

# NATIONAL QUALITY FORUM

## Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the [submitting standards web page](#).

NQF #: 0102      NQF Project: <a href="#">Pulmonary Project</a>
(for Endorsement Maintenance Review) Original Endorsement Date: <a href="#">Aug 10, 2009</a> Most Recent Endorsement Date: <a href="#">Aug 10, 2009</a>
<b>BRIEF MEASURE INFORMATION</b>
De.1 Measure Title: <a href="#">COPD: inhaled bronchodilator therapy</a>
Co.1.1 Measure Steward: <a href="#">American Medical Association - Physician Consortium for Performance Improvement</a>
De.2 Brief Description of Measure: <a href="#">Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC &lt; 70% and have symptoms who were prescribed an inhaled bronchodilator</a>
2a1.1 Numerator Statement: <a href="#">Patients who were prescribed an inhaled bronchodilator</a>
2a1.4 Denominator Statement: <a href="#">All patients aged 18 years and older with a diagnosis of COPD, who have an FEV1/FVC &lt;70% and have symptoms (eg, dyspnea, cough/sputum, wheezing)</a>
2a1.8 Denominator Exclusions: <a href="#">Documentation of medical reason(s) for not prescribing an inhaled bronchodilator; documentation of patient reason(s) for not prescribing an inhaled bronchodilator; documentation of system reason(s) for not prescribing an inhaled bronchodilator</a>
1.1 Measure Type: <a href="#">Process</a> 2a1. 25-26 Data Source: <a href="#">Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</a> 2a1.33 Level of Analysis: <a href="#">Clinician : Group/Practice, Clinician : Individual, Clinician : Team</a>
1.2-1.4 Is this measure paired with another measure? <a href="#">No</a>
De.3 If included in a composite, please identify the composite measure ( <i>title and NQF number if endorsed</i> ):

<b>STAFF NOTES</b> ( <i>issues or questions regarding any criteria</i> )
Comments on Conditions for Consideration:
Is the measure untested? Yes <input type="checkbox"/> No <input type="checkbox"/> If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure ( <i>check De.5</i> ): 5. Similar/related <a href="#">endorsed</a> or submitted measures ( <i>check 5.1</i> ): Other Criteria:
Staff Reviewer Name(s):

<b>1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT</b>
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See <a href="#">guidance on evidence</a> . <b><i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i></b>

(evaluation criteria)

1a. High Impact: H  M  L  I

(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

De.4 Subject/Topic Areas (Check all the areas that apply): Pulmonary/Critical Care, Pulmonary/Critical Care : Chronic Obstructive Pulmonary Disease (COPD)

De.5 Cross Cutting Areas (Check all the areas that apply):

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of chronic morbidity and mortality in the United States, (NHLBI, 2004) and is projected to rank fifth in 2020 in burden of disease caused worldwide (Lopez, et. al., 2006). The direct costs of COPD in the US were \$18 billion in 2002, and the indirect costs totaled \$14.1 billion (NHLBI, 2004).

According to the World Health Organization (WHO) estimates, currently 210 million people have COPD and 3 million people died of COPD in 2005. The WHO predicts that COPD will become the fourth leading cause of death worldwide by 2030 (COPD 2007). The burden of COPD assessed by disability-adjusted life years(DALYs) ranks 10th worldwide (WHO 2008). Total deaths from COPD are projected to increase by more than 30% in the next 10 years unless urgent preventive measures are in place (COPD 2007).

COPD affects more than 12 million Americans. This respiratory disease is commonly evaluated and managed by primary care physicians (PCPs), particularly when symptoms are of mild-to-moderate severity (Salinas et al, 2011).

Worldwide, the prevalence of COPD in the general population is estimated to be 1% across all ages, rising steeply to 8% to 10% or higher among those aged 40 years and with nearly 80% of COPD cases remaining undiagnosed (Chapman et al 2006; Halbert et al 2006).

Hospitalizations for persons with COPD result in significant health care resource use and excess expenditures. In a recent study, almost 3.8 million COPD hospitalization records were extracted from Medicare claims for 1995–2006, and the total population of eligible Medicare beneficiaries was extracted from the Medicare enrollment records to calculate COPD hospitalization rates by Health Service Area (HSA). The overall COPD hospitalization rate was 11.30 per 1,000 beneficiaries for the aggregated period 1995–2006 (Holt et al, 2011).

The annual number of inpatient days for COPD (8.18 days) is only second to chronic kidney disease (9.51 days) (Schneider et al, 2009). COPD is highly prevalent and associated with comorbid disease and physical dysfunction (Methvin et al, 2009).

1a.4 Citations for Evidence of High Impact cited in 1a.3: National Heart, Lung, and Blood Institute. Morbidity and mortality chartbook on cardiovascular, lung and blood diseases. Bethesda, Maryland: US Department of Health and Human Services, Public Health Service, National Institutes of Health. Accessed at: <http://www.nhlbi.nih.gov/resources/docs/cht-book.htm>; 2004.

Lopez AD, Shibuya K, Rao C, Mathers CD, Hansell AL, Held LS, et al. Chronic obstructive pulmonary disease: current burden and future projections. *Eur Respir J* 2006;27(2):397-412.

Chronic Obstructive Pulmonary Disease (COPD). Fact sheet No 315. November 2007[online]. Accessed February 26, 2008. URL: <http://www.who.int/mediacentre/factsheets/fs315/en/index.html>.

World Health Organization. Chronic Respiratory Diseases [online]. Accessed February 26, 2008. URL: [http://www.who.int/gard/publications/chronic\\_respiratory\\_diseases.pdf](http://www.who.int/gard/publications/chronic_respiratory_diseases.pdf).

Gregory D Salinas, James C Williamson, Ravi Kalhan, Byron Thomashow, Jodi L Scheckermann, John Walsh, Maziar Abdolrasulnia, Jill A Foster. Barriers to adherence to chronic obstructive pulmonary disease guidelines by primary care physicians.

International Journal of COPD 2011;6 171–179.

Chapman KR, Mannino DM, Soriano JB, et al. 2006. Epidemiology and costs of chronic obstructive pulmonary disease. *Eur Respir J*, 27:188–207.

Halbert RJ, Natoli JL, Gano A, et al. 2006. Global burden of COPD: systematic review and meta-analysis. *Eur Respir J*, 28:523–32.

James B Holt, Xingyou Zhang, Letitia Presley-Cantrell, Janet B Croft. Geographic disparities in chronic obstructive pulmonary disease (COPD) hospitalization among Medicare beneficiaries in the United States. *International Journal of COPD* 2011;6 321–328.

Schneider KM, O'Donnell BE, Dean D. Prevalence of multiple chronic conditions in the United States' Medicare population. *Health Qual Life Outcomes*. 2009;7:82.

Methvin JN, Mannino DM, Casey BR. COPD Prevalence in Southeastern Kentucky: The Burden of Lung Disease Study. *Chest*. 2009;135 (1):102–107.

**1b. Opportunity for Improvement:** H  M  L  I

*(There is a demonstrated performance gap - variability or overall less than optimal performance)*

**1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:**

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend inhaled bronchodilators as a cornerstone of COPD symptom management;

however, PCPs often turn to other agents as first-line COPD therapy (Barr et al, 2005; Foster et al, 2007). A cross-sectional study U.S. PCPs found that although 78.4% of PCPs agreed that a long-acting bronchodilator (LABD) should be added for patients with stage 2–3 COPD whose dyspnea during daily activities is not relieved with an as-needed short-acting bronchodilator, only 25.8% of the PCPs “nearly always” recommend using an LABD daily for patients with COPD and mild exertional dyspnea (Salinas et al, 2011). The annual number of inpatient days for COPD (8.18 days) is only second to chronic kidney disease (9.51 days) (Schneider et al, 2009). COPD is highly prevalent and associated with comorbid disease and physical dysfunction (Methvin et al, 2009). The goals of COPD treatment are to reduce long-term lung function decline, prevent and treat exacerbations, reduce hospitalizations and mortality, relieve disabling dyspnea, and improve exercise tolerance and health-related quality of life (Qaseem et al, 2011). This measure encourages the prescription of an inhaled bronchodilator to assist patients in management of COPD symptoms and reduction of long-term lung function decline, which should reduce COPD exacerbations, inpatient hospitalizations, and mortality.

**1b.2 Summary of Data Demonstrating Performance Gap** *(Variation or overall less than optimal performance across providers):*

**[For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]**

According to a study analyzing the quality of health care in the United States, on average, patients with COPD received the recommended care at an aggregate rate (based on 20 quality indicators) of 58 percent (McGlynn et al., 2003).

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend inhaled bronchodilators as a cornerstone of COPD symptom management;

however, PCPs often turn to other agents as first-line COPD therapy (Barr et al, 2005; Foster et al, 2007).

A cross-sectional study implemented in July 2008 was designed to assess attitudes and barriers to COPD guideline usage. Five hundred U.S. PCPs (309 family medicine physicians, 191 internists) were included in the analysis. 78.4% of PCPs agreed that a long-acting bronchodilator (LABD) should be added for patients with stage 2–3 COPD whose dyspnea during daily activities is not relieved with an as-needed short-acting bronchodilator. However, only 25.8% of the PCPs “nearly always” recommend using an LABD daily for patients with COPD and mild exertional dyspnea (Salinas et al, 2011).

In a recent study of general medicine practices, 154 clinicians completed a survey to identify barriers to implementing seven recommendations from the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines. Adherence was only 54% to prescribing long-acting bronchodilators when FEV(1) <80% predicted (Perez, et al, 2011).

Another study of 615 patients being treated for COPD by a general practitioner, less than half the patients in all groups used short-acting bronchodilators. Prescribing long-acting bronchodilators or inhaled corticosteroids conformed to GOLD guidelines in two-

thirds of patients with GOLD stage III or IV disease, and approximately half of the less severe patients (Jochmann et al, 2010).

CMS Physician Quality Reporting Initiative/System:

This measure was used in the CMS Physician Quality Reporting Initiative/System (PQRI/S) in the: 2007 through 2011 claims option; 2009 through 2011 registry option; and the 2011 group practice reporting II option.

There is a gap in care as shown by this 2008 data; 53.61% of patients reported on did not meet the measure.(1)

10th percentile: 0.00%  
 25th percentile: 1.75%  
 50th percentile: 30.77%  
 75th percentile: 74.07%  
 90th percentile: 89.44%

Exception rate: 9.98%

**1b.3 Citations for Data on Performance Gap:** [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]

McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, Kerr EA. The quality of health care delivered to adults in the United States. *New England Journal of Medicine*. 2003;348(26):2635-2645.

Barr RG, Celli BR, Martinez FJ, et al. Physician and patient perceptions in COPD: the COPD Resource Network Needs Assessment Survey. *Am J Med*. 2005;118(12):1415.

Foster JA, Yawn BP, Abdolrasulnia M, et al. Enhancing COPD management in primary care settings. *Med Gen Med*. 2007;9(3):24.

Gregory D Salinas, James C Williamson, Ravi Kalhan, Byron Thomashow, Jodi L Scheckermann, John Walsh, Maziar Abdolrasulnia, Jill A Foster. Barriers to adherence to chronic obstructive pulmonary disease guidelines by primary care physicians. *International Journal of COPD* 2011;6 171–179.

Perez X, Wisnivesky JP, Lurslurchachai L, Kleinman LC, Kronish IM. Barriers to adherence to COPD guidelines among primary care providers. *Respir Med*. 2011 Oct 12. [Epub ahead of print]

A. Jochmann, F. Neubauer, D. Miedinger, S. Schafroth, P.N. Chhajed, M. Tamm, J.D. Leuppi. General practitioners' adherence to the COPD GOLD guidelines: baseline data from the Swiss COPD Cohort Study. *Swiss Medical Weekly: European Journal of Medical Sciences*. Early Online Publication, 19 April 2010. [www.smw.ch](http://www.smw.ch)

(1) Confidential CMS PQRI 2008 Performance Information by Measure. Jan-Sept TAP file.

**1b.4 Summary of Data on Disparities by Population Group:** [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]

A recent cohort study with 126,019 participants (55% whites, 27% blacks, 11% Asians, and 4% Hispanics) found that for COPD, whites were at highest risk; compared with whites, relative risks (RR) with 95% confidence intervals (95% CI) for COPD among other groups were: blacks, 0.9 (0.7-1.0); Hispanics, 0.6 (0.3-0.9); and Asians, 0.4 (0.3-0.6). (Tran et al, 2011)

The EPOCA (Enfermedad Pulmonar Obstructiva Crónica en Acción) project, an international web-based survey of doctors and their COPD patients, found that patients of a lower socioeconomic class were older and had a more severe impairment of FEV1(%) than patients belonging to an upper class. They were also more exposed to biomass smoke (36.1% vs 13.5% and 18.6% for low, middle, and high class, respectively,  $p < 0.0001$ ). Lower class patients tended to require more visits to emergency rooms and admissions for exacerbations ( $p = 0.058$  and  $p = 0.083$ , respectively). (Miravittles et al 2008)

In another study, almost 3.8 million COPD hospitalization records were extracted from Medicare claims for 1995–2006, and the total population of eligible Medicare beneficiaries was extracted from the Medicare enrollment records to calculate COPD hospitalization rates by Health Service Area (HSA). The overall COPD hospitalization rate was 11.30 per 1,000 beneficiaries for the aggregated

period 1995–2006. HSA-level COPD hospitalization rates had a median of 11.7 and a range of 3.0 (Cache, UT) to 76.3 (Pike, KY). Excessive hospitalization risk was concentrated in Appalachia, the southern Great Lakes, the Mississippi Delta, the Deep South, and west Texas (Holt et al, 2011).

An additional study assessed the quality of care delivered to a national sample of the US population. COPD patients received 58.0% of recommended care but received better exacerbation care (60.4%) than routine care (46.1%). After adjusting for other covariates, African Americans received better overall care than all other race categories (67%), and Latinos with COPD received worse care (37%) (Mularski et al, 2006).

Shaya and colleagues concluded that in a Medicaid population, healthcare utilization rates for obstructive lung disease, both outpatient and inpatient, were lower for African-American than white patients. African-American patients consistently used fewer overall medical services, outpatient physician visits, and hospitalizations than their white counterparts, which accounted for lower medical costs associated with obstructive lung disease. This finding held true even after adjusting for age, gender, and comorbidities, and in the presence of uniform socioeconomic status. The finding that lower health-care costs are associated with African Americans than with whites could represent, in addition to other factors, poorer access to care (Shaya et al, 2009).

**1b.5 Citations for Data on Disparities Cited in 1b.4:** [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]

Tran HN, Siu S, Iribarren C, Udaltsova N, Klatsky AL. Ethnicity and risk of hospitalization for asthma and chronic obstructive pulmonary disease. *Ann Epidemiol.* 2011 Aug;21(8):615-22. doi: 10.1016/j.annepidem.2010.10.015. Epub 2011 Mar 17.

Marc Miravittles, Cristina Murio, Gema Tirado-Conde, et al. Geographic differences in clinical characteristics and management of COPD: the EPOCA study. *International Journal of COPD* 2008;3(4) 803–814.

James B Holt, Xingyou Zhang, Letitia Presley-Cantrell, Janet B Croft. Geographic disparities in chronic obstructive pulmonary disease (COPD) hospitalization among Medicare beneficiaries in the United States. *International Journal of COPD* 2011;6 321–328.

Richard A. Mularski, Steven M. Asch, William H. Shrank, Eve A. Kerr, et al. The Quality of Obstructive Lung Disease Care for Adults in the United States as Measured by Adherence to Recommended Processes. *Chest* 2006;130:1844-1850.

Fadia T. Shaya, PhD, MPH; Mark S. Maneval, BS Pharm; Confidence M. Gbarayor, MPH; et al. Burden of COPD, Asthma, and Concomitant COPD and Asthma Among Adults: Racial Disparities in a Medicaid Population. *Chest* 2009;136:405-411; Prepublished online March 24, 2009.

**1c. Evidence** (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)  
Is the measure focus a health outcome? Yes  No  **If not a health outcome**, rate the body of evidence.

Quantity: H  M  L  I  Quality: H  M  L  I  Consistency: H  M  L  I

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the measure pass subcriterion1c?  
Yes  IF rationale supports relationship

**1c.1 Structure-Process-Outcome Relationship** (*Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome*):

The measure focus is the process of prescribing an inhaled bronchodilator to patients with a diagnosis of COPD and symptoms (eg,

dyspnea, cough/sputum, wheezing). This process is directly related to managing COPD symptoms, as well as reducing long-term lung function decline, COPD exacerbations, inpatient hospitalizations, and mortality. Inhaled bronchodilator therapy is effective in treating and managing the symptoms of COPD and improving quality of life, particularly for those patients with moderate to very severe COPD, which should lead to less comorbid disease, physical dysfunction, and death from COPD.

**1c.2-3 Type of Evidence** (*Check all that apply*):

Clinical Practice Guideline, Systematic review of body of evidence (other than within guideline development)

**1c.4 Directness of Evidence to the Specified Measure** (*State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population*):

The evidence cited for this measure is directly related to the usefulness of prescribing an inhaled bronchodilator for adults with COPD and symptoms. There are no differences from the measure focus and measure target population.

**1c.5 Quantity of Studies in the Body of Evidence** (*Total number of studies, not articles*): The quantity of studies reviewed in the ACP/ACCP/ATS/ERS guideline was not explicitly stated, but the guideline paper references 62 articles, and there is some specific information regarding evidence for bronchodilator use. This guideline is based on a targeted literature update from March 2007 to December 2009 to evaluate the evidence and update the 2007 ACP clinical practice guideline on diagnosis and management of stable COPD. Pooled results from 9 long-term trials, some of which were not statistically significant, demonstrated that inhaled therapies (long-acting bronchodilators, inhaled corticosteroids, or combination bronchodilator and corticosteroid therapy) reduced the annual decline in mean FEV1 more than placebo did. Monotherapy trials reported absolute decreases in the annual rate of FEV1 decline associated with use of tiotropium (40 mL/y), inhaled corticosteroids (44 mL/y), and long-acting  $\beta$ -agonists (42 mL/y). Other studies have demonstrated that combinations of inhaled agents are not more effective than monotherapy for slowing declines in lung function. (Qaseem et al, 2011)

The quantity of studies reviewed in the GOLD report was not stated, but the paper references 503 articles, and there is some specific information regarding Evidence Category A:

Sources of Evidence: Randomized controlled trials (RCTs). Rich body of data.

Definition: Evidence is from endpoints of well-designed RCTs that provide a consistent pattern of findings in the population for which the recommendation is made. Category A requires substantial numbers of studies involving substantial numbers of participants. (GOLD 2011)

**1c.6 Quality of Body of Evidence** (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): The ACP/ACCP/ATS/ERS guideline recommendation was graded as a strong recommendation, with moderate-quality evidence. A strong recommendation means that benefits clearly outweigh risks and burden, or risks and burden clearly outweigh benefits. Evidence is considered moderate quality when it is obtained from RCTs with important limitations—for example, biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, well designed cohort or case-control analytic studies, and multiple time series with or without intervention are in this category. Moderate-quality evidence also means that further research will probably have an important effect on our confidence in the estimate of effect and may change the estimate. (Amir Qaseem, MD, PhD, MHA; Vincenza Snow, MD; Douglas K. Owens, MD, MS; and Paul Shekelle, MD, PhD, for the Clinical Guidelines Committee of the American College of Physicians. The Development of Clinical Practice Guidelines and Guidance Statements of the American College of Physicians: Summary of Methods. *Ann Intern Med.* 2010;153:194-199.)

The quality of studies reviewed in the GOLD report was not addressed, but there is some specific information regarding Evidence Category A:

Sources of Evidence: Randomized controlled trials (RCTs). Rich body of data.

Definition: Evidence is from endpoints of well-designed RCTs that provide a consistent pattern of findings in the population for which the recommendation is made. Category A requires substantial numbers of studies involving substantial numbers of participants. (GOLD 2011)



**1c.7 Consistency of Results across Studies** (*Summarize the consistency of the magnitude and direction of the effect*): The ACP/ACCP/ATS/ERS guideline recommendation for inhaled bronchodilators is not consistently recommended for all COPD populations. Rather, the guideline explains that updated evidence reconfirms prior findings that the patients who benefit the most from inhaled therapies (anticholinergics, long-acting  $\beta$ -agonists, or corticosteroids) are those who have respiratory symptoms and airflow obstruction with FEV1 less than 60% predicted. Although some patients who were studied had an FEV1 greater than 60% predicted, the mean FEV1 of the included patients has been 60% predicted or less for most COPD treatment trials. Among symptomatic patients with FEV1 greater than 50% predicted but less than 80% predicted or those with normal airflow but who have chronic sputum production (at-risk individuals), 7 large studies of inhaled corticosteroids or short- or long-acting anticholinergics that lasted at least 1 year (including 2 published since the 2007 review) found little to no improvement in exacerbations, health-related quality of life, COPD hospitalizations, or mortality. Therefore, there is limited and conflicting evidence of health benefits resulting from initiation of inhaled bronchodilators (anticholinergics or long-acting  $\beta$ -agonists) in symptomatic patients with FEV1 between 60% and 80% predicted as documented by spirometry. Individual patients may benefit from the therapy and may show improvement in their respiratory symptoms. However, the duration of maintenance therapy and the frequency of reevaluation once a patient is receiving therapy are unknown because evidence is limited. Further research is needed to evaluate the health benefits of inhaled therapies (anticholinergics or long-acting  $\beta$ -agonists) in symptomatic patients with FEV1 between 60% and 80% predicted. The mean FEV1 was less than 60% predicted in the majority of the trials that evaluated the management of COPD. Monotherapy with a long-acting inhaled  $\beta$ -agonist or a long-acting inhaled anticholinergic is beneficial in reducing exacerbations and improving health-related quality of life. Evidence was inconclusive regarding the effect of inhaled agents (anticholinergics and long-acting  $\beta$ -agonists) on mortality, hospitalizations, and dyspnea. This recommendation does not address the occasional use of short-acting inhaled bronchodilators for acute symptom relief. (Qaseem et al, 2011)

The consistency of studies reviewed in the GOLD report was not addressed, but there is some specific information regarding Evidence Category A:

Sources of Evidence: Randomized controlled trials (RCTs). Rich body of data.

Definition: Evidence is from endpoints of well-designed RCTs that provide a consistent pattern of findings in the population for which the recommendation is made. Category A requires substantial numbers of studies involving substantial numbers of participants. (GOLD 2011)

**1c.8 Net Benefit** (*Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms*):

The ACP/ACCP/ATS/ERS guideline panel included representatives from each of the 4 collaborating organizations, and the resulting guideline represents an official and joint clinical practice guideline from those organizations. The guideline panel communicated via conference calls and e-mails. The members reached agreement and resolved any disagreements through facilitated discussion. The final recommendations were approved by unanimous vote.

The net benefit of studies reviewed in the GOLD report was not addressed, but there is some specific information regarding Evidence Category A:

Sources of Evidence: Randomized controlled trials (RCTs). Rich body of data.

Definition: Evidence is from endpoints of well-designed RCTs that provide a consistent pattern of findings in the population for which the recommendation is made. Category A requires substantial numbers of studies involving substantial numbers of participants. (GOLD 2011)

**1c.9 Grading of Strength/Quality of the Body of Evidence.** Has the body of evidence been graded? **Yes**

**1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:** The ACP/ACCP/ATS/ERS guideline panel included representatives from each of the 4 collaborating organizations, and the resulting guideline represents an official and joint clinical practice guideline from those organizations.

Potential Conflicts of Interest: Any financial and nonfinancial conflicts of interest of the group members were declared, discussed, and resolved. Dr. Wilt: Grant: American College of Physicians; Payment for manuscript preparation: American College of Physicians. Dr. Hanania: Consultancy: GlaxoSmithKline, Boehringer Ingelheim, Novartis, Pfizer, Sunovion, Pearl, Forest; Grants/grants pending (money to institution): GlaxoSmith-Kline, Boehringer Ingelheim, Novartis, Pfizer, Sunovion; Payment for lectures including service on speakers bureaus: GlaxoSmithKline, Astra-Zeneca, Boehringer Ingelheim, Merck. Dr. Criner:

Consultancy: Uptake Medical, PortAero, Pulmonx; Grants/grants pending (money to institution): Aeris Therapeutics, Emphyas Medica. Dr. van der Molen: Consultancy: MSD, AstraZeneca, GlaxoSmithKline, Nycomed; Grants/grants pending (money to institution): AstraZeneca, GlaxoSmithKline, Novartis; Payment for lectures including service on speakers bureaus: AstraZeneca, Nycomed, GlaxoSmithKline, MSD. Dr. Marciniuk: Board membership: American College of Chest Physicians, Chest Foundation, Lung Association of Saskatchewan, Canadian COPD Alliance, Canadian Thoracic Society; Consultancy (no payment received): Public Health Agency of Canada, Canadian Agency for Drugs and Technology in Health; Consultancy: Saskatchewan Medical Association; Consultancy (money to institution): AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Saskatchewan Health Quality Council, Novartis, Nycomed, Pfizer; Employment: University of Saskatchewan, Saskatoon Health Region; Grants/grants pending (money to institution): Canadian Institute of Health Research, AstraZeneca, GlaxoSmithKline, Lung Association of Saskatchewan, Nycomed, Pfizer, Novartis, Saskatchewan Health Research Foundation, Schering-Plough, Saskatchewan Ministry of Health; Payment for lectures including service on speakers bureaus: AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Pfizer, Lung Association of Saskatchewan, Canadian Thoracic Society, American Thoracic Society. Dr. Wedzicha: Grants/grants pending (money to institution): Boehringer Ingelheim; Board membership: GlaxoSmithKline, Novartis, Bayer, Pfizer, Medimmune/Astra-Zeneca, Danone/Nutricia, Nycomed; Consultancy: Chiesi; Consultancy (money to institution): Novartis; Grants/grants pending (money to institution): GlaxoSmithKline, Novartis, Chiesi, AstraZeneca, Johnson & Johnson; Payment for lectures including service on speakers bureaus: Boehringer Ingelheim, GlaxoSmithKline, Pfizer, Bayer, Nycomed, Chiesi; Travel/accommodations/meeting expenses unrelated to activities listed: Boehringer Ingelheim. Dr. Shekelle: Employment: Veterans Affairs Medical Center; Grants/grants pending (money to institution): Agency for Healthcare Research and Quality, National Institutes of Health, Veterans Administration; Royalties: UpToDate; Travel/accommodations/meetings expenses unrelated to activities listed: Travel to meetings sponsored by AHRQ, the Health Foundation, the University of Michigan, VA, Italian regional health authority, and RAND. Disclosures can also be viewed at [www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M11-0925](http://www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M11-0925).

The GOLD Science Committee includes physician representatives from around the globe, including Denmark, Spain, Italy, England, Germany, Japan, Canada, Washington, Michigan, and Texas; disclosure forms are posted on the GOLD website, [www.goldcopd.org](http://www.goldcopd.org).

1c.11 System Used for Grading the Body of Evidence: **GRADE**

1c.12 If other, identify and describe the grading scale with definitions:

1c.13 Grade Assigned to the Body of Evidence: **Moderate**

1c.14 Summary of Controversy/Contradictory Evidence: Adverse effects related to inhaled long-acting anticholinergics or long-acting  $\beta$ -agonists range from mild (for example, dry mouth) to potentially serious (for example, cardiovascular events). Pooled analyses of results from trials of monotherapy show no statistically significant differences in outcomes among various monotherapies. However, some of the large recent trials have shown that different monotherapies may have a greater effect on certain outcomes. These observed effects need to be confirmed with further comparative effectiveness studies. Clinicians should base selection of treatment from among various monotherapies on individual patient preferences, cost, and adverse effect profile. (Qaseem et al, 2011)

1c.15 Citations for Evidence other than Guidelines (*Guidelines addressed below*):

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):

Recommendation 3: For stable COPD patients with respiratory symptoms and FEV1 <60% predicted, ACP, ACCP, ATS, and ERS recommend treatment with inhaled bronchodilators (Grade: strong recommendation, moderate-quality evidence).

Recommendation 4: ACP, ACCP, ATS, and ERS recommend that clinicians prescribe monotherapy using either long-acting inhaled anticholinergics or long-acting inhaled  $\beta$ -agonists for symptomatic patients with COPD and FEV1 <60% predicted. (Grade: strong recommendation, moderate-quality evidence). Clinicians should base the choice of specific monotherapy on patient preference, cost, and adverse effect profile. (Qaseem et al, 2011)

Bronchodilator medications are given on either an as-needed basis or a regular basis to reduce or prevent symptoms (Evidence A).



Bronchodilator medications are central to symptom management in COPD. Inhaled therapy is preferred. Long-acting inhaled bronchodilators are convenient and more effective at producing maintained symptom relief than short-acting bronchodilators. (GOLD 2011)

**1c.17 Clinical Practice Guideline Citation:** Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Steven E. Weinberger, MD; Nicola A. Hanania, MD, MS; Gerard Criner, MD; Thys van der Molen, PhD; Darcy D. Marciniuk, MD; Tom Denberg, MD, PhD; Holger Schunemann, MD, PhD, MSc; Wisia Wedzicha, PhD; Roderick MacDonald, MS; and Paul Shekelle, MD, PhD, for the American College of Physicians, the American College of Chest Physicians, the American Thoracic Society, and the European Respiratory Society. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guideline Update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med.* 2011;155:179-191.

Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2011. Available at <http://www.goldcopd.org>.

**1c.18 National Guideline Clearinghouse or other URL:**

**1c.19 Grading of Strength of Guideline Recommendation.** Has the recommendation been graded? **Yes**

**1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:** [See 1.c.10](#)

**1c.21 System Used for Grading the Strength of Guideline Recommendation:** **GRADE**

**1c.22 If other, identify and describe the grading scale with definitions:**

**1c.23 Grade Assigned to the Recommendation:** **Strong**

**1c.24 Rationale for Using this Guideline Over Others:** It is the PCPI policy to use guidelines, which are evidence-based, applicable to physicians and other health-care providers, and developed by a national specialty organization or government agency. In addition, the PCPI has now expanded what is acceptable as the evidence base for measures to include documented quality improvement (QI) initiatives or implementation projects that have demonstrated improvement in quality of care.

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: **Moderate** 1c.26 Quality: **Moderate** 1c.27 Consistency: **Moderate**

Was the threshold criterion, *Importance to Measure and Report*, met?  
(1a & 1b must be rated moderate or high and 1c yes) Yes  No

Provide rationale based on specific subcriteria:

**For a new measure if the Committee votes NO, then STOP.**

**For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.**

## 2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (**evaluation criteria**)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

**S.1 Measure Web Page** (*In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? **Yes**

S.2 If yes, provide web page URL: [www.physicianconsortium.org](http://www.physicianconsortium.org)

2a. RELIABILITY. Precise Specifications and Reliability Testing: H  M  L  I

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement (*Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome*):

Patients who were prescribed an inhaled bronchodilator

2a1.2 Numerator Time Window (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*):

At least once during the measurement period

2a1.3 Numerator Details (*All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*):

Numerator Definitions:

Prescribed – Includes patients who are currently receiving medication(s) that follow the treatment plan recommended at an encounter during the reporting period, even if the prescription for that medication was ordered prior to the encounter.

For EHR:

See attached eMeasure

For Claims/Administrative Data:

To submit the numerator option for Patient Prescribed Inhaled Bronchodilator Therapy, report the following:

CPT II 4025F: Inhaled bronchodilator prescribed

2a1.4 Denominator Statement (*Brief, narrative description of the target population being measured*):

All patients aged 18 years and older with a diagnosis of COPD, who have an FEV1/FVC <70% and have symptoms (eg, dyspnea, cough/sputum, wheezing)

2a1.5 Target Population Category (*Check all the populations for which the measure is specified and tested if any*): Adult/Elderly Care

2a1.6 Denominator Time Window (*The time period in which cases are eligible for inclusion*):

12 consecutive months

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses*):

For EHR:

See attached eMeasure

For Claims/Administrative Data:

Patients aged >= 18 years on date of encounter

AND

Diagnosis for COPD (ICD-9-CM): 491.0, 491.1, 491.20, 491.21, 491.22, 491.8, 491.9, 492.0, 492.8, 496

Diagnosis for COPD (ICD-10-CM): J41.0, J41.1, J41.8, J42, J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9

AND

Patient encounter during the reporting period (CPT): 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245

AND

CPT II 3025F: Spirometry test results demonstrate FEV1/FVC < 70% with COPD symptoms (eg, dyspnea, cough/sputum, wheezing)

2a1.8 Denominator Exclusions (*Brief narrative description of exclusions from the target population*):

Documentation of medical reason(s) for not prescribing an inhaled bronchodilator; documentation of patient reason(s) for not prescribing an inhaled bronchodilator; documentation of system reason(s) for not prescribing an inhaled bronchodilator

**2a1.9 Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):*

The PCPI methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples may be provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. Where examples of exceptions are included in the measure language, these examples are coded and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception. Additional details by data source are as follows:

For EHR:  
See attached eMeasure

For Claims/Administrative Data:

Documentation of medical, patient, or system reason(s) for not prescribing an inhaled bronchodilator.

- Append modifier 1P to CPT Category II code 4025F to report documented medical reason(s) that appropriately exclude patients from the denominator: 4025F-1P
- Append modifier 2P to CPT Category II code 4025F to report documented patient reason(s) that appropriately exclude patients from the denominator: 4025F-2P
- Append modifier 3P to CPT Category II code 4025F to report documented system reason(s) that appropriately exclude patients from the denominator: 4025F-3P

**2a1.10 Stratification Details/Variables** *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):*

We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

**2a1.11 Risk Adjustment Type** *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13):* No risk adjustment or risk stratification    **2a1.12 If "Other," please describe:**

**2a1.13 Statistical Risk Model and Variables** *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.):*

No risk adjustment or risk stratification.

**2a1.14-16 Detailed Risk Model Available at Web page URL** (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

**2a1.17-18. Type of Score:** Rate/proportion

**2a1.19 Interpretation of Score** *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score):* Better quality = Higher score

**2a1.20 Calculation Algorithm/Measure Logic** (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

To calculate performance rates:

- 1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).
- 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.
- 3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator
- 4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception when exceptions have been specified [for this measure: medical reason(s), patient reason(s), or system reason(s)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation.

--Although the exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.

**2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:**

[Attachment](#)

[Measure Calculation\\_0102.pdf](#)

**2a1.24 Sampling (Survey) Methodology.** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

[Not applicable. The measure does not require sampling or a survey.](#)

**2a1.25 Data Source** (Check all the sources for which the measure is specified and tested). If other, please describe:

[Administrative claims](#), [Electronic Clinical Data](#), [Electronic Clinical Data : Electronic Health Record](#), [Electronic Clinical Data : Registry](#), [Paper Records](#)

**2a1.26 Data Source/Data Collection Instrument** (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): [Not Applicable](#)

**2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:**

**2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:**

**2a1.33 Level of Analysis** (Check the levels of analysis for which the measure is specified and tested): [Clinician : Group/Practice](#), [Clinician : Individual](#), [Clinician : Team](#)

**2a1.34-35 Care Setting** (Check all the settings for which the measure is specified and tested): [Ambulatory Care : Clinician Office](#)

**2a2. Reliability Testing.** (Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.)

**2a2.1 Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if

*a sample, characteristics of the entities included):*

Refer to the validity section for a description of the data sample for our EHR testing project.

**2a2.2 Analytic Method** *(Describe method of reliability testing & rationale):*

Refer to the validity section for a description of the analytic methods for our EHR testing project

**2a2.3 Testing Results** *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted):*

Refer to the validity section for the testing results for our EHR testing project

**2b. VALIDITY. Validity, Testing, including all Threats to Validity:** H  M  L  I

**2b1.1 Describe how the measure specifications** *(measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence:*

The evidence cited for this measure is directly related to the usefulness of prescribing an inhaled bronchodilator for adults with COPD and symptoms. There are no differences from the measure focus and measure target population.

**2b2. Validity Testing.** *(Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)*

**2b2.1 Data/Sample** *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):*

EHR Measure Validity

The measure was calculated using data collected using two different methods of collection:

- Automated EHR report
- Visual inspection of the medical record by professional data abstractors to capture the data elements to manually construct the performance

The data source was electronic health records in an ambulatory care setting.

The data sample came from 1 site representing an academic medical center located in an urban area.

The sample consisted of 106 patient encounters.

Data collected from patients seen between 01/01/2010-10/30/2011.

Visual inspection of the medical record was performed between 02/06/2012 and 02/10/2012.

Face Validity

An expert panel was used to assess face validity of the measure. This panel consisted of 12 members, with representation from a number of specialties, including internal medicine, methodology, pulmonology, family medicine, critical care medicine, emergency medicine, pharmacy science, nursing, and health plan representation.

Co-Chairs:

William E. Golden, MD, FACP (University of Arkansas College of Medicine)

Linus Santo Tomas, MD, MS (American College of Chest Physicians)

Members:

Bruce Bagley, MD (American Academy of Family Physicians)

Troy T. Fiesinger, MD (American Academy of Family Physicians)

David G. Jaimovich, MD (Society of Critical Care Medicine)

Bruce Krieger, MD (American Thoracic Society)

Thomas W. Lukens, MD, PhD, FACEP (American College of Emergency Physicians)

Deborah Patterson, MS, RN (Blue Cross Blue Shield Association)

Sam J. W. Romeo, MD, MBA (Tower Health & Wellness Center)

Ralph M. Schapira, MD (VA Medical Center)

Sean D. Sullivan, RPh, PhD (Department of Pharmacy, University of Washington)

Dennis E. Richling, MD (Midwest Business Group on Health)

**2b2.2 Analytic Method** *(Describe method of validity testing and rationale; if face validity, describe systematic assessment):*

EHR Measure Validity

Data from a performance report for the measure automatically-generated from the EHR (designed to collect the necessary data



elements to identify eligible cases and calculate the performance score) were compared to data elements found and scores calculated manually on visual inspection of the medical record by trained abstractors.

Data analysis included:

- Percent agreement at the denominator and numerator (exception - for those measures with exception)
- Kappa statistic to ensure that agreement rates are not a phenomenon of chance

Face Validity

Face validity of the measure score as an indicator of quality was systematically assessed as follows.

After the measure was fully specified, the expert panel (workgroup membership) was asked to rate their agreement with the following statement:

The scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality.

Scale 1-5, where 1= Strongly Disagree; 3=Neither Agree nor Disagree; 5= Strongly Agree

**2b2.3 Testing Results** (*Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment*):

EHR Measure Validity

This measure demonstrates slight agreement when comparing the automated EHR report to visual inspection.

Reliability: N, % Agreement, Kappa

Numerator: 106, 82.08%, kappa 0.1444\* (0.0000-0.3248 CI)

Denominator: 106, 100%, kappa non-calculable\*\* (non-calculable CI)

\*Refer to the Data Collection Strategy regarding measure implementation changes made at the site.

\*\*Kappa statistic could not be calculated because of complete agreement. Confidence intervals cannot be calculated because to do so would involve dividing by zero which cannot be done.

Face Validity

The results of the expert panel rating of the validity statement were as follows: N = 7; Mean rating = 4.57 and 100% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality

Frequency Distribution of Ratings

1 - 0 (Strongly Disagree)

2 - 0

3 - 0 (Neither Agree nor Disagree)

4 - 3

5 - 4 (Strongly Agree)

**POTENTIAL THREATS TO VALIDITY.** (*All potential threats to validity were appropriately tested with adequate results.*)

**2b3. Measure Exclusions.** (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

**2b3.1 Data/Sample for analysis of exclusions** (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

EHR Measure Validity

The data sample came from 1 site representing an academic medical center located in an urban area.

The sample consisted of 106 patient encounters.

Data collected from patients seen between 01/01/2010-10/30/2011.

Visual inspection of the medical record was performed between 02/06/2012 and 02/10/2012.

**2b3.2 Analytic Method** (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference*):  
Exceptions included medical, patient and system reasons. Exceptions were analyzed for frequency and variability across providers.

**2b3.3 Results** (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses*):  
**EHR Measure Validity**  
Although specifications allowed for documented exceptions, including medical, system and patient reasons, for the COPD: Bronchodilator Therapy measure, there were no documented exceptions in this project. All sampled patients were able to be assessed.

**2b4. Risk Adjustment Strategy.** (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

**2b4.1 Data/Sample** (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):  
This measure is not risk adjusted.

**2b4.2 Analytic Method** (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables*):  
This measure is not risk adjusted.

**2b4.3 Testing Results** (*Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata*):  
This measure is not risk adjusted.

**2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment:** As a process measure, no risk adjustment is necessary.

**2b5. Identification of Meaningful Differences in Performance.** (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

**2b5.1 Data/Sample** (*Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):  
CMS Physician Quality Reporting Initiative:  
80,785 cases were reported on for the 2008 program, the most recent year for which data is available.

The following information is for the 2009 program, the only year for which such data is available.

Clinical Condition and Measure: #52 Bronchodilator Therapy

# Eligible Professionals: 212,885

# Professionals Reporting: 1,336

% Professionals Reporting: 0.63%

# Professionals Reporting >=80% of eligible instances: 424

% Professionals Reporting >=80% of eligible instances: 31.74%

**2b5.2 Analytic Method** (*Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance*):

CMS Physician Quality Reporting Initiative:

The inter-quartile range (IQR) was calculated to determine the variability of performance on the measure.

**2b5.3 Results** (*Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance*):  
Scores on this measure: N = 80,785; Mean = 46.39%

10th percentile: 0.00%  
 25th percentile: 1.75%  
 50th percentile: 30.77%  
 75th percentile: 74.07%  
 90th percentile: 89.44%

The inter-quartile range (IQR) provides a measure of the dispersion of performance. The IQR is 72.32 and indicates that 50% of physicians have performance on this measure ranging from 1.75% and 74.07% and 10% of physicians have performance rates less than or equal to 0%. (1)

(1)Confidential CMS PQRI 2008 Performance Information by Measure. Jan-Sept TAP file.

**2b6. Comparability of Multiple Data Sources/Methods.** (If specified for more than one data source, the various approaches result in comparable scores.)

**2b6.1 Data/Sample** (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

The measure was calculated using data collected using two different methods of collection:

- Automated EHR report
- Visual inspection of the medical record by professional data abstractors to capture the data elements to manually construct the performance

**2b6.2 Analytic Method** (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):

Data from a performance report for the measure automatically-generated from the EHR (designed to collect the necessary data elements to identify eligible cases and calculate the performance score) were compared to data elements found and scores calculated manually on visual inspection of the medical record by trained abstractors.

Data analysis included:

- Percent agreement at the denominator and numerator (exception - for those measures with exception)
- Kappa statistic to ensure that agreement rates are not a phenomenon of chance

**2b6.3 Testing Results** (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):

EHR Measure Validity

This measure demonstrates slight agreement when comparing the automated EHR report to visual inspection.

Reliability: N, % Agreement, Kappa

Numerator: 106, 82.08%, kappa 0.1444\* (0.0000-0.3248 CI)

Denominator: 106, 100%, kappa non-calculable\*\* (non-calculable CI)

\*Refer to the Data Collection Strategy regarding measure implementation changes made at the site.

\*\*Kappa statistic could not be calculated because of complete agreement. Confidence intervals cannot be calculated because to do so would involve dividing by zero which cannot be done.

**2c. Disparities in Care:** H  M  L  I  NA  (If applicable, the measure specifications allow identification of disparities.)

**2c.1 If measure is stratified for disparities, provide stratified results** (Scores by stratified categories/cohorts): We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

**2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:**

The PCPI advocates that performance measure data should, where possible, be stratified by race, ethnicity, and primary language

to assess disparities and initiate subsequent quality improvement activities addressing identified disparities, consistent with recent national efforts to standardize the collection of race and ethnicity data. A 2008 NQF report endorsed 45 practices including stratification by the aforementioned variables.(1) A 2009 IOM report “recommends collection of the existing Office of Management and Budget (OMB) race and Hispanic ethnicity categories as well as more fine-grained categories of ethnicity(referred to as granular ethnicity and based on one’s ancestry) and language need (a rating of spoken English language proficiency of less than very well and one’s preferred language for health-related encounters).”(2)

References:

(1)National Quality Forum Issue Brief (No.10). Closing the Disparities Gap in Healthcare Quality with Performance Measurement and Public Reporting. Washington, DC: NQF, August 2008.

(2)Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. March 2010. AHRQ Publication No. 10-0058-EF. Agency for Healthcare Research and Quality, Rockville, MD. Available at: <http://www.ahrq.gov/research/iomracereport>. Accessed May 25, 2010.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met? (Reliability and Validity must be rated moderate or high) Yes  No

Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use (Check all the purposes and/or uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization)

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following questions): Public Reporting, Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H  M  L  I

(The measure is meaningful, understandable and useful for public reporting.)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.]

This measure is in current use in CMS’s PQRS program and has been continuously since 2007. The PCPI believes that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. Continued NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The PCPI believes that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. Continued NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): [This measure is being used in two Maintenance of Certification programs: ABIM's Chronic Obstructive Pulmonary Disease \(COPD\) PIM™ Practice Improvement Module Measures Catalogue, as well as AAFP's METRIC \(Measuring, Evaluating and Translating Research into Care\) program, which qualifies for MOC Part IV.](#)

3b. Usefulness for Quality Improvement: H  M  L  I

(The measure is meaningful, understandable and useful for quality improvement.)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):

[For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

This measure is being used in ABIM's Chronic Obstructive Pulmonary Disease(COPD) PIM™ Practice Improvement Module Measures Catalogue, as well as AAFP's METRIC (Measuring, Evaluating and Translating Research into Care) program, which qualifies for MOC Part IV. All PCPI measures are suitable for use in quality improvement initiatives and are made freely available on the PCPI website and through the implementation efforts of medical specialty societies and other PCPI members. The PCPI strongly encourages the use of its measures in QI initiatives and seeks to provide information on such initiatives to PCPI members.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results:

The PCPI believes that the use of PCPI measures in quality improvement initiatives is a beneficial way to gather scientific data with which to improve physician performance. This is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this quality improvement objective.

Overall, to what extent was the criterion, *Usability*, met? H  M  L  I

Provide rationale based on specific subcriteria:

#### 4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H  M  L  I

4a.1-2 How are the data elements needed to compute measure scores generated? (Check all that apply).

Data used in the measure are:

[generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition](#)

4b. Electronic Sources: H  M  L  I

4b.1 Are the data elements needed for the measure as specified available electronically (Elements that are needed to compute measure scores are in defined, computer-readable fields): [ALL data elements in electronic health records \(EHRs\)](#)

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H  M  L  I

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:

[We are not aware of any unintended consequences related to this measurement.](#)

4d. Data Collection Strategy/Implementation: H  M  L  I

A.2 Please check if either of the following apply (regarding proprietary measures):

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time



**and cost of data collection, other feasibility/implementation issues** (e.g., fees for use of proprietary measures):  
 The agreement rate and kappa statistic are not indications of a measure problem rather a measure implementation problem. During the first six months of the data collection period, the site did not collect the "documentation of presence of symptoms" in a discrete or searchable field. These findings were generally documented in the history and physical note. After an assessment of its collection methods, the site created a documentation template to capture the components of the numerator.

Overall, to what extent was the criterion, *Feasibility*, met? H  M  L  I   
 Provide rationale based on specific subcriteria:

### OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes  No   
 Rationale:

**If the Committee votes No, STOP.**  
**If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.**

### 5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures (either same measure focus or target population) or competing measures (both the same measure focus and same target population), list the NQF # and title of all related and/or competing measures:  
 0549 : Pharmacotherapy Management of COPD Exacerbation (PCE)  
 0628 : COPD with Exacerbations – Use of Long-Acting Bronchodilator Therapy

#### 5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as [NQF-endorsed measure\(s\)](#):  
 Are the measure specifications completely harmonized? No

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

These measures have distinct differences in their denominators and numerators. First, our measure is broader in denominator population than both the related measures, being for all patients age 18 years and older with a diagnosis of COPD and symptoms (eg, dyspnea, cough/sputum, wheezing), while 0549 and 0628 are both for patients age 40 years and older with COPD exacerbations, indicated by NCOA as an acute inpatient discharge or ED encounter with a principal diagnosis of COPD. Our measure is more consistent with COPD guidelines, which do not state an age to start prescribing an inhaled bronchodilator; rather, the guidelines recommend inhaled bronchodilators as a cornerstone of COPD symptom management for adults of all ages, and not only after COPD exacerbations. Our measure encourages the regular prescription of an inhaled bronchodilator to assist patients in routine management of COPD symptoms, which should reduce COPD exacerbations and inpatient hospitalizations. Second, our measure's numerator is more flexible than either 0549 or 0628, allowing an inhaled bronchodilator prescription anytime during the one-year measurement period, rather than 0549's requirement that a systematic corticosteroid prescription be dispensed within 14 days and a bronchodilator prescription be dispensed within 30 days, or 0628's requirement that a long acting bronchodilator prescription refill be dispensed within 6 months.

#### 5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s):  
 Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):  
 N/A

### CONTACT INFORMATION

<p><b>Co.1 Measure Steward (Intellectual Property Owner):</b> American Medical Association - Physician Consortium for Performance Improvement, 515 N. State St., Chicago, Illinois, 60654</p>
<p><b>Co.2 Point of Contact:</b> Mark S., Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement, mark.antman@ama-assn.org, 312-464-5056-</p>
<p><b>Co.3 Measure Developer if different from Measure Steward:</b> American Medical Association - Physician Consortium for Performance Improvement, 515 N. State St., Chicago, Illinois, 60654</p>
<p><b>Co.4 Point of Contact:</b> Katherine, Ast, MSW, LCSW, Policy Analyst, Measure Development Operations Performance Improvement, katherine.ast@ama-assn.org, 312-464-4920-</p>
<p><b>Co.5 Submitter:</b> Katherine, Ast, MSW, LCSW, Policy Analyst, Measure Development Operations Performance Improvement, katherine.ast@ama-assn.org, 312-464-4920-, American Medical Association - Physician Consortium for Performance Improvement</p>
<p><b>Co.6 Additional organizations that sponsored/participated in measure development:</b></p>
<p><b>Co.7 Public Contact:</b> Mark S., Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement, mark.antman@ama-assn.org, 312-464-5056-, American Medical Association - Physician Consortium for Performance Improvement</p>

### ADDITIONAL INFORMATION

<p><b>Workgroup/Expert Panel involved in measure development</b></p> <p><b>Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.</b></p> <p>PCPI measures are developed through cross-specialty, multi-disciplinary work groups. All medical specialties and other health care professional disciplines participating in patient care for the clinical condition or topic under study are invited to participate as equal contributors to the measure development process. In addition, the PCPI strives to include on its work groups individuals representing the perspectives of patients, consumers, private health plans, and employers. This broad-based approach to measure development ensures buy-in on the measures from all stakeholders and minimizes bias toward any individual specialty or stakeholder group. All work groups have at least two co-chairs who have relevant clinical and/or measure development expertise and who are responsible for ensuring that consensus is achieved and that all perspectives are voiced.</p> <p>The Work Group Panel consisted of:</p> <p>Co-Chairs:</p> <p>William E. Golden, MD, FACP          Linus Santo Tomas, MD, MS</p> <p>Members:</p> <p>Bruce Bagley, MD (AAFP)          Troy T. Fiesinger, MD (AAFP)          David G. Jaimovich, MD (SCCM)          Bruce Krieger, MD (ATS)          Thomas W. Lukens, MD, PhD, FACEP (ACEP)          Susan Nedza, MD, MBA, FACEP (CMS)          Deborah Patterson, MS, RN (BCBSA)          Sam J. W. Romeo, MD, MBA          Ralph M Schapira, MD (VA)          Sean D. Sullivan, RPh, PhD          Dennis E. Richling, MD          Nancy Lawler, RN (Joint Commission)</p>
<p><b>Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:</b></p>
<p><b>Measure Developer/Steward Updates and Ongoing Maintenance</b></p>

Ad.3 Year the measure was first released: 2006

Ad.4 Month and Year of most recent revision: 12, 2011

Ad.5 What is your frequency for review/update of this measure? See Ad.9.

Ad.6 When is the next scheduled review/update for this measure? 12, 2012

Ad.7 **Copyright statement:** Physician Performance Measures (Measures) and related data specifications, developed by the Physician Consortium for Performance Improvement® (PCPI), are intended to facilitate quality improvement activities by physicians.

These measures are intended to assist physicians in enhancing quality of care. Measures are designed for use by any physician who manages the care of a patient for a specific condition or for prevention. These performance measures are not clinical guidelines and do not establish a standard of medical care. The PCPI has not tested its measures for all potential applications. The PCPI encourages the testing and evaluation of its measures.

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Ad.8 **Disclaimers:**

Ad.9 **Additional Information/Comments:** Coding/Specifications updates occur annually. The PCPI has a formal measurement review process that stipulates regular (usually on a three-year cycle, when feasible) review of the measures. The process can also be activated if there is a major change in scientific evidence, results from testing or other issues are noted that materially affect the integrity of the measure.

Date of Submission (MM/DD/YY): 10/18/2011

**Basic Measure Calculation:**

$$\frac{(N)}{(D) - (E)} = \%$$

The PCPI strongly recommends that exception rates also be computed and reported alongside performance rates as follows:

**Exception Calculation:**

$$\frac{(E)}{(D)} = \%$$

**Exception Types:**

E= E1 (Medical Exceptions) + E2 (Patient Exceptions) + E3 (System Exceptions)

**For patients who have more than one valid exception, only one exception should be counted when calculating the exception rate**

<p><b>Initial Patient Population (IPP)</b></p> <p><b>Definition:</b> The initial patient population identifies the general group of patients that the performance measure is designed to address; usually focused on a specific clinical condition (e.g., coronary artery disease, asthma). For example, a patient aged 18 years and older with a diagnosis of CAD who has at least 2 Visits during the measurement period.</p>	<p><b>Denominator (D)</b></p> <p><b>Definition:</b> The denominator defines the specific group of patients for inclusion in a specific performance measure based on specific criteria (e.g., patient's age, diagnosis, prior MI). In some cases, the denominator may be identical to the initial patient population.</p>	<p><b>Numerator (N)</b></p> <p><b>Definition:</b> The numerator defines the group of patients in the denominator for whom a process or outcome of care occurs (e.g., flu vaccine received).</p>	<p><b>Denominator Exceptions (E)</b></p> <p><b>Definition:</b> Denominator exceptions are the valid reasons why patients who are included in the denominator population did not receive a process or outcome of care (described in the numerator). Patients may have Denominator Exceptions for medical reasons (e.g., patient has an egg allergy so they did not receive flu vaccine); patient reasons (e.g., patient declined flu vaccine); or system reasons (e.g., patient did not receive flu Vaccine due to vaccine shortage). These cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported. This group of patients constitutes the Denominator Exception reporting population – patients for whom the numerator was not achieved and there is a valid Denominator Exception.</p>
<p>Find the patients who meet the Initial Patient Population criteria (IPP)</p>	<p>Find the patients who qualify for the denominator (D):</p> <ul style="list-style-type: none"> <li>○ From the patients within the Patient Population criteria (IPP) select those people who meet Denominator selection criteria.</li> </ul> <p>(In some cases the IPP and D are identical).</p>	<p>Find the patients who qualify for the Numerator (N):</p> <ul style="list-style-type: none"> <li>○ From the patients within the Denominator (D) criteria, select those people who meet Numerator selection criteria.</li> <li>○ Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator</li> </ul>	<p>From the patients who did not meet the Numerator criteria, determine if the patient meets any criteria for the Denominator Exception (E1 + E2+E3). If they meet any criteria, they should be removed from the Denominator for performance calculation. As a point of reference, these cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported.</p>