Brief Background:

- Effective July 7, 2011 Medicare covers MRI scans for patients with implanted pacemakers when the pacemakers are used according to the FDA-approved labeling for use in the MRI environment.
- Effective (October 2014), The Medtronic SureScan™ pacing system, which consists of an MRI SureScan device with two SureScan leads, is FDA approved for use in the MRI environment.
- Medicare released a Claims Processing Transmittal and a National Coverage Determination Transmittal on September 20, 2011 that identify the recommended modifier and diagnosis codes to use when submitting a claim for an MRI scan if the Medicare patient has an FDA-approved pacemaker.

MRI Coding Information When Patient Meets Medical Criteria:

**Dates of service:** On or after July 7, 2011.

**CPT® code:** Appropriate MRI procedure code.

**Modifier:** The KX modifier is appended (attached) to the MRI procedure code. KX indicates attestation by the provider that documentation is on file verifying that FDA-approved labeling requirements are met. This modifier does not apply to claims associated with clinical trials.

**ICD-10-CM® diagnosis code:** Z95.0 (Presence of cardiac pacemaker) plus applicable MRI diagnosis code.

**Medicare denials:**
- Medicare contractors shall deny MRI line items when billed with an applicable MRI code and ICD-10-CM® diagnosis code Z95.0 if modifier KX is not included.
- Medicare contractors shall deny line items not meeting the published guidelines. The following Medicare remittance advice codes will be used with these denials:
  - Group code: Contractual Obligation (CO)
  - Claim Adjustment Reason Codes (CARC) 188: This product/procedure is only covered when used according to FDA recommendations.
  - Medicare Summary Notices (MSN) 21.8: Services performed using equipment that has not been approved by the FDA are not covered.

These coding suggestions do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third party payers as to the correct form of billing or the amount that will be paid to providers of service.

**References**

2. CPT copyright 2014 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Medtronic SureScan™ pacing systems are MR Conditional and as such are designed to allow patients to undergo MRI under the specified conditions for use. A complete SureScan pacing system, which consists of an MRI SureScan device with two SureScan leads, is required for use in the MRI environment.
Brief Statement: SureScan™ Pacing Systems
Medtronic SureScan pacing systems are MR Conditional and as such are designed to allow patients to undergo MRI under the specified conditions for use. A complete SureScan pacing system, which consists of an MRI SureScan device with two SureScan leads, is required for use in the MRI environment. Consult the device manuals to ensure all system components are MR Conditional.

Indications
Medtronic SureScan pacing systems are indicated for the following:
- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity
- Accepted patient conditions warranting chronic cardiac pacing include:
  - Symptomatic paroxysmal or permanent second- or third-degree AV block
  - Symptomatic bilateral bundle branch block
  - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders
  - Bradyarrhythmia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

Note: the Advisa MRI™ pacing system includes the following additional indication:
- Vasovagal syndromes or hypersensitive carotid sinus syndromes

The systems are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:
- Various degrees of AV block to maintain the atrial contribution to cardiac output
- VVI intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm

Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.

Contraindications
Medtronic SureScan pacing systems are contraindicated for:
- Concomitant implantation with another bradycardia device
- Concomitant implantation with an implantable cardioverter defibrillator

There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient’s age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician.

- Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate
- Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter
- Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms
- Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance
- ATP therapy is contraindicated in patients with an accessory antegrade pathway

Warnings and Precautions
Changes in patient’s disease and/or medications may alter the efficacy of the device’s programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Use of the device should not change the application of established anticoagulation protocols.

Patients and their implanted systems must be screened to meet the MRI Conditions of Use. Do not scan patients who do not have a complete Medtronic SureScan pacing system consisting of a SureScan device and two SureScan leads; patients who have broken, abandoned or intermittent leads; or patients who have a lead impedance value of < 200 Ω or > 1,500 Ω. Do not scan patients with a SureScan pacing system implanted in sites other than the left pectoral region.

Potential Complications
Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibrillation, thrombosis, thrombotic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial rub, infection, myocardial irritability, and pneumothorax. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block. The SureScan system has been designed to minimize potential complications in the MRI environment. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

See the device manuals before performing an MRI Scan for detailed information regarding the implant procedure, indications, MRI conditions of use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Medtronic at 1 (800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.