TO: Consensus Standards Approval Committee (CSAC)

FR: Karen Johnson and Suzanne Theberge

RE: *Neurology Endorsement Maintenance Phase II* Member Voting Results

DA: February 7, 2013

The CSAC will review recommendations from the *Neurology Endorsement Maintenance Phase II* project during its February 12 conference call.

This memo includes a summary of the project, list of recommended measures, themes identified from, and Steering Committee responses to, public and member comments, and member voting results.

This project followed the National Quality Forum's (NQF) version 1.9 of the Consensus Development Process (CDP). Member voting on these recommended measures ended on February 6.

Accompanying this memo are the following documents:

1. **Neurology Phase II Draft Report.** The draft report has been updated to reflect the changes made following Steering Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment table.** This table lists the comments received, and the NQF, Steering Committee, and developer responses to those comments.

CSAC ACTION REQUIRED
Pursuant to the CDP, the CSAC may consider approval of 5 candidate consensus standards.

Neurology Phase 2 Measures Recommended for Endorsement:
2091: Persistent indicators of dementia without a diagnosis—long stay
2092: Persistent indicators of dementia without a diagnosis—short stay
1814: Counseling for women of childbearing potential with epilepsy
0507: Stenosis measurement in carotid imaging studies
2111: Antipsychotic use in persons with dementia

Neurology Phase 2 Measures Not Recommended:
1973: Annual Parkinson's Disease diagnosis review
1982: Parkinson's Disease psychiatric disorders or disturbance assessment
1983: Parkinson's Disease cognitive impairment or dysfunction assessment
1985: Parkinson's Disease querying about sleep disturbances
1988: Parkinson's Disease rehabilitative therapy options
1989: Parkinson's Disease medical and surgical treatment options reviewed
1953: Seizure type(s) and current seizure frequency(ies)
1954: Documentation of etiology of epilepsy or epilepsy syndrome

1990: Dementia: Staging of dementia
2009: Dementia: Neuropsychiatric symptom assessment
2011: Dementia: Management of neuropsychiatric symptoms
2016: Dementia: Screening for depressive symptoms
2000: Dementia: Cognitive assessment
2004: Dementia: Functional status assessment
2028: Dementia: Counseling regarding safety concerns
2029: Dementia: Counseling regarding risks of driving
2030: Dementia: Caregiver education and support

BACKGROUND

Neurological conditions and injuries affect millions of Americans each year, taking a tremendous toll on patients, families, and caregivers, and costing billions of dollars in treatment, rehabilitation, and lost or reduced earnings. Specifically:

- An estimated 5.4 million Americans have Alzheimer's disease, and an estimated 16 million will have Alzheimer's by 2050.[i] The disease accounts for 70 percent of the cases of dementia in the country.[ii] In 2009, Alzheimer's disease was the fifth leading cause of death for adults ages 65 and over. Medicare and Medicaid spending on people with Alzheimer's disease totaled $130 billion in 2011; this could rise to $1.1 trillion by 2050.[iii]
- Epilepsy affects two million Americans and is estimated to cost $15.5 billion each year in medical costs and lost or reduced earnings and production.[iv]
- One million Americans have Parkinson's disease, and the combined direct and indirect costs are estimated at $25 billion per year.[v]

In Phase II of this project, NQF sought performance measures that could be used for accountability and quality improvement in neurological conditions excluding stroke (measures for stroke were reviewed in Phase I) for adults and children in all settings of care. Specifically, measures related to epilepsy, Parkinson's disease, and dementia were evaluated in this phase. A 24-member Steering Committee reviewed 22 measures, and recommended 5 of those measures for endorsement. Public and member commenting took place from October 31-November 29, 2012.

Three overarching issues emerged during the Committee's evaluation of the measures and were factored into the Committee's ratings and recommendations for many of the measures. Two of the issues—measure foci that are distal to desired outcomes and insufficient evidence—were particularly salient in the Committee's decisions not to recommend measures for endorsement. The third overarching issue for the project was that of untested measures: 18 of the 22 measures under consideration have not yet been tested for reliability or validity (and thus were eligible for time-limited endorsement only). Per NQF's policy on evaluation of untested measures, these measures (for epilepsy, Parkinson's disease, and dementia) are process measures that are included in the 2012 PQRS program and fill gap areas in NQF's measure portfolio. Prior to accepting these measures for evaluation during the project, developers confirmed their intent to complete reliability and validity testing within 12 months, if granted time-limited endorsement. To evaluate the untested measures for Scientific Acceptability, the Committee considered whether the measures were precisely specified and whether the measure specifications are consistent with the evidence presented for the measure.

DRAFT REPORT

The Neurology Phase II Draft Report presents the results of the evaluation of measures considered under the CDP. Five measures were recommended for endorsement as voluntary consensus standards suitable for accountability and quality improvement, and 17 measures were not recommended. Two maintenance measures were withdrawn prior to the start of the project.

	MAINTENANCE	NEW	TOTAL
Measures considered	1	21	24
Measures withdrawn from consideration before start of project	2	0	2
Measures recommended	1	4	5
Measures not recommended	0	17	17
Reasons for not recommending		Importance – 15 Scientific Acceptability – 2	

COMMENTS AND THEIR DISPOSITION

NQF received comments from 10 NQF member organizations and 20 members of the public pertaining to the general draft report and to the measures under consideration.

A table of comments submitted during the comment period, with responses to each comment and actions taken by the Steering Committee, is posted to the Neurology Project Page under the NQF Member Voting section.

Comment Themes and Committee Responses

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

Major Themes

Four major themes were identified in the comments, as follows:

Topic 1: Reconsideration of the AAN/AMA-PCPI Measures

The AAN formally requested that the Committee reconsider the following eight measures:

- 1953: Seizure type(s) and current seizure frequency(ies)
- 1954: Documentation of etiology of epilepsy or epilepsy syndrome
- 1973: Annual Parkinson's disease diagnosis review
- 1982: Parkinson's disease psychiatric disorders or disturbance assessment
- 1983: Parkinson's disease cognitive impairment or dysfunction assessment

- 1985: Parkinson's disease querying about sleep disturbances
- 1988: Parkinson's disease rehabilitative therapy options
- 2029: Dementia: Counseling regarding risks of driving

Fifteen comments regarding these and other AAN/AMA-PCPI measures from NQF member organizations and the public were received, many of which were submitted through the Behavioral Neurology & Geriatric Neurology Section of the AAN. Most—but not all—of these comments were supportive of some or all of the 18 measures submitted by AAN/AMA-PCPI.

The majority of the Committee's discussion of these measures during the in-person meeting centered around the evidence criterion. The following NQF criteria and guidance was considered by the Committee at that time:

- Process measures should measure those aspects of care with the most direct evidence of a strong relationship to the desired outcome; such evidence is most often about the relationship between some intervention and a desired health outcome, and, therefore, interventions are the preferred focus of process measures.
- Empirical evidence and specific information on the quantity, quality, and consistency from a systematic review of a body of evidence is required. Such evidence should support that the measured healthcare process leads to desired health outcomes in the target population with benefits that outweigh harms to patients.
- Expert opinion is not considered empirical evidence; if a measure is based only on expert consensus, it does not meet the NQF evidence criterion. An exception to the evidence criterion should only be considered if no empirical evidence exists, the expert opinion is systematically assessed, and there is a strong rationale for why the specific structure or process should be the focus of a quality performance measure. Use of this evidence exception should not be a routine occurrence.
- Clinical practice guidelines alone do not meet NQF criteria for evidence. If a guideline does not provide the necessary information on quantity, quality, and consistency, developers should seek other sources such as the Cochrane Collaboration, AHRQ evidence reports, USPSTF, or systematic reviews published in the literature, which often are cited in the guidelines.
- Guidance provided by the CSAC on measure construction practices recommends avoiding specifying measures so that they can be met primarily through documentation without an evaluation of the quality of the activity (examples of documentation measures include assessment completed; care plan created; or instruction or advice given).

<u>Staff summary of overall rationale for reconsideration articulated by the developer and/or other commenters:</u>

- These measures were developed prior to the updates of the NQF measure evaluation criteria.
- NQF expects empirical data that supports the relationship between the measure and desired outcome; however, this type of evidence currently rarely exists for most neurological conditions.
- Not all members of the Steering Committee have expertise (or related experience) in Parkinson's disease, epilepsy, or dementia; this may have affected the Committee's overall understanding of the key issues and intricacies related to the management of patients with these conditions.

- These measures address patient and family engagement, which is a critical part of the National Priorities Partnership and few endorsed measures exist that address this area.
- Querying and counseling of patients has been associated with improving the patients' positive perceptions of care and is associated with better recovery from discomfort and concerns, better emotional health, improved health status, and fewer diagnostic tests and referrals (references cited).
- Epilepsy is a common and widely recognized neurologic condition, but it is often poorly understood, misdiagnosed, and improperly treated.
- Parkinson's disease significantly affects health related quality of life (HRQOL), a measurable patient-reported outcome.
- Dementia is a chronic condition that poses a major and growing threat to the public's health, yet studies have shown low and/or variable adherence to recommended practices for the assessment, management, and treatment of patients with dementia.
- The development of reliable outcome measures for dementia proved impracticable. The AAN/AMA-PCPI dementia measures were developed in the context of care management, where the goals are to improve the quality of life for patients and caregivers, maintain optimal function, and provide maximum comfort. The dementia measures target underemphasized, yet vital, aspects of the evaluation and management of dementia patients.
- Steering Committees are given minimal guidance around the exception to the evidence criterion, and therefore, invoking the exception is a subjective process.
- These measures are currently in use in the PQRS program; the AAN/AMA-PCPI will urge continued use of these measures in this and other programs regardless of NQF endorsement status.
- NQF endorsement of these measures would support performance of assessment more uniformly (anecdotal evidence of beneficial effects of counseling on quality of life was provided).

1953: Seizure type(s) and current seizure frequency(ies)

<u>Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:</u>

- Documentation is viewed as the surrogate term for asking about seizure type/frequency and providing appropriate treatment and/or referral.
- Patients whose seizures are controlled have better quality of life: this provides an indirect link between the measure and desired outcomes.
- Poor seizure control is associated with increased risk of death.
- Seizure type and seizure frequency are linked to early treatment costs.
- The potential benefit greatly outweighs harm.

Action Taken: The Committee agreed that asking about seizure frequency and documenting the result are important steps in the care process, but noted that the process of care that is most closely related to improved patient outcomes is how a clinician acts on the information regarding seizure frequency. Committee members also agreed that no additional information was presented to change their evaluation of the measure and declined to revote on the measure.

1954: Documentation of etiology of epilepsy or epilepsy syndrome

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- Documentation is viewed as the surrogate for ascertaining the patient's etiology of epilepsy/syndrome and providing appropriate treatment.
- The measure focus represents the standard of care to ensure that patients receive appropriate treatment.
- The evolving classification system for epilepsy should not affect this measure because as the classification evolves, so must the treatment.

Action Taken: The Committee agreed that reviewing and documenting epilepsy etiology are important steps in the care process, but noted that appropriate treatments must then be provided. Members noted that evidence linking the review and documentation of epilepsy etiology to improved patient outcomes had not been initially submitted by the developer and agreed that no additional evidence demonstrating that link was subsequently provided. The Committee declined to revote on the measure.

1973: Annual Parkinson's disease diagnosis review

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- At least one recommendation used to support the measure has Level B strength behind it.
- The potential harm from not regularly reviewing the Parkinson's disease diagnosis and looking for atypical features is significant.
- The concern that this is a "check box" measure should not have been included in the evaluation of the evidence subcriterion.
- The NICE recommendations regarding optimal frequency of diagnosis review and referral to a specialist for a definitive diagnosis were not used to support this measure.

Action Taken: The Committee did not dispute the importance of having a correct diagnosis of Parkinson's disease. However, members noted that, as originally submitted, no evidence was presented that reviewing and documenting a diagnosis would result in more accurate diagnosis and/or improved patient outcomes, and they agreed that no additional evidence to support the measure was subsequently provided by the developer. The Committee also verified with NQF staff that in their evaluation of the evidence for the measure, it was appropriate to discuss their concern that this is a "check-box" measure. After review of the comments submitted and additional discussion, the Committee declined to revote on the measure.

1982: Parkinson's disease psychiatric disorders or disturbance assessment

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- Psychiatric symptoms are prevalent among patients with Parkinson's disease, are a major cause of disability, and are often under-diagnosed and poorly treated (several references cited).
- There is no validated tool that could be used to assess for all psychiatric symptoms.
- No evidence exists to recommend one validated tool over another.
- A minority of SC members thought the measure should focus only on depression; however, Parkinson's disease is associated with a wide range of psychiatric disorders and disturbances that are often overlooked
- It was infeasible to re-specify the measure to focus on depression only, given in the timeframe allowed (5 days).

Action Taken: Committee members noted their initial concerns regarding the clarity of the measure specifications (in particular, which tools could be used and how the assessment would be performed). After review of the comments submitted, the Committee agreed that no additional information was provided to alleviate those concerns and declined to revote on the measure.

1983: Parkinson's disease cognitive impairment or dysfunction assessment

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- The onset of cognitive decline/dementia often occurs over a prolonged time period, and although there is limited treatment, it is important to identify.
- Cognitive impairment is prevalent among patients with Parkinson's disease; assessment will lead to identification of dysfunction, which will then lead to appropriate treatment/referrals, and ultimately, to better quality of life.
- In terms of evidence supporting the measure, depression was only cited in the context of non-motor symptoms of Parkinson's disease.

Action Taken: The Committee agreed that no additional evidence was presented to show that assessing cognitive impairment annually would result in better patient outcomes and declined to revote on the measure.

1985: Parkinson's disease querying about sleep disturbances

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- By not querying the patient about sleep disturbances the clinician may miss key factors such as sleep fragmentation (80% of PD patients), restless leg syndrome (20%), REM behavior sleep disorder (>40%), and excessive daytime sleepiness (~50%).

Action Taken: The Committee agreed that sleep disturbances are important in Parkinson's disease, but noted that no evidence had been presented to link annual query about sleep disturbances with improved outcomes. The Committee declined to revote on the measure.

1988: Parkinson's disease rehabilitative therapy options

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- The argument for including in the measure those patients with no known disability is not evidence-based and should not have been used to argue against this measure.
- Multiple studies cite the link between the discussion of rehabilitation therapy options to an increase in referrals to rehab and/or improved patient outcomes.
- The potential benefit greatly outweighs harm.

Action Taken: The Committee noted that the evidence exception had been invoked for this measure and also noted that concerns regarding measure exclusions had not been addressed. The Committee did not re-vote on the measure but encouraged the developer to re-work the measure specifications and re-submit the measure to NQF.

2029: Dementia: Counseling regarding risks of driving

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- Everyone with dementia will eventually become an unsafe driver because of impairments in memory, judgment, reasoning, spatial perception, and reaction time.

- Clinicians can influence their patients' decision to modify or stop driving, and help their patients maintain safe driving skills.
- Many groups have tools, position statements, and advisory kits that demonstrate the importance of physician to counsel about driving safety issues.
- Counseling patients with dementia about driving is under-reported in the medical record compared to the caregiver interview (reference cited).

Action Taken: After review of the comments, the Committee agreed that no new evidence was submitted to support the measure. The Committee declined to revote on the measure.

Topic 2: Reconsideration of measure #2111: Antipsychotic use in persons with dementia

Six comments were received regarding this measure, five of which advocated reconsideration of the measure by the Committee. The commenters offered the following reasons for reconsideration:

- Although there are limitations with the use of claims based data (e.g., inability to evaluate appropriateness of regimen), identifying variability in use is important. For example, very high rates might suggest that non-use of non-drug management strategies or inadequate evaluation.
- While claims-based measures cannot capture all possible exclusions, such data are accurate enough for health plan level measures.
- Provider feedback to a large Pharmacy Benefits Manager indicates that providers rarely prescribe the Alzheimer's drugs for a non-dementia reason, suggesting that the false-positive identification of dementia using Alzheimer's drugs as a proxy is remote.

One commenter agreed with the Committee's initial decision not to recommend the measure, noting that "appropriate use (for psychosis and psychosis related agitation and in lowest effective doses) is to be promoted and not discouraged for optimal patient management."

The developer provided additional information via letter in response to questions raised by the Committee during the in-person meeting; the full text of this letter (PDF) is posted on the project page. Briefly, the developers noted the following:

- ***A comparatively narrower list of ICD-9 codes is used to identify patients with dementia compared to what is used in other measures***—Codes that indicate a behavioral disturbance or psychosis are not included because the measure is intended to focus on those dementia patients who do not have a clear indication for an antipsychotic drug.
- ***Variability in performance rates***—Additional analysis at the plan contract level shows that the performance rate varied from 10.2% to 20.3%, with an average of 13.9% and standard deviation of 3.7%. Thus, there is variation in performance across the Medicare contracts with some of the contracts having a rate that is nearly 2 standard deviations above the average.
- ***Use of dementia drugs for conditions other than dementia***—Such drugs may be used for the late effects of traumatic brain injury (ICD-9 code 907.0). Additional analysis show that out of 48,341 patients identified as having dementia, only 46 patients had a claim with this diagnosis (less than 0.1%).

- ***Relatively low prevalence of dementia identified in pilot studies***—Using the combination of medication marker and dementia diagnosis code, there was a fairly consistent rate dementia patients across the numerous Medicare contracts (average of 4.6%; range of 3.4% to 5.9%). The percentage of the population included in the measure is not intended to replicate the overall rate of dementia in the general population, given the focus on a subset of dementia patients who do not have a diagnosis indicating psychoses or behavioral disturbance.

Action Taken: After review of the comments and the additional information provided by the developer, the Committee agreed to re-vote the measure. Upon re-vote, the Committee agreed the additional information provided by the developers was adequate to address their initial concerns about the validity of the measure and recommended the measure for endorsement.

Topic 3: Measure #0507: Stenosis measurement in carotid imaging studies

Six comments were received regarding this measure, three of which were supportive. However, two commenters expressed concern that the measure is a documentation measure and therefore of limited (or no) use for accountability purposes. Another commenter expressed the concern that the stenosis is based on the physician's judgment of patient symptoms.

Developer response (regarding physician judgment): Thank you for your comment. The intent of this measure is to quantify stenosis as precisely and reproducibly as possible. Patients with stenoses will benefit from physicians using a standardized method for stenosis calculation. There is wide variation in the use of methods for stenosis calculation, which may also lead to variation in the appropriateness of carotid intervention. Since the degree of stenosis is an important element of the decision for carotid intervention, characterization of the degree of stenosis needs to be standardized. Evidence-based guidelines are cited in support of the measure, along with several individual studies and systematic reviews.

Action Taken: Although the Committee agreed that this measure is a documentation measure, members reiterated their agreement that there is sufficient evidence indicating that the results of the documentation are interpretable and decisions can be made based on those results. The Committee did not wish to re-consider their vote on the measure.

Topic 4: Support for other recommended measures

Twenty-two comments were received regarding the remaining three measures that were recommended for endorsement:

- #1814: Counseling for women with childbearing potential with epilepsy
- #2091: Persistent Indicators of Dementia without a Diagnosis—Long Stay
- #2092: Persistent Indicators of Dementia without a Diagnosis—Short Stay

Of these 22 comments, 19 expressed support for the measures. Of the remaining three comments, two suggested additional ideas for measure development and one comment (on measure #2091) questioned why patients with psychiatric disorders are excluded from the measure denominator, noting possible misdiagnosis of psychiatric disorders on admission to a long-term care facility.

Developer response, measure #2091: While the reviewer is correct that patients with severe psychiatric disease have higher rates of dementia, AMDA needs to be consistent with the Center for Medicare & Medicaid Service (CMS) definition and exclusions for severe dementia as we are using their instrument (the MDS 3.0 and more specifically, the BIMMS). We were requested by the Neurology Measure review committee at the October 3rd NQF meeting in Washington DC to actually broaden the exclusions as a precaution about mislabeling diseases that frequently co-exist with dementia as only dementia (i.e., the quality measure is saying "this is probably undiagnosed dementia"), as we want to be a certain as we can that it is, in fact, undiagnosed dementia and not something else. AMDA also wishes to harmonize with the CMS focus on patients with dementia who are inappropriately prescribed antipsychotics without having a diagnosis of schizophrenia or bipolar disease. As an aside note, Down's syndrome and other "mental retardations" referred to in this reviewer's comment are not exclusions.

Action Taken: None.

NQF MEMBER VOTING RESULTS

All five of the recommended measures were approved with 86% approval or higher. Representatives of 44 member organizations voted; no votes were received from the Public/Community Health Agency Council. Results for each measure are provided below. (Links are provided to the full measure summary evaluation tables.)

Measure #0507: Stenosis measurement in carotid imaging studies

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	9	0	0	9	100%
Health Plan	5	0	0	5	100%
Health Professional	7	1	1	9	88%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	5	0	1	6	100%
Supplier/Industry	3	1	1	5	75%
All Councils	**38**	**3**	**3**	**44**	**93%**
Percentage of councils approving (>50%)					100%

Average council percentage approval	91%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- AmeriHealth Mercy Family of Companies (voted yes): This is a process measure. It may be considered a bridge measure "until the developer can present an outcome measures that may be of greater importance to the public and to patient outcomes."

Measure #1814: Counseling for women of childbearing potential with epilepsy

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	9	0	0	9	100%
Health Plan	5	0	0	5	100%
Health Professional	7	0	2	9	100%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	3	0	3	6	100%
Supplier/Industry	4	0	1	5	100%
All Councils	**37**	**1**	**6**	**44**	**97%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					96%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- AmeriHealth Mercy Family of Companies (voted yes): I would hope that the developers would move toward Patient Reported Outcomes measures for the management of pregnant patients with epilepsy

Measure #2091: Persistent indicators of dementia without a diagnosis—long stay

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	9	0	0	9	100%
Health Plan	4	1	0	5	80%
Health Professional	7	0	2	9	100%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	3	1	2	6	75%
Supplier/Industry	4	0	1	5	100%
All Councils	**36**	**3**	**5**	**44**	**92%**
Percentage of councils approving (>50%)					100%

Average council percentage approval	90%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- AmeriHealth Mercy Family of Companies (voted no): This appears to be a measure where the determination of denominator (who has dementia) comes from review rather than from the clinician caring for the patient. That can change the landscape of quality measures if diagnosis is arrived at by others after the fact.
    - **NQF Staff Response:** The measure denominator requires a BIMS score < 8 on at least two occasions that are at least 90 days apart or on a staff assessment of severe impairment; however, the actual diagnosis of dementia (which is counted in the numerator) is made by a physician or nurse practitioner.

Measure #2092: Persistent indicators of dementia without a diagnosis—short stay

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	9	0	0	9	100%
Health Plan	4	1	0	5	80%
Health Professional	7	0	2	9	100%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	2	1	3	6	67%
Supplier/Industry	4	0	1	5	100%
All Councils	**35**	**3**	**6**	**44**	**92%**
Percentage of councils approving (>50%)					100%
Average council percentage approval					89%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- AmeriHealth Mercy Family of Companies (voted no): This appears to be a measure where the determination of denominator (who has dementia) comes from review rather than from the clinician caring for the patient. That can change the landscape of quality measures if diagnosis is arrived at by others after the fact.
    - **NQF Staff Response:** The measure denominator requires a BIMS score < 8 on at least two occasions that are at least 90 days apart or on a staff assessment of severe impairment; however, the actual diagnosis of dementia (which is counted in the numerator) is made by a physician or nurse practitioner.

Measure #2111: Antipsychotic use in persons with dementia

Measure Council	Yes	No	Abstain	Total Votes	% Approval*

Consumer	9	0	0	9	100%
Health Plan	4	1	0	5	80%
Health Professional	8	0	1	9	100%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	6	0	0	6	100%
QMRI	2	3	1	6	40%
Supplier/Industry	3	1	1	5	75%
All Councils	**35**	**6**	**3**	**44**	**85%**
Percentage of councils approving (>50%)					86%
Average council percentage approval					81%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- AmeriHealth Mercy Family of Companies (voted no): We believe that the use of the Beer's List would better handle all drugs for patients at risk rather than one class of drug for one diagnosis

- American Psychiatric Institute for Research and Education (voted no): The APA cannot support Measure 2111 (Antipsychotic Use in Patients with Dementia) in its current form, as it does not account for serious behavioral and psychological symptoms in dementia as an evidence-based indication for prescribing antipsychotic medications. That these are health plan level measures, and that the target performance rate would be above zero, both partially address this concern, but the potential for unintended consequences remains significant. While performance measurement may be a useful tool in identifying and reducing indiscriminant use of antipsychotics in this patient population, it must do so in a way that does not adversely impact those patients who are experiencing clinical benefit.

  Psychosis and serious behavioral and psychological symptoms in dementia (BPSD) are associated with both patient and family/caregiver discomfort and angst, and regularly results in ostracization of the patient from socially enjoyable activities and in institutionalization in alien structured living environments which may then further exacerbate isolation and such symptoms. As such, efforts to ameliorate psychosis and other serious BPSD are merited and should almost always begin with non-pharmacological, psychosocial interventions. However, when psychosocial interventions fail, the use of antipsychotic agents may be indicated, especially when informed by the evidence-based literature which particularly supports use in comorbid psychosis and agitation with hostility/aggression. Nevertheless, antipsychotic treatment should not be routinely prescribed, but thoughtfully individualized, with close monitoring for impact on target symptoms and for adverse effects, and consideration of discontinuation on amelioration of symptoms.

  As this measure is currently constructed, those dementia patients who receive antipsychotics for psychotic disorder not otherwise specified, dementia with delusions or dementia with behavioral disturbance in the above manner would be counted in with those dementia patients who may truly have been prescribed antipsychotics indiscriminately. Use of this measure

potentially may give the wrong impression to clinicians and the public that the use of antipsychotics in dementia patients is never clinically warranted, and this may increase the barriers to antipsychotic medication use for those whose illness symptoms and quality of life are improved with antipsychotics.

REMOVE ENDORSEMENT OF MEASURES

Two measures previously endorsed by NQF have not been re-submitted; therefore they were withdrawn from maintenance of endorsement. The following measures are being retired from endorsement:

Measure	Reason for retirement
602: Adult(s) with frequent use of acute medications that also received prophylactic medications (Ingenix)	Developer elected not to pursue maintenance of endorsement.
644: Patients with a transient ischemic event ER visit that had a follow up office visit (Ingenix)	Developer elected not to pursue maintenance of endorsement.

Measure Evaluation Summary Tables – Recommended Measures

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

2091: Persistent Indicators of Dementia without a Diagnosis—Long Stay

Status: New Submission
Description: Percentage of nursing home residents age 65+ with persistent indicators of dementia and no diagnosis of dementia.
Numerator Statement: Number of adult patients 65 and older who are included in the denominator (i.e., have persistent signs and symptoms of dementia) and who do not have a diagnosis of dementia on any MDS assessment within the last 12 months.
Denominator Statement: The denominator is the total of all long-stay residents in the nursing facility who have at least two MDS assessments which may be an admission annual, quarterly, significant change or significant correction assessment during the selected quarter and who do not meet the exclusion criteria.
The denominator includes (i) residents with Section C Brief Interview for Mental Status (BIMS) score <8 on most recent target assessment and a BIMS < 8 on the prior assessment; or (ii) residents with a staff assessment for cognitive status on both the most recent target assessment and the prior assessment that shows severe cognitive impairment.
Exclusions: Residents who are hospice or end of life, or who are comatose or with delirium, or with psychotic disorders including hallucinations, anxiety disorder, manic depressive disease, post-traumatic stress disorder, bipolar disorder or schizophrenia will be excluded from the denominator.
Adjustment/Stratification: No risk adjustment or risk stratification N/A
Level of Analysis: Facility
Type of Measure: Process
Data Source: Electronic Clinical Data
Measure Steward: American Medical Directors Association

STEERING COMMITTEE MEETING [10/3/2012]

Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: **H-14**; **M-9**; **L-0**; **I-0**; 1b. Performance Gap: **H-18**; **M-5; L-0**; **I-0** 1c. Evidence: **Y-14**; **N-8**; **I-1**

<u>Rationale</u>:

- Some Committee members questioned the evidence of a linkage between having a dementia diagnosis and lower healthcare costs. Developers pointed to evidence from the community setting that indicates that when a dementia diagnosis has not been made, inappropriate care is delivered; they maintained that such inappropriate care leads to increased costs.
- Data submitted by the developer suggests that more than half of nursing facility residents have dementia but do not necessarily have a diagnosis of dementia and that older patients may be at higher risk of under-diagnosis.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2091: Persistent Indicators of Dementia without a Diagnosis—Long Stay

2a. Reliability: **H-9**; **M-12**; **L-1**; **I-1** 2b. Validity: **H-2**; **M-11**; **L-9**; **I-1**

Rationale:

- The Committee agreed that the measure, which relies on data from MDS 3.0, is precisely specified. NOTE: Because developers provided data element validity testing results for the relevant MDS 3.0 items, they were not required to show results of data element reliability testing.
- Committee members noted that a Brief Interview for Mental Status (BIMS) score (the portion of the MDS 3.0 assessment used to assess cognition) of 7 (indicating severe impairment) has a specificity of 0.92. They questioned why approximately 8 percent of nursing home patients would show severe impairment according to the BIMS but not actually have dementia. Developers suggested that these patients may have other conditions (e.g., delirium, depression) that would cause the low BIMS scores.
- Committee members asked who in the nursing facility conducts the MDS assessment. Developers stated that trained RNs or social workers perform the assessments, noting that they receive on-going training to assure accuracy and consistency in conducting the assessments.
- One Committee member expressed a concern that someone with cognitive impairment but not dementia would be given a diagnosis of dementia, particularly if a staff assessment of cognition was used rather than the BIMS score. Developers explained that the measure denominator requires a BIMS score < 8 on at least two occasions that are at least 90 days apart or a staff assessment of severe impairment. They emphasized that the actual diagnosis of dementia (which is counted in the numerator) must be made by a physician or nurse practitioner.
- Committee members questioned what happens when a patient does have cognitive impairment but a physician has ruled out dementia as the cause of the impairment (e.g., cognitive impairment due to static encephalopathy). Developers noted that they have specified the measure to exclude some conditions that might result in cognitive impairment in the absence of dementia (e.g., schizophrenia, bipolar disorder). However, Committee members mentioned other conditions (e.g., TBI) that might result in not meeting the measure for particular patients. Developers expressed a willingness to include TBI as one of the exclusions for the measure. ***NQF note***: *The developers have since modified this measure to exclude TBI (ICD-9-CM 854.0) and encephalopathy (ICD-9-CM 348.30).*
- One Committee member questioned why dementia was the focus of the measure, rather than cognitive impairment, noting that patients with cognitive impairment also require specialized care. Developers explained they must work within the long-term care systems as it currently exists, and noted that a diagnosis of dementia in nursing facilities triggers the use of a comprehensive guideline for dementia.

3. Usability: H-6; M-15; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- One Committee questioned the usability of a measure when the optimal value is unknown (note that developers do not expect this measure to reach zero). Developers explained that facilities would use the measure to see how they compare to other facilities.
- Committee members again expressed concern about the usability of the measure if facilities score poorly

because patients have cognitive impairment that is not due to dementia. The Committee voted on the usability criterion contingent on the assumption that developers would add two additional exclusions: 1) patients with TBI and 2) patients for whom a dementia diagnosis has been ruled out by a physician or other practitioner. ***NQF note***: *The developers have since modified this measure to exclude TBI (ICD-9-CM 854.0) and encephalopathy (ICD-9-CM 348.30). They also investigated how they might indicate, as part of the MDS assessment, that a provider has ruled out a dementia diagnosis; however, they concluded that this cannot be done.*

4. Feasibility: H-14; M-8; L-1; I-0

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

Rationale:

- This measure is computed from data collected as part of the MDS 3.0 assessment, which is required for all nursing facility patients on a routine basis.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: **Y-20**; **N-3**

Public & Member Comment

Comments included:

- Eight supportive comments.
- A question about why patients with psychiatric disorders are excluded from the measure denominator, noting possible misdiagnosis of psychiatric disorders on admission to a long-term care facility.

***Developer response*:** While the reviewer is correct that patients with severe psychiatric disease have higher rates of dementia, AMDA needs to be consistent with the Center for Medicare & Medicaid Service (CMS) definition and exclusions for severe dementia as we are using their instrument (The MDS 3.0 and more specifically, the BIMMS). We were requested by the Neurology Measure review committee at the October 3rd NQF meeting in Washington DC to actually broaden the exclusions as a precaution about mislabeling diseases that frequently co-exist with dementia as only dementia (i.e., the quality measure is saying "this is probably undiagnosed dementia"), as we want to be a certain as we can that it is, in fact, undiagnosed dementia and not something else. AMDA also wishes to harmonize with the CMS focus on patients with dementia who are inappropriately prescribed antipsychotics without having a diagnosis of schizophrenia or bipolar disease. As an aside note, Down's syndrome and other "mental retardations" referred to in this reviewer's comment are not exclusions.

Committee response:

- **Committee members reviewed the comments and the developer response and did not wish to change their recommendation.**

2092: Persistent Indicators of Dementia without a Diagnosis—Short Stay

Status: New Submission

Description: Number of adult patients 65 and older who are included in the denominator (i.e., have persistent signs and symptoms of dementia) and who do not have a diagnosis of dementia on any MDS assessment.

Numerator Statement: Number of adult patients 65 and older who are included in the denominator (i.e., have persistent signs and symptoms of dementia) and who do not have a diagnosis of dementia on any MDS assessment.

Denominator Statement: The denominator is the total of all short-stay residents in the nursing facility who have at least two MDS PPS assessments (A0310 = 01. 5-day scheduled assessment or 02. 14-day scheduled assessment or 03. 30-day scheduled assessment or 04. 60-day scheduled assessment or 05. 90-day scheduled assessment or 06. Readmission/return assessment), and who do not meet the exclusion criteria.

The denominator includes (i) residents with Section C Brief Interview for Mental Status (BIMS) score <8 on most recent target assessment and a BIMS < 8 on the prior assessment; or (ii) residents with a staff assessment for cognitive status on both the most recent target assessment and the prior assessment that shows severe cognitive impairment.

Exclusions: Residents who are hospice or end of life, or who are comatose or with delirium, manic depressive disease, bipolar disorder or schizophrenia will be excluded from the denominator.

Adjustment/Stratification: No risk adjustment or risk stratification NA

Level of Analysis: Facility

Type of Measure: Process

Data Source: Electronic Clinical Data

Measure Steward: American Medical Directors Association

STEERING COMMITTEE MEETING [10/3/2012]

Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

51a. Impact: **H-15**; **M-7**; **L-1**; **I-0**; 1b. Performance Gap: **H-11**; **M-12**; **L-0**; **I-0** 1c. Evidence: **Y-17**; **N-4**; **I-2**

<u>Rationale</u>:

- This measure is identical to measure #2091, except that it covers short-stay nursing facility residents (where length of stay < 100 days) and therefore the timing of the MDS assessments are different. The discussion for this measure is the same as for measure #2091, but is repeated here for ease of review.
- Some Committee members questioned the evidence of a linkage between having a dementia diagnosis and lower healthcare costs. Developers pointed to evidence from the community setting that indicates that when a dementia diagnosis has not been made, inappropriate care is delivered; they maintained that such inappropriate care leads to increased costs.
- Data submitted by the developer suggests that more than half of nursing facility residents have dementia but do not necessarily have a diagnosis of dementia and that older patients may be at higher risk of under-diagnosis.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2092: Persistent Indicators of Dementia without a Diagnosis—Short Stay

2a. Reliability: **H-4**; **M-17**; **L-2**; **I-0** 2b. Validity: **H-3**; **M-17**; **L-3**; **I-0**

Rationale:

- The discussion for this measure is the same as for measure #2091, but is repeated here for ease of review.
- The Committee agreed that the measure, which relies on data from MDS 3.0, is precisely specified. NOTE: Because developers provided data element validity testing results for the relevant MDS 3.0 items, they were not required to show results of data element reliability testing. .
- Committee members noted that a Brief Interview for Mental Status (BIMS) score (the portion of the MDS 3.0 assessment used to assess cognition) of 7 (indicating severe impairment) has a specificity of 0.92. They questioned why approximately 8 percent of nursing home patients would show severe impairment according to the BIMS yet do not actually have dementia. Developers suggested that these patients may actually have other conditions (e.g., delirium, depression) that would cause the low BIMS scores. Committee members asked who in the nursing facility conducts the MDS assessment. Developers stated that trained RNs or social workers perform the assessments, noting that they receive on-going training to assure accuracy and consistency in conducting the assessments.
- One Committee member expressed a concern that someone with cognitive impairment but not dementia would be given a diagnosis of dementia, particularly if a staff assessment of cognition was used rather than the BIMS score. Developers explained that the measure denominator requires a BIMS score < 8 on at least two occasions that are at least 90 days apart or a staff assessment of severe impairment. They emphasized that the actual diagnosis of dementia (which is counted in the numerator) must be made by a physician or nurse practitioner.
- Committee members questioned what happens when a patient does have cognitive impairment but a physician has ruled out dementia as the cause of the impairment (e.g., cognitive impairment due to static encephalopathy). Developers noted that they have specified the measure to exclude some conditions that might result in cognitive impairment in the absence of dementia (e.g., schizophrenia, bipolar disorder). However, Committee members mentioned other conditions (e.g., TBI) that might result in not meeting the measure for particular patients. Developers expressed a willingness to include TBI as one of the exclusions for the measure. ***NQF note***: *The developers have since modified this measure to exclude TBI (ICD-9-CM 854.0) and encephalopathy (ICD-9-CM 348.30).*
- One Committee member questioned why dementia was the focus of the measure, rather than cognitive impairment, noting that patients with cognitive impairment also require specialized care. Developers explained they must work within the long-term care systems as it currently exists, and noted that a diagnosis of dementia in nursing facilities triggers the use of a comprehensive guideline for dementia.

2092: Persistent Indicators of Dementia without a Diagnosis—Short Stay

3. Usability: H-8; M-13; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- The discussion for this measure is the same as for measure #2091, but is repeated here for ease of review.
- One Committee questioned the usability of a measure when the optimal value is unknown (note that developers do not expect this measure to reach zero). Developers explained that facilities would use the measure to see how they compare to other facilities.
- Committee members again expressed concern about the usability of the measure if facilities score poorly because patients have cognitive impairment that is not due to dementia. The Committee voted on the usability criterion contingent on the assumption that developers would add two additional exclusions: 1) patients with TBI and 2) patients for whom a dementia diagnosis has been ruled out by a physician or other practitioner ***NQF note***: *The developers have since modified this measure to exclude TBI (ICD-9-CM 854.0) and encephalopathy (ICD-9-CM 348.30). They also investigated how they might indicate, as part of the MDS assessment, that a provider has ruled out a dementia diagnosis; however, they concluded that this cannot be done.*

4. Feasibility: H-10; M-13; L-0; I-0

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

Rationale:

- The discussion for this measure is the same as for measure #2091, but is repeated here for ease of review.
- This measure is computed from data collected as part of the MDS 3.0 assessment, which is required for all nursing facility patients on a routine basis.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: **Y-20**; **N-3**

Public & Member Comment

Comments included:

- Seven supportive comments.

Committee response: N/A

1814: Counseling for women of childbearing potential with epilepsy

Status: New Submission
Description: All female patients of childbearing potential (12–44 years old) diagnosed with epilepsy who were counseled about epilepsy and how its treatment may affect contraception and pregnancy at least once a year
Numerator Statement: Female patients counseled about epilepsy and how its treatment may affect contraception and pregnancy and documented in the medical record at least once a year.
Denominator Statement: All females of childbearing potential (12-44 years old) with a diagnosis of epilepsy.
Exclusions: Medical reasons (eg, not indicated, contraindicated, other medical reason)
Adjustment/Stratification: N/a
Level of Analysis: Clinician : Individual
Type of Measure: Process
Data Source: Administrative claims, Paper Medical Records
Measure Steward: American Academy of Neurology **Other organizations:** AMA convened Physician Consortium for Performance Improvement-measurement set was developed through the PCPI Independent Measure Development Process

STEERING COMMITTEE MEETING [10/3/2012]

Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: **H-23**; **M-1**; **L-0**; **I-0**; 1b. Performance Gap: **H-24**; **M-0**; **L-0**; **I-0** 1c. Evidence: **Y-11**; **N-0**; **I-13**; **L-0**

Evidence Exception: Y-23; N-1

<u>Rationale</u>:

- The Committee disagreed about the level of evidence supporting this measure. Several noted that the submission did not provide evidence of a direct link between counseling and patient outcomes. Others noted that the submission did provide evidence that epilepsy treatments can affect both contraception and child development during pregnancy, as well as evidence that women with epilepsy feel that they are not getting adequate information about pregnancy. Committee members recommended invoking the evidence exception because the measure impacts a specific population and there is the potential for great harm if such counseling is not done. Upon vote, the Committee almost unanimously agreed to invoke the exception to the evidence subcriterion.
- The Committee overwhelmingly agreed this measure meets the impact criterion because it potentially would affect roughly half of the population of epilepsy patients (i.e., approximately 500,000 women) and because evidence has shown an increased risk for congenital malformations and impaired cognition in children of women treated during pregnancy with one of the common epilepsy medications.
- Data submitted by the developer indicate that only 2-20% of women with epilepsy receive counseling around issues of contraception and pregnancy.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria for</u>

1814: Counseling for women of childbearing potential with epilepsy

untested measures

Precise specifications: Y-21; N-3

Rationale:

- Committee members expressed concern about the lack of an operational definition of "counseling" (e.g., an actual discussion with the patient vs. handing the patient a pamphlet or directing a patient to a website). One member noted that the measure could be a "check-box" measure. Some members preferred a more prescriptive approach (e.g., discussion about medications with the highest fetal anomalies, the impact of pregnancy on seizure control, use of contraceptives, and use of folate); however, other members noted that different patients would require different types of counseling (e.g., the counseling needs for a 12-year old patient might be very different from those for a 30-year old patient).
- Committee members noted that epilepsy treatment can also impact patients' choices for contraception and that this should be should be reflected in the measure.
- The Committee also emphasized the need for the measure to explicitly include discussion of the impact of pregnancy on the patient's epilepsy and on the treatment of epilepsy (i.e., the potential decrease in seizure control).
- **Because this is an untested measure, the Committee voted on whether the measure is** precisely specified and whether the specifications are consistent with the evidence presented for the measure. *(NQF note: As initially submitted, this measure was specified for clinician offices/clinics, home health, and post-acute care/long-term care facilities. However, the developer has determined that there will be insufficient sample sizes available for testing of the measure in the home health and post-acute/long-term care settings. Accordingly, the developer has modified the measure specifications to include only the clinician office/clinic setting.)*

3. Usability: H-10; M-12; L-1; I-1

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- This measure will be publicly reported through the PQRS program, beginning in 2012; also, it is currently in use in AAN's Maintenance of Certification Performance in Practice (NeuroPI) Epilepsy Module. Developers indicated that clinicians using this program have found this measure to be extremely helpful in making them aware of the need for counseling regarding contraception and pregnancy.
- Some members questioned how a measure can be considered useful when no data have been provided to show that the measure has been useful in improving quality of care. NQF staff clarified that there is no an expectation that a measure be in use when first endorsed and if data on usefulness for quality improvement is not yet available, Committee members should base their vote on whether—based on the information that has been provided—they believe that the measure can be useful for quality improvement and informative for public reporting or other accountability purposes.

1814: Counseling for women of childbearing potential with epilepsy

4. Feasibility: H-4; M-15; L-2; I-3

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

Rationale:

- Committee members noted that for claims data, reporting of the measure would be done through CPT-II codes. There was some concern over how data would be collected from paper records; however, the measure has not been specified for paper medical records.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: **Y-24**; **N-0**

Public & Member Comment

Comments included:

- Four supportive comments.
- Several commenters noted the need for outcome measures around issues of contraception and pregnancy for women with epilepsy.

Committee response:

- **The Committee agreed with the suggestions for future measure development and the report has been updated to include them.**

0507: Stenosis measurement in carotid imaging studies

Status: Maintenance, Original Endorsement: Oct 28, 2008 , Time-limited status not yet removed
Description: Percentage of final reports for carotid imaging studies (neck MR angiography [MRA], neck CT angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement
Numerator Statement: Final carotid imaging study reports that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement
Denominator Statement: All final reports for carotid imaging studies (neck MR angiography [MRA], neck CT angiography [CTA], neck duplex ultrasound, carotid angiogram) performed
Exclusions: None
Adjustment/Stratification: No risk adjustment or risk stratification Not applicable 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: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry
Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) **Other organizations:** American Academy of Neurology
American College of Radiology
National Committee for Quality Assurance

STEERING COMMITTEE MEETING [10/4/2012]
Importance to Measure and Report: <u>The measure meets the Importance criteria</u>
(1a. High Impact: 1b. Performance Gap, 1c. Evidence)
1a. Impact: **H-21**; **M-3**; **L-0**; **I-0**; 1b. Performance Gap: **H-21**; **M-3**; **L-0**; **I-0;** 1c. Evidence: **Y-17**; **N-6**; **I-1**

<u>Rationale</u>:

- The evidence cited as support for this measure includes clinical practice guidelines, systematic reviews, and additional studies. One Committee member noted there is good evidence that stenosis, as measured using the North American Symptomatic Carotid Endarterectomy Trial (NASCET) technique, in symptomatic patients, accurately predicts stroke risk. This member suggested that while it is reasonable to assume that documenting the stenosis measurement would be useful for improving patient outcomes, evidence does not exist to support this process of care.
- The Committee questioned whether results are inaccurate if the NASCET method is not used. Another member clarified that different methods yield different results, so the method must be specified. However, this member noted that most of the data used for stroke risk prediction from carotid stenosis severity uses measures from the NASCET approach.
- Data submitted by the developer stated that stroke is a leading cause of death and disability, that approximately 85% of strokes are ischemic, and that there is evidence of complete occlusion of the internal carotid artery for a large percentage of ischemic stroke patients.
- Data provided by the developer from PQRS in 2008 and 2010 PQRS indicate there is evidence of non-optimal performance of this measure.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-9**; **M-15**; **L-0**; **I-0;** 2b. Validity: **H-3**; **M-20**; **L-1**; **I-0**

<u>Rationale</u>:

- One Committee member cautioned that while this measure focuses only on the reporting of stenosis, there are other important elements that should be included in the report (e.g., ulceration and plaque composition).
- This member also noted that as written, the measure seems to require reporting of stenosis severity for all neck vessel imaging studies, even if the carotid is not the issue of interest (e.g., imaging to detect vessel tears, tumors). This member suggested that the reporting requirement may cause undue burden for clinicians and may also cause harm to patients who are asymptomatic for carotid disease if they are then given additional medical therapy (e.g., endarterectomies or stenting).
- The Committee questioned whether ultrasound should be included as an acceptable methodology for measuring stenosis. One Committee member noted that ultrasound results have been correlated with NASCET results and the developer noted the clarification in the numerator details section of the submission that for ultrasound results to meet the measure, they must correlate with anatomic measurements that use the distal internal carotid lumen as the denominator for stenosis measurement.
- The Committee agreed that this expanded definition addressed their concerns and requested that it also be reflected in the brief numerator statement.

3. Usability: H-3; M-20; L-1; I-0
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

<u>Rationale</u>:

- The measure is used in the CMS PQRS program.
- One Committee member reiterated a concern that this measure applies to all neck vessel imaging studies (not just carotid imaging studies), stating that this adversely impacts the usefulness of the measure to some extent.

4. Feasibility: H-18; M-5; L-1; I-0
(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee had no questions or comments on the feasibility of this measure, other than noting that it can be met as a part of usual care practices.

5. Related and Competing Measures

- No related or competing measures noted.

Steering Committee Recommendation for Endorsement: **Y-24**; **N-0**

Public & Member Comment

Comments included:

- Three supportive comments.
- A concern that the measure is a documentation measure and therefore of limited (or no) use for

accountability purposes.

- A concern that the stenosis is based on the physician's judgment of patient symptoms.

Developer response: Thank you for your comment. The intent of this measure is to quantify stenosis as precisely and reproducibly as possible. Patients with stenoses will benefit from physicians using a standardized method for stenosis calculation. There is wide variation in the use of methods for stenosis calculation, which may also lead to variation in the appropriateness of carotid intervention. Since the degree of stenosis is an important element of the decision for carotid intervention, characterization of the degree of stenosis needs to be standardized. Evidence-based guidelines are cited in support of the measure, along with several individual studies and systematic reviews.

Committee response:

- The Committee agreed that the concern that stenosis is based on physician's judgment of patient's symptoms reflected a misunderstanding of the intent of the measure.
- Committee members agreed that this measure is a documentation measure, but reiterated their agreement that there is sufficient evidence indicating that the results of the documentation are interpretable and decisions can be made based on those results.
- Committee members reviewed the comments and the developer response but did not wish to re-consider their vote on this measure.

2111: Antipsychotic Use in Persons with Dementia

Status: New Submission
Description: The percentage of individuals 65 years of age and older with dementia who are receiving an antipsychotic medication without evidence of a psychotic disorder or related condition.
Numerator Statement: The number of patients in the denominator who had at least one prescription and > 30 days supply for any antipsychotic medication during the measurement period and do not have a diagnosis of schizophrenia, bipolar disorder, Huntington's disease or Tourette's Syndrome.
Denominator Statement: All patients 65 years of age and older continuously enrolled during the measurement period with a diagnosis of dementia and/or two or more prescription claims and >60 days supply for a cholinesterase inhibitor or an NMDA receptor antagonist.
Exclusions: N/A
Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A
Level of Analysis: Health Plan
Type of Measure: Process
Data Source: Administrative claims
Measure Steward: Pharmacy Quality Alliance

STEERING COMMITTEE MEETING [10/3/2012]
Importance to Measure and Report: <u>The measure does meet the Importance criteria</u>
(1a. High Impact: 1b. Performance Gap, 1c. Evidence)
1a. Impact: **H-20**; **M-2**; **L-1**; **I-0**; 1b. Performance Gap: **H-11; M-11**; **L-0**; **I-1** 1c. Evidence: **Y-16**; **N-2**; **I-5**

<u>Rationale</u>:

- Approximately 5.2 million people in the U.S. ages 65+ have dementia.
- According to one study cited by the developer, in 2006, more than 30% of nursing home patients received at least one antipsychotic medication, but there was no clinical indication for the medication for 43% of these patients.
- Pilot testing results reported by the developer found that 14-16% of Medicare Advantage patients with dementia received an antipsychotic medication without evidence of a psychotic disorder. The Committee agreed that although the expected rate would not be zero, these results suggest there is likely room for improvement.
- A study cited by the developer found facility-level variation in the prescription of antipsychotic medications in nursing facilities.
- The evidence base for the measure included two systematic reviews, a meta-analysis, and a clinical practice guideline. The Committee agreed that use of antipsychotic medications in dementia patients may lead to negative outcomes, including cardiovascular problems and death.
- Committee members questioned whether appropriate use of antipsychotics varies based on stage of dementia (i.e., should the rate potentially be lower for those with less cognitive impairment compared to those with greater cognitive impairment?). One member noted that the evidence for the measure is not stratified by stage of dementia; this member also noted that behaviors or psychological symptoms which might instigate a prescription for antipsychotics actually can occur over in each stage of the disease, although the actual behaviors/symptoms themselves may vary by stage.
- The Committee agreed the rate of antipsychotic prescription among dementia patients cannot be zero because, for some patients, the risks associated with certain behavioral or psychological symptoms (e.g.,

becoming a danger to themselves or others) are deemed greater than the risks associated with the use of antipsychotics. However, the Committee expressed discomfort with the lack of evidence to suggest what the appropriate rate should be.

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-7**; **M-12**; **L-2**; **I-2** 2b. Validity: **H-1**; **M-9**; **L-12**; **I-1**

<u>Rationale</u>:

- Some committee members voiced discomfort with the measure because there are conditions for which antipsychotic use may be appropriate, even in those with dementia (e.g., "agitated delirium", dyskinesia in Parkinson's disease patients). One member suggested that adding a "psychosis not otherwise specified" code (to exclude such patients from the numerator) might be a way to handle this problem. However, other Committee members noted that there are a variety of ways to treat of psychosis in dementia patients and were not in favor of including additional exceptions to the measure.
- Another member asked why the specifications do not more closely follow the guideline recommendation to avoid use of antipsychotics among dementia patients "unless non-pharmacological options have failed and patient is a threat to self or others." The developer was unsure that this level of specification would be possible using claims data.
- The developer noted that they specified the measure to count antipsychotic use only if the prescription(s) exceeds a 30-day supply; this was done as a way to differentiate what might be short-term use for an acute psychotic episode. Committee members agreed that 30 days might be a sufficient amount of time for some patients, but not for all.
- Committee members questioned why Parkinson's disease patients were not excluded from the measure, given that antipsychotic medications often are used appropriately for dementia-related psychosis in these patients. However, there was not agreement among Committee members as to whether Parkinson's disease patients should or should not be excluded.
- Committee members acknowledged the effort to try to identify dementia patients by looking at both diagnosis and prescription of medications for dementia (per the assumption that dementia is under-diagnosed). However, they noted that the prevalence of dementia found in the pilot studies was much lower than might be expected. They also questioned whether dementia medications are actually over-prescribed and, if so, if this measure as specified actually captures patients who have dementia. They acknowledged the developer's assertion that the use of dementia medications for other indications (e.g., TBI) is rare, but noted a lack of evidence to support that assertion.
- A Committee member noted this measure uses fewer ICD-9 codes for dementia than do other dementia measures. The developer noted that they created their list of ICD-9 codes for dementia based on input from their expert panels and relevant studies in the literature, but were open to adding additional codes to their list.
- Several Committee members suggested that because this is a health-plan level measure, problems with the specifications may be somewhat less concerning, particularly given the importance of the problem of overuse of antipsychotics in dementia patients.

Steering Committee Recommendation for Endorsement: **No**

- The measure did not pass the criterion of Scientific Acceptability. Although the Committee liked the

intent of this measure, many agreed that the validity of the measure as specified was adversely impacted because of the difficulties in identifying dementia patients and the fact that antipsychotic use in dementia patients is sometimes warranted.

Public & Member Comment

Comments included:

- Five supportive comments that advocated reconsideration of the measure by the Committee; commenters offered the following reasons for reconsideration:
  - Although there are limitations with the use of claims based data (e.g., inability to evaluate appropriateness of regimen), identifying variability in use is important. For example, very high rates might suggest non-use of non-drug management strategies or inadequate evaluation.
  - While claims-based measures cannot capture all possible exclusions, such data are accurate enough for health plan level measures.
  - Provider feedback to a large Pharmacy Benefits Manager indicates that providers rarely prescribe Alzheimer's drugs for a non-dementia reason, suggesting that the false-positive identification of dementia using Alzheimer's drugs as a proxy is remote.
- One comment supporting the Committee's decision not to recommend the measure.

Developer response: The developer provided additional information via letter in response to questions raised by the Committee during the in-person meeting. In this letter, which is posted on NQF's public website, the developers note the following:

- **A comparatively narrower list of ICD-9 codes is used to identify patients with dementia compared to what is used in other measures**—Codes that indicate a behavioral disturbance or psychosis are not included because the measure is intended to focus on those dementia patients who do not have a clear indication for an antipsychotic drug.
- **Variability in performance rates**—Additional analysis at the plan contract level shows that the performance rate varied from 10.2% to 20.3%, with an average of 13.9% and standard deviation of 3.7%. Thus, there is variation in performance across the Medicare contracts, with some of the contracts having a rate that is nearly 2 standard deviations above the average.
- **Use of dementia drugs for conditions other than dementia**—Such drugs may be used for the late effects of traumatic brain injury (ICD-9 code 907.0). Additional analysis show that out of 48,341 patients identified as having dementia, only 46 patients had a claim with this diagnosis (less than 0.1%).
- **Relatively low prevalence of dementia identified in pilot studies—**Using the combination of medication marker and dementia diagnosis codes, there was a fairly consistent rate dementia patients across the numerous Medicare contracts (average of 4.6%; range of 3.4% to 5.9%). The percentage of the population included in the measure is not intended to replicate the overall rate of dementia in the general population, given the focus on a subset of dementia patients who do not have a diagnosis indicating psychoses or behavioral disturbance.

Committee response:

- After review of the comments, one Committee member expressed the belief that the additional analysis

submitted by the developer provided evidence that use of dementia medications as a way to identify dementia patient is a valid proxy, while another member noted that earlier concerns around whether TBI patients would be included in this measure had also been addressed by the developer. These members recommended reconsideration of the measure by the Committee.

- The Committee agreed to re-vote on the measure.

Vote Following Consideration of Public and Member Comments (note: because the measure initially failed on validity, the Committee re-vote included only the validity, usability, and feasibility criteria and the overall vote on the suitability of the measure for endorsement)**:**

2. Scientific Acceptability of Measure Properties (based on decision logic): **The measure meets the Scientific Acceptability criteria**

2b. Validity: H-2; M-12; L-1; I- 2

Usability: H-3; M-12; L-2; I-0

Feasibility: H-4; M-11; L-2; I-0

Steering Committee Recommendation on Overall Suitability for Endorsement: Y-13; N-4

Upon re-vote, the Committee agreed the additional information provided by the developers was adequate to address their initial concerns about the validity of the measure.

[i] Centers for Disease Control. Available at http://www.cdc.gov/mentalhealth/data_stats/alzheimers.htm

[ii] American Health Assistance Foundation. Available at http://www.ahaf.org/alzheimers/about/understanding/facts.html Last accessed February 2012

[iii] Centers for Disease Control. Available at http://www.cdc.gov/mentalhealth/data_stats/alzheimers.htm Last accessed February 2012

Alzheimer's Association. Available at http://www.alz.org/documents_custom/2011_Facts_Figures_Fact_Sheet.pdf Last accessed February 2012

[iv] Centers for Disease Control. Available at http://www.cdc.gov/epilepsy/basics/fast_facts.htm

[v] Parkinson's Disease Foundation. Available at http://www.pdf.org/en/parkinson_statistics Last accessed February 2012