Indications and Limitations of Coverage and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Cardiac Rehabilitation (CR) is a comprehensive program of medical evaluation, prescribed exercise, cardiac risk factor modification, education and counseling (psychosocial assessment) designed to restore certain patients with coronary or valvular heart disease to active and productive lives (outcomes assessment). CR as described in the medical literature is divided into three phases: Phase I is the immediate in-hospital post-cardiac event phase; Phase II is the outpatient immediate post-hospitalization recuperation phase; and Phase III is the long-term maintenance phase and is not payable under Medicare. This LCD encompasses Phase II or outpatient post-hospital CR. Phase II programs are typically initiated one to three weeks after hospital discharge and consist of a series of medically supervised exercise sessions with Continuous Electrocardiograph Monitoring (CEM). Clinically optimal results are obtained if these sessions are conducted two to three times per week over a 12–18-week period, generally for a total of 36 sessions.

Phases of Cardiac Rehabilitation

- Phase I: Acute in-hospital phase of CR. This is included in the hospital care for the acute illness and is not included under the CR benefit.
- Phase II: For the purposes of this LCD, Phase II is divided into Phase IIA and Phase IIB.
- Phase IIA is the initial outpatient CR, consisting of 36 or fewer sessions, occurring up to two sessions per day.
Phase IIB consists of up to an additional 36 sessions and will only be allowed if determined medically necessary. Phase IIB benefits must meet additional medical necessity criteria. Specifically, there must be clear demonstration that the patient is benefiting from CR and that the exit criteria below from phase IIA have not been met. The maximum number of allowable sessions under Phase IIA and IIB is 72.

- Phase III: CR programs that are self-directed or self-controlled/monitored exercise programs.
- Phase IV: CR programs or maintenance therapy that may be safely carried out without medical supervision.

**NOTE:** Only Phase II CR programs meet the supervisory requirements of the benefit and are covered under Medicare.

Individualized treatment plan is a written plan tailored to each individual patient that includes all of the following:
- A description of the individual’s diagnosis.
- The type, amount, frequency and duration of the items and services furnished under the plan.
- The goals set for the individual under the plan.

Intensive Cardiac Rehabilitation (ICR) services must include the comprehensive program components of a CR program but must also demonstrate that it improves patients’ cardiovascular disease through specific outcome measurements described in 42 CFR 410.49(c).

**Standards for an ICR program:**

- To be approved as an ICR program, 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.
  - Reduced the need for percutaneous coronary interventions.

- An ICR 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 CR services to after CR services:
  - Low-density lipoprotein.
  - Triglycerides.
  - Body mass index.
  - Systolic blood pressure.
  - Diastolic blood pressure.
  - The need for cholesterol, blood pressure and diabetes medications. (See 42 CFR 410.49.)

**Indications for CR and ICR**

CR and ICR are covered for the following patients:

- Patients who begin the program within 12 months of an acute Myocardial Infarction (MI).
- Patients who have had Coronary Artery Bypass Graft (CABG) surgery.
- Patients with stable angina pectoris.
- Patients who have had heart valve repair/replacement.
- Patients who have had Percutaneous Transluminal Coronary Angioplasty (PTCA) or coronary stenting.
- Patients who have had a heart or heart-lung transplant.

**Limitations**

ICR services **must** be provided in a program approved through the NCD process:

- ICR programs must be approved by CMS through the NCD process and must meet certain criteria for approval.
ICR programs that are approved through the NCD process will be identified in the NCD manual (Pub. 100-03), on the CMS Web site and in the Federal Register. Once ICR programs are approved through the NCD process, sites wishing to furnish ICR services via an approved ICR program may begin to enroll as ICR program suppliers using the CMS-855A for the fiscal intermediary or Part A Medicare Administrative Contractor (MAC) or the CMS-855B for the carrier or Part B MAC.

Contractors and MACs will ensure that claims submitted from individual ICR sites are submitted by enrolled ICR program sites and enrolled in Medicare as specialty 31. (See CMS Pub. 100-08, Medicare Program Integrity Manual, Chapter 10, Section 2.2.8.)

A. Facilities for Both CR and ICR

CR programs may be provided by either the outpatient department of a hospital or a physician-directed clinic. Coverage for either program is subject to the following conditions:

- The facility meets the definition of a hospital outpatient department or a physician-directed clinic, i.e., a physician is on the premises available to perform medical duties at all times the facility is open and each patient is under the care of a hospital or clinic physician.
- The facility has available for immediate use all the necessary cardiopulmonary emergency diagnostic and therapeutic life-saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment or defibrillator.
- The program is staffed by personnel necessary to conduct the program safely and effectively and who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. When conducted in a hospital, an identified physician must be immediately available. This does not require that a physician be physically present in the exercise room itself but must be immediately available (without the passage of time) and accessible at all times in case of an emergency.
- When conducted in the hospital, the non-physician personnel are employees of the hospital conducting the program.
- When conducted in a clinic or physician’s office, the services furnished by non-physician personnel are under the physician’s direct supervision.

B. CR/ICR Program Physician Requirements

Physicians responsible for CR/ICR programs are identified as medical directors who oversee or supervise the CR/ICR program at a particular site.

- The medical director, in consultation with staff, is involved in directing the progress of individuals in the program.
- The medical director, as well as physicians acting as the supervising physician, must possess all of the following:
  - Expertise in the management of individuals with cardiac pathophysiology.
  - Cardiopulmonary training in basic life support or advanced cardiac life support.
  - Licensed to practice medicine in the state in which the CR/ICR program is offered.
- Direct physician supervision may be provided by a supervising physician or the medical director.

C. Diagnoses for Both CR and ICR

- For MI, the date of entry into the program must be within 12 months of the date of infarction. (ICD-9-CM diagnosis codes: 410.XX (see “ICD-9-CM Codes That Support Medical Necessity” section below for complete list); or 412 if the Acute Myocardial Infarction (AMI) occurred more than eight weeks and less than 12 months before the first CR or ICR session).
- For CABG, the initiation of the program should be early enough to have a restorative effect on the recuperative process. Optimal results are generally expected when the program is started within three months of the CABG procedure (ICD-9-CM diagnosis code V45.81). Exceptions to this (rationale for a later start) must be documented in the medical record and made available to Medicare upon request.
For patients with current stable angina, the diagnosis of angina must be based on a detailed symptom history, focused physical examination, directed risk factor assessment, and appropriate confirmatory testing such as a stress test (ICD-9-CM diagnosis codes 413.9 or 414.8).

For patients with heart valve repair or replacement, the program should be early enough to provide a restorative benefit. Therefore, the date of entry must be within three months of surgery (ICD-9-CM diagnosis codes: V42.2 or V43.3).

For patients who have had a PTCA or stent replacement, the program should be early enough to provide a restorative benefit. Therefore, the date of entry must be within three months of surgery (ICD-9-CM diagnosis code: V45.82).

Patients who have had a heart or heart-lung transplant may present special and complex post-transplant management problems. The date of entry is extended to within one year of the surgery (ICD-9-CM diagnosis codes: V42.1 or V42.89).

D. Frequency and Duration for CR and ICR

Once a beneficiary begins CR, he may not switch to ICR, and once a beneficiary begins ICR, he may not switch to CR. Upon completion of a CR or ICR program, beneficiaries must experience another indication in order to be eligible for additional coverage for CR or ICR. Should a beneficiary experience more than one indication simultaneously, he may participate in a single series of CR or ICR sessions (e.g., a patient who had a myocardial infarction within 12 months and currently experiences stable angina is entitled to one series of CR sessions).

- CR Program:
  - The frequency and duration of the program is generally a total of 36 sessions over a maximum of 36 weeks.
  - A single session must last at least 31 minutes in order to be billable. If two sessions are billed for a single day, then the total combined time must be at least 91 minutes (60 minutes for the first session and at least 31 minutes for the second session) in duration.
  - No more than two one-hour sessions, utilizing any combination of the CPT codes (93797 and 93798) will be allowed per day for up to 36 sessions over a maximum of 36 weeks (Phase IIA).
  - An additional 36 sessions may be allowed if a significant intercurrent illness or comorbidity occurred during the first 36 sessions and the exit criteria have not been met (Phase IIB). Inclusion of the KX modifier on the claim line(s) will be accepted as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond 36 sessions of CR up to a total of 72 sessions meets the CR coverage requirements.
  - An additional series of 36 sessions may be allowed as a new series of CR initiated after an intervening event described as an indication for CR in this LCD. Inclusion of the KX modifier on the claim line(s) will be accepted as an attestation by the provider of the service that documentation is on file verifying that an additional series of CR meets the CR coverage requirements.

- ICR Program:
  - The frequency and duration of the program are generally a total of 72 sessions over a maximum of 18 weeks (126 days).
  - A single session must last at least 31 minutes in order to be billable. If two or more sessions are billed for a single day, then the total combined time must be at least 91 minutes for two sessions or at least 181 minutes for three sessions, etc. in duration.
  - Six sessions may be allowed per day, not to exceed a total of 72 sessions over a period of up to 18 weeks (126 days).
  - Additional sessions may be allowed if a significant intercurrent illness or comorbidity occurred beyond 126 days from the date of the first session and the exit criteria have not been met. Inclusion of the KX modifier on the claim line(s) will be accepted as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond the 126 days meets the ICR coverage requirements.
  - An additional series of 72 sessions may be allowed as a new series of ICR initiated after an intervening event described as an indication for ICR in this LCD. Inclusion of the KX modifier on the claim line(s) will be...
accepted as an attestation by the provider of the service that documentation is on file verifying that an additional series of ICR meets the ICR coverage requirements.

E. Exit Criteria for Both CR and ICR

Outcome assessments should include:

- Minimally, assessments from the commencement and conclusion of CR/ICR, based on patient-centered outcomes, which must be measured by the physician immediately at the beginning and end of the program.
- Objective clinical measures of the effectiveness of the CR/ICR program for the individual patient, including exercise performance and self-reported measures of exertion and behavior.

Once a patient has reached the following, further CR may not be considered reasonable and necessary unless medical record documentation clearly indicates otherwise:

- Ischemic heart disease: Patient’s status following MI, CABG, PTCA or stent, and patients with angina undergoing stress testing without demonstrating significant ischemia or dysrhythmia after completion of six minutes of a Bruce protocol, or equivalent, achieving a stable level of exercise tolerance (7 METS). (See the American Heart Association’s functional classification: Class I, or normal function status, begins at 7 metabolic equivalent units (METS).)
- Following valve repair/replacement: Patients achieving a stable level of exercise tolerance (7 METS).
- Heart and heart-lung transplant patients: Issues such as deconditioning and cachexic deterioration may complicate the definition of reasonable exit criteria. Based on the study of long term cardiopulmonary exercise performed after heart transplant (Osada et al), a peak oxygen consumption (VO2) of greater than 90 percent of predicted will be used as the exit criterion for phase IIA. Patients whose peak VO2 is less than 90 percent of predicted may qualify for phase IIB.

F. Non-Covered Diagnoses for Both CR and ICR

- Use of any ICD-9-CM diagnosis code not in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this LCD will be cause for denial of claims.
- A patient with unstable angina or a patient status post-non-cardiac surgery will not qualify for CR services.
- Congestive heart failure in the absence of other covered conditions is not included as a covered condition of CR in the CMS Claims Processing Manual, IOM Pub.100-04, Chapter 32, Section 140.

G. Other Services

- Evaluation and Management (E/M) services, Electrocardiograms (ECGs) and other diagnostic services may be covered on the day of CR if these services are separate and distinct from the CR program and are reasonable and necessary, but would not be covered if provided routinely as part of the CR program.
- Forms of counseling, such as dietary counseling, psychosocial intervention, lipid management and stress management, are components of the CR program and are not separately reimbursed.

Notice: This LCD imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

As published in CMS IOM 100-08, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD, are considered reasonable and necessary).

Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:

- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member.
- Furnished in a setting appropriate to the patient’s medical needs and condition.
- Ordered and furnished by qualified personnel.
- One that meets, but does not exceed, the patient’s medical needs.
- At least as beneficial as an existing and available medically appropriate alternative.

Coding Information

Bill Type Codes

 Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

<table>
<thead>
<tr>
<th>Bill Type Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>013x</td>
<td>Hospital Outpatient</td>
</tr>
<tr>
<td>085x</td>
<td>Critical Access Hospital</td>
</tr>
</tbody>
</table>

Revenue Codes

 Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Note: The contractor has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual Publication 100-04, Claims Processing Manual, for further guidance.

Place of Service (POS)

- Physician’s office (11).
- Hospital outpatient (22).

<table>
<thead>
<tr>
<th>POS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0943</td>
<td>Other Therapeutic Services - Cardiac Rehabilitation</td>
</tr>
<tr>
<td>0969</td>
<td>Professional Fees - Other Professional Fee</td>
</tr>
<tr>
<td>0977</td>
<td>Professional Fees - Physical Therapy</td>
</tr>
<tr>
<td>0982</td>
<td>Professional Fees - Outpatient Services</td>
</tr>
</tbody>
</table>

CPT/HCPCS Codes
providers are reminded to refer to the long descriptors of the CPT codes in their CPT book. the American medical Association (AMA) and CMS require the use of short CPT descriptors in policies published on the Web.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>93797</td>
<td>Cardiac rehab</td>
</tr>
<tr>
<td>93798</td>
<td>Cardiac rehab/monitor</td>
</tr>
<tr>
<td>G0422</td>
<td>Intens cardiac rehab w/exerc</td>
</tr>
<tr>
<td>G0423</td>
<td>Intens cardiac rehab no exer</td>
</tr>
</tbody>
</table>

**ICD-9 Codes that Support Medical Necessity**

*Note*: Providers should continue to submit ICD-9-CM diagnosis codes without decimals on their claim forms and electronic claims.

The CPT/HCPCS codes included in this LCD will be subjected to “procedure to diagnosis” editing. The following lists include only those diagnoses for which the identified CPT/HCPCS procedures are covered. If a covered diagnosis is not on the claim, the edit will automatically deny the service as not medically necessary.

Medicare is establishing the following limited coverage for CPT/HCPCS codes 93797, 93798, G0422 and G0423:

**Covered for:**

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>410.00 - 410.02</td>
<td>ACUTE MYOCARDIAL INFARCTION OF ANTEROLATERAL WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF ANTEROLATERAL WALL SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>410.10 - 410.12</td>
<td>ACUTE MYOCARDIAL INFARCTION OF OTHER ANTERIOR WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF OTHER ANTERIOR WALL SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>410.20 - 410.22</td>
<td>ACUTE MYOCARDIAL INFARCTION OF INFEROLATERAL WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF INFEROLATERAL WALL SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>410.30 - 410.32</td>
<td>ACUTE MYOCARDIAL INFARCTION OF INFEROPOSTERIOR WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF INFEROPOSTERIOR WALL SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>410.40 - 410.42</td>
<td>ACUTE MYOCARDIAL INFARCTION OF OTHER INFERIOR WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF OTHER INFERIOR WALL SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>410.50 - 410.52</td>
<td>ACUTE MYOCARDIAL INFARCTION OF OTHER LATERAL WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF OTHER LATERAL WALL SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>410.60 - 410.62</td>
<td>TRUE POSTERIOR WALL INFARCTION EPISODE OF CARE UNSPECIFIED - TRUE POSTERIOR WALL INFARCTION SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>410.70 - 410.72</td>
<td>SUBENDOCARDIAL INFARCTION EPISODE OF CARE UNSPECIFIED - SUBENDOCARDIAL INFARCTION SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>410.80 - 410.82</td>
<td>ACUTE MYOCARDIAL INFARCTION OF OTHER SPECIFIED SITES EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF OTHER SPECIFIED SITES SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>Code</td>
<td>Diagnosis</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>410.90</td>
<td>ACUTE MYOCARDIAL INFARCTION OF UNSPECIFIED SITE EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF UNSPECIFIED SITE SUBSEQUENT EPISODE OF CARE</td>
</tr>
<tr>
<td>412*</td>
<td>OLD MYOCARDIAL INFARCTION</td>
</tr>
<tr>
<td>413.9</td>
<td>OTHER AND UNSPECIFIED ANGINA PECTORIS</td>
</tr>
<tr>
<td>414.8</td>
<td>OTHER SPECIFIED FORMS OF CHRONIC ISCHEMIC HEART DISEASE</td>
</tr>
<tr>
<td>V15.1</td>
<td>PERSONAL HISTORY OF SURGERY TO HEART AND GREAT VESSELS PRESENTING HAZARDS TO HEALTH</td>
</tr>
<tr>
<td>V42.1</td>
<td>HEART REPLACED BY TRANSPLANT</td>
</tr>
<tr>
<td>V42.2</td>
<td>HEART VALVE REPLACED BY TRANSPLANT</td>
</tr>
<tr>
<td>V42.89*</td>
<td>OTHER SPECIFIED ORGAN OR TISSUE REPLACED BY TRANSPLANT</td>
</tr>
<tr>
<td>V43.3</td>
<td>HEART VALVE REPLACED BY OTHER MEANS</td>
</tr>
<tr>
<td>V45.81</td>
<td>POSTSURGICAL AORTOCORONARY BYPASS STATUS</td>
</tr>
<tr>
<td>V45.82</td>
<td>PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY STATUS</td>
</tr>
</tbody>
</table>

**Note:** ICD-9-CM code 412* (old myocardial infarction) refers to an MI that has occurred more than eight weeks prior to cardiac rehabilitation services.

**Note:** Use V42.89* for heart-lung transplant.

**Diagnoses that Support Medical Necessity**
N/A

**ICD-9 Codes that DO NOT Support Medical Necessity**
N/A

**ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation**

**Diagnoses that DO NOT Support Medical Necessity**
All diagnoses not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this LCD.

A patient with unstable angina or a patient status post-non-cardiac surgery does not qualify for CR services.

Congestive heart failure in the absence of other covered conditions is not included as a covered condition of CR in CMS IOM Pub. 100-04, Medicare Claims Processing Manual, Chapter 32, Section 140.

**Other Information**

**Documentation Requirements**
Documentation supporting medical necessity should be legible, maintained in the patient’s medical record and made available to Medicare upon request.

ICD-9-CM diagnosis codes supporting medical necessity must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.

Any diagnosis submitted must have documentation in the patient’s record to support coverage and medical necessity.
All CR providers must have documentation of the qualifying event in the patient’s medical record. This information may include copies of the referring physician’s records or reports. A prescription for CR from the referring physician must be maintained in the patient’s medical record by the provider of the CR service.

When billing HCPCS/CPT codes 93798, G0422 or G0423, the documentation must clearly indicate the patient is receiving continuous ECG monitoring.

For CABG, the initiation of the program should be early enough to have a restorative effect on the recuperative process. Optimal results are generally expected when the program is started within three months of the CABG procedure (ICD-9-CM diagnosis code V45.81). Exceptions to this (rationale for a later start) must be documented in the medical record and made available to Medicare upon request.

A CR record must be maintained. All components, including ECG strips, must be maintained. All components of the service (medical assessment, ECG monitoring, smoking cessation, dietary counseling and psychological counseling) must be assessed and provided, where appropriate. It is not expected that every component is provided at each session, but the total Phase II (A and B) record must reflect those benefits.

A record must be kept indicating the identity of the supervising physician and the identity of the physician who will respond immediately should an adverse consequence develop. This record must be made available to Medicare upon request.

Appendices
N/A

Utilization Guidelines
Refer to “Indications and Limitations of Coverage and/or Medical Necessity,” Section C – “Frequency and Duration,” above.

Notice: This LCD imposes utilization guideline limitations. Although Medicare allows up to these maximums, each patient’s condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient’s medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.