CHAPTER 4
SECTION 9.1

CARDIOVASCULAR SYSTEM

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I. CPT[1] PROCEDURE CODES

33010 - 33130, 33140, 33141, 33200 - 37186, 37195 - 37215, 37250 - 37785, 92950 - 93272, 93303 - 93581, 93600 - 93745, 93770, 93797 - 93799, 0075T, 0076T

II. DESCRIPTION

The cardiovascular system involves the heart and blood vessels, by which blood is pumped and circulated through the body.

III. POLICY

A. Medically necessary services and supplies required in the diagnosis and treatment of illness or injury involving the cardiovascular system are covered.

B. Ventricular Assist Devices (VADs).

1. VADs (external and implantable) are covered if the device is Food and Drug Administration (FDA) approved and used in accordance with FDA approved indications.

2. VADs as destination therapy (CPT[1] 33979) are covered if they have received approval from the FDA for that purpose and are used according to the FDA-approved labeling instructions. Benefits are authorized when the procedure is performed at a TRICARE-certified heart transplantation center, a TRICARE-certified pediatric consortium heart transplantation center, or a Medicare facility which is approved for VAD implantation as destination therapy, for patients who meet all of the following conditions:

a. The patient has chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than two years).

b. The patient is not a candidate for heart transplantation.

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c. The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including a dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors (if tolerated) for at least 60 of the last 90 days.

d. The patient has Left Ventricular Ejection Fraction (LVEF) less than 25%.

e. The patient has demonstrated functional limitation with a peak oxygen consumption of less than 12 ml/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion.

f. The patient has the appropriate body size (by device per FDA labeling) to support the VAD implantation.

C. Gamma and beta intracoronary radiotherapy (brachytherapy) is covered for the treatment of in-stent restenosis in native coronary arteries.

D. Transmyocardial Revascularization (TMR) (CPT[2] procedures codes 33140 and 33141).

1. Coverage is available for patients with stable class III or IV angina which has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages. In addition, the angina symptoms must be caused by areas of the heart not amenable to surgical therapies such as percutaneous transluminal coronary angioplasty, stenting, coronary atherectomy or coronary bypass.

2. Coverage is limited to those uses of the laser used in performing the procedure which have been approved by the FDA for the purpose for which they are being used.

E. TMR as an adjunct to Coronary Artery Bypass Graft (CABG) is covered for patients with documented areas of the myocardium that are not amenable to surgical revascularization due to unsuitable anatomy.

F. FDA approved IDE clinical trials. See Chapter 8, Section 5.1, paragraph D. and F. for policy.

G. Endovenous Radiofrequency Ablation (RFA)/obliteration (CPT[2] procedure codes 36475 and 36476) and endovenous laser ablation/therapy (CPT[2] procedure codes 36478 and 36479) for the treatment of saphenous venous reflux with symptomatic varicose veins is covered when:

1. One of the following indications is present:

a. Persistent symptoms interfering with activities of daily living in spite of conservative/non-surgical management. Symptoms include aching, cramping, burning, itching and/or swelling during activity or after prolonged standing.

b. Significant recurrent attacks of superficial phlebitis.

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c. Hemorrhage from a ruptured varix.

d. Ulceration from venous stasis where incompetent varices are a contributing factor.

e. Symptomatic incompetence of the great or small saphenous veins (symptoms as in paragraph III.G.1.a.).

2. A trial of conservative, non-operative treatment has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings.

3. The patient's anatomy is amenable to endovenous ablation.

H. Ambulatory Blood Pressure Monitoring (ABPM) is only covered for beneficiaries with suspected white coat hypertension and is NOT covered for any other uses. The information obtained by ABPM is necessary in order to determine the appropriate medical management of the beneficiary. Suspected white coat hypertension is considered to exist when the following is documented:

1. There is no evidence of end-organ damage;

2. Office blood pressure greater than 140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; and

3. At least two blood pressure measurements taken outside the office which are less than 140/90 mm Hg.

I. Pulmonary vein isolation/ablation (CPT[3] procedure code 93651) is covered for beneficiaries who meet the guidelines published in the Heart Rhythm Society (HRS)/ European Heart Rhythm Association (EHRA)/European Cardiac Arrhythmia Society (ECAS) 2007 Consensus Statement as follows:

1. Symptomatic Atrial Fibrillation (AF) refractory or intolerant to at least one Class 1 or 3 antiarrhythmic medication.

2. In rare clinical situations, as first line therapy.

3. Selected symptomatic patients with heart failure and/or reduced ejection fraction.

4. The presence of a Left Atrial (LA) thrombus is a contraindication.

J. Primary percutaneous transluminal mechanical thrombectomy (CPT[3] procedure codes 37184 and 37185) and secondary percutaneous transluminal mechanical thrombectomy (CPT[3] procedure code 37186) are proven and are covered for the treatment of acute limb ischemia due to peripheral arterial occlusion.

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K. Percutaneous Transluminal Angioplasty (PTA) of the carotid artery with stenting (CPT[4] procedure codes 37215, 0075T, and 0076T) in beneficiaries at high risk for Carotid Endarterectomy (CEA) is proven and covered when all of the following criteria are met:

1. Beneficiaries who have symptomatic Carotid Artery Stenosis (CAS) greater than 70%.

2. Beneficiaries are at high risk for CEA due to one or more of the following significant comorbidities and/or anatomic risk factors:

a. Congestive heart failure (New York Heart Association Class I, II/IV).

b. Left ventricular ejection fraction of less than 30%.

c. Myocardial Infarction (MI) within past 30 days.

d. Unstable Angina.

e. Known severe Coronary Artery Disease (CAD).

f. Severe Chronic Obstructive Pulmonary Disease (COPD).

g. Contralateral carotid artery occlusion.

h. Contralateral laryngeal nerve palsy.

i. Previous radiation therapy to the neck.

j. Previous radical neck dissection.

k. Previous ipsilateral endarterectomy with restenosis.

l. Surgically inaccessible lesion.

m. Inability to move the neck to a suitable position for surgery.

n. Tracheostomy.

o. Coagulopathy or other coagulation issues leading to contraindication for endarterectomy.

3. Beneficiaries who have had a disabling stroke are excluded from coverage.

4. Coverage is limited to procedures performed using FDA approved carotid artery stents and embolic protection devices.

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5. The use of a distal embolic protection device is required. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted due to the risks of CAS without distal embolic protection.

6. The degree of CAS shall be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the beneficiary's medical records. If the stenosis is measured by ultrasound prior to the procedure, then the degree of stenosis must be confirmed by angiography at the start of the procedure. If the stenosis is determined to be less than 70% by angiography, then CAS should not proceed.

7. All procedures are performed in a Centers for Medicare and Medicaid Services (CMS) approved facility that has been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes.

IV. EXCLUSIONS

A. Thermogram; cephalic (CPT[5] procedure code 93760); peripheral (CPT[5] procedure code 93762) are unproven.

B. Percutaneous Myocardial Laser Revascularization (PMR) is unproven.

C. Cardiomyoplasty (Cardiac Wrap) for treatment of heart failure is unproven.

D. Minimally Invasive CABG surgery to include Minimally Invasive Direct Coronary Artery Bypass (MIDCAB) and Port Access Coronary Artery Bypass (PACAB) are unproven.

E. Percutaneous Transluminal Angioplasty (PTA) in the treatment of obstructive lesions of the vertebral and cerebral arteries is unproven. PTA of the carotid artery without stenting is unproven. PTA of the carotid artery with stenting but without embolic protection (CPT[5] procedure code 37216) is unproven.

F. Signal-Average Electrocardiography (CPT[5] procedure code 93278) is unproven.

G. Percutaneous transluminal mechanical thrombectomy vein(s) including intraprocedural pharmacological thrombolytic injections and fluroscopic guidance (CPT[5] procedure code 37187) is unproven.

H. Percutaneous transluminal mechanical thrombectomy, vein(s) including intraprocedural pharmacological thrombolytic injections and fluroscopic guidance, repeat treatment on subsequent day during course of thrombolytic therapy (CPT[5] procedure code 37188) is unproven.

I. Intracranial angioplasty with stenting (CPT[5] procedure code 61635) of the venous sinuses for treatment of pseudotumor cerebri (also known as idiopathic intracranial hypertension and benign intracranial hypertension) is unproven.

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J. Endovenous RFA (CPT[6] procedure codes 36475 and 36476) for the treatment of incompetent perforator veins is unproven. Endovenous laser ablation/therapy (CPT[6] procedure codes 36478 and 36479) for the treatment of incompetent perforator veins is excluded on the basis that this is off-label use of a device and is unproven.

V. EFFECTIVE DATES

A. March 1, 2001, for gamma and beta intracoronary radiotherapy (brachytherapy).

B. January 1, 2002, for TMR.

C. October 1, 2003, for VADs as destination therapy.

D. December 1, 2003, for endovenous RFA/obliteration.

E. January 1, 2005, for ABPM.

F. March 17, 2005, for PTA of the carotid artery with stenting in beneficiaries at high risk for CEA.

G. March 21, 2006, for percutaneous transluminal mechanical thrombectomy for acute limb ischemia.

H. January 1, 2007, for pulmonary vein isolation/ablation.

I. January 1, 2009, for endovenous laser ablation/therapy.

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