SUBJECT: Magnetic Resonance Imaging (MRI)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective for claims with dates of service on and after April 10, 2018 Medicare will allow for coverage of MRI for beneficiaries under certain conditions.

EFFECTIVE DATE: April 10, 2018
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: December 10, 2018

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-Only One Per Row.

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<th>R/N/D</th>
<th>CHAPTER / SECTION / SUBSECTION / TITLE</th>
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III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.
IV. ATTACHMENTS:
Business Requirements
Manual Instruction
SUBJECT: Magnetic Resonance Imaging (MRI)

EFFECTIVE DATE: April 10, 2018
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: December 10, 2018

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) opened this national coverage analysis (NCA) to reconsider coverage indications for Magnetic Resonance Imaging (MRI), specifically section 220.2(C)(1) Contraindications. This NCA focused on the contraindications for implanted pacemaker (PM), implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy pacemaker (CRT-P), or cardiac resynchronization therapy defibrillator (CRT-D) in patients undergoing MRIs both on and off Food & Drug Administration (FDA) label. The Coverage with Evidence Development (CED) requirement has been effective since 2011 and generated numerous data collection.

B. Policy: Effective for claims with dates of service on or after April 10, 2018, CMS determined the evidence is sufficient to conclude that MRI for Medicare beneficiaries with an implanted PMs, ICDs, CRT-Ps, or CRT-Ds is reasonable and necessary under section 1862(a) (1)(A) of the Social Security Act (the Act) under certain circumstances. We are modifying our national coverage determination (NCD) to eliminate the collection of additional information under the CED paradigm under section 1862(a)(1)(E) of the Act.

CMS is revising the language in the NCD Manual sections as follows:

(1) remove the contraindication for Medicare coverage of MRI in a beneficiary who has an implanted PM or ICD under section 220(C)(1);

(2) expand coverage to include CRT-P or CRT-D devices under section 220.2(B)(3);

(3) expand coverage for beneficiaries who have an implanted FDA-approved, ICD, CRT-P, or CRT-D correspondingly under section 220.2(B)(3);

(4) expand coverage for beneficiaries with an implanted PM, ICD, CRT-P, or CRT-D device that does not have FDA labeling specific for an MRI under certain conditions under section 220.2(B)(3); and,

(5) remove the CED requirement.

Effective April 10, 2018, the -Q0 and -KX modifiers are no longer required on ICD claims (see CR7441 for reference).

NOTE: Medicare coverage for MRIs performed on Medicare beneficiaries without implanted PMs, implanted ICDs, CRT-Ps, and CRT-Ds is not affected by this CR.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.
<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
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</thead>
<tbody>
<tr>
<td>10877 - 04.1</td>
<td>Effective for claims with dates of service on and after April 10, 2018, contractors shall allow for coverage of MRIs for beneficiaries with implanted PMs, implantable ICDs, CRT-Ps, and CRT-Ds both on and off FDA label for use in an MRI environment as described in section 220.2.B.3 of the NCD Manual.</td>
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<tr>
<td>10877 - 04.2</td>
<td>Effective for claims with dates of service on or after April 10, 2018, contractors shall allow line items for MRIs for beneficiaries with implanted PMs, implanted ICDs, CRT-Ps, and CRT-Ds that include the following: An appropriate MRI code, AND, ICD-10 dx Z95.0 with presence of cardiac pacemaker, (Z95.0 also includes presence of CRT-P), OR, ICD-10 dx Z95.810 with presence of automatic ICD (Z95.810 also includes presence of automatic ICD with CRT-P, and, presence of CRT-D).</td>
<td>X X</td>
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<tr>
<td>10877 - 04.2.1</td>
<td>Contractors shall deny line items not complying with the requirements of 10877-04.2 using the following messaging: Group code – CO Claim Adjustment Reason Code (CARC) 146 – Diagnosis was invalid for the date(s) of service reported. Medicare Summary Notice (MSN) 21.21 - This service was denied because Medicare only covers this service under certain circumstances. Spanish Version Este servicio fue denegado porque Medicare solamente lo cubre bajo ciertas circunstancias.</td>
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</tr>
<tr>
<td>Number</td>
<td>Requirement</td>
<td>Responsibility</td>
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<tr>
<td>10877 - 04.3</td>
<td>Effective April 10, 2018, the -Q0 and -KX modifiers on claims for MRIs for beneficiaries with an implanted pacemaker are no longer required and can be end-dated. (see CR7441-04.1.1, 04.1.2, and 04.2.1 for reference).</td>
<td></td>
</tr>
<tr>
<td>10877 - 04.4</td>
<td>For claims with dates of service on or after April 10, 2018, but received before the implementation date of this CR, contractors need not search their files. However, contractors shall adjust claims brought to their attention.</td>
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**III. PROVIDER EDUCATION TABLE**

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
<th>A/B MAC</th>
<th>D M E C F I S S M C S V M S C W F</th>
<th>Other</th>
</tr>
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<tbody>
<tr>
<td>10877 - 04.5</td>
<td>MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.</td>
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<td>X</td>
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**IV. SUPPORTING INFORMATION**

Section A: Recommendations and supporting information associated with listed requirements: N/A

*Should* denotes a recommendation.
Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage), Kimberly Long, 410-786-5702 or Kimberly.Long@cms.hhs.gov (Coverage), Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage), Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Practitioner Claims Processing), William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Claims Processing)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0
40.2 – Medicare Summary Notices (MSN), Claim Adjustment Reason Codes (CARCs), and Remittance Advice Remark Codes (RARCs)
The Centers for Medicare & Medicaid Services (CMS) finds that the non-coverage of magnetic resonance imaging (MRI) for blood flow determination is no longer supported by the available evidence. CMS is removing the phrase “blood flow measurement” and local Medicare contractors will have the discretion to cover (or not cover).

Consult Publication (Pub.) 100-03, National Coverage Determinations (NCD) Manual, chapter 1, section 220.2, for specific coverage and non-coverage indications associated with MRI and MRA (Magnetic Resonance Angiography).

A/B MACs (B) do not make additional payments for three or more MRI sequences. The relative value units (RVUs) reflect payment levels for two sequences.

The technical component (TC) RVUs for MRI procedures that specify “with contrast” include payment for paramagnetic contrast media. A/B MACs (B) do not make separate payment under code A4647.

A diagnostic technique has been developed under which an MRI of the brain or spine is first performed without contrast material, then another MRI is performed with a standard (0.1mmol/kg) dose of contrast material and, based on the need to achieve a better image, a third MRI is performed with an additional double dosage (0.2mmol/kg) of contrast material. When the high-dose contrast technique is utilized, A/B MACs (B):

- Do not pay separately for the contrast material used in the second MRI procedure;
- Pay for the contrast material given for the third MRI procedure through supply code Q9952, the replacement code for A4643, when billed with Current Procedural Terminology (CPT) codes 70553, 72156, 72157, and 72158;
- Do not pay for the third MRI procedure. For example, in the case of an MRI of the brain, if CPT code 70553 (without contrast material, followed by with contrast material(s) and further sequences) is billed, make no payment for CPT code 70551 (without contrast material(s)), the additional procedure given for the purpose of administering the double dosage, furnished during the same session. Medicare does not pay for the third procedure (as distinguished from the contrast material) because the CPT definition of code 70553 includes all further sequences; and
- Do not apply the payment criteria for low osmolar contrast media in §30.1.2 to billings for code Q9952, the replacement code for A4643. Effective January 1, 2008, Q9952 is replaced with A9579.

With the implementation for calendar year 2007 of a bottom-up methodology, which utilizes the direct inputs to determine the practice expense (PE) relative value units (RVUs), the cost of the contrast media is not included in the PE RVUs. Therefore, a separate payment for the contrast media used in various imaging procedures is paid. In addition to the CPT code representing the imaging procedure, separately bill the appropriate HCPCS “Q” code (Q9945 – Q9954; Q9958-Q9964) for the contrast medium utilized in performing the service. Effective January 1, 2008, HCPCS code ranges changed to Q9950-Q9954, Q9958-Q9967.

For claims with dates of service on or after February 24, 2011, through April 9, 2018, Medicare will allow for coverage of MRI for beneficiaries with implanted pacemakers (PMs) or cardioverter defibrillators.
(ICDs) for use in an MRI environment in a Medicare-approved clinical study as described in section 220.C.1 of the NCD Manual.

For claims with dates of service on or after July 7, 2011, through April 9, 2018, Medicare will allow for coverage of MRI for beneficiaries with implanted PMs when the PMs are used according to the Food and Drug Administration (FDA)-approved labeling for use in an MRI environment as described in section 220.2.C.1 of the NCD Manual.

For claims with dates of service on or after April 10, 2018, Medicare will allow for coverage for MRIs for beneficiaries with implanted PMs, ICDs, cardiac resynchronization therapy pacemakers (CRT-Ps), or cardiac resynchronization therapy defibrillators (CRT-Ds), both on and off FDA label, for use in an MRI environment as described in section 220.2.B.3 of the NCD Manual. The data collection requirement under coverage with evidence development ceases April 9, 2018.

40.1.4 – Payment Requirements
(Rev. 4147, Issued: 10-19-18, Effective: 04-10-18, Implementation: 12-10-18)

A. For claims with dates of service on and after February 24, 2011, through April 9, 2018, the following diagnosis code and modifier shall be reported on MRI claims for beneficiaries with implanted PMs, that are outside FDA-approved labeling for use in an MRI environment (in a Medicare-approved clinical study):

- Appropriate MRI code
- Q0 modifier
- Condition code 30 (for institutional claims)

If ICD-9-CM is applicable
- ICD-9 code V70.7- Examination of participant in clinical trial (for institutional claims)
- ICD-9 code V45.02 (automatic implantable cardiac defibrillator) or
- ICD-9 code V45.01 (cardiac pacemaker)

If ICD-10-CM is applicable

- Z00.6 - Encounter for examination for normal comparison and control in clinical research program
- Z95.810 - Presence of automatic (implantable) cardiac defibrillator or
- Z95.0 - Presence of cardiac pacemaker

B. For claims with dates of services on and after July 7, 2011, through April 9, 2018, the following codes shall be reported on MRI claims for beneficiaries with implanted PMs that have FDA-approved labeling for use in an MRI environment:

- Appropriate MRI code
- -KX modifier

If ICD-9-CM is applicable
- ICD-9 code V45.01 (cardiac pacemaker)

If ICD-10-CM is applicable
- ICD-10 code Z95.0 (cardiac pacemaker)

Payment is as follows:
• Professional claims (practitioners and suppliers) - based on the Medicare Physician Fee Schedule (MPFS)

• Inpatient (11x) - Prospective payment system (PPS), based on the diagnosis-related group (DRG)

• Hospital outpatient departments (13x) - Outpatient PPS, based on the ambulatory payment classification

• Rural Health Clinics/Federally Qualified Health Centers (RHCs/FQHCs) (71x/77x) - All-inclusive rate (AIR), professional component only, based on the visit furnished to the RHC/FQHC beneficiary to receive the MRI. The technical component is outside the scope of the RHC/FQHC benefit. Therefore the provider of the technical service bills their A/B MAC (B) on the ASC X12 837 professional claim format or hardcopy Form CMS-1500 and payment is made under the MPFS.

• Critical access hospitals (CAHs) (85x) –
  
  o For CAHs that elected the optional method of payment for outpatient services, the payment for technical services would be the same as the CAHs that did not elect the optional method - Reasonable cost.

  o The A/B MAC (A) pays the professional component at 115% of the MPFS.

Deductible and coinsurance apply.

C. For claims with dates of service on and after April 10, 2018, the following diagnosis coding shall be reported on MRI claims for beneficiaries with implanted PMs, ICDs, CRT-Ps, or CRT-Ds in patients undergoing MRIs both on and off FDA label:

• An appropriate MRI code, AND,

• Z95.0 Presence of cardiac pacemaker (Z95.0 also includes Presence of CRT-P), OR,

• Z95.810 Presence of automatic (implantable) cardiac defibrillator (Z95.810 also includes Presence of automatic ICD with synchronous cardiac pacemaker, and Presence of CRT-D).

Payment is as follows:

• Professional claims (practitioners and suppliers) - based on the MPFS.

• Inpatient (11x) - PPS, based on the DRG

• Hospital outpatient departments (13x) - Outpatient PPS, based on the ambulatory payment classification

• RHCs/FQHCs (71x/77x) – Air, professional component only, based on the visit furnished to the RHC/FQHC beneficiary to receive the MRI. The technical component is outside the scope of the RHC/FQHC benefit. Therefore the provider of the technical service bills their A/B MAC (B) on the ASC X12 837 professional claim format or hardcopy Form CMS-1500 and payment is made under the MPFS.
CAHs (85x) –

- For CAHs that elected the optional method of payment for outpatient services, the payment for technical services would be the same as the CAHs that did not elect the optional method - Reasonable cost.

- The A/B MAC (A) pays the professional component at 115% of the MPFS.

Deductible and coinsurance apply.

40.2 – Medicare Summary Notices (MSN), Claim Adjustment Reason Codes (CARCs), and Remittance Advice Remark Codes (RARCs)
(Rev. 4147, Issued: 10-19-18, Effective: 04-10-18, Implementation: 12-10-18)
For claims with dates of service July 7, 2011, through April 9, 2018, the A/B MAC denies MRI line items on claims when billed with the appropriate MRI code and a diagnostic code for cardiac pacemaker if modifier -KX is not present.

The contractor shall use the following messages and associated codes when rejecting/denying claims under this policy. This Claim Adjustment Reason Code (CARC)/Remittance Advice Remark Code (RARC) combination is compliant with The Council for Affordable Quality Healthcare (CAQH)/The Committee on Operating Rules for Information Exchange (CORE) Business Scenario Three.

Group Code: CO
CARC: 188
RARC: N/A
Medicare Summary Notice (MSN): 21.8

For claims with dates of service February 24, 2011, through April 9, 2018, the A/B MAC denies MRI line items that do not include all of the following line items:

- An appropriate MRI code,

- If ICD-9-CM is applicable, ICD-9 code V45.02 (automatic implantable cardiac defibrillator) or ICD-9 code V45.01 (cardiac pacemaker),

- ICD-10-CM is applicable, ICD-10 code Z95.810 (automatic implantable cardiac defibrillator) or ICD-10 code Z95.0 (cardiac pacemaker),

- Modifier Q0,

- If ICD-9-CM is applicable, ICD-9 code V70.7 Examination of participant in clinical trial (for institutional claims only) or

- If ICD-10-CM is applicable, ICD-10 code Z00.6 – Examination of participant in clinical trial (for institutional claims only), and

- Condition code 30 (for institutional claims only).
The contractor shall use the following messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: 272
RARC: N386
MSN: 21.21

For claims with dates of service on or after April 10, 2018, the contractor shall use the following messages and associated codes when rejecting/denying claims not complying with the billing coding requirements in Section 40.1.4.C:
Group Code: CO
CARC: 146
MSN: 21.21