**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** Click here to enter NQF number

**Measure Title**: Heart Failure: Symptom and Activity Assessment

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: Click here to enter a date

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| **Instructions**  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Click here to name the process

Structure: Click here to name the structure

Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

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**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

The initial evaluation and follow-up of patients with heart failure (HF) involve continuing reassessment of symptoms and functional capacity to determine disease severity. These assessments serve as the basis for making treatment decisions, monitoring therapeutic effectiveness, and modifying treatment as appropriate to maximize symptom relief and functional status.

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH,Fonarow GC, Geraci SA, Horwich T,

Januzzi JL, Johnson MR, Kasper EK, Levy WC, Masoudi FA, McBride PE, McMurray JJV, Mitchell JE,

PetersonPN, Riegel B, Sam F, Stevenson LW, Tang WHW, Tsai EJ, Wilkoff BL. 2013 ACCF/AHA guideline

for the management of heart failure: a report of theAmerican College of Cardiology

Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013;128:e240

e327. <http://my.americanheart.org/professional/ScienceNews/2013-ACCFAHA-Guideline-for-the-Management-of-Heart-Failure_UCM_452902_Article.jsp>

**2010 Heart Failure Society of America (HFSA) Comprehensive Heart Failure Practice Guideline**

Lindenfeld J, Albert NM, Boehmer JP, Collins SP, Ezekowitz JA, Givertz MM, Klapholz M, Moser

DK, Rogers JG, Starling RC, Stevenson WG, Tang WHW, Teerlink JR, Walsh MN. Executive Summary:

HFSA 2010 Comprehensive Heart Failure Practice Guideline. *J Card Fail* 2010;16:475e539

<http://www.heartfailureguideline.org/home/3>

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

Section 6.1 Recommendation 1:

A thorough history and physical examination should be obtained/performed in patients presenting with

HF to identify cardiac and noncardiac disorders or behaviors that might cause or accelerate the development or progression of HF. (p e253)

Table 6 on page e254 of the guideline includes the components of a focused history and physical examination for the patient with HF which include:

Severity and triggers of dyspnea and fatigue, presence of chest pain, exercise capacity, physical

activity, sexual activity - To determine NYHA class; identify potential symptoms of coronary ischemia.

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

Recommendations for the Evaluation of Patients with Established HF

Recommendation 4.9: In addition to symptoms characteristic of HF (dyspnea, fatigue, decreased exercise tolerance, fluid retention), evaluation of the following symptoms should be considered in the diagnosis of HF (page e187)

* Angina
* Symptoms suggestive of embolic events
* Symptoms suggestive of sleep-disordered breathing
* Symptoms suggestive of arrhythmias, including palpitations
* Symptoms of possible cerebral hypoperfusion, including syncope, presyncope, or lightheadedness

Recommendation 4.10: Functional Capacity/Activity Level. It is recommended that the severity of clinical disease and functional limitation be evaluated and recorded and the ability to perform typical daily activities be determined. This evaluation may be graded by metrics such as New York Heart Association (NYHA) functional class. (page e188)

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

**2013 ACCF/AHA Guideline for the Management of Heart Failure Recommendation:**

Class I: Procedure/Treatment should be performed/administered

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

The HFSA guideline recommends that symptom evaluation “should be considered”. Recommendations that state that an action “should be considered” mean that the majority of patients should receive the intervention, but some discretion in application to individual patients should be allowed**.**

The HFSA guideline states that “it is recommended that” the severity of clinical disease and functional limitation be evaluated and recorded and the ability to perform typical daily activities be determined. Recommendations that state that an action “is recommended” mean that the action should be part of routine care and that exceptions to therapy should be minimized.

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

**2013 ACCF/AHA Guideline for the Management of Heart Failure Grading scheme**

Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm.

Class IIa: It is reasonable to perform procedure/administer treatment

Class IIb: Procedure/Treatment may be considered

Class III: No benefit (Not helpful or No proven benefit)

Class III: Harm (Excess cost w/o benefit or Harmful to patients)

**Specific COR and LOE definitions are included in Table 1 below.**

**Table 1. Applying Classification of Recommendation and Level of Evidence**

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**2010 HFSA Comprehensive Heart Failure Practice Guideline**

Recommendations that state that an action “may be considered” mean that individualization of therapy is indicated.

Recommendations that state that an action “is not recommended” means the therapeutic intervention should not be used.

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

ACCF/AHA Task Force on Practice Guidelines. Methodology Manual and Policies From the ACCF/AHA

Task Force on Practice Guidelines. American College of Cardiology Foundation and American Heart

Association, Inc. Cardiosource.com. 2010. Available at:

http://assets.cardiosource.com/Methodology\_Manual\_for\_ACC\_AHA\_Writing\_Committees.pdf and

http://my.americanheart.org/idc/groups/ahamah-

public/@wcm/@sop/documents/downloadable/ucm\_319826.pdf

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

The HFSA methodology for grading recommendations is included in the guideline cited in Section 1a.4.1.

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

This guideline covers multiple management issues for the adult patient with Heart Failure (HF) including the initial and serial evaluation of the HF patient encompassing the history and physical examination.

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

Evaluation of patients with established heart failure.

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

Level C: Very limited populations evaluated; only consensus opinion of experts, case studies or standard of care

The initial evaluation and follow-up of HF patients involve continuing reassessment of symptoms and functional capacity to determine disease severity. These assessments serve as the basis for making treatment decisions, monitoring therapeutic effectiveness, and modifying treatment as appropriate to maximize symptom relief and functional status. The intent of this measure is to help ensure that these assessments take place to help maximize patient outcomes.

Specific COR and LOE definitions are included in Table 1 found in Section 1a.4.4. above.

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

The evidence for the HFSA guideline recommendation regarding symptom assessment was assigned a level B for strength of evidence, which is defined as evidence arising from cohort studies or smaller clinical trials with physiologic or surrogate endpoints. Level B evidence is derived from studies that are diverse in design and may be prospective or retrospective in nature. They may involve subgroup analyses of clinical trials or have a case control or propensity design using a matched subset of trial populations. Dose-response studies, when available, may involve all or a portion of the clinical trial population. Evidence generated from these studies has well-recognized, inherent limitations. Nevertheless, their value is enhanced through attention to factors such as pre-specification of hypotheses, biologic rationale, and consistency of findings between studies and across different populations.

The evidence for the HFSA guideline recommendation regarding functional capacity/activity level assessment was assigned a level A for strength of evidence, which is defined as evidence arising from randomized controlled clinical trials. A single randomized, controlled, outcome-based clinical trial can be sufficient for level A evidence when the single trial is large with a substantial number of endpoints and has consistent and robust outcomes. However, randomized clinical trial data is evaluated for endpoints studied, level of significance, reproducibility of findings, generalizability of study results, and sample size and number of events on which the outcome results are based.

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

Level A: Multiple populations evaluated; Data derived from multiple randomized clinical trials or meta-analysis

Level B: Limited populations evaluated; Data derived from a single randomized trial or nonrandomized studies

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

The HFSA guideline also has a level C for strength of evidence, which is defined as evidence arising from expert opinion. The need to formulate recommendations based on level C evidence is driven primarily by a paucity of scientific evidence in many areas critical to a comprehensive guideline. Recommendations based on expert opinion alone have been limited to those circumstances when a definite consensus could be reached across the guideline panel and reviewers.

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**:

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

Recommendation that procedure or treatment is useful/effective is based on consensus opinion of experts, case studies or standard of care

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

: The HFSA guideline does not specify which studies were reviewed for the specific recommendations. However, the body of evidence for the entire guideline ranges from 1971-2009

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

The initial evaluation and follow-up of patients with heart failure (HF) involve continuing reassessment of symptoms and functional capacity to determine disease severity. These assessments serve as the basis for making treatment decisions, monitoring therapeutic effectiveness, and modifying treatment as appropriate to maximize symptom relief and functional status. Therefore, the 2013 ACC/AHA guideline recommends initial evaluation and follow-up as useful/effective and this recommendation is based on consensus opinion of experts, case studies or standard of care.

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

The HFSA guideline does not specify which studies were reviewed for the cited recommendations.

This measure focuses on the evaluation of symptom burden and activity level for patients with heart failure. The evaluation of symptom burden and functional status is an aspect of care that generally does not have a direct body of supporting evidence. However, thorough evaluation of symptoms and functional status is critically important in the appropriate management of the symptoms of heart failure.

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

The 2013 ACC/AHA guideline recommends initial evaluation and follow-up as useful/effective based on consensus opinion of experts, case studies or standard of care.

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

The HFSA guideline does not make any qualifying statements about the overall quality of the body of evidence that was reviewed for the formation of the symptom assessment and functional capacity/level of activity assessment recommendations. However, the guideline does provide a ranking for the strength of evidence for each recommendation. In the case of the symptom assessment and activity level assessment recommendations, they were assigned a grade of level B and level A respectively for strength of evidence. In addition to grading the strength of evidence, the HFSA guideline also has a system for grading the strength of the recommendation which is based on the totality of evidence. Under this system described in section 1a.4.3, the guideline states that assessment of symptom burden “should be considered” and that assessment of functional status “is recommended”.

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

**2013 ACCF/AHA Guideline for the Management of Heart Failure**

Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm. The ACCF/AHA recommendation is a Class I recommendation suggesting the benefits outweigh the risks although an exact quantitative estimate of benefit is not provided.

**2010 HFSA Comprehensive Heart Failure Practice Guideline**

The HFSA clinical guideline writing committee formulated the recommendations, used as the foundation for this measure, based on a body of evidence on the symptom and quality of life improvements associated with comprehensive evaluation and care for heart failure patients. The HFSA clinical guideline does not, however, provide a quantitative estimate of benefit across the entire body of evidence reviewed.

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

There is no expectation that continuing reassessment of symptoms and functional capacity as part of an initial evaluation and follow-up of patients with heart failure (HF) would pose a risk of harm to a patient. The reasonable expectation is that completing these assessments will elicit improved physician-patient communication and provide information necessary for effective and shared decision making related to the symptom burden and functional status. In turn, this would benefit a patient in terms of symptom relief and overall improvements in quality of life. Neither the ACCF/AHA nor the HFSA guideline include a focused attention to the net benefit and harm as a result of symptom and activity assessment in heart failure patients.

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

Recently completed studies do not focus on the benefits of physician assessment of symptoms and activity level for heart failure patients. Rather, they focus on population-based assessment of quality of life for heart failure patients.

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**1a.8 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.8.1** **What process was used to identify the evidence?**

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**