SUBJECT: Update to Intensive Cardiac Rehabilitation (ICR) Programs

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors of the changes to section 51004 of the Bipartisan Budget Act (BBA) of 2018, Pub. L. No. 115-123 (2018), amended section 1861(eee)(4)(B) of the Act to add to expand coverage in an ICR to additional conditions that became effective February 9, 2018.

EFFECTIVE DATE: February 9, 2018
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: March 19, 2019

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.

<table>
<thead>
<tr>
<th>R/N/D</th>
<th>CHAPTER / SECTION / SUBSECTION / TITLE</th>
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</thead>
<tbody>
<tr>
<td>R</td>
<td>32/140.3/Intensive Cardiac Rehabilitation (ICR) Program Services Furnished On or After January 1, 2010</td>
</tr>
</tbody>
</table>

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: Update to Intensive Cardiac Rehabilitation (ICR) Programs

EFFECTIVE DATE: February 9, 2018
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I. GENERAL INFORMATION

A. Background: The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, Pub. L. No. 110-275, § 144 (2008) established coverage for cardiac rehabilitation (CR) programs and intensive cardiac rehabilitation (ICR) programs under Part B. These provisions are primarily codified in section 1861(eee) of the Social Security Act (the Act). CMS implemented the statutory provisions through rulemaking codified at 42 C.F.R. § 410.49. The CR and ICR coverage provisions included in section 42 CFR 410.49 were effective January 1, 2010.

Effective January 1, 2010, Medicare Part B covered ICR program services for beneficiaries who have experienced one or more of the following:

- An acute myocardial infarction within the preceding 12 months;
- A coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty or coronary stenting;
- A heart or heart-lung transplant.

B. Policy: Effective February 9, 2018, section 51004 of the Bipartisan Budget Act (BBA) of 2018, Pub. L. No. 115-123 (2018), amended section 1861(eee)(4)(B) of the Act to add to expand coverage in an ICR to additional conditions:

- Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks; or,
- Any additional condition for which the Secretary has determined that a CR program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a CR program, that such coverage is not supported by the clinical evidence.

NOTE: CMS plans to amend our ICR regulations specified at 42 CFR 410.49 to reflect this expanded coverage. CMS anticipates that the changes will be included in the 2020 Medicare Physician Fee Schedule notice of proposed rulemaking. However, because the expanded coverage under the statutory change was effective on enactment, expanded coverage for these conditions will be made effective for services furnished on or after February 9, 2018. See Publication (Pub.) 100-02, Medicare Benefit Policy Manual, Chapter 15, section 232 and Pub 100-04, Chapter 32, section 140.3.
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>11117 - 04.1</td>
<td>Effective for claims with dates of service on and after February 9, 2018, contractors shall allow coverage for ICR for beneficiaries with the following additional covered conditions:</td>
<td>X X</td>
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<td>• Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks; or</td>
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<td>• Any additional condition for which the Secretary has determined that a cardiac rehabilitation (CR) program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a CR program, that such coverage is not supported by the clinical evidence.</td>
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<td>See Pub. 100-02, BPM, Chapter 15, section 232 and Pub 100-04, chapter 32, section 140.3.</td>
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<td>11117 - 04.2</td>
<td>For claims with dates of service on or after February 9, 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>
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<tbody>
<tr>
<td>11117 - 04.3</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</td>
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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.

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A "Should" denotes a recommendation.

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<thead>
<tr>
<th>X-Ref Requirement Number</th>
<th>Recommendations or other supporting information:</th>
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Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Sarah Fulton, 410-786-2749 or sarah.fulton@cms.hhs.gov (Coverage and Analysis), Patricia Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov (Coverage and Analysis), William Ruiz, 410-786-9283 or william.ruiz@cms.hhs.gov (Institutional Claims), Thomas Dorsey, 410-786-7434 or thomas.dorsey@cms.hhs.gov (Professional Claims), Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage and Analysis).

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: 1
As specified at 42 CFR 410.49, Medicare covers intensive cardiac rehabilitation items and services for patients who have experienced one or more of the following:

- An acute myocardial infarction within the preceding 12 months;
- A coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty or coronary stenting;
- A heart or heart-lung transplant.

Effective February 9, 2018, section 51004 of the Bipartisan Budget Act (BBA) of 2018, Pub. L. No. 115-123 (2018), amended section 1861(eee)(4)(B) of the Social Security Act to expand coverage in an intensive cardiac rehabilitation program to additional conditions:

- Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks; or
- Any additional condition for which the Secretary has determined that a cardiac rehabilitation program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.

NOTE: CMS plans to amend our intensive cardiac rehabilitation regulations specified at 42 CFR 410.49 to reflect this expanded coverage. CMS anticipates that the changes will be included in the 2020 Medicare Physician Fee Schedule notice of proposed rulemaking. However, because the expanded coverage under the statutory change was effective on enactment, expanded coverage for these conditions will be made effective for services furnished on or after February 9, 2018.

Intensive cardiac rehabilitation programs must include the following components:

- Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished;
- Cardiac risk factor modification, including education, counseling, and behavioral intervention at least once during the program, tailored to patients’ individual needs;
- Psychosocial assessment;
- Outcomes assessment; and,
- An individualized treatment plan detailing how components are utilized for each patient.

Intensive cardiac rehabilitation programs must be approved by Medicare. In order to be approved, a program must demonstrate through peer-reviewed published research that it has accomplished one or more of the following for its patients:

- Positively affected the progression of coronary heart disease;
- Reduced the need for coronary bypass surgery; and,
- Reduced the need for percutaneous coronary interventions.

An intensive cardiac rehabilitation program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services:

- Low density lipoprotein;
- Triglycerides;
• Body mass index;
• Systolic blood pressure;
• Diastolic blood pressure; and,
• The need for cholesterol, blood pressure, and diabetes medications.

Intensive cardiac rehabilitation items and services must be furnished in a physician’s office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision of physician office services as specified at 42 CFR 410.26 and for hospital outpatient therapeutic services as specified at 42 CFR 410.27. As specified at 42 CFR 410.49(f)(2), ICR program sessions are limited to 72 1-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.