CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Cardiovascular Magnetic Resonance (CMR)**

Effective Date 9/15/2010
Next Review Date 9/15/2011
Coverage Policy Number 0168

Table of Contents

Hyperlink to Related Coverage Policies

Computed Tomography Angiography (CTA)
Coronary Intravascular Ultrasound (IVUS)
Electron Beam Computed Tomography (EBCT) and Multidetector Computed Tomography (MDCT) for Coronary Artery Calcification
Magnetic Resonance Angiography (MRA)
Magnetic Resonance Spectroscopy (MRS)

INSTRUCTIONS FOR USE

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Coverage Policy

CIGNA covers cardiovascular magnetic resonance (CMR) imaging as medically necessary for ANY of the following indications:

- myocardial viability study when percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) is being contemplated
- stress perfusion study following a recent cardiac imaging study (e.g. echo, stress echo, myocardial perfusion imaging [MPI], angiography)
- left ventricular (LV) or right ventricular (RV) structural and/or functional assessment when there are technically limited images on echocardiogram or nuclear study for ANY of the following:
  - acute myocardial infarction
  - heart failure
  - cardiotoxic therapy
  - myocarditis
  - a condition where other imaging studies yielded inconclusive or conflicting results
- questionable or indeterminate findings on echocardiogram for ANY of the following:
  - cardiomyopathy (e.g., dilated and hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy [ARVC])
  - valvular heart disease (e.g., valvular regurgitation, valve stenosis)

- disease of the pericardium (e.g., pericardial mass, pericardial effusion, pericardial tamponade, constrictive pericarditis, complications of cardiac surgery)
- cardiac tumor or thrombus
- pre- or post-intervention/treatment assessment of congenital heart disease (e.g., anomalies of coronary circulation, great vessels, and cardiac chambers and valves)

- evaluation of a disorder or disease of a major vessel (e.g., aortic or pulmonary aneurysm, dissection, and follow-up)
- evaluation of the pulmonary veins and left atrium prior to radiofrequency ablation for atrial fibrillation or supraventricular tachycardia

CIGNA does not cover CMR for any other indication, including but not limited to screening for coronary artery disease (CAD) in an asymptomatic individual, because it is considered experimental, investigational or unproven.

General Background

Magnetic resonance imaging (MRI) is a multiplanar image method based on the interaction between radiofrequency electromagnetic fields and certain atomic nuclei in the body (usually hydrogen), after the body has been placed in a strong magnetic field. It is particularly useful in detecting soft tissue damage or disease. MRI is unique in that it can also create detailed images of blood vessels without the use of contrast material, although there is a trend toward the use of special noniodinated MRI contrast material (e.g., gadolinium).

Cardiovascular magnetic resonance (CMR) is an imaging modality that provides a mechanism to assess cardiac or vascular anatomy, function, perfusion, and tissue characteristics in a highly reproducible manner during a single examination. Images can be acquired in patients of various body habitus, in a time-efficient fashion, without an invasive procedure or exposure to ionizing radiation or iodinated intravenous contrast medium (American College of Cardiology, 2010).

U.S. Food and Drug Administration (FDA)
MRI systems are regulated by the U.S. Food and Drug Administration (FDA) as Class II devices, and a large number of these systems have been approved via the FDA 510(k) process.

Literature Review
Cardiovascular MRI is a useful and accurate cardiac imaging modality. Numerous clinical and experimental studies have demonstrated the equality and superiority of CMR compared to other imaging modalities (e.g., nuclear imaging, transthoracic echocardiography [TTE]). Supported in the peer-reviewed scientific literature, common clinical applications of CMR include: assessment of ventricular function; myocardial viability; myocardial perfusion; valvular disease; differential diagnosis of inflammatory heart disease and cardiomyopathies; congenital heart disease; structural abnormalities; and evaluation of the aorta and pulmonary vessels (Mertens, et al., 2010; Stork, et al., 2007; Larose, et al., 2007; Ibrahim, et al., 2007; Dewey, et al., 2006; Kwong, et al., 2006; Pilz, et al., 2006; Rickers, et al., 2005; Kuijpers, et al., 2004; Grothues, et al., 2002; Al-Saadi, et al., 2000; Schulz-Menger, et al., 2000; Friedrich, et al., 1998). Myocardial function with myocardial viability and perfusion exam is a comprehensive assessment for coronary artery disease (CAD) completed in one imaging session. Late gadolinium-enhanced scar imaging by CMR is currently the most accurate non-invasive method to examine myocardial viability (Pilz, et al., 2009). CMR is a strong predictor of all-cause mortality (Cheong, et al., 2009). Current literature does not support a role for cardiovascular MRI in screening for CAD in an asymptomatic individual. The current U.S. Preventive Services Task Force (USPSTF, 2004) recommendations on screening for coronary heart disease do not address MRI.

Professional Societies/Organizations

American College of Cardiology (ACC)
Note: See Appendix A for definition of pre-test probability of coronary artery disease (CAD).
The American College of Cardiology Foundation in conjunction with the American College of Radiology (ACR), Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, American Society of Nuclear Cardiology (ASNC), North American Society for Cardiac Imaging, Society for Cardiovascular

Angiography and Interventions and the Society of Interventional Radiology, assessed the risks and benefits of CT, CT angiography, CMR and MR angiography for several cardiac indications or clinical scenarios (Hendel, et al., 2006). They were rated as follows:

- "Appropriate" test for specific indication (test is generally acceptable and is a reasonable approach for the indication).
- "Uncertain" for specific indication (test may be generally acceptable and may be a reasonable approach for the indication; however, critical data were lacking or significant differences of opinion exist among Panel members regarding the value of the method for that particular indication. Uncertainty also implies that more research and/or patient information is needed to classify the indication definitively.)
- "Inappropriate" test for that indication (test is not generally acceptable and is not a reasonable approach for the indication). The CMR indications or clinical scenarios are as follows:

For the detection of CAD in symptomatic patients, evaluation of chest pain syndrome (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR), MRI is:

- Appropriate for intermediate pre-test probability of CAD and ECG uninterpretable or unable to exercise
- Uncertain for intermediate pre-test probability of CAD and ECG interpretable and able to exercise
- Uncertain for high pre-test probability of CAD
- Inappropriate for low pre-test probability of CAD and ECG interpretable and able to exercise

For the detection of CAD in symptomatic patients, acute chest pain (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR), MRI is:

- Uncertain for intermediate pre-test probability of CAD and no ECG changes and serial cardiac enzymes negative
- Inappropriate for high pre-test probability of CAD and ECG—ST-segment elevation and/or positive cardiac enzymes

Note: It should be noted that there is no evaluation of CMR for risk assessment of the general population, but there is for CT.

Risk Assessment with prior test results (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR), MRI is:

- Appropriate for coronary angiography (catheterization or CT) and stenosis of unclear significance
- Uncertain for equivocal stress test (exercise, stress SPECT, or stress echo) and intermediate CHD risk (Framingham)
- Inappropriate for normal prior stress test (exercise, nuclear, echo, MRI) and high CHD risk (Framingham) and within one year of prior stress test

Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery, Low-Risk Surgery (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR) MRI is:

- Inappropriate for intermediate perioperative risk predictor

Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery, Intermediate- or High-Risk Surgery (Use of Vasodilator Perfusion CMR or Dobutamine Stress Function CMR), MRI is:

- Uncertain for intermediate perioperative risk predictor

Evaluation of Ventricular and Valvular Function, procedures may include LV/RV mass and volumes, MR angiography, quantification of valvular disease, and delayed contrast enhancement, MRI/MRA is:

- Appropriate for assessment of complex congenital heart disease, including anomalies of coronary circulation, great vessels, and cardiac chambers and valves, and procedures may include LV/RV mass and volumes, MR angiography, quantification of valvular disease, and contrast enhancement
- Appropriate for evaluation of LV function following myocardial infarction or in heart failure patients and patients with technically limited images from echocardiogram
- Appropriate for quantification of LV function and discordant information that is clinically significant from prior tests
- Appropriate for evaluation of specific cardiomyopathies (infiltrative [amyloid, sarcoid], HCM, or due to cardiotoxic therapies, and use of delayed enhancement

- Appropriate for characterization of native and prosthetic cardiac valves—including planimetry of stenotic disease and quantification of regurgitant disease and patients with technically limited images from echocardiogram or TEE
- Appropriate for evaluation for arrhythmogenic right ventricular cardiomyopathy (ARVC) and patients presenting with syncope or ventricular arrhythmia
- Appropriate for evaluation of myocarditis or myocardial infarction with normal coronary arteries and positive cardiac enzymes without obstructive atherosclerosis on angiography
- Uncertain for evaluation of LV function following myocardial infarction or in heart failure patients

For structure and function, evaluation of intra- and extra-cardiac structures, LV/RV mass and volumes, MRA, quantification of valvular disease, and delayed contrast enhancement, MRI/MRA is:
- Appropriate for evaluation of cardiac mass (suspected tumor or thrombus) and use of contrast for perfusion and enhancement
- Appropriate for evaluation of pericardial conditions (pericardial mass, constrictive pericarditis)
- Appropriate for evaluation for aortic dissection
- Appropriate for evaluation of pulmonary veins prior to radiofrequency ablation for atrial fibrillation and left atrial and pulmonary venous anatomy, including dimensions of veins for mapping purposes

Detection of Myocardial Scar and Viability, Evaluation of Myocardial Scar (Use of Late Gadolinium Enhancement), MRI is:
- Appropriate to determine the location and extent of myocardial necrosis including 'no reflow' regions and post-acute myocardial infarction
- Appropriate to determine viability prior to revascularization and establish likelihood of recovery of function with revascularization (percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG]) or medical therapy
- Appropriate to determine viability prior to revascularization and viability assessment by SPECT or dobutamine echo has provided "equivocal or indeterminate" results
- Uncertain to detect post-PCI myocardial necrosis (Hendel, et al., 2006).

ACC/AHA
The ACC/AHA 2008 Guidelines for the Management of Adults With Congenital Heart Disease (Warnes, et al., 2008) included numerous Class I and Class IIa recommendations for the use of MRI under the following subheadings: Left-Sided Heart Obstructive Lesions (Aortic Valve Disease, Subvalvular and Supravalvular Aortic Stenosis, Associated Disorders of the Ascending Aorta, and Coarctation); Right Ventricular Outflow Tract Obstruction; Coronary Artery Abnormalities; Pulmonary Hypertension/Eisenmenger Physiology; Tetralogy of Fallot; Dextro-Transposition of the Great Arteries; and Congenitally Corrected Transposition of the Great Arteries. (See Appendix B for ACC/AHA Definitions of Classifications).

ACC/AHA
ACC/AHA 2006 guidelines for the management of patients with valvular heart disease (Bonow, et al., 2006) note that, depending on the specific clinical circumstances, transesophageal echocardiography, cardiac magnetic resonance, or cardiac catheterization may be indicated for better characterization of the valvular lesion.

Diagnosis and Initial Evaluation recommendations that address CMR include:
- Radionuclide angiography or magnetic resonance imaging is indicated for the initial and serial assessment of LV volume and function at rest in patients with aortic regurgitation (AR) and suboptimal echocardiograms (Class I)
- MRI is reasonable for the estimation of AR severity in patients with unsatisfactory echocardiograms (Class IIa)

Bicuspid Aortic Valve with Dilated Ascending Aorta recommendations regarding CMR include:
- Cardiac MRI or cardiac CT is indicated in patients with bicuspid aortic valves when morphology of the aortic root or ascending aorta cannot be assessed accurately by echocardiography (Class I)
- Patients with bicuspid aortic valves and dilatation of the aortic root or ascending aorta (diameter greater than 4.0 cm) should undergo serial evaluation of aortic root/ascending aorta size and morphology by echocardiography, cardiac magnetic resonance, or computed tomography on a yearly basis (Class I)

- Cardiac MRI or cardiac CT is reasonable in patients with bicuspid aortic valves when aortic root dilatation is detected by echocardiography to further quantify severity of dilatation and involvement of the ascending aorta (Class IIa) (Bonow, et al., 2006). (See Appendix B for ACC/AHA Definitions of Classifications).

ACCF/AHA
Clinical Competence Statement on Cardiac Imaging With Computed Tomography and Magnetic Resonance (Budoff, et al., 2005) states that "a comprehensive review of the clinical indications for CMR is beyond the scope of this report. Interested readers are referred elsewhere." Pennell et al. (2004) is cited for reference (see below). Next, the document states, "a brief overview of broad clinical indications is presented in the text. These are intended to serve as a general guide for CMR training to include a broad spectrum of pathologic cases inclusive of these indications." General indications addressed include:
- ischemic heart disease: regional and global function, perfusion, viability, and coronary angiography
- non-ischemic cardiomyopathies
- pericardial disease
- valvular heart disease
- congenital heart disease

Society for Cardiovascular Magnetic Resonance (SCMR)/European Society of Cardiology
The European Society of Cardiology published Clinical Indications for CMR: Consensus Panel report (Pennell, et al., 2004). Some of the key cardiac areas discussed include:

- Congenital heart disease: Indications may include initial evaluation and follow-up of adult congenital heart disease, assessment of shunt size, and anomalies (e.g., anomalies of the viscero-atrial situs, atria and venous return, atrioventricular valve, ventricles, semilunar valves and arteries).
- Acquired vascular disease: Indications may include vascular lumen imaging features of vessel wall (e.g., hematoma/thrombus, inflammation, and atherosclerotic plaque). "In addition to morphologic imaging of blood vessels, velocity mapping can be used to assess and measure the blood flow. Blood velocity and flow can be integrated across the cardiac cycle and the vessel lumen for reliable volume flow measurements."
- For coronary artery disease (CAD), indications may include:
  - assessment of global ventricular (left and right) function and mass:
    "CMR is accurate, reproducible and well validated for measuring left ventricular (LV) and right ventricular (RV) volumes and mass; this makes it valuable for the assessment of fundamental parameters of cardiac function as well as longitudinal follow-up of patients over time."
  - detection of coronary artery disease (e.g., regional left ventricular function at rest and during dobutamine stress, assessment of myocardial perfusion):
    "There are several approaches to detecting CAD using CMR. These include the visualization of the effects of induced ischemia (wall motion, perfusion) and direct visualization of coronary arteries (coronary angiography and flow). Early detection of atherosclerosis and endothelial dysfunction is also possible (arterial wall imaging, brachial artery reactivity)."
  - assessment of chronic coronary syndromes:
    "Myocardial infarction (MI) can be detected with high accuracy and sensitivity using late gadolinium-enhanced CMR." In addition, "in the assessment of myocardial viability for the clinical scenario of consideration of bypass surgery for improvement of LV function, CMR has been shown to be very useful."
  - evaluation of acute coronary syndromes:
    "CMR has been used in the emergency room in the assessment of chest pain. CMR showed a sensitivity and specificity of 84% and 85% for identifying patients with CAD, and multi-variate analysis including standard clinical tests (electrocardiogram, troponin, thrombolysis in myocardial infarction [TIMI] risk score) showed that CMR was the strongest predictor of CAD and added diagnostic value over clinical parameters, including identification of enzyme-negative unstable angina. This promising data needs to be confirmed in other centers." "CMR is effective in demonstrating the complications of acute MI including ventricular aneurysm, pseudoaneurysms, ventricular septum perforation, and mitral regurgitation."
- Cardiomyopathies and cardiac transplantation: Indications may include "constrictive pericarditis, detection and characterization of cardiac and pericardiac tumors, ventricular thrombus, hypertrophic cardiomyopathy, dilated cardiomyopathy, differentiation from dysfunction related to coronary artery disease, arrhythmogenic

right ventricular cardiomyopathy (dysplasia), restrictive cardiomyopathy, siderotic cardiomyopathy (in particular thalassemia), and noncompaction."
- Pericardial disease: "Both CMR and computed tomography (CT) are well suited to define anatomic abnormalities of the pericardium including pericardial thickening and effusions. CMR has the advantage of being able to depict and quantify the functional abnormalities which may be associated with pericardial disease."
- Cardiac tumors: "Transthoracic echocardiography is the usual technique which detects intracardiac tumors. However, in many cases the characterization is incomplete, and CMR is particularly helpful in determining the relationship to normal intracardiac structures and tumor extension to adjacent vascular and mediastinal structures, infiltration into the pericardium, and surgical planning."
- Valvular heart disease: "CMR may play a complementary role when transthoracic acoustic windows are poor and a transesophageal echocardiography (TEE) approach is undesirable, or when results of echocardiography and catheterization are conflicting" (Pennell, et al., 2004).

American College of Radiology (ACR)
The ACR Practice Guideline for the Performance and Interpretation of Cardiac MRI (2006) states primary indications for cardiac MRI include, but are not limited to, assessment of the following: Acquired Heart Disease and Congenital Heart Disease.
The ACR discusses the following topics under 'acquired':
- dynamic cardiac anatomy and ventricular function
- assessment of cardiomyopathies, myocardial fibrosis, and infarction
- myocardial ischemia and viability assessed through the use of pharmacologic agents
- characterization of cardiac masses
- pericardial disease
- valvular disease
- coronary artery disease

The ACR discussed the following under 'congenital':
- congenital shunts
- complex congenital anomalies
- pericardial anomalies
- congenital valve disease
- coronary artery anomalies

The ACR Clinical statement on noninvasive cardiac imaging (Weinreb, et al., 2005) states that cardiac MRI represents the specialized application of MR to imaging the heart to help diagnose both acquired and congenital disease. Applications of cardiac MR include, but are not limited to, the following:
- assessment of myocardial scar, infiltrative processes, and inflammation
- assessment of myocardial ischemia
- assessment of ventricular function
- characterization of cardiac chamber morphology and function
- detection and characterization of congenital heart disease
- characterization of cardiac masses
- diagnosis of pericardial disease
- quantification of valvular disease and shunt physiology
- detection of coronary artery atherosclerosis
- detection and characterization of coronary artery anomalies
- detection and characterization of coronary artery aneurysms

Summary
Evidence in the published peer-reviewed scientific literature, textbooks, as well as current clinical practice support cardiovascular magnetic resonance (CMR) as an established imaging modality, well-recognized for its value in the initial assessment and monitoring of a wide range of diseases of the heart, great vessels and surrounding related structures. Studies are ongoing that compare various state-of-the-art imaging technologies to one another for use in the cardiac patient. Cardiovascular MRI is not indicated for screening for CAD in an asymptomatic individual.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
75557	Cardiac MRI for morphology and function without contrast materials
75558	Cardiac MRI for morphology and function without contrast materials; with flow/velocity quantification; (code deleted 12/31/2009)
75559	Cardiac MRI for morphology and function without contrast materials; with stress imaging;
75560	Cardiac MRI for morphology and function without contrast materials; with flow/velocity quantification and stress; (code deleted 12/31/2009)
75561	Cardiac MRI for morphology and function without contrast materials, followed by contrast material(s) and further sequences.
75562	Cardiac MRI for morphology and function without contrast materials, followed by contrast material(s) and further sequences; with flow/velocity quantification. (code deleted 12/31/2009)
75563	Cardiac MRI for morphology and function without contrast materials, followed by contrast material(s) and further sequences; with stress imaging.
75564	Cardiac MRI for morphology and function without contrast materials, followed by contrast material(s) and further sequences; with flow/velocity quantification and stress; (code deleted 12/31/2009)
75565	Cardiac magnetic resonance imaging for velocity flow mapping (List separately in addition to code for primary procedure)

ICD-9-CM Diagnosis Codes	Description
164.1	Malignant neoplasm of heart
394.0-394.9	Diseases of the mitral valve
395.0-395.9	Diseases of the aortic valve
396.0-396.9	Diseases of the mitral and aortic valves
410.00-410.92	Acute myocardial infarction
414.10-414.19	Aneurysm and dissection of heart
417.1	Aneurysm of pulmonary artery
420.0-420.99	Acute pericarditis
422.0-422.93	Acute myocarditis
425.4	Other primary cardiomyopathies
427.5	Cardiac arrest
428.0-428.9	Heart failure
429.4	Functional disturbances following cardiac surgery
	Multiple/varied

Experimental/Investigational/Unproven/Not Covered for any indication other than those mentioned in this policy.

ICD-9-CM Diagnosis Codes	Description
	Multiple/varied codes

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APPENDIX A

From the American College of Cardiology (Hendel, et al., 2009):

Pre-Test Probability of CAD by Age, Gender, and Symptoms*

Age (Yrs)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain	Asymptomatic
<39	M F	Intermediate Intermediate	Intermediate Very low	Low Very low	Very low Very low
40-49	M F	High Intermediate	Intermediate Low	Intermediate Very low	Low Very low
50-59	M F	High Intermediate	Intermediate Intermediate	Intermediate Low	Low Very low
>60	M F	High High	Intermediate Intermediate	Intermediate Intermediate	Low Low

High: Greater than 90% pre-test probability; Intermediate: Between 10% and 90% pre-test probability;
Low: Between 5% and 10% pre-test probability; Very Low: Less than 5% pre-test probability.
*Modified from the ACC/AHA Exercise Testing Guidelines to reflect all age ranges (Gibbons, et al., 2002).

APPENDIX B

American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification used:

Class I: Conditions for which there is evidence for and/or general agreement that the procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/ efficacy of a procedure or treatment.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	09/15/2008	0168	Cardiovascular Magnetic Resonance (CMR)