.

Three LVADs have received FDA approval for short-term use as a BTT in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. These include the HeartMate® System and its enhanced version, the HeartMate® Extended Lead, as well as earlier versions, such as the HeartMate® Implantable Pneumatic (IP) LVAS and the HeartMate® VE LVAS, the Thoratec® Ventricular Assist Device (VAD) System and the Novacor® LVAS.

In addition to approval for use as BTT, 3 Thoratec devices have been approved for use as DT: the HeartMate SNAP VE LVA, the HeartMate XVE LVAS, and the HeartMate II. For the HeartMate VE/XVE, DT is indicated as an alternative to optimal medical therapy for end-stage HF patients who are not eligible for cardiac transplantation (patients with NYHA Class IV end-stage left ventricular failure who have received optimal medical management (OMM) for at least 60 of the last 90 days, have a life expectancy of < 2 years, and are not eligible for cardiac transplantation).

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0451T</td>
<td>Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes)</td>
</tr>
<tr>
<td>0452T</td>
<td>; aortic counterpulsation device and vascular hemostatic seal</td>
</tr>
<tr>
<td>0455T</td>
<td>Removal of permanently implantable aortic counterpulsation ventricular assist system; complete system (aortic counterpulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes)</td>
</tr>
<tr>
<td>0456T</td>
<td>; aortic counterpulsation device and vascular hemostatic seal</td>
</tr>
<tr>
<td>0458T</td>
<td>; subcutaneous electrode</td>
</tr>
<tr>
<td>0459T</td>
<td>Relocation of skin pocket with replacement of implanted aortic counterpulsation ventricular assist device, mechano-electrical skin interface and electrodes</td>
</tr>
<tr>
<td>0460T</td>
<td>Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode</td>
</tr>
<tr>
<td>0461T</td>
<td>; aortic counterpulsation device</td>
</tr>
<tr>
<td>0463T</td>
<td>Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable aortic counterpulsation ventricular assist system, per day</td>
</tr>
<tr>
<td>33975</td>
<td>Insertion of ventricular assist device; extracorporeal, single ventricle</td>
</tr>
</tbody>
</table>
Cardiovascular Policies, Continued

Ventricular Assist Devices, continued

33976 ; extracorporeal, biventricular
33977 Removal of ventricular assist device; extracorporeal, single ventricle
33978 ; extracorporeal, biventricular
33979 Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33980 Removal of ventricular assist device, implantable intracorporeal, single ventricle
33981 Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33990 Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only
33991 Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
33992 Removal of percutaneous ventricular assist device at separate and distinct session from insertion
33993 Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion
33995 Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33999 Unlisted procedure, cardiac surgery
92970 Cardioassist-method of circulatory assist; internal
92971 ; external
93750 Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report

HCPCS CODES

Q0480 Driver for use with pneumatic ventricular assist device, replacement only
Q0481 Microprocessor control unit for use with pneumatic ventricular assist device, replacement only
Q0482 Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only
Q0483 Monitor/display module for use with pneumatic ventricular assist device, replacement only
Q0484 Monitor/display module for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0485 Monitor control cable for use with pneumatic ventricular assist device, replacement only
Q0486 Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only
Q0487 Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only
Q0488 Power pack base for use with pneumatic ventricular assist device, replacement only
Q0489 Power pack base for use with electric/pneumatic ventricular assist device, replacement only
Q0490 Emergency power source for use with pneumatic ventricular assist device, replacement only
Q0491 Emergency power source for use with electric/pneumatic ventricular assist device, replacement only
Ventricular Assist Devices, continued

Q0492 Emergency power supply cable for use with pneumatic ventricular assist device, replacement only
Q0493 Emergency power supply cable for use with electric/pneumatic ventricular assist device, replacement only
Q0494 Emergency hand pump for use with electric/pneumatic ventricular assist device, replacement only
Q0495 Battery power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0496 Battery for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0497 Battery clip for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0498 Holster for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0499 Belt/vest for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0500 Filters for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0502 Mobility cart for pneumatic ventricular assist device, replacement only
Q0503 Battery for pneumatic ventricular assist device, replacement only, each
Q0506 Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0507 Miscellaneous supply or accessory for use with an external ventricular assist device
Q0508 Miscellaneous supply or accessory for use with an implanted ventricular assist device

Key References


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VERTICAL AUTO PROFILING (VAP™) 
CHOLESTEROL TEST

Policy # 298
Implementation Date: 2/15/06
Review Dates: 5/17/07, 4/24/08, 4/23/09, 2/18/10, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 5/7/15, 4/14/16, 4/27/17, 7/20/18, 4/27/19, 4/15/20
Revision Dates:

Description
Coronary heart disease (CHD) affects about 14 million men and women in the United States. Atherosclerosis is an important risk factor in the development of CHD. Routine cholesterol screening, which measures HDL, LDL (calculated), and triglycerides is a major component of CHD risk management. The Vertical Auto Profile (VAP) cholesterol test from Atherocare not only includes these standard tests, but also, measures atherogenic remnant lipids (VLDL and IDL), Lp(a), LDL pattern density, and HDL subtypes. This additional testing purports to improve CHD risk stratification by measuring these additional risk factors along with the traditional cholesterol panel. By measuring these lipid factors, the test also provides a screen for metabolic syndrome, a constellation of metabolic risk factors that increase risk for CHD.

The VAP test is the only commercially available test that measures possible cardiovascular risk factors Lp(a), LDL particle size, lipoprotein remnants, and HDL subfractions at the same time. Alternatively, providers can order each test individually. Additionally, many other tests are available to assess cardiovascular risk. Tests covered by SelectHealth include fasting lipid profiles, PLACTM testing, and hs-CRP. Other risk factors for CHD can be assessed through a variety of methods including the Framingham Risk Assessment tool.

Commercial Plan Policy
SelectHealth does NOT cover vertical autoprofiling (VAP™) cholesterol testing for assessment of cardiovascular risk. This testing meets the plan’s definition of investigational/experimental.

SelectHealth Advantage (Medicare/CMS) (No Preauthorization Required but criteria may apply if appropriate)

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 SelectHealth 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.
SelectHealth Community Care (Medicaid/CHIP) (No Preauthorization Required but criteria may apply if appropriate)

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 SelectHealth 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
The extant literature is somewhat equivocal on the prognostic value of the risk factors the VAP test adds to the traditional lipid panel:

**Remnant lipoproteins:** Fukushima et al.’s 2004 2-year follow-up study of 240 diabetes patients with or without CAD found remnant lipoproteins to be a strong independent risk factor for CAD. Inoue et al. reported similar findings in their 2004 study of 188 CAD patients and 68 controls. In contrast, Imke et al.’s study of 1,156 Japanese-American men over 7 years found that remnant lipoproteins levels did not improve the prediction of future CHD incidence beyond that already provided by total triglycerides.

**Lp(a):** Ariyo et al. studied 5,888 adults over 7.5 years (median) and concluded that Lp(a) level is an independent risk factor of future vascular events in men, but not in women. Danesh et al.’s meta-analysis of 27 studies supported the association between CHD and Lp(a) but called for additional research to determine the extent to which this relationship is causal. Moliterno et al.’s study of 140 African American subjects concluded that Lp(a) is not an independent risk factor for CAD in that population.

**LDL particle size:** Berneis et al. studied LDL size in 38 type II diabetics and concluded that, among other lipid parameters, LDL particle size is the strongest predictor of CHD and atherosclerosis. Mykkanen et al., in contrast, studied 86 patients who were MI-free over 3.5 years and observed that LDL particle size was not an independent risk factor of CHD events once controlling for diabetes status. St-Pierre et al.’s study of 2,072 men over 13 years demonstrated that accumulation of small LDL particles was primarily responsible for the risk attributable to LDL size.

**HDL subtypes:** Lamarche et al.’s 1990 study of 1,169 men followed over 11 years found a statistical association between HDL2 and CHD but concluded that in the clinical setting, measurement of HDL subtypes provides no additional information about CHD risk over traditional lipid risk markers. Sweetnam et al. followed 4,860 men between 3–5 years and observed an inverse association between HDL2 and HDL3 cholesterol and the incidence of CHD. They further noted that the predicting adding HDL subtype measurement to traditional HDL did not improve predication of CHD risk.

Only 2 studies located for this literature review examined the impact of treating these risk factors on future atherosclerosis or CHD events. Campos et al. administered pravastatin or placebo to 837 MI survivors and matched controls with similarly elevated LDL and tracked outcomes over 5 years. In patients taking placebo, large LDL predicted coronary events, but this association was not present in patients taking pravastatin. However, the authors concluded that identifying LDL size 5, not to be very useful clinically since elevated LDL cholesterol and large LDL are both effectively treated in the same manner. Miller et al. prospectively followed 213 men enrolled in a cardiac risk reduction program that included lipid-altering therapies with counseling and training in the modification of diet, exercise, and other lifestyle factors. After four years, patients with higher dense LDL levels showed significant benefit from the program while subjects with higher buoyant (less dense) LDL had no benefit from the intervention.

ATP-III identifies lipoprotein remnants, Lp(a), LDL particle size, and HDL subtypes as "emerging risk factors", suggesting that their association with CHD and the impact of modifying them on CHD risk is not well understood. Additional prospective trials are needed to more fully explain the relationship between these risk factors and atherosclerosis and future CHD events. Research is particularly needed to determine whether adding these emerging risk factors to traditional lipid panels adds any value to the prediction of CHD. The interaction between these emerging risk factors and other lipid and non-lipid risk factors in producing CHD risk must also be examined. Finally, research is needed to determine whether measuring these risk factors would have any unique impact on treatment decisions, whether treatments can be sufficiently tailored for specific lipid profiles, and whether patients with particular lipid parameters respond differently to lipid lowering therapies.
A June 2012 literature review identified the 2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults and does not recommend lipid/lipoprotein subfraction. Similarly, the 2011 National Lipid Association Expert Panel did not recommend HDL and LDL subfraction measurements for clinical assessment. However, Apo-B or LDL particle measurement and LPa are endorsed by NLA reasonable for many subjects at intermediate risk, those with a positive family history, and those with recurrent events, and selectively in those with coronary heart disease and CHD equivalents. These recommendations follow recent studies and metaanalyses that indicate that LDL particle number (measured by NML or as Apo-B) may be a letter indicator of CHD risk than LDLc or non-HDLc.

Billing/Coding Information

Not Covered: Investigational/Experimental/Unproven for this indication (when used in this combination)

CPT CODES

3011F Lipid panel results documented and reviewed (must include total cholesterol, HDL-C, triglycerides and calculated LDL-C) (CAD)

80050 General health panel This panel must include the following: Comprehensive metabolic panel (80053) Blood count, complete (CBC), automated and automated differential WBC count (85025 or 85027 and 85004) OR Blood count, complete (CBC), automated (85027) and appropriate manual differential WBC count (85007 or 85009) Thyroid stimulating hormone (TSH) (84443)

80061 Lipid panel. This panel must include the following: Cholesterol, serum, total (82465) Lipoprotein, direct measurement, high density cholesterol (HDL cholesterol) (83718)
Triglycerides (84478)

82465 Cholesterol, serum or whole blood, total

83698 Lipoprotein-associated phospholipase A2 (Lp-PLA2)

83701 Lipoprotein, blood; high-resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (e. electrophoresis, ultracentrifugation)

83718 Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)

83719 Lipoprotein, direct measurement; VLDL cholesterol

83721 Lipoprotein, direct measurement; LDL cholesterol

84478 Triglycerides

HCPCS CODES

No specific codes identified

Key References

10. Atherotech. The VAP™ Cholesterol Test as a Replacement for the Traditional Lipid Profile. 2005.


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WEARABLE CARDIOVERTER-DEFIBRILLATOR

Policy # 406
Implementation Date: 8/1/08
Review Dates: 6/11/09, 9/15/11, 11/29/12, 2/20/14, 3/19/15, 2/16/17, 2/15/18, 2/5/19, 2/17/20, 12/23/20
Revision Dates: 6/17/10, 2/29/16, 2/15/18, 3/2/22

Description
The term "sudden cardiac death" (SCD) is used to describe cardiac arrest with cessation of cardiac function, whether resuscitation or spontaneous reversion occurs. This definition of SCD is misleading because not all affected individuals die, and the use of SCD in this sense has been challenged.

The implantable cardioverter defibrillator (ICD) is considered a cornerstone of modern cardiology practice for reducing the incidence of sudden cardiac death related to ventricular fibrillation (VF) or ventricular tachycardia (VT). However, several factors limit the prophylactic implantation of the ICD, mainly the inability of invasive and noninvasive laboratory investigations to predict sudden death accurately in a patient population bearing the risk of dying suddenly. As a result, a substantial portion of the at-risk population does not receive adequate preventive therapy and others with lower risk will have the ICD implanted. A potential solution to this problem could be the use of an external, wearable cardioverter defibrillator (vest) that has defibrillation features similar to those of the ICD (i.e., no operator required to defibrillate), providing protection to the patient until it is determined that the implantation of the ICD is warranted, or another strategy pursued (e.g., heart transplant). A device used as a "bridge" to ICD implantation must be capable of reliably terminating episodes of VF/VT, have a highly sensitive and specific algorithm for the detection of VT/VF, and be user-friendly, thereby, ensuring patient compliance.

The vest-like device consists of a chest garment with electrode belt, monitor/defibrillator, patient base station, and physician programming console. The belt is strapped under the heart directly onto the patient’s skin to continuously sense electrical activity. If a life-threatening arrhythmia is detected and no response to device alarms is noted, the patient is presumed to be unconscious and the device delivers a shock to restore normal rhythm. Additional treatment may be delivered if the initial shock is not effective. The device weighs approximately 3 pounds. It is worn continuously, but it is not waterproof. For proper use, patients are trained to connect the device to an external modem and send data over the phone to the physician’s computer for medical evaluation.

Commercial Plan Policy/CHIP (Children's Health Insurance Program)

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

SelectHealth covers wearable cardioverter-defibrillators when EITHER of the following criteria are met (A or B).

A. Wearable cardioverter-defibrillators will be approved if recommended by Intermountain Healthcare Cardiovascular Clinical Program,

OR
B. For all other clinicians, wearable cardioverter-defibrillators will be approved when at least one of the following criteria are met (1–4):

Criteria for coverage include:

1. The patient is at high risk for sudden cardiac death and meets criteria for implantable cardioverter defibrillator (ICD) placement, but is not currently a suitable candidate for ICD placement because of one of the following:
   - Awaiting heart transplantation
   - Awaiting ICD reimplantation following infection-related removal of ICD
   - Systemic infectious process or other temporary medical condition precludes implantation
   - ICD lead malfunction with anticipated lead revision
   OR

2. As a bridge to ICD risk stratification and possible implantation for patients:
   - Had ventricular tachycardia (VT) or ventricular fibrillation (VF) within 48 hours of a myocardial infarction (MI), or
   - The first 40 days after myocardial infarction (MI) in patients with an ejection fraction (EF) < 35%, or
   - Within 3 months of CABG or PCI with ejection fraction (EF) < 35%, or
   - With non-ischemic cardiomyopathy and EF of < 35%
   OR

3. Newly diagnosed non-ischemic/idiopathic dilated cardiomyopathy (EF ≤ 35) with ICD implantation deferred to titrate therapy with at least one of the following risk markers as listed below:
   - Left or right bundle branch block
   - Marked impairment or left ventricular function (EF < 20)
   - Left ventricular end-diastolic dimension < 7.0 cm
   - Consistent right ventricular dysfunction
   - Non-sustained ventricular arrythmias
   - No obvious reversible causes (e.g., ETOH on thyroid induced cardiomyopathy)
   OR

4. Recent myocardial infarction (< 40 days) with severe left ventricular dysfunction (EF < 35) and additional markers of early mortality risk with at least one additional marker of risk:
   - Left or right bundle branch block
   - History of chronic ischemic heart failure (EF ≤ 40) with severe left ventricular dysfunction
Wearable Cardioverter-Defibrillator, continued

- Sustained ventricular tachycardia induced during electrophysiology study
- Frequent premature ventricular ectopy and/or non-sustained ventricular tachycardia during telemetry monitoring
- T wave alternans
- Late potentials on signal average ECG

SelectHealth Advantage (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 SelectHealth 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.

SelectHealth 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 SelectHealth 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

The U.S. Food and Drug Administration (FDA) approved the Lifecor Wearable Cardioverter Defibrillator 2000 system via 510(k) approval in December 2001, based on clinical data submitted to the FDA by the manufacturer, which has subsequently been published in the peer-reviewed literature, and referred to as the BIROAD and WEARIT studies. The trials consisted of prospective, non-randomized studies, which compared the outcomes of the WCD with historical controls of patients suffering sudden cardiac arrest who called 911 emergency services. While this study demonstrated that the WCD could detect arrhythmias and appropriately deliver a counter shock, its long-term efficacy will depend on patient compliance, and from a practical perspective, the WCD cannot be continuously worn. For example, the BIROAD and WEARIT studies included 289 patients; there were 12 deaths reported, and 50% occurred in patients either not wearing the device or wearing it inappropriately. Additionally, 68 of the 289 patients discontinued wearing the device due to comfort issues or adverse reactions. Therefore, an implantable cardiac defibrillator (ICD) is considered the gold standard, and, as such, a WCD would be considered an alternative to an ICD only in the small subset of patients who have co-morbidities or other contraindications for an ICD. Patients with an infected ICD requiring removal may benefit from a WCD worn during the limited interim period until an ICD can be re-implanted. Additionally, a small subset of patients awaiting heart transplantation may be considered at high risk for arrhythmia but are not candidates for an ICD due to co-morbidities. A WCD may be considered an alternative to an ICD in these patients while they are on the heart transplant waiting list.

There has been interest in offering WCDs to patients in the immediate post myocardial infarction (MI) period, when patients are considered at high risk of arrhythmia. However, the DINAMIT trial demonstrated that an ICD is not indicated during this period, thus, the WCD cannot be considered an alternative to an ICD in this setting. The DINAMIT trial randomized 674 patients to receive either an ICD or no ICD within 40 days of a myocardial infarction. All patients had reduced ejection fractions (ejection fraction ≤ 35%) and impaired cardiac autonomic function. There was no difference in overall mortality between the two groups. While the nonrandomized BIROAD study investigated patients treated with a WCD in the immediate post MI period, the results of the large randomized DINAMIT study provide a higher level of evidence, which may be extrapolated to WCD.

A 2009 technology assessment published by the California Technology Assessment Forum (CTAF), concluded that the use of a wearable cardioverter defibrillator (WCD) for patients at risk for sudden
cardiac arrest and who are not candidates for or refuse an ICD does not meet the CTAF criteria. The assessment included uncontrolled case series by Auricchio (1998, n = 15), and Reek (2003, n = 12) that evaluated the ability of the device to detect and terminate tachyarrhythmias induced in the controlled setting of the electrophysiology laboratory. The author concluded that the limited scientific evidence, consisting of one pivotal trial with a precursor device and a small number of events, does not permit conclusions regarding the effectiveness of the WCD regarding health outcomes. A multicenter cohort study evaluating the impact of the WCD on mortality and quality of life in patients who meet criteria for, but are unable or unwilling to have an ICD, is needed before definitive conclusions can be made regarding safety and effectiveness. For patients who do not meet criteria for an ICD, but who are considered to be at increased risk of SCD (e.g., post-acute MI with reduced EF), a randomized controlled trial with mortality data is recommended before the safety and efficacy of the device can be evaluated for use in clinical practice.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES
93292 Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
93745 Initial set-up and programming by a physician of wearable cardioverter-defibrillator, includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events

HCPCS CODES
K0606 Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607 Replacement battery for automated external defibrillator, garment type only, each
K0608 Replacement garment for use with automated external defibrillator, each
K0609 Replacement electrodes for use with automated external defibrillator, garment type only, each

Key References

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CARDIOVASCULAR POLICIES, CONTINUED

WIRELESS CARDIAC MONITORING (E.G., CARDIOMEMS)

Policy # 642
Implementation Date: 9/28/20
Review Dates:
Revision Dates:

Description
Heart failure (HF) is a chronic condition that develops over time due to circumstances that overwork and damage the heart. The primary causes include coronary heart disease, high blood pressure, and diabetes. HF is characterized by the inability of the heart to pump blood efficiently. HF is estimated to affect approximately 5.7 million people in the United States. Currently, there is no cure for HF. It can affect both children and adults, although it most commonly occurs in adults 65 years of age or older.

The CardioMEMS (CM) Heart Failure (HF) System (Abbott) is a wireless implantable hemodynamic monitor (IHM), for use at home in patients with HF. The CM-IHM system includes an implantable pulmonary artery pressure (PAP) sensor, a transvenous catheter delivery system, a patient home-monitoring electronic system, and a secure Internet-accessible database that allows clinicians to access patient data. The CM-IHM system provides measurement of the systolic, diastolic, and mean PAP, intending to allow for adjustment of HF medical therapy based on pressure trends and specified pressure goals. Once implanted, the patient will take a wireless reading from their PAP sensor once a day from home. Pressure data from this daily reading is then transmitted to a secure website for the physician and clinical team to review and make any necessary adjustments to HF treatment.

Commercial Plan Policy/CHIP (Children’s Health Insurance Program)

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

SelectHealth covers the CardioMEMS wireless cardiac monitor for heart failure patients, if either A or B are documented:

A. Recommended by Intermountain Healthcare Cardiovascular Clinical Program, OR

B. All the following criteria are met:

1. Left-sided heart failure diagnosis (preserved or reduced ejection fraction) for at least 3 months
2. History of ≥ 1 heart failure hospitalizations/events in the past year
3. HFrEF (heart failure with reduced ejection fraction) patients must be on optimal heart failure medications (GDMT [guideline-directed medical therapy] at best-tolerated doses)
4. NYHA (New York Heart Association) class III heart failure symptoms
Cardiovascular Policies, Continued

Wireless Cardiac Monitoring (e.g., Cardiomems), continued

5. The patient is an outpatient, and actively being monitored by a cardiologist specializing in heart failure with the capability of daily monitoring of the CardioMEMS data

6. The patient agrees to the patient training and home measurement schedule

Absolute Contraindications to CardioMEMS:

a. Non-adherence with medication use, and/or laboratory follow-up recommendations
b. The patient has refused CRT (cardiac resynchronization therapy)
c. Inability to take dual antiplatelet therapy or anticoagulation for one-month post-implantation
d. Patient cannot tolerate a right heart catheterization
e. Mechanical tricuspid or pulmonic valve
f. BMI > 35 with chest circumference (at axillary level) > 165cm

Relative Contraindications to CardioMEMS:

g. Patients with an active but treatable infection
h. Patients with a history of recurrent (> 1) pulmonary embolism or deep vein thrombosis
i. Patients with a GFR < 25 ml/min who are non-responsive to diuretic therapy.
j. Patients with ESRD on dialysis
k. Patients with congenital heart disease
l. Patients with known coagulation disorders
m. Patients with a hypersensitivity or allergy to aspirin, and/or clopidogrel
n. CRT implantation in the past 3 months (as these patients may clinically improve post-CRT)
o. Recent pacemaker, ICD, or CRT implantation (risk of lead dislodgement and would need to discuss timing with electrophysiology)
p. Tricuspid valve clip (would need to be discussed with structural heart team)

SelectHealth Advantage (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 SelectHealth 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&](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&) or the manual website.

SelectHealth 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 SelectHealth 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](http://health.utah.gov/medicaid/manuals/directory.php) or the Utah Medicaid code Look-Up tool.

Summary of Medical Information
CardioMEMS pulmonary artery monitoring device has been approved by the US Food and Drug Administration to monitor pulmonary artery pressure and heart rate in patients with NYHA class III HF who have been hospitalized during the previous year. Further study is needed to determine the efficacy and safety of this device. The 2016 ESC HF (European Society of Cardiology Heart Failure) guidelines included only a very weak recommendation stating that this device may be considered in symptomatic patients with HF with previous HF hospitalization.

The CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes In NYHA Class III Heart Failure Patients (CHAMPION) randomized single-blind trial of 550 patients found that transmission of pulmonary artery pressure data from the device reduced HF-related hospitalizations at six months (31 versus 44 percent, HR 0.70, 95% CI 0.60–0.84). There was a 1.5 percent rate of device- or system-related complications. An exploratory subgroup analysis found that device-guided management reduced HF-related hospitalization in patients with preserved LVEF (left ventricular ejection fraction) (LVEF ≥ 40 percent or LVEF ≥ 50 percent), as well as in patients with LVEF < 40 percent. Another exploratory analysis found that device-guided management reduced respiratory hospitalization rates as well as HF hospitalization rates in the entire cohort, as well as in a subgroup of 187 patients with chronic obstructive pulmonary disease.

A later analysis reported sustained reduction in HF-related hospitalization in the device-guided management group compared with the control at 18-month average follow-up (46 versus 68 percent, HR 0.67, 95% CI 0.55 to 0.80). During a subsequent open access period (mean duration 13 months), pulmonary artery pressure information was made available to guide therapy in the former control group; the rate of admission was reduced compared with that in the control group during the randomized access period (36 versus 68 percent; HR 0.52, 95% CI 0.40 to 0.69). The rate of device- or system-related complications was 1 percent and the rate of procedure-related adverse events was 1 percent.

However, the efficacy of the CardioMEMS device is uncertain given concerns raised about potential bias introduced in the conduct of the CHAMPION trial (including interaction between the trial sponsor and clinical investigators on certain treatment group subjects) and the analysis of data.

Billing/Coding Information

CPT CODES

33289 Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed

93264 Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care

HCPCS CODES

C2624 Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

Key References


Disclaimer
Wireless Cardiac Monitoring (e.g., Cardiomems), continued

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