**Proposed New Measure for HEDIS® MY 2020**

**Cardiac Rehabilitation (CRE)**

NCQA seeks comments on the proposed new measure for inclusion in HEDIS 2020.

**Cardiac Rehabilitation:** The percentage of members 18 years and older who attended cardiac rehabilitation following a qualifying cardiac event, including myocardial infarction, percutaneous coronary intervention, coronary artery bypass graft, heart and heart/lung transplantation or heart valve repair/replacement. Three rates are reported:

- **Initiation.** The percentage of members who attended 2 or more sessions of cardiac rehabilitation following a qualifying event.
- **Engagement.** The percentage of members who attended 12 or more sessions of cardiac rehabilitation within 90 days after a qualifying event.
- **Achievement.** The percentage of members who attended 36 or more sessions of cardiac rehabilitation within 180 days after a qualifying event.

Cardiac rehabilitation is a comprehensive secondary prevention program designed to improve cardiovascular health following a cardiac event or procedure. An optimal cardiac rehab experience consists of 36 one-hour sessions that include team-based supervised exercise training, education and skills development for heart-healthy living, and counseling on stress and other psychosocial factors. It is supported by a Class IA-B recommendations of the American Heart Association and the American College of Cardiology and is associated with decreased total mortality, cardiac mortality and rehospitalizations. It has also been shown to improve functional status, quality of life, mood and medication adherence. Despite this, it is underutilized for individuals who have experienced a significant cardiac event.

With the support of our expert panels, NCQA developed and tested the proposed measure with multiple rates to address the known gaps in care related to the use of cardiac rehabilitation for patients who experience cardiac events. Testing demonstrated that approximately 19% of Medicare members and 29% of commercial members completed at least 2 CR sessions. Roughly 14% of Medicare members and 9% of commercial members completed at least 12 sessions. Our findings show that approximately 5% of Medicare members and 2% of commercial members achieved the guideline-recommended goal of at least 36 sessions. Overall variation in performance within and across product lines suggests significant room for improvement.

NCQA seeks general feedback on both measures and on the following questions:

1. The proposed new measure assesses members 18 years and older. Should NCQA consider an upper age limit for this measure?

2. During discussions with our panels, we heard many comments about home-based cardiac rehabilitation. Should NCQA consider recognizing such programs for the numerator?

Supporting documents include the draft measure specification and evidence workup.

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NCQA acknowledges the contributions of the Cardiovascular Measurement Advisory Panel, the Care Coordination Work Group, the Geriatric Measurement Advisory Panel and the Technical Measurement Advisory Panel.

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Cardiac Rehabilitation (CRE)

SUMMARY OF CHANGES TO HEDIS MEASUREMENT YEAR 2020

- First-year measure.

Description

The percentage of members 18 years and older, who attended cardiac rehabilitation following a qualifying cardiac event, including myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, heart and heart/lung transplantation or heart valve repair/replacement. Three rates are reported:

- **Initiation.** The percentage of members who attended 2 or more sessions of cardiac rehabilitation following a qualifying event.
- **Engagement.** The percentage of members who attended 12 or more sessions of cardiac rehabilitation within 90 days after a qualifying event.
- **Achievement.** The percentage of members who attended 36 or more sessions of cardiac rehabilitation within 180 days after a qualifying event.

Definitions

**Intake Period**

A 12-month window that begins on July 1 of the year prior to the measurement year and ends on June 30 of the measurement year. The intake period is used to capture the most recent cardiac event.

**Episode Date**

The date of service for the most recent cardiac event during the Intake Period, including myocardial infarction (MI), coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), heart or heart/lung transplant, or heart valve repair/replacement.

For MI, CABG, heart or heart/lung transplant or heart valve repair/replacement, the Episode Date is the **date of discharge**.

For PCI, the Episode Date is the **date of service**.

For direct transfers, the Episode Date is the discharge **date from the last admission**.

**Direct transfer**

A **direct transfer** is when the discharge date from the first inpatient setting precedes the admission date to a second inpatient setting by one calendar day or less. For example:

- An inpatient discharge on June 1, followed by an admission to another inpatient setting on June 1, is a direct transfer.
- An inpatient discharge on June 1, followed by an admission to an inpatient setting on June 2, is a direct transfer.
- An inpatient discharge on June 1, followed by an admission to another inpatient setting on June 3, is not a direct transfer; these are two distinct inpatient stays.

Use the following method to identify admissions to and discharges from inpatient settings.

1. Identify all acute and nonacute inpatient stays (**Inpatient Stay Value Set**).
2. Identify the admission and discharge dates for the stay.

Note: The direct transfer does not require a cardiac event diagnosis.

**Eligible Population**

Note: Members in hospice are excluded from the eligible population. Refer to General Guideline 17: Members in Hospice.

- **Product lines**: Commercial, Medicaid, Medicare (report each product line separately).
- **Ages**: 18 years and older as of December 31 of the measurement year. Report the following age stratifications and total rate:
  - 18–64 years.
  - 65 and older.
  - Total.

The total is the sum of the age stratifications for each product line.

- **Continuous enrollment**: Episode Date through the following 180 days.
- **Allowable gap**: No gaps in enrollment.
- **Anchor date**: Episode Date.
- **Benefits**: Medical.

- **Event/diagnosis**: Follow the steps below to identify the eligible population.

  **Step 1** Identify all members who had any of the following during the Intake Period:
  - Discharged from an inpatient setting with any of the following on the discharge claim:
    - MI (MI Value Set).
    - CABG (CABG Value Set; Percutaneous CABG Value Set).
    - Heart or heart/lung transplant (Heart Transplant Value Set).
    - Heart valve repair or replacement. (Heart Valve Repair or Replacement Value Set).

  To identify discharges:
  1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
  2. Identify the discharge date for the stay.

  - PCI. Members who had PCI (PCI Value Set; Other PCI Value Set) in any setting.

  **Step 2** Select the Episode Date. For each member identified in step 1, identify the date of the most recent eligible episode. If a member has more than one episode that meets the event/diagnosis criteria include only the most recent during the Intake Period.

  For direct transfers, use the second discharge date as the Episode Date.
Step 3  
**Required Exclusions**

Exclude members who had any of the following from July 1 through December 21 of the measurement year:

- Discharged from an inpatient setting with any of the following on the discharge claim:
  - MI (MI Value Set).
  - CABG (CABG Value Set; Percutaneous CABG Value Set).
  - Heart or heart/lung transplant (Heart Transplant Value Set).
  - Heart valve repair or replacement. (Heart Valve Repair or Replacement Value Set).

To identify discharges:

1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
2. Identify the discharge date for the stay.
3. PCI. Members who had PCI (PCI Value Set; Other PCI Value Set) in any setting.

Exclude members who meet any of the following criteria:

- Medicare members 66 years of age and older as of December 31 of the measurement year who meet either of the following:
  - Enrolled in an Institutional SNP (I-SNP) any time during the measurement year.
  - Living long-term in an institution any time during the measurement year as identified by the LTI flag in the Monthly Membership Detail Data File. Use the run date of the file to determine if a member had an LTI flag during the measurement year.

- Members 66 years of age and older as of December 31 of the measurement year (all product lines) with frailty and advanced illness.

Members must meet **BOTH** of the following frailty and advanced illness criteria to be excluded:

1. At least one claim/encounter for frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set) during the measurement year.
2. Any of the following during the measurement year or the year prior to the measurement year (count services that occur over both years):
   - At least two outpatient visits (Outpatient Value Set), observation visits (Observation Value Set), ED visits (ED Value Set), nonacute inpatient encounters (Nonacute Inpatient Value Set) or nonacute inpatient discharges (instructions below; the diagnosis must be on the discharge claim) on different dates of service, with an advanced illness diagnosis (Advanced Illness Value Set). Visit type need not be the same for the two visits. To identify a nonacute inpatient discharge:
     1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
     2. Confirm the stay was for nonacute care based on the presence of a nonacute code (Nonacute Inpatient Stay Value Set) on the claim.
     3. Identify the discharge date for the stay.
At least one acute inpatient encounter (Acute Inpatient Value Set) with an advanced illness diagnosis (Advanced Illness Value Set).

At least one acute inpatient discharge with an advanced illness diagnosis (Advanced Illness Value Set) on the discharge claim. To identify an acute inpatient discharge:

1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
2. Exclude nonacute inpatient stays (Nonacute Inpatient Stay Value Set).
3. Identify the discharge date for the stay.

A dispensed dementia medication (Dementia Medications List).

- Members 81 years of age and older as of December 31 of the measurement year (all product lines) with frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set) any time on or between July 1 of the year prior to the measurement year and the end of the measurement year.

### Dementia Medications

<table>
<thead>
<tr>
<th>Description</th>
<th>Prescription</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholinesterase inhibitors</td>
<td>• Donepezil</td>
</tr>
<tr>
<td></td>
<td>• Galantamine</td>
</tr>
<tr>
<td></td>
<td>• Rivastigmine</td>
</tr>
<tr>
<td>Miscellaneous central nervous system agents</td>
<td>• Memantine</td>
</tr>
</tbody>
</table>

### Administrative Specification

**Denominator**

The eligible population.

**Numerators**

**Initiation** At least 2 sessions of cardiac rehabilitation (Cardiac Rehabilitation Value Set) on different dates of service after the Episode Date.

**Engagement** At least 12 sessions of cardiac rehabilitation (Cardiac Rehabilitation Value Set) on different dates of service within 90 days after the Episode Date.

**Achievement** At least 36 sessions of cardiac rehabilitation (Cardiac Rehabilitation Value Set) on different dates of service within 180 days after the Episode Date.

### Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.
**Table CRE—1/2/3: Data Elements for Cardiac Rehabilitation**

<table>
<thead>
<tr>
<th>Data Elements</th>
<th>Administrative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement year</td>
<td>✓</td>
</tr>
<tr>
<td>Data collection methodology (Administrative)</td>
<td>✓</td>
</tr>
<tr>
<td>Eligible population</td>
<td>For each age stratification and total</td>
</tr>
<tr>
<td>Number of required exclusions</td>
<td>Each rate, for each age stratification and total</td>
</tr>
<tr>
<td>Numerator events by administrative data</td>
<td>Each rate, for each age stratification and total</td>
</tr>
<tr>
<td>Numerator events by supplemental data</td>
<td>Each rate, for each age stratification and total</td>
</tr>
<tr>
<td>Reported rate</td>
<td>Each rate, for each age stratification and total</td>
</tr>
</tbody>
</table>
Heart disease is the leading cause of death in the United States. By some estimates, by 2030 more than 40% of Americans will have a form of heart/cardiovascular disease (Heidenreich et al., 2011). According to CDC estimates, 30 million (12%) of American adults had heart disease in 2018 (CDC, 2017a). Key risk factors include high blood pressure, high cholesterol, diabetes and obesity. Behaviors such as unhealthy diet, physical inactivity, alcohol use and tobacco use can also place patients at higher risk for developing heart disease (CDC, 2015).

Heart disease encompasses several cardiac conditions that can lead to decreased heart function (AHA, 2017). It may lead to increased risk for certain events such as myocardial infarction (MI), or for certain procedures such as percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG), heart transplant and heart valve repair/replacement. In 2014, there were an estimated 805,000 MIs, 480,000 PCIs, 371,000 CABGs and 156,000 heart valve repairs/replacements. In 2017, heart transplants reached a record high: 3,244 (Benjamin et al., 2019).

National efforts to reduce cardiovascular disease are underway by the Million Hearts® initiative and others. This initiative was established by the U.S. Department of Health and Human Services and is co-led by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) in collaboration with 120 private and public sector official partners. Million Hearts® was launched in 2012 with the goal of preventing 1 million heart attacks and strokes within 5 years. A progress update revealed that approximately 115 thousand cardiovascular events were prevented in the first two years of the initiative, and an estimated half million cardiovascular events were prevented by 2017. The initiative set new goals for 2022 to continue implementation efforts, increase participation to more than 70% and reach its goal of 1 million events prevented (CDC, 2017b).

Cardiac rehabilitation (CR) is a medical program that aims to help patients regain cardiovascular health and heart function after a cardiac-related event. Most commonly delivered in outpatient settings, CR programs provide exercise training, healthy lifestyle education and stress counseling (AHA, 2016). The comprehensive components of CR promote physical and psychological recovery, reduce cardiovascular risk and mortality and prevent secondary cardiac events (Ades et al., 2017). Additional improvements such as exercise tolerance, medical regimen compliance and smoking cessation have also been associated with participation (O’Gara et al., 2013).

The American College of Cardiology and American Heart Association (ACC/AHA) recommend CR for patients who have experienced MI, CABG, PCI, coronary revascularization or coronary artery and other atherosclerotic vascular disease. Participation in CR can decrease recurrent cardiac-related events, reduce mortality by more than 12% reduce hospitalizations by 20%–30% and improve quality of life (Thomas et al., 2018).

Heart disease is the leading diagnosis for direct U.S. health expenditures. In 2014–2015, the average direct cost for heart disease in the U.S. totaled approximately $109.4 billion annually; indirect costs added approximately $109.3 billion. At a total of $218.7 billion in direct and indirect costs, heart disease accounted for 88% of all cardiovascular disease and stroke expenditures. (Benjamin et al., 2019)
CR is associated with decreased hospitalizations and health system costs. Compared with usual care, CR cost-effectiveness ratios range from $1,065 to $71,755 per quality-adjusted life year (Shields et al., 2018). Per person, cardiac rehabilitation saves approximately $4,950 to $9,200 per year of life saved (Edwards et al., 2017).

**Safety considerations and contraindications**

CR is a secondary prevention program for improving cardiovascular health. While it is considered safe for most patients, there are safety concerns to consider before referral and throughout rehabilitation. The patient’s health care team should evaluate the patient’s medical history and conduct a physical examination prior to CR referral, to assess appropriateness. There is also a small risk of injury (e.g. strained muscles or sprains) or cardiovascular complications. According to the 2014 AHA/ACC guidelines, older patients (75 years and older) can experience the same benefits of CR as younger patients.

**Initiation and Adherence**

Following a qualifying cardiac event, time to initiation is an important factor of adherence, completion and outcomes. Referral for CR can be provided as early as pre-discharge or at the first follow-up visit (Smith et al., 2011). Depending on the patient’s condition and previous functional status, physical activity can begin immediately after discharge with daily walking; aerobic training can begin within 1–2 weeks and resistance training can begin within 2–4 weeks (Amsterdam et al., 2014). All factors considered, the ACC defines CR initiation as one or more CR sessions within 21 days of the qualifying cardiac event (Ritchey et al., 2019).

There is a strong dose-response relationship for CR: Attending more sessions is linked with improved outcomes. A national study of Medicare beneficiaries found that mortality rates at 5 years after discharge for a qualifying cardiac event or condition were 8% lower for patients who attended CR than for patients who did not. When comparing CR attendees, patients who attended 25 or more sessions were 3% less likely to die than patients who attended 24 or fewer sessions (Suaya et al., 2009). An additional Medicare beneficiary sample found that patients who attended 36 sessions of CR had a lower risk of death than patients who attended 1, 12 and 24 sessions by 47%–58%, 22%–29% and 14%–18%, respectively (Hammill et al., 2010). The recommended dose of 36 sessions and 25 sessions has been shown to be meaningful. Both thresholds are associated with improved survival rates and decreased cardiac risk factors (CDC, 2018).

**Health care disparities**

Heart disease has significant disparities and many studies have shown both demographic and geographic disparities associated with CR. Participation in CR programs is lower for older patients, women, racial minorities, rural patients and patients with low socio-economic status. White patients are more likely to be referred for CR than Black, Hispanic and Asian patients by 20%, 36%, and 50%, respectively (Li et al., 2018). A recent study based on Medicare claims and the AHA Coronary Artery Disease registry found that females were 12% less likely than males to be referred for CR.

A study based on the Behavioral Risk Factor Surveillance System (BRFSS) found that women of lower income and of ethnic and racial minorities were less likely to be referred for CR services (Patel et al., 2019). For patients that are referred, research has demonstrated that poor physician endorsement, actual or perceived, is the most influential factor for low CR utilization (Tsui et al., 2012).
Geographic burden directly impacts CR participation. A narrative review identified rurality and travel distance/time as significant barriers to initiation. Of the studies reviewed, 55% found that rurality has a significant negative relationship with CR participation and 60% found that travel distance/time has a significant negative relationship with CR participation (Leung et al., 2010).

**Gaps in care**

Despite the Class IA recommendation and stated benefits, CR is historically underused, with participation ranging from 19%–34% nationally, with geographic variances (Ades et al., 2017). A recent study of Medicare A and B claims found that of more than 366,000 eligible beneficiaries, fewer than 24% participated in CR (Ritchey, et al, 2019). Another study that examined CR participation found that approximately 16% of CR eligible Medicare beneficiaries attended CR sessions. The highest regional participation was observed in the West North Central region (Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota), where approximately 34% of the eligible beneficiaries attended sessions. The lowest regional participation was observed in the Pacific region (Alaska, California, Hawaii, Oregon, Washington) where approximately 10% of the eligible beneficiaries attended CR sessions (Beatty et al., 2018). Other studies have shown that participation in CR is lowest in the South (Ades et al., 2017).

The ACC found that, among eligible Medicare beneficiaries, only 24% participated in CR. Of those beneficiaries, only 24% initiated within the 21-day threshold, and only 27% completed the recommended dose of 36 sessions. Clear gaps in care were also observed. Males had greater participation, initiation, and completion rates than women by 10%, 3% and 2%. Hispanic patients had the lowest participation rate (13%), Asian patients had the lowest initiation rate (17%) and Hispanic patients had the lowest completion rate (24%). The greatest participation and completion rates (55% and 30%) were reported for patients who had a CABG procedure (Ritchey et al., 2019).
References


Li, Shanshan, Gregg C. Fonarow, Kenneth Mukamal, Haolin Xu, Roland A. Matsouaka, Adam D. Devore, and Deepak L. Bhatt. 2018. “Sex and Racial Disparities in Cardiac Rehabilitation Referral at Hospital Discharge and
Gaps in Long-Term Mortality.” *Journal of the American Heart Association: Cardiovascular and Cerebrovascular Disease* 7 (8). [https://doi.org/10.1161/JAHA.117.008088](https://doi.org/10.1161/JAHA.117.008088)


### Specific Guideline Recommendations

**Clinical Practice Guidelines: Cardiac Rehabilitation after Qualifying Event**

<table>
<thead>
<tr>
<th>Organization, Year</th>
<th>Guideline</th>
<th>Recommendation</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHA/ACC, 2014</td>
<td>Guideline for the Management of Patients With Non–ST-Elevation Acute Coronary Syndromes</td>
<td>All eligible patients with NSTE-ACS should be referred to a comprehensive cardiovascular rehabilitation program either before hospital discharge or during the first outpatient visit.</td>
<td>Class I, Level of Evidence: B</td>
</tr>
<tr>
<td>ACCF/AHA, 2013</td>
<td>Guideline for the Management of Patients With ST-Elevation Myocardial Infarction</td>
<td>Exercise-based cardiac rehabilitation/secondary prevention programs are recommended for patients with STEMI</td>
<td>Class I, Level of Evidence: B</td>
</tr>
<tr>
<td>AHA/ACCF, 2011</td>
<td>Secondary Prevention and Risk Reduction Therapy for Patients With Coronary Artery and Other Atherosclerotic Vascular Disease</td>
<td>All eligible patients with ACS or whose status is immediately post coronary artery bypass surgery or post-PCI should be referred to a comprehensive outpatient cardiovascular rehabilitation program either prior to hospital discharge or during the first follow-up office visit. \ All eligible outpatients with the diagnosis of: \ • ACS, coronary artery bypass surgery or PCI. \ • Chronic angina. \ • Peripheral artery disease... within the past year should be referred to a comprehensive outpatient cardiovascular rehabilitation program.</td>
<td>Class I, Level of Evidence: A \ Class I, Level of Evidence: B \ Class I, Level of Evidence: B</td>
</tr>
<tr>
<td>AHA, 2011</td>
<td>Effectiveness-Based Guidelines for the Prevention of Cardiovascular Disease in Women</td>
<td>A comprehensive CVD risk-reduction regimen such as cardiovascular or stroke rehabilitation or a physician-guided home- or community-based exercise training program should be recommended to women with a recent: \ • Acute coronary syndrome or coronary revascularization, new-onset or chronic angina, recent cerebrovascular event, peripheral arterial disease. \ • Or current/prior symptoms of heart failure and an LVEF 35%.</td>
<td>Class I; Level of Evidence A \ Class I; Level of Evidence B</td>
</tr>
<tr>
<td>ACCF/AHA, 2011</td>
<td>Guideline for Coronary Artery Bypass Graft Surgery</td>
<td>Cardiac rehabilitation is recommended for all eligible patients after CABG</td>
<td>Class I, Level of Evidence: A</td>
</tr>
<tr>
<td>ACCF/AHA/SCAI, 2011</td>
<td>Guideline for Percutaneous Coronary Intervention</td>
<td>Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted.</td>
<td>Class I; Level of Evidence: A</td>
</tr>
</tbody>
</table>
## Grading System Key

**Grading System Key: ACC/AHA Classification of Recommendations and Levels of Evidence**

<table>
<thead>
<tr>
<th>Size of Treatment Effect</th>
<th>CLASS I Benefit &gt;&gt;&gt; Risk Procedure/Treatment SHOULD be performed/administered</th>
<th>CLASS Ia Benefit &gt;&gt; Risk Additional studies with focused objectives needed IT IS REASONABLE to perform procedure/administer treatment</th>
<th>CLASS Iib Benefit ≥ Risk Additional studies with broad objectives needed; additional registry data would be helpful Procedure/Treatment MAY BE CONSIDERED</th>
<th>CLASS III No Benefit or CLASS III Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LEVEL A</strong></td>
<td>Recommendation that procedure or treatment is useful/effective</td>
<td>Recommendation in favor of treatment or procedure being useful/effective</td>
<td>Recommendation’s usefulness/efficacy less well established</td>
<td>Recommendation that procedure or treatment is not useful/effective and may be harmful</td>
</tr>
<tr>
<td>Multiple populations evaluated*</td>
<td>Sufficient evidence from multiple randomized trials or meta-analyses</td>
<td>Some conflicting evidence from multiple randomized trials or meta-analyses</td>
<td>Greater conflicting evidence from multiple randomized trials or meta-analyses</td>
<td>Sufficient evidence from multiple randomized trials or meta-analyses</td>
</tr>
<tr>
<td>Data derived from multiple randomized clinical trials or meta-analyses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **LEVEL B**               | Recommendation that procedure or treatment is useful/effective   | Recommendation in favor of treatment or procedure being useful/effective | Recommendation’s usefulness/efficacy less well established      | Recommendation that procedure or treatment is not useful/effective and may be harmful |
| Limited populations evaluated* | Evidence from single randomized trial or nonrandomized studies | Some conflicting evidence from single randomized trial or nonrandomized studies | Greater conflicting evidence from single randomized trial or nonrandomized studies | Evidence from single randomized trial or nonrandomized studies |
| Data derived from a single randomized trial or nonrandomized studies |                                                                                  |                                                                                  |                                                                                  |                                                                                  |

| **LEVEL C**               | Recommendation that procedure or treatment is useful/effective   | Recommendation in favor of treatment or procedure being useful/effective | Recommendation’s usefulness/efficacy less well established      | Recommendation that procedure or treatment is not useful/effective and may be harmful |
| Very limited populations evaluated* | Only expert opinion, case studies, or standard of care | Only diverging expert opinion, case studies, or standard of care | Only diverging expert opinion, case studies, or standard of care | Only expert opinion, case studies, or standard of care |
| Only consensus opinion of experts, case studies, or standard of care |                                                                                  |                                                                                  |                                                                                  |                                                                                  |

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and Iia; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

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### Grading System Key: AHA—Effectiveness-Based Guidelines for the Prevention of Cardiovascular Disease in Women

<table>
<thead>
<tr>
<th>Classification and Level of Evidence</th>
<th>Strength of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification</strong></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>Intervention is useful and effective</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Weight of evidence/opinion is in favor of usefulness/efficacy</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Usefulness/efficacy is less well established by evidence/opinion</td>
</tr>
<tr>
<td>Class III</td>
<td>Procedure/test not helpful or treatment has no proven benefit</td>
</tr>
<tr>
<td></td>
<td>Procedure/test excess cost without benefit or harmful or treatment harmful to patients</td>
</tr>
</tbody>
</table>

| **Level of Evidence**               |                                                                  |
| A                                   | Sufficient evidence from multiple randomized trials              |
| B                                   | Limited evidence from single randomized trial or other nonrandomized studies |
| C                                   | Based on expert opinion, case studies, or standard of care        |