

<b>eMeasure Title</b>	Changes in Patient-Reported Outcomes (PROs) following Non-Emergent PCI
<b>Measurement Period</b>	January 1, 20xx through December 31, 20xx
<b>Measure Steward</b>	Centers for Medicare & Medicaid Services (CMS)
<b>Measure Developer</b>	The Lewin Group
<b>Description</b>	Percentage of patients aged 18 years or older undergoing a qualifying non-emergent percutaneous coronary intervention (PCI) procedure with documented improvement in self-reported functional status, health-related quality of life (HRQoL), and symptoms, using a combination of disease-specific patient-reported outcome measures (PROMs). The select PROMs are: Seattle Angina Questionnaire Short Form (SAQ-7) and Rose Dyspnea Scale (RDS).
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<b>Measure Scoring</b>	Proportion
<b>Measure Type</b>	Outcome
<b>Stratification</b>	None
<b>Risk Adjustment</b>	None
<b>Rate Aggregation</b>	None
<b>Rationale</b>	<p>An estimated 15.5 million Americans over the age of 20 have coronary heart disease (CHD), the underlying cause of about one in seven deaths in the United States in 2011 (Mozaffarian et al., 2015). Including the cost of health care services, medications, and lost productivity, CHD costs the United States an estimated \$108.9 billion each year, a number projected to increase by up to 100% between 2013 and 2030 (CDC, 2015; Mozaffarian et al., 2015; Heidenreich et al., 2011). CHD can lead to serious, often fatal acute coronary syndromes, and can also result in chronic and debilitating heart conditions, such as angina or heart failure (Mozaffarian et al., 2015).</p> <p>Angina, one of the most common symptoms of CHD, is characterized by chronic or episodic pain or discomfort in the chest and throughout the shoulder, arms, neck, jaw, or back, often as a result of exertion or stress (Fihn et al., 2012; Young et al., 2013). It results from cardiac ischemia, i.e., when the oxygen supply to the heart muscle is insufficient to meet metabolic demands, which is usually caused by CHD. In 2012, 8.2 million Americans reported having angina (Mozaffarian et al., 2015). Angina symptoms often impose a significant burden on a person's functional status (Mozaffarian et al., 2015; Young et al., 2013). Similarly, dyspnea, or breathlessness, is one of the most common and distressing symptoms experienced</p>

<b>Rationale (cont.)</b>	<p>by patients with CHD and is independently associated with impaired HRQoL (Arnold et al., 2009).</p> <p>Non-emergent percutaneous coronary intervention (PCI) is a procedure that can be used to improve the HRQoL, functional status, and angina and dyspnea symptoms of patients with CHD (Levine et al., 2011; Weintraub et al., 2008). It is one of the most commonly performed cardiovascular procedures; from July 2014 to June 2015, 245,213 non-emergent PCI procedures were performed in the United States (ACCF, 2015). As there is limited evidence to suggest that PCI reduces a patient's risk of myocardial infarction (MI) or death in most circumstances, the primary, if not only, expected benefit of non-emergent PCI is to improve a patient's health status (YNHHSC/CORE, 2016; Kureshi et al., 2014; Spertus et al., 2013).</p> <p>These benefits have been measured with disease-specific, validated tools that assess changes in HRQoL, functional status, and symptom burden (Spertus et al., 2004; Chan et al., 2014, McNamara et al., 2015). PROMs are increasingly recognized as a valuable source of information about a patient's health status and are guiding more informed discussions about the management of their care (McNamara et al., 2015). It is important to capture the patient's perspective of their own health status through self-reporting, which providers can interpret and use in clinical action, as well as inform and support shared decision making (Rumsfeld et al., 2013; Spertus 2014, Bradley 2014). Specifically, this measure incorporates the short SAQ-7, which measures physical limitation, angina frequency, and quality of life (Chan et al., 2014), and the RDS, which measures a patient's dyspnea (Arnold et al., 2009).</p>
<b>Clinical Recommendation Statement</b>	<p>The 2012 Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease (SIHD) from ACA/AHA and endorsed by other organizations includes recommendations on chronic stable angina (Fihn et al., 2012, Fihn et al., 2014) and states:</p> <p>"For patients with SIHD, disease management should include an annual follow-up, and monitoring and treatment of angina involving 'assessment of symptoms and clinical function'." Class I, Level of Evidence: C</p> <p>In addition to the 2012 Guideline from the ACA/AHA, the 2011 Guideline for Percutaneous Coronary Intervention from ACCF/AHA and endorsed by other organizations also includes recommendations for the appropriate use of PCI (Levine et al., 2011) and states:</p> <p>"CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (<math>\geq 70\%</math> diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite guideline-directed medical treatment (GDMT)." Class I, Level of Evidence: A</p> <p>Lastly, the International Consortium for Health Outcomes Measurement (ICHOM) published a consensus document (McNamara et al., 2015) recommending standardized outcome measurement for patients with coronary artery disease, which included PROMs measured using the SAQ-7 and RDS:</p> <p>"The SAQ-7, which is short, widely translated into many languages, and has a high degree of clinically interpretability most closely aligned with these qualities [domain coverage, psychometric properties, feasibility to implement, and clinical interpretability] and was recommended in the standard set. The Working Group desired additional questions to assess patients' level of dyspnea and depressive symptoms. The PHQ-2, a widely used 2-item questionnaire assessing signs of depression, and 2 items from the Rose Dyspnea Score were included to cover these domains."</p>
<b>Improvement Notation</b>	A higher rate indicates better quality.
<b>Reference</b>	American College of Cardiology Foundation (ACCF). National Cardiovascular Data Registry (NCDR®) CathPCI Registry® Institutional Outcomes Report 2015Q2. 2015 October.

<b>Reference</b>	Arnold SV, Spertus JA, Jones PG, Xiao L, Cohen DJ. The impact of dyspnea on health-related quality of life in patients with coronary artery disease: results from the PREMIER registry. <i>Am Heart J</i> . 2009 Jun;157(6):1042-9.e1.
<b>Reference</b>	Bradley SM. The routine clinical capture of patient-reported outcomes: how competition on value will lead to change. <i>Circ Cardiovasc Qual Outcomes</i> . 2014 Sep;7(5):635-6.
<b>Reference</b>	Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention. Heart Disease Fact Sheet. Updated November 30 2015. Accessed December 17 2015. Available at: <a href="http://www.cdc.gov/dhdsdp/data_statistics/fact_sheets/fs_heart_disease.htm">http://www.cdc.gov/dhdsdp/data_statistics/fact_sheets/fs_heart_disease.htm</a> .
<b>Reference</b>	Chan PS, Jones PG, Arnold SA, Spertus JA. Development and validation of a short version of the Seattle angina questionnaire. <i>Circ Cardiovasc Qual Outcomes</i> . 2014 Sep;7(5):640-7.
<b>Reference</b>	Fihn SD, Gardin JM, Abrams J, Berra K, Blankenship JC, Dallas AP, Douglas PS, Foody JM, Gerber TC, Hinderliter AL, King SB 3rd, Kligfield PD, Krumholz HM, Kwong RY, Lim MJ, Linderbaum JA, Mack MJ, Munger MA, Prager RL, Sabik JF, Shaw LJ, Sikkema JD, Smith CR Jr, Smith SC Jr, Spertus JA, Williams SV. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease. <i>J Am Coll Cardiol</i> . 2012 Dec; 60(24): e44-e164.
<b>Reference</b>	Fihn SD, Blankenship JC, Alexander KP, Bittl JA, Byrne JG, Fletcher BJ, Fonarow GC, Lange RA, Levine GN, Maddox TM, Naidu SS, Ohman EM, Smith PK. 2014 ACC/AHA/AATS/PCNA/SCAI/STS focused update of the guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines, and the American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. <i>J Am Coll Cardiol</i> . 2014 Nov 4; 64(18):1929-49.
<b>Reference</b>	Heidenreich PA, Trogdon JG, Khavjou OA, Butler J, Dracup K, Ezekowitz MD, Finkelstein EA, Hong Y, Johnston SC, Khera A, Lloyd-Jones DM, Nelson SA, Nichol G, Orenstein D, Wilson PW, Woo YJ; Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. <i>Circulation</i> . 2011 Mar; 123(8): 933-944.
<b>Reference</b>	Kureshi F, Jones PG, Buchanan DM, Abdallah MS, Spertus JA. Variation in patients' perceptions of elective percutaneous coronary intervention in stable coronary artery disease: cross sectional study. <i>BMJ</i> 2014;349:g5309.
<b>Reference</b>	Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, Chambers CE, Ellis SG, Guyton RA, Hollenberg SM, Khot UN, Lange RA, Mauri L, Mehran R, Moussa ID, Mukherjee D, Nallamothu BK, Ting HH. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. <i>J Am Coll Cardiol</i> . 2011 Dec 6;58(24):e44-122.
<b>Reference</b>	McNamara RL, Spatz ES, Kelley TA, Stowell CJ, Beltrame J, Heidenreich P, Tresserras R, Jernberg T, Chua T, Morgan L, Panigrahi B, Rosas Ruiz A, Rumsfeld JS, Sadwin L, Schoeberl M, Shahian D, Weston C, Yeh R, Lewin J. (ICHOM). Standardized Outcome Measurement for Patients With Coronary Artery Disease: Consensus From the International Consortium for Health Outcomes Measurement (ICHOM). <i>J Am Heart Assoc</i> . 2015 May 19;4(5).

<b>Reference</b>	Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, de Ferranti S, Després JP, Fullerton HJ, Howard VJ, Huffman MD, Judd SE, Kissela BM, Lackland DT, Lichtman JH, Lisabeth LD, Liu S, Mackey RH, Matchar DB, McGuire DK, Mohler ER 3rd, Moy CS, Muntner P, Mussolino ME, Nasir K, Neumar RW, Nichol G, Palaniappan L, Pandey DK, Reeves MJ, Rodriguez CJ, Sorlie PD, Stein J, Towfighi A, Turan TN, Virani SS, Willey JZ, Woo D, Yeh RW, Turner MB; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics – 2015 Update. <i>Circulation</i> . 2015; 131: e29-322.
<b>Reference</b>	Rumsfeld JS, Alexander KP, Goff DC Jr, Graham MM, Ho PM, Masoudi FA, Moser DK, Roger VL, Slaughter MS, Smolderen KG, Spertus JA, Sullivan MD, Treat-Jacobson D, Zerwic JJ; American Heart Association Council on Quality of Care and Outcomes Research, Council on Cardiovascular and Stroke Nursing, Council on Epidemiology and Prevention, Council on Peripheral Vascular Disease, and Stroke Council. Cardiovascular health: the importance of measuring patient-reported health status. 2013 May; 127: 2233-2249.
<b>Reference</b>	Spertus JA. Editor's Perspective: Barriers to the Use of Patient-Reported Outcomes in Clinical Care. <i>Circulation: Cardiovascular Quality and Outcomes</i> . 2014; 7: 2-4.
<b>Reference</b>	Spertus JA, Maron DJ, Cohen DJ, Kolm P, Hartigan P, et al. Frequency, Predictors, and Consequences of Crossing Over to Revascularization Within 12 Months of Randomization to Optimal Medical Therapy in the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) Trial. <i>Circulation: Cardiovascular Quality and Outcomes</i> . 2013; 6: 409-418.
<b>Reference</b>	Spertus JA, Salisbury AC, Jones PG, Conway DG, Thompson RC. Predictors of quality-of-life benefit after percutaneous coronary intervention. <i>Circulation</i> . 2004 Dec; 110(25): 3789-3794.
<b>Reference</b>	Weintraub WS, Spertus JA, Kolm P, Maron DJ, Zefeng Z, Jurkovitz C, Zhang W, Hartigan PM, Lewis C, Veledar E, Bowen J, Dunbar SB, Deaton C, Kaufman S, O'Rourke RA, Goeree R, Barnett PG, Teo KK, Boden WE, for the COURAGE Trial Research Group. Effect of PCI on quality of life in patients with stable coronary disease. <i>N Engl J Med</i> . 2008 Aug; 359: 677-687.
<b>Reference</b>	Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE). Draft Measure Methodology Report for Public Comment: Hospital-Level Patient-Reported Outcome Performance Measure for Patients Undergoing Non-Emergent Percutaneous Coronary Intervention. Prepared for Centers for Medicare & Medicaid Services (CMS). 2016 July.
<b>Reference</b>	Young JW, Melander S. Evaluating symptoms to improve quality of life in patients with chronic stable angina. <i>Nursing Research and Practice</i> . 2013 Aug; <a href="http://doi.org/10.1155/2013/504915">http://doi.org/10.1155/2013/504915</a> .
<b>Definition</b>	The minimally important difference (MID) approach is used to define the smallest measurable difference in symptom status that is clinically meaningful. Non-emergent PCI is defined as a PCI procedure that is not performed during an episode of acute coronary syndrome (i.e., unstable angina or myocardial infarction).
<b>Guidance</b>	PROMs must be administered in the following timeframes to count for this measure: 30 days up to and including the day of the PCI procedure and 28-60 days following the procedure.  The measure scoring is considered most attributable to interventional cardiologists performing the PCI procedures.
<b>Initial Patient Population</b>	Patients 18 years of age and older with a diagnosis of stable coronary artery disease who undergo a qualifying non-emergent percutaneous coronary intervention (PCI) procedure during the measurement period.
<b>Denominator</b>	Equals Initial Patient Population

<b>Denominator Exclusions</b>	<p>As coded at the time of the PCI procedure:</p> <ul style="list-style-type: none"> <li>• Patients with acute coronary syndromes (ST-segment myocardial infarction [STEMI], non-ST segment myocardial infarction [NSTEMI], and unstable angina)</li> <li>• Patients with other acute processes (e.g., decompensated heart failure)</li> <li>• Patients undergoing PCI in anticipation of another procedure (e.g., patients with aortic stenosis undergoing PCI prior to transcatheter aortic valve replacement [TAVR])</li> </ul>
<b>Numerator</b>	<p>Patients with documented improvement in self-reported functional status, HRQoL, or symptoms, defined as an improvement of at least the minimally important difference (MID) for one of two disease-specific PROMs: five points in the summary score for the short Seattle Angina Questionnaire (SAQ-7), or one point in the Rose Dyspnea Scale (RDS) (only if the patient does not experience a five point worsening in the SAQ-7 summary score).</p>
<b>Denominator Exceptions</b>	None
<b>Supplemental Data Elements</b>	<p>For every patient evaluated by this measure also identify payer, race, ethnicity and gender.</p>