NATIONAL QUALITY FORUM

1030 15TH STREET, NW, SUITE 800
WASHINGTON, DC 20005
202 783-1300 MAIN 783-3434 FAX

TO: Consensus Standards Approval Committee

FR: Helen Burstin, MD, MPH

SU: Letters of Appeal on Pulmonary and Critical Care Measure

DA: October 1, 2012

A letter of appeal was submitted regarding measure ***102: COPD: inhaled bronchodilator therapy*** endorsed in the *Pulmonary and Critical Care Endorsement Maintenance* project. The letter was submitted by Forest Research Institute, Inc. In accordance with the NQF CDP, this measure was evaluated and recommended by the NQF Pulmonary and Critical Care Measures Steering Committee and released for member and public comment. The committee recommendations and member voting results were reviewed by the CSAC. The CSAC recommended the measures for endorsement and the Board of Directors endorsed the set of measures on July 31, 2012.

The following materials are attached for your reference:

- Appendix A: *102: COPD: inhaled bronchodilator therapy* measure specifications;
- Appendix B: Letter of Appeal (from Forest Research Institute, Inc.);
- Appendix C: Response from the measure developer (American Medical Association – Physician Consortium for Performance Improvement);
- Appendix D: Prior CSAC memo on the measure, including voting results.

The NQF Consensus Development Process version 1.9 includes an appeal process and states that "*anyone may register a request for reconsideration of an endorsed voluntary consensus standard by notifying the NQF in writing within 30 days of public notification that the voluntary consensus standard had been approved by the CSAC. For an appeal to be considered, the notification letter to the NQF must include information clearly demonstrating that the appellant has interests that are directly and materially affected by the NQF-endorsed voluntary consensus standard(s), and that the NQF decision has had (or will have) an adverse effect on those interests. Appeals will be reviewed by NQF staff and management, who may consult with the project's technical advisors, Steering Committee, and/or other sources, as appropriate, before a recommendation is provided to the CSAC and BoD. Following consultation with the CSAC, the BoD shall act on an appeal within seven calendar days of the CSAC's recommendation to BoD regarding the appeal. The result of this BoD action shall be promulgated in the same manner as*

the original decision. NQF will maintain a record of all appeals, as well as post them on the web site."

Subject of the Appeal
An appeal from Forest Research Institute, Inc. was received regarding the following measure:

> **102: COPD: inhaled bronchodilator therapy (American Medical Association – Physician Consortium for Performance Improvement)**
> *Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC < 70% and have symptoms who were prescribed an inhaled bronchodilator.*

Forest Research Institute, Inc requested that Tudorza™ and Pressair™ (aclidinium bromide inhalation powder) be included in the list of medications for this measure. The appellant's primary objection is that as the measure is currently written, patient access to all new treatments may be limited as healthcare professionals may be discouraged from trying new therapeutic options. As the company who manufactures and sells Tudorza™ and Pressair™, they are concerned that this will not only directly and materially impact Forest, but will also directly impact patients who suffer from COPD.

The appeal letter and the measure developer's response are attached (Appendices B and C). Please refer to the letters for a complete discussion. Verbatim portions of the appeal letter are verbatim excerpted below.

- On July 23, 2012, Forest Laboratories, Inc. received approval from the U.S. Food and Drug Administration (FDA) for Tudorza™ Pressair™ (aclidinium bromide inhalation powder). Tudorza™ Pressair™ is indicated for the long-term maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema.
- NQF measure 0102: COPD: inhaled bronchodilator therapy is one of the NQF Pulmonary and Critical Care measures, which were endorsed on July 31, 2012. This measure was undergoing maintenance and endorsement prior to the approval of Tudorza™ Pressair™. Since NQF's goal is to ensure that measures reflect current knowledge and state-of-the-art, high quality care, we respectfully request the addition of Tudorza™ Pressair™ to the measure.
- Because the Centers for Medicare & Medicaid Services (CMS) has proposed to use this measure under its Physician Quality Reporting System as an individual quality measure available for reporting via claims, registry, Electronic Health Records (EHR) or Group Practice Reporting Option (GPRO) web-interface for 2013 and beyond, adherence to this measure, as it is currently written, not currently including all

approved therapeutic options, has the potential to adversely impact both patients with COPD as well as Forest.

Response

Evaluation of Measure During the Consensus Development Process

0102 COPD: inhaled bronchodilator therapy
Status: Maintenance, Original Endorsement: Aug 10, 2009 **Description:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC < 70% and have symptoms who were prescribed an inhaled bronchodilator **Numerator Statement:** Patients who were prescribed an inhaled bronchodilator **Denominator Statement:** 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) **Exclusions:** 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 **Adjustment/Stratification:** No risk adjustment or risk stratification; No risk adjustment or risk stratification. 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. **Level of Analysis:** Clinician : Group/Practice, Clinician : Individual, Clinician : Team **Type of Measure:** Process **Data Source:** Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records Retooled eMeasure **Measure Steward:** American Medical Association – Physician Consortium for Performance Improvement
IMPLEMENTATION COMMENTS The American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC): None of the QIC members use this measure at their institution and have never seen any data related to this measure. The QIC questions whether or not this measure sees widespread use.
Steering Committee Evaluations
Importance to Measure and Report (***based on decision logic***)**: PASSED all three sub-criteria.** **1a. Impact: H-18; M-2; L-0; I-0**; 1b**. Performance Gap: H-13; M-4; L-0; I-0** **Rationale:** • 1a: Measure focuses on high impact condition affecting 12M Americans and costing $18B per year. • 1b: The develoepr reported that this measure was used in the CMS Physician Quality Reporting Initiative/System (PQRS) in the: 2007 through 2011 claims option; 2009 through 2011 registry option; and the 2011 group practice reporting II option. In the 2008 data 53.61% of patients reported on did not meet the measure. **1c. Evidence** (*based on decision logic*): **Y-17; N-1** **Rationale:** • Agree with developer's assessment of evidence. The measure includes the range of 60-70% FEV1/FVC ratio for which the evidence is less than clear. • This is the GOLD crieria. • Data showing that long-acting beta agonists (LABAs) reduce FEV1 decline are few. There is limited performance data for the 60-80% range for FEV1/FVC ratio population.

2. Scientific Acceptability of Measure Properties (***based on decision logic***)**: PASSED reliability and validity**.
2a. Reliability: H-7; M-11; L-0; I-0 2b**. Validity: H-14; M-4; L-0; I-0**
Rationale:
• Measure includes eSpecifications. Tested in EHRs only.
  ○ The Committee agrees with need for stratification for disparities.
  ○ CPAP is included in mechanical ventilation – captures both invasive and non-invasive ventilation.

3. Usability: H-15; M-3; L-0; I-0 (*Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)* **Rationale:**

0102 COPD: inhaled bronchodilator therapy

- This measure is in current use in CMS´s PQRS program and has been continuously since 2007.
- 3a: History of use in certification and public reporting demonstrate usability.
- 3b: Lack of evidence that measure is currently informing quality improvement.

4. Feasibility: H-15; M-4; L-0; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Currently in use in PQRS using a variety of data sources
- EHR specifications exist.

Steering Committee Assessment of Criteria Met/Suitable for Endorsement: Y-18; N-0

Rationale:

- There is good evidence that bronchodilators improve function and there is a good data to suggest that people who meet the individual criteria are not getting bronchodilators.
- Measure is in use; retooled eMeasure.

RECOMMEND FOR ENDORSEMENT

Public & Member Comment

Comments themes included:

- Suggest changing the denominator of this measure to patients with an FEV1 <60% of predicted, thus brining it in line with the most current guidelines. Concern that the measure as written would penalize physicians even when their practice aligns with current clinical practice guidelines.
  Developer response: This measure was originally developed prior to the 2011 ACP, ACCP, ATS, and ERS guideline recommendation of treatment with inhaled bronchodilators for stable COPD patients with respiratory symptoms and FEV1 <60% predicted. The PCPI agrees that the measure should be brought in line with the most current guidelines and will bring back the suggested measure change to our COPD Work Group for proposed revision.

- Recommendation that the medications and/or drug classes included in these measures be included as part of the NQF technical specifications. Should the measure developer not specify these, BIPI suggests that this level of detail be a requirement for measure submissions.
- **NQF response:** The complete specifications for all measures as submitted by the developers are included in Appendix A:Technical Specifications in the draft report.

- Questioning the reference for the FEV1 <70% figure.
  Developer response: Thank you for your comment. This measure was originally developed prior to the 2011 ACP, ACCP, ATS, and ERS guideline recommendation of treatment with inhaled bronchodilators for stable COPD patients with respiratory symptoms and FEV1 <60% predicted. The PCPI agrees that the measure should be brought in line with the most current guidelines and will bring back the suggested measure change to our COPD Work Group for proposed revision.

Committee response:

The Committee reviewed the comments and the developer responses and made no changes to their reocmmendations.

During the comment period on the report, NQF received 139 comments from 20 member organizations. Six comments were in reference to measure 102; two of these comments were in support of the measure; four raised concerns around specifications or coding; and one lack of support, stating that the measure represents the standard of care. The appellant did not submit a comment in reference to this measure.

NQF Member Voting

The 30-day voting period for the Pulmonary and Critical Care Endorsement Maintenance project closed on July 12, 2012.

Measure #0102 COPD: inhaled bronchodilator therapy

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	1	1	0	2	50%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**1**	**2**	**10**	**88%**
Percentage of councils approving (>50%)					80%
Average council percentage approval					90%

*equation: Yes/ (Total - Abstain)

Response from the measure developer

On September 27, 2012, the American Medical Association-convened Physician Consortium for Performance Improvement (AMA-PCPI) responded to the letter of appeal as follows:

> *"Our clinical experts have determined that the newly approved (ie, granted FDA approval July 23, 2012) drug, aclidinium bromide inhalation powder (classified as a long-acting muscarinic antagonist [LAMA]) would be appropriate to add to the AMA-PCPI Bronchodilator Value Set. As such, over the course of the next month or so, we will be working to evaluate and determine the appropriate LAMA RXNORM concepts to add to our value set accordingly. Once complete, we will work on updating the eSpecification and will provide this to you by 11.1.12.*
>
> *Lastly, it is important to note that AMA-PCPI protocol is to include the Semantic Clinical Drug Name in our supporting specifications rather than the Brand Name. As such, we will not be including the Brand Names Tudorza™ and Pressair™, as referenced in the appeal letter by Forest Laboratories, Inc., but the generic (ie, Semantic Clinical Drug) drug name will be included."*

Discussion

FDA approval of the drug Tudorza™ Pressair™ occurred very recently, after the Steering Committee evaluation of the measure and the CSAC review. The primary issue is the timing of updating of measures that specify certain medications when new drugs become available. Measure developers have different processes and timetables for routine updating of measures that may not be known by NQF, pharmaceutical companies or the general public. The appellant was concerned that the measure would not be updated in time for the planned implementation by CMS in 2013. The developer has agreed to update the measure by November 1.

Appendix A – Measure Specifications

	0102 COPD: Inhaled bronchodilator therapy
Status	Maintenance, Original Endorsement: Aug 10, 2009, Most Recent Endorsement: Aug 10, 2009
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)
Description	Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC < 70% and have symptoms who were prescribed an inhaled bronchodilator
Type	Process
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records Not Applicable
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office
Numerator Statement	Patients who were prescribed an inhaled bronchodilator
Numerator Details	**Time Window:** At least once during the measurement period 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
Denominator Statement	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)
Denominator Details	**Time Window:** 12 consecutive months 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)
Exclusions	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
Exclusion Details	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

	0102 COPD: Inhaled bronchodilator therapy
	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
Risk Adjustment	No risk adjustment or risk stratification No risk adjustment or risk stratification.
Stratification	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.
Type Score	Rate/proportion better quality = higher score
Algorithm	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. Attachment Measure Calculation_0102.pdf
Copyright/ Disclaimer	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. Measures are subject to review and may be revised or rescinded at any time by the PCPI. The measures may not be altered without the prior written approval of the PCPI. Measures developed by the PCPI, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, eg, use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of measures for commercial gain, or incorporation of the measures into a product or service that is sold, licensed or distributed for commercial gain. Commercial uses of the measures require a license agreement between the user and American Medical Association, on behalf of the PCPI. Neither the PCPI nor its members shall be responsible for any use of these measures. THE MEASURES ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND

	0102 COPD: Inhaled bronchodilator therapy
	Limited proprietary coding is contained in the Measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. The AMA, the PCPI and its members disclaim all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specifications. CPT® contained in the Measure specifications is copyright 2004- 2010 American Medical Association. LOINC® copyright 2004-2010 Regenstrief Institute, Inc. This material contains SNOMED Clinical Terms® (SNOMED CT®) copyright 2004-2010 International Health Terminology Standards Development Organisation. All Rights Reserved.

Forest Research Institute, Inc.
A Subsidiary of Forest Laboratories, Inc.
Harborside Financial Center • Plaza V, Suite 1900 • Jersey City, NJ 07311 • P: 201-427-8000

August 30, 2012

Reva Winkler, MD, MPH
Senior Director, Performance Measures
National Quality Forum
1030 15th Street, NW, Suite 800
Washington, DC 20005

Dear Dr. Winkler:

Forest Laboratories, Inc. (Forest) is a U.S.-based pharmaceutical company with a long track record of building partnerships and developing and marketing products that improve patient care and clinical outcomes.

Forest supports NQF's mission to improve quality of American healthcare by endorsing national consensus standards for measuring and publicly reporting on performance.

We appreciate the opportunity to participate in the National Quality Forum's appeal process for Measure 0102: *COPD: inhaled bronchodilator therapy (AMA-PCPI).* This measure does not currently include all approved standards of care. We request that Tudorza™ Pressair™ (aclidinium bromide inhalation powder) be included in the list of medications for this measure. As the measure is currently written, patient access to all new treatments may be limited as healthcare professionals may be discouraged from trying new therapeutic options. As the company who manufactures and sells Tudorza™ Pressair™ (aclidinium bromide inhalation powder), we are concerned that this will not only directly and materially impact Forest, but will also directly impact patients who suffer from Chronic Obstructive Pulmonary Disease.

Chronic Obstructive Pulmonary Disease (COPD) is a common, progressive, and debilitating lung disease characterized by persistent airflow limitation that makes it hard to breathe; it is currently the third leading cause of mortality in the US.[1] Characteristic symptoms include breathlessness, excessive production of sputum, and a chronic cough. Even with available COPD treatments, patients with COPD continue to experience bronchospasm and other COPD symptoms. Therefore, COPD patients may benefit from having access to all available COPD therapies.

On July 23, 2012, Forest Laboratories, Inc. received approval from the U.S. Food and Drug Administration (FDA) for Tudorza™ Pressair™ (aclidinium bromide inhalation powder). Tudorza ™Pressair ™ is indicated for the long-term maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema.[2] It is not indicated for the initial treatment of acute episodes of bronchospasm (i.e., rescue therapy.) Tudorza™ Pressair™ 400 mcg is inhaled (one inhalation, twice daily) long-acting anticholinergic, also referred to as a long-acting muscarinic antagonist (LAMA). Tudorza™ Pressair™ produces bronchodilation by

inhibiting acetylcholine's effect on muscarinic receptors in the airway smooth muscle in the lungs. Tudorza™ Pressair™, the second approved LAMA, has been shown in clinical studies to improve lung function (based on morning pre-dose [trough] FEV_1 and peak FEV_1), reduce dyspnea (based on the Transition Dyspnea Index [TDI]), and reduce the requirement for the use of rescue short- acting beta agonists. Inhaled medications, including Tudorza Pressair, may cause paradoxical bronchospasm. If this occurs, treatment with Tudorza Pressair should be stopped and other treatments considered. Tudorza Pressair should be used with caution in patients with narrow angle glaucoma or urinary retention. Patients should be instructed to consult a physician immediately should any signs or symptoms of narrow-angle glaucoma or prostatic hyperplasia or bladder-neck obstruction develop. Immediate hypersensitivity reactions may occur after administration of Tudorza Pressair. Given the structural similarity of the formula of atropine to aclindinium, patients with a history of hypersensivity reactions to atropine should be monitored for similar hypersensitivity reactions to Tudorza Pressair. Tudorza Pressair should be used with caution in patients with severe hypersensitivity to milk proteins. The most common adverse reactions (> or equal to 3% incidence and greater than placebo) were headache, nasopharyngitis and cough..[2]

Tudorza™ Pressair™ is administered via the Pressair™ inhaler, a preloaded, breath-actuated, multidose dry powder inhaler designed for the effective and reliable delivery of Tudorza™ Pressair™.[3,4,5,6] The Pressair™ inhaler provides accurate and consistent dose delivery of Tudorza™ Pressair™ to patients, delivering the target dose at flow rates as low as 35 L/min.[2] The Pressair™ inhaler also has several key attributes that distinguish it from other inhalers. It provides both visual and acoustic feedback to reassure patients that they have taken their medication correctly, including a colored control window that changes from green to red with an audible click on successful actuation of each dose. [2]

Given the seriousness of this disease, Forest supports measures that positively impact the healthcare of patients who suffer with COPD. We believe it is important to ensure these measures embody the best clinical practice. National Quality Forum Measure 0102: COPD: inhaled bronchodilator therapy (AMA-PCPI) is one of the NQF Pulmonary and Critical Care Measures which were endorsed on July 31, 2012. This measure was undergoing maintenance and endorsement prior to the approval of Tudorza™ Pressair™. Since NQF's goal is to ensure that measures reflect current knowledge and state-of-the-art, high quality care, we respectfully request the addition of Tudorza™ Pressair™ to the measure.

Because the Centers for Medicare & Medicaid Services (CMS) has proposed to use this measure under its Physician Quality Reporting System as an individual quality measure available for reporting via claims, registry, Electronic Health Records (EHR) or Group Practice Reporting Option (GPRO) web-interface for 2013 and beyond,[7] adherence to this measure, as it is currently written, not currently including all approved therapeutic options, has the potential to adversely impact both patients with COPD as well as Forest. We urge NQF to work with the measure developer to ensure that measure 0102 appropriately incorporates Tudorza™ Pressair™ prior to the January 1, 2013, effective date of CMS' rule.

We greatly appreciate the opportunity to submit information for your consideration. Should you have additional questions regarding Tudorza™ Pressair™ or on the information provided, please contact either Medical Information Communications at (800) 678-1605, ext.66297 or me at (201) 427-8203.

Thank you for your consideration,

Kim Thacker, MD
VP, Medical Affairs and Health Outcomes
Forest Research Institute, Inc.

References:

1. Centers for Disease Control and Prevention and National Center for Health Statistics. *National Vital Statistics Reports.* Hyattsville, MD. U.S. Department of Health and Human Services. 2012.

2. Tudorza Pressair [package insert]. St. Louis, MO: Forest Pharmaceuticals, Inc.; July 2012.

3. Block K, Folger S, Fyrnys B, Kurtz S. Delivered dose and fine particle dose of aclidinium 200 mcg via the Genuair inhaler are independent of the flow rate within the working area of the device. Presented at European Respiratory Society Annual Congress; September 18-22, 2010. Barcelona, Spain.

4. Fuhr R, Magnussen H, Singh D, de Miquel G, Caracta C, Garcia Gil E. Patient assessments of ease of use of Genuair® versus Aerolizer® and HandiHaler®. Poster presented at the European Respiratory Society Annual Congress; September 24-28, 2011. Amsterdam, The Netherlands.

5. Hass C, Engdahl K, Albert W, Setyawan J, Mateo N. Patient preferences and perceived ease of use in inhaler features: Genuair® vs other inhalers. Poster presented at the American College of Chest Physicians Annual Congress; October 30-November 4, 2010. Vancouver, BC, Canada.

6. Chrystyn H, Niederlaender C. The Genuair® inhaler: a novel, multidose dry powder inhaler. *Int J Clin Pract.* 2012 Mar;66(3):309-17.

7. See U.S. Centers for Medicare & Medicaid Services. Table 32: Proposed PQRS Individual Quality Measures Available for Reporting via Claims, Registry, EHR, or GRPO Web-Interface for 2013 and Beyond. 77 Fed. Reg. 44722, at 44855 (July 30, 2012).

Appendix C- Appeal Response

TO: Kathryn Streeter

FROM: Katherine Ast

RE: Measure 102: Appeal Response

Hi Katie,

I'm writing to let you know that we have received feedback from our clinical experts regarding the NQF Appeal letter from Forest Laboratories, Inc. Our clinical experts have determined that the newly approved (ie, granted FDA approval July 23, 2012) drug, aclidinium bromide inhalation powder (classified as a long-acting muscarinic antagonist [LAMA]) would be appropriate to add to the AMA-PCPI Bronchodilator Value Set. As such, over the course of the next month or so, we will be working to evaluate and determine the appropriate LAMA RXNORM concepts to add to our value set accordingly. Once complete, we will work on updating the eSpecification and will provide this to you by 11.1.12.

Lastly, it is important to note that AMA-PCPI protocol is to include the Semantic Clinical Drug Name in our supporting specifications rather than the Brand Name. As such, we will not be including the Brand Names Tudorza™ and Pressair™, as referenced in the appeal letter by Forest Laboratories, Inc., but the generic (ie, Semantic Clinical Drug) drug name will be included.

Please let us know if you have any questions.

Regards,
Katherine

NATIONAL QUALITY FORUM

TO: Consensus Standards Approval Committee (CSAC)

FR: Reva Winkler, Kathryn Streeter and Jessica Weber

RE: NQF Member Voting for *Pulmonary and Critical Care Endorsement Maintenance*

DA: July 11, 2012

The CSAC will review the recommendations from the project, *Pulmonary and Critical Care Endorsement Maintenance* during the July 11-12, 2012, in-person meeting. This memo includes the list of recommended measures and summary information about the project. Member voting closes on Tuesday, July 10, 2012. The voting results will be provided at the in-person meeting. The individual measure evaluation summary tables from the draft report are in the Appendix. The complete voting draft report and detailed measure information are available on the project webpage and via links throughout this memo.

CSAC ACTION REQUIRED

Pursuant to the Consensus Development Process (CDP), the CSAC may consider approval of 22 candidate consensus standards:

BACKGROUND

NQF has previously endorsed consensus standards to evaluate the quality of care for pulmonary and critical care. This project seeks to identify and endorse performance measures that could be used in accountability and public reporting in the following topic areas for adults and children in all settings of care: asthma; chronic obstructive pulmonary disease (COPD); pneumonia; dyspnea; pneumonia; and intensive/critical care.

PROCESS

This project followed the National Quality Forum's (NQF's) version 1.9 of the CDP. The Steering Committee met by conference calls in February 2012 and then in person on March 21-22, 2012, to evaluate the measures. The Committee met via conference call on June 21, 2012, to address the comments received during the NQF member and public comment period.

Pulmonary and Critical Care Endorsement Maintenance

	MAINTENANCE	NEW	TOTAL
Measures under consideration	35*	8	43
Withdrawn from consideration	8	0	8
Recommended	17	5	22
Not recommended	8	2	10
Reasons for Not Recommending	Importance – 6 Scientific Acceptability – 2 Overall – 0 Competing measure – 0	Importance – 1 Scientific Acceptability – 1 Overall – 0 Competing measure – 0	

***Includes two measures that are paired**

Addendum

For three measures comments have prompted actions that will require several weeks to resolve. To accommodate these issues, primarily addressing harmonization and exclusions for planned readmissions, an addendum to the Pulmonary and Critical Care report will be available for NQF member voting in several weeks on the following three measures:

- ***0356: PN3a--Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival***
- ***0506 Thirty-day all-cause risk standardized readmission rate following pneumonia hospitalizations***
- ***1891 Thirty-day all-cause risk standardized readmission rate following COPD hospitalizations***

The CSAC will review the voting results on the August 13 conference call.

MEASURE EVALUATION

The measures were evaluated against the 2011 measure evaluation criteria. The Steering Committee encountered several overarching issues during its discussions and evaluations of the measures. These issues were factored into the Committee's ratings and recommendations for multiple measures and are explained below.

Incomplete titles and descriptions

The Committee noted that many measure titles are vague and not informative or the descriptions are incomplete as to the population being measured and the focus of the measure. The Committee urges developers to use thoughtful measure titles that convey the measure's intent to general audiences and descriptions that provide enough detail (e.g., population, setting, measure

focus) to inform audiences what information the measure results will provide. The Committee specifically noted that clearly identifying whether the target population is in-patient or ambulatory is critical.

Evidence and guidelines

Many of the measure submissions referenced guidelines as the evidence for a process measure without summarizing the actual body of evidence on which the guideline is based. NQF's 2011 Evidence Task Force report specifies evaluation of the quantity, quality and consistency of the body of evidence. The Committee struggled with evaluating measures against the evidence criteria when this information was not provided.

Data on current performance and disparities

The Committee expected more detailed information on current performance than was typically submitted. A mean was not considered to be not sufficient information to assess current performance of the measure. Data on the number of facilities or practices and the number of patients, the range of results and the percentiles are critical to understanding the opportunity for improvement. Very little data was submitted on the use of the measures to identify disparities. A greater emphasis should be made to collect data on disparities when the measures are tested and implemented.

Asthma versus Chronic Obstructive Pulmonary Disease (COPD)

The Committee noted that there is a spectrum of airways diseases from asthma to COPD. Identifying patients with asthma or COPD is confounded by the overlapping pathophysiology of airway disease and the reliability of coding for the diagnosis. Measures attempt to address the sensitivity of the diagnosis by using age criteria, such as up to age 64 years for asthma and 40 years and above for COPD. Some Committee members expressed concern with lower age inclusions for measures for COPD asking whether this is a different population with different therapeutic expectations. Similarly, the lack of measures for asthma for the Medicare population is explained by the difficulty in determining who has asthma or COPD or other co-morbidities in that population.

Reserve status

Two endorsed measures, **0143 CAC-1: Relievers for inpatient asthma** and **0144 CAC-2 Systemic corticosteroids for inpatient asthma,** were found to have very high compliance at 100% reported on Hospital Compare . The developer noted that only a small number of hospitals are reporting on the measure so additional opportunity may exist if new hospitals are recruited to report on their performance. The Committee determined that these measures met the criteria for "endorsed with reserve status." Endorsement with reserve status requires that the measure meet all other criteria except for *1b. Opportunity for Improvement*. Reserve status

applies only to highly credible, reliable, and valid measures that have high levels of performance due to quality improvement actions (often facilitated or motivated through public reporting and other accountability programs).

Complex proprietary measures

Two measures, **0334 PICU Severity-adjusted length of stay** and **0343 PICU Standardized Mortality Ratio,** were submitted that use a proprietary risk-adjustment model that is only available to participants in a private registry. NQF's Measure Steward Agreement allows for complex proprietary to be submitted if the submission is accompanied by a statement of the participation fees which are considered in the evaluation of the feasibility of the measure. Details of the risk model were reviewed by the Steering Committee and are included in submission materials. The Committee rated the measures low on feasibility, but recommended the measures for continued endorsement because the measures use a highly credible and valid risk model for pediatric intensive care.

COMMENTS ON THE DRAFT REPORT AND THEIR DISPOSITION

NQF received 139 comments from a variety of stakeholders, including 20 member organizations, on measures both recommended and not recommended for endorsement as well as general comments on the draft report.

A table of complete comments submitted during the comment period, with the responses to each comment and the actions taken by the Steering Committee, is posted to the Pulmonary Endorsement Maintenance project page on the NQF website, along with the measure submission forms. The Steering Committee reviewed and responded to all comments received.

The Steering Committee reviewed the comments and focused its discussion on specific measures or topic areas with the most significant and recurring issues. Comments about specific measure specifications and rationale were forwarded to the measure developers, who were invited to respond.

COMMENT THEMES

In addition to many comments that support the recommendations of the Steering Committee, comments were received regarding:

1. Parsimony
2. Lack of Support for Recommended Measures
3. Requests for Reconsideration of Measures not Recommended

4. Related and Competing Measures
5. Outcome measures
6. Questions on specifications or coding
7. Reserve status
8. Various measure-specific comments that may warrant Committee consideration

Theme 1- Parsimony

Several NQF members noted that "consumers and purchasers strive for parsimony in measurement because an abundance of measures present an unnecessary burden to the health care system. The pulmonary measures currently undergoing the maintenance review and initial endorsement processes unnecessarily overlap in their measure focus and target population, and are overly reliant on process measures."

Committee Response: NQF's portfolio of measures for pulmonary and critical care includes eight additional measures that are not currently under maintenance review. Appendix D of the draft report lists all the measures in the portfolio. Of those eight measures, six are outcome measures including measures of ED visits for asthma patients, function status and quality of life for COPD patients in pulmonary rehabilitation programs, mortality and length of stay measures for the adult ICU and potentially preventable complications for pneumonia patients. Overall there are a significant number of outcome measures in the pulmonary and critical care portfolio,

Addressing whether the measures should continue to be endorsed with the goal of a more parsimonious set for these conditions was discussed by the Committee and the related and competing measures are discussed in Theme 4.

Theme 2- Lack of Support for Recommended Measures

Comments indicated lack of support for several recommended measures:

- ***0356: PN3a--Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival***

Comments from APIC, SCCM and ACEP indicated lack of support for this measure, citing lack of any high level evidence that this process measure is directly linked to improved patient outcomes for pneumonia patients; the measure does not state that blood cultures should be obtained before the initiation of treatment; and the measure may create an

unnecessary distraction from the delivery of more important care that needs to be delivered in the ED or ICU settings for not supporting this measure.

ACTION TAKEN: After reviewing the comments and additional discussion with the measure developer, the Committee decided to reconsider their recommendation of the measure. The Committee reviewed the evidence that the process will improve outcomes again and then voted against recommending the measure for endorsement (YES – 5; NO - 10). This revised recommendation will be included in the addendum voting for the NQF membership.

Multiple comments were received on three pneumonia severity assessment measures:

1895: Assessment of Mental Status for Community-Acquired Bacterial Pneumonia

0232: Vital Signs for Community-Acquired Bacterial Pneumonia

0233: Assessment of Oxygen Saturation for Community-Acquired Bacterial Pneumonia for endorsement ***(not recommended)***

ACP questioned why mental status was selected as a specific element of pneumonia severity assessment as a measure, thereby suggesting this individual item is more important than a more comprehensive assessment utilizing a validated score. Other comments indicate that mental status and vital signs are very basic expectations of care and questions whether there is really a gap in these care processes. These factors should become part of composite measure that includes all elements of assessment by the physician and hospital. Another comment disagreed with not recommending measure 0233 because there is widespread evidence that the degree of O2 saturation influences morbidity and mortality and determination of whether a patient is hospitalized or admitted to the ICU.

ACTION TAKEN: After reviewing the comments, the Committee agreed that a composite measure would be preferable to individual measures. In the absence of a composite measure to recommend at this time, the Committee agreed to maintain their current recommendations, but indicated that at the next maintenance review individual measures should not be endorsed. The Committee also noted that the data on the opportunity for improvement for these measures was very limited and much better data is needed to understand the gap.

Theme 3- Requests for Reconsideration of Measures Not Recommended

Comments requested reconsideration of three measures:

- ***0338 CAC-3 Home management plan of care (HMPC) document given to patient /caregiver***

The comment suggests the measure should be reconsidered because it is important for care coordination efforts and there is a lack of quality measures addressing the high-priority area in the current NQF measures portfolio.

Committee Response: This measure did not meet the NQF criteria for evidence. The Committee noted the recent publication in JAMA by Morse in October 5, 2011 that found "Among children admitted to pediatric hospitals for asthma, there was high hospital-level compliance with CAC-1 and CAC-2 quality measures and moderate compliance with the CAC-3 measure but no association between CAC-3 compliance and subsequent ED visits and asthma-related readmissions". http://jama.ama-assn.org/content/306/13/1454.abstract

- ***0549 Pharmacotherapy management of COPD exacerbation (PCE)***

The developer requested reconsideration of this measure because they believe that the Committee discussed issues outside of the scope of the measure evaluation sub-criteria. For example, during the discussion of Importance, the SC discussion focused exclusively on the sub-criteria of validity with no further discussion of this measure's high impact, performance gap, and evidence.

Summary of Previous Committee Discussion: The Committee rated the sub-criteria for Importance high in all areas by large majorities and so the measure easily passed the Importance criterion despite questions of why there had been no improvement in performance over 3 years of data. The issues of concern to the Committee centered on the validity of the critical data elements of the numerator. The measure submission information did not include empiric validity testing of the numerator data elements or the measure score. Scientific acceptability is a must pass criterion and it was not further evaluated.

ACTION TAKEN: After reviewing the developer's letter, the Committee agreed that they had given a fair evaluation of the measure, as well as reconsideration following the in-person meeting. When the developer offered to provided recently discovered testing data from 2005 on the Committee call on June 21st, the Committee agreed it was too late in the process to accept additional information that could have been provided in the submission or at previous meetings and conference calls. The Committee encourages the developer to re-submit the measure at the next opportunity.

- ***0341 PICU Pain Assessment on Admissions***
- ***0342 PICU Periodic Pain Assessment***

The Children's Hospital Association requests reconsideration of these measures because there are very few endorsed measures available for pediatric inpatient care and these measures were included in the proposed rule for Stage 2 of Meaningful Use.

Committee Response: The Committee first recommended that the measures be combined as periodic assessment can easily include the first assessment on admission. On further evaluation of the measures the Committee found that there was no testing data or information addressing reliability or validity for the measure and therefore does not meet NQF's criteria for Scientific Acceptability.

Theme 4- Related and Competing Measures

Several commenters noted the number of overlapping measures recommended for asthma medication management and recommend reducing the number to achieve parsimony:

0036 Use of appropriate medications for people with asthma

0047 Asthma: Pharmacologic Therapy for Persistent Asthma

0548 Suboptimal Asthma Control (SAC) and Absence of Controller Therapy (ACT)

1799 Medication Management for People with Asthma (MMA)

1800 Asthma Medication Ratio (AMR)

Comments noted that neither 0036 nor 0047 reflect improvement or decline in the patient's condition, nor do they track how well asthma is managed over time; a single prescription is a very basic standard of care and more robust measures are indicated to assess control that is related to improved outcomes; and preference for medication dispensation (0036) rather than prescription (0047) though other commenters prefer prescribed.. Measures 1799 and 1800 are potentially more meaningful to consumers because they include a care management component and therefore a stronger link to improved outcomes. Some commenters questioned the evidence for the 50% and 75% thresholds in measure 1799 which seem arbitrary. Additionally, one commenter noted that an MPR of 0.50 for measure 1800 seems arbitrary though another commenter reported that a panel of experts from the ACAAI and AAAAI Joint Task Force, documented the correlation between a ratio > 0.5 and lower Emergency Department and Hospitalization rates for asthma The ratio measure was most discriminating if a denominator definition of one or more medical claims with a diagnosis of asthma plus 4 or more asthma medication dispensing events during the year prior to measurement was used. (Schatz M; et al Ann Allergy Asthma Immunol. 2009)

The developers for measures 0036 and 0047 submitted a plan for harmonization pending the approval of their respective measure development panels.

ACTION TAKEN:

- After reviewing the comments, particularly regarding parsimony, the Committee did not change their recommendations of the five asthma measures.
- The Committee recommended that full harmonization of measures 0036 and 0047 should occur by the next annual update to continue endorsement.

Comments supported harmonization of two measures for spirometry in COPD patients:

0091: COPD: spirometry evaluation

0577: Use of Spirometry Testing in the Assessment and Diagnosis of COPD

The developers for measures 0091 and 0577 submitted a plan for harmonization pending the approval of their respective measure development panels.

ACTION TAKEN: The Committee recommended that full harmonization of measures 0091 and 0577 should occur by the next annual update to continue endorsement.

Theme 5 - Outcome measures

Multiple comments from the American Hospital Association addressed several issues pertaining to the four outcome measures from CMS/Yale:

0506 Thirty-day all-cause risk standardized readmission rate following pneumonia hospitalizations

0468 Thirty-day all-cause risk standardized mortality rate following pneumonia hospitalizations

1891 Thirty-day all-cause risk standardized readmission rate following COPD hospitalizations

1893 Thirty-day all-cause risk standardized mortality rate following COPD hospitalizations

In a detailed comment letter, AHA urges the Committee to ask the developer to respond to the following issues:

- Failure to adjust for factors beyond the hospital's control such as patient characteristics, extreme circumstances, patient compliance and quality of post-acute care.

- Reliability – A recent CMS study required by the Accountable Care Act "shows the claims-based measures are unreliable." Additional reliability analyses are provided by KNG showing similar results.
- Harmonization with the recently endorsed measure *1789: Hospital-wide all-cause readmission measure* to exclude planned readmissions; harmonization of exclusions in the COPD measures compared to the pneumonia measures that include exclusions for discharged alive on day 0 or 1
- Exclusions for all Medicare patients in hospice rather than just FFS Medicare patients enrolled in hospice.

ACTION TAKEN:

- The Committee reviewed the AHA comments and the extensive responses provided by the developer. The Committee indicated that the responses adequately addressed the issues raised by AHA.
- The Committee supports the plan of Yale/CMS to include the algorithm for planned readmissions in measures 0506 and 1891 and looks forward to reviewing the additional information in the next few weeks. These two readmission measures will be voted on as part of the addendum.

Other comments raised concerns with the validity of the coding for pneumonia and COPD:

- ***0231 Inpatient pneumonia mortality***

  0506 Thirty-day all-cause risk standardized readmission rate following pneumonia hospitalizations

  0468 Thirty-day all-cause risk standardized mortality rate following pneumonia hospitalizations

  The claims-based definition of pneumonia (for measures *0231 Inpatient pneumonia mortality* and 0506 and 0468) lacks sufficient validity and requested that the definition be updated to reflect coding trends, noting that this measure does not include patients with a primary diagnosis of sepsis or respiratory failure and a secondary diagnosis of pneumonia. A recent published study demonstrated that hospital admissions with a primary diagnosis of pneumonia are declining over time, while at the same time admissions with a primary diagnosis of sepsis or respiratory failure and a secondary diagnosis of pneumonia are on the rise possibly due to the performance measures: http://jama.jamanetwork.com/article.aspx?volume=307&issue=13&page=1405

- ***1891 Thirty-day all-cause risk standardized readmission rate following COPD hospitalizations***

1893 Thirty-day all-cause risk standardized mortality rate following COPD hospitalizations

Research demonstrates that different algorithms for identifying COPD admission yield widely differing cohorts and there are no practical solutions at this time. A validation study examining the sensitivity and specificity of this coding strategy compared with the reference standard of a clinical diagnosis of an acute COPD exacerbation is necessary to ensure that these codes reliably and validly identify the intended target population, helping to mitigate the possibility that observed variation in outcome is due to variation in coding practices. Similar validation studies were performed prior to NQF endorsement of related measures for acute myocardial infarction, congestive heart failure and pneumonia, and the commenters believe that the COPD measures should be held to the same high standard.

CMS/Yale and AHRQ have responded to the various issues raised and are aware of the recent JAMA article by Dr. Lindenauer:

- AHRQ notes that for measure 0231 "the coding of principal diagnosis is governed by ICD-9-CM Official Guidelines for Coding and Reporting (CDC, 2011) and is defined as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care." Although there are special circumstances in which a patient admitted in acute respiratory failure (ARF) due to an underlying diagnosis of pneumonia may be coded with a principal diagnosis of ARF rather than pneumonia, this change would affect relatively few cases and would reduce harmonization between the AHRQ measure and the CMS measure."
- CMS responded "The recent paper by Dr. Lindenauer is useful and informative. CMS has an annual process to maintain and re-evaluate the measures and this process incorporates any important recent literature. The analyses in Dr. Lindenauer's paper suggest some additional cohort codes that could be incorporated into the measure in the future. Because the pneumonia mortality measure has been successfully used in public reporting for four years now and changes to the cohort will have an impact on hospitals and stakeholders, any potential changes must be undertaken with careful consideration. Dr. Lindenauer's paper was a patient-level analysis and our maintenance evaluation will need to take into account the implications for hospital results as well as the potential benefits and risks of changing the cohort definition."

The developers and Committee discussed the need for updating the coding and harmonization among the process and outcome measures for inpatient pneumonia. The developers identified some differences due to the chart-based data for the process measures differs from the claims-based data for the outcome measures

ACTION TAKEN: The Committee encourages the Committee to harmonize the definitions of pneumonia as soon as possible.

CMS/Yale advised the Committee that, in response by a recommendation from this Committee, the age range for measures 1891 and 1893 to 40 years and above. The developers note that COPD is rare in the less than 40 age group (1.5% of patients in our 2006 California all payer dataset), and a diagnosis at younger ages is likely to represent the misclassification of patients with asthma or other pulmonary conditions. This approach is commonly used in the research literature.

ACTION TAKEN: The Committee agreed with the change in age to 40 and above for measures 1891 and 1893.

NQF MEMBER VOTING

The 15-day voting period for the Pulmonary and Critical Care Endorsement Maintenance project will conclude on July 10, 2012. The voting results will be provided at the in-person meeting.

MEASURES WITHDRAWN FROM CONSIDERATION

Eight measures previously endorsed by NQF have not been re-submitted or withdrawn from maintenance of endorsement:

Measure	Steward	Description	Reason Withdrawn
0001: Asthma assessment	AMA-PCPI	Percentage of patients who were evaluated during at least one office visit for the frequency (numeric) of daytime and nocturnal asthma symptoms.	Withdrawn and no longer supported by evidence.
0025: Management plan for people with asthma	IPRO	Percentage of patients for whom there is documentation that a written asthma management plan was provided either to the patient or the patient's caregiver or, at minimum, specific written instructions on under what conditions the patient's doctor should be contacted or the patient should go to the emergency room.	IPRO is no longer using and will not be maintaining the measure.
0080: Chronic Obstructive Pulmonary Disease (COPD): assessment of oxygen saturation	AMA-PCPI	Percentage of patients with COPD with oxygen saturation assessed at least annually.	Withdrawn and superseded by new measure.
0140: Ventilator-associated pneumonia for ICU and high-risk nursery (HRN) patients	CDC	Percentage of ICU and HRN patients who over a certain amount of days have ventilator-associated pneumonia.	CDC is currently working on developing a new measure for VAE outcomes.
0151: Initial antibiotic received within 6	CMS	Percentage of pneumonia patients 18 years of age and older who receive	CMS will no longer be maintaining the measure.

hours of hospital arrival		their first dose of antibiotics within 6 hours after arrival at the hospital.	
0332: Severity-Standardized ALOS - Special Care	The Leapfrog Group	Standardized ALOS for special inpatient care (i.e., care provided in intensive care units).	Leapfrog does not have the resources to take the measure through maintenance.
0341: PICU pain assessment on admission	VPS	Percentage of PICU patients receiving: a. Pain assessment on admission, b. Periodic pain assessment.	Withdrawn from consideration and combined with 0342.
0628: COPD with exacerbations – use of long-acting bronchodilator therapy	ActiveHealth Management	Percentage of patients 40 years and older with COPD exacerbations that are receiving a long acting bronchodilator	ActiveHealth indicated that this measure is no longer in line with evidence-based medical literature and has developed a new measure that they feel is better supported.

NATIONAL QUALITY FORUM

TO: Consensus Standards Approval Committee (CSAC)

FR: Reva Winkler, Kathryn Streeter and Jessica Weber

RE: Result of Voting for *Pulmonary and Critical Care Endorsement Maintenance*

DA: July 12, 2012

The CSAC will review the recommendations from the project, *Pulmonary and Critical Care Endorsement Maintenance* during the July 11-12, 2012, in-person meeting. This memo includes NQF member voting results. Member voting closed on Tuesday, July 10, 2012. The complete voting draft report and detailed measure information are available on the project webpage.

NQF MEMBER VOTING

The 15-day voting period for the Pulmonary and Critical Care Endorsement Maintenance project concluded on July 10, 2012. 10 member organizations voted; no votes were received from the Public/Community Health Agency council. All 22 measures were approved with total approval ranging from 57% to 100%.

Voting Results

Voting results for the 22 candidate consensus standards are provided below. Comments were submitted by one Health Plan voter (Humana) and are included below the individual voting tables. (Links are provided to the measure submission forms.)

Measure #0036 Use of appropriate medications for people with asthma

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	1	1	0	2	50%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	0	0	1	100%
Supplier/Industry	0	1	0	1	0%
All Councils	**7**	**2**	**1**	**10**	**78%**
Percentage of councils approving (>50%)					71%
Average council percentage approval					79%

*equation: Yes/ (Total - Abstain)

- Humana comment: In its current format the measure allows such wide variation in drug treatment without regard to the stage of asthma, that this all but ignores the standards of care from the NHBLI (http://www.nhlbi.nih.gov/guidelines/asthma/) The concept is well intended.

Measure #0047 Asthma: Pharmacologic Therapy for Persistent Asthma

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	1	0	1	0%
All Councils	**7**	**1**	**2**	**10**	**88%**
Percentage of councils approving (>50%)					83%
Average council percentage approval					83%

*equation: Yes/ (Total - Abstain)

- Humana comment: This measure is much more specific and a better measure in our estimation than 0036.

Measure #1799 Medication Management for People with Asthma (MMA)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	0	0	1	100%
Supplier/Industry	1	0	0	1	100%
All Councils	**10**	**0**	**0**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #1800 Asthma Medication Ratio (AMR)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	1	0	3	67%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	0	0	1	100%
Supplier/Industry	1	0	0	1	100%
All Councils	**9**	**1**	**0**	**10**	**90%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					95%

*equation: Yes/ (Total - Abstain)

Measure #0548 Suboptimal Asthma Control (SAC) and Absence of Controller Therapy (ACT)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	1	0	1	0%
All Councils	**7**	**1**	**2**	**10**	**88%**
Percentage of councils approving (>50%)					83%
Average council percentage approval					83%

*equation: Yes/ (Total - Abstain)

Measure #0091 COPD: spirometry evaluation

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	1	1	0	2	50%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	

All Councils	**7**	**1**	**2**	**10**	**88%**
Percentage of councils approving (>50%)					80%
Average council percentage approval					90%

*equation: Yes/ (Total - Abstain)

- Humana comment: The measure developer responded to concerns that spirometry evaluation could not be captured from administrative data; but only considered this in the ambulatory setting. There may not be submitted claims if spirometry testing is performed in the hospital.

Measure #0102 COPD: inhaled bronchodilator therapy

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	1	1	0	2	50%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**1**	**2**	**10**	**88%**
Percentage of councils approving (>50%)					80%
Average council percentage approval					90%

*equation: Yes/ (Total - Abstain)

Measure #0577 Use of Spirometry Testing in the Assessment and Diagnosis of COPD

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	1	1	0	2	50%
Health Professional	3	0	0	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	0	0	1	100%
Supplier/Industry	0	0	1	1	
All Councils	**8**	**1**	**1**	**10**	**89%**
Percentage of councils approving (>50%)					83%
Average council percentage approval					92%

*equation: Yes/ (Total - Abstain)

- Humana comment: Same concerns as with 0091 - The measure developer responded to concerns that spirometry evaluation could not be captured from administrative data; but only considered this in the ambulatory setting. There may not be submitted claims if spirometry testing.

Measure #1825 COPD - Management of Poorly Controlled COPD

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	1	0	3	67%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**1**	**2**	**10**	**88%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					93%

*equation: Yes/ (Total - Abstain)

Measure #1893 Hospital 30-Day All-Cause Risk-Standardized Mortality Rate (RSMR) following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**0**	**3**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

- Humana Comment: Should be harmonized with 1891.

Measure #0231 Pneumonia Mortality Rate (IQI #20)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	1	0	1	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	

Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**6**	**0**	**4**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

- Humana comment: Unsure of what may be the unintended consequences in terms of actual patient management and patient admission coding.

Measure #0147 Initial antibiotic selection for community-acquired pneumonia (CAP) in immunocompetent patients

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**0**	**3**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

- Humana comment: This should be harmonized with 0096. This measure uses chart data.

Measure #0096 Empiric Antibiotic for Community-Acquired Bacterial Pneumonia

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**0**	**3**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

- Humana comment: This measure should be harmonized with 0147. This one uses claims based data.

Measure #0232 Vital Signs for Community-Acquired Bacterial Pneumonia

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	1	1	0	2	50%
Health Professional	0	2	1	3	0%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**4**	**3**	**3**	**10**	**57%**
Percentage of councils approving (>50%)					60%
Average council percentage approval					70%

*equation: Yes/ (Total - Abstain)

- Humana comment: This appears to be a low bar measure. Would recommend returning to measure developer to become integrated into a composite measures that could include mental status determination and empiric antibiotics to parsimoniously create a community acquired pneumonia.

Measure #0468 Hospital 30-day all-cause risk-standardized mortality rate (RSMR) following pneumonia hospitalization

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**0**	**3**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #1895 Assessment of Mental Status for Community-Acquired Bacterial Pneumonia

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	1	1	0	2	50%
Health Professional	1	2	0	3	33%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**5**	**3**	**2**	**10**	**63%**
Percentage of councils approving (>50%)					60%
Average council percentage approval					77%

*equation: Yes/ (Total - Abstain)

- Humana comment: This appears to be a low bar measure. Would recommend returning to measure developer to become integrated into a composite measure that could include vital signs determination and empiric antibiotics to parsimoniously create a community acquired pneumonia.

Measure #0513 Thorax CT: Use of Contrast Material

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**0**	**3**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0334 PICU Severity-adjusted Length of Stay

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%

Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**0**	**3**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

- Humana comment: Would recommend stratification of patients into similar intensity conditions using the model in skilled nursing facility stratifications so that the resource consumption of measure 0334 can become an actionable measure.

Measure #0335 PICU Unplanned Readmission Rate

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**0**	**3**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0343 PICU Standardized Mortality Ratio

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	0	0	1	1	
All Councils	**7**	**0**	**3**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

- Humana comment: Would look for a standardized pediatric risk adjustment

Measure #0143 CAC-1: Relievers for Inpatient Asthma

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	1	0	0	1	100%
All Councils	**8**	**0**	**2**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

- Humana comment: This is a low bar measure. Would be surprised if there is a significant gap. This would require EHR or chart abstraction as the billing by most hospitals would not allow for use of administrative data.

Measure #0144 CAC-2 Systemic corticosteroids for Inpatient Asthma

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	2	0	0	2	100%
Health Professional	2	0	1	3	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	1	1	
Supplier/Industry	1	0	0	1	100%
All Councils	**8**	**0**	**2**	**10**	**100%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

- Humana comment: This is a low bar measure. Would be surprised if there is a significant gap. This would require EHR or chart abstraction as the billing by most hospitals would not allow for use of administrative data