NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

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

NQF #: 0021 NQF Project: Patient Safety Measures-Complications Project

(for Endorsement Maintenance Review)
Original Endorsement Date: Aug 10, 2009 Most Recent Endorsement Date: Aug 10, 2009

BRIEF MEASURE INFORMATION

De.1 Measure Title: Annual monitoring for patients on persistent medications

Co.1.1 Measure Steward: National Committee for Quality Assurance

De.2 Brief Description of Measure: The percentage of members 18 years of age and older who received at least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year. For each product line, report each of the four rates separately and as a total rate.

- Annual monitoring for members on angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB)
- Annual monitoring for members on digoxin
- Annual monitoring for members on diuretics
- Annual monitoring for members on anticonvulsants
- Total rate (the sum of the four numerators divided by the sum of the four denominators)

2a1.1 Numerator Statement: For annual monitoring for members on ACE inhibitors or ARBs, digoxin, and diuretics:

The number of patients with at least one serum potassium and either a serum creatinine or a blood urea nitrogen therapeutic monitoring test in the measurement year.

For annual monitoring for members on anticonvulsants:

At least one drug serum concentration level monitoring test for the prescribed drug in the measurement year.

Sum of the 4 numerators.

2a1.4 Denominator Statement: Members on persistent medications—defined as members who received at least 180 treatment days of ambulatory medication in the measurement year.

2a1.8 Denominator Exclusions: For Annual Monitoring for Members on Anticonvulsants:
(optional) Members from each eligible population rate who had an inpatient (acute or nonacute) claim/encounter during the measurement year.

1.1 Measure Type: Process
2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy
2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Health Plan

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*):
N/A

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

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria)
1a. High Impact: H☐ M☐ L☐ I ☐ (*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)
De.4 Subject/Topic Areas *(Check all the areas that apply)*: Cardiovascular, Cardiovascular : Acute Myocardial Infarction, Cardiovascular : Atrial Fibrillation, Cardiovascular : Congestive Heart Failure, Cardiovascular : Hyperlipidemia, Cardiovascular : Hypertension, Cardiovascular : Ischemic Heart Disease, Coronary Artery Disease, Cardiovascular : Percutaneous Coronary Intervention (PCI), Endocrine, Endocrine : Diabetes, GI, GI : Appendicitis, GI : Bleeding, GI : Cirrhosis, GI : Gall Bladder Disease, GI : Gastroenteritis, GI : Gastro-Esophageal Reflux Disease (GERD)/Peptic Ulcer, GI : Polyps, Musculoskeletal, Musculoskeletal : Functional Status, Neurology, Neurology : Dementia/Delirium, Neurology : Stroke/Transient Ischemic Attack (TIA), Prevention, Prevention : Screening, Pulmonary/Critical Care, Renal, Renal : Chronic Kidney Disease (CKD), Renal : End Stage Renal Disease (ESRD) De.5 Cross Cutting Areas (*Check all the areas that apply)*: Care Coordination, Safety, Safety : Complications, Safety : Medication Safety
1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, High resource use, Patient/societal consequences of poor quality, Severity of illness 1a.2 If "Other," please describe: 1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*: Adverse drug events cause over 700,000 Americans to visit an emergency room each year, and 1 of 6 will need to be hospitalized (Budnitz, 2006). Nearly 120,000 of these patients need to be hospitalized for further treatment (CDC, 2010). Drugs that commonly require monitoring in outpatient settings accounted for over half of all unintentional drug overdoses that resulted in an emergency room visit (Budnitz, 2006). With monitoring, clinicians can adjust the patient's dosage to prevent avoidable adverse events. As people age, they typically take more medicines, resulting with an increased risk of adverse events. Older adults (65 years or older) are twice as likely as others to come to emergency departments for adverse drug events (over 177,000 emergency visits each year) and nearly seven times more likely to be hospitalized after an emergency visit (CDC, 2010). 1a.4 Citations for Evidence of High Impact cited in 1a.3: Budnitz, D et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006;296:1858-1866. CDC – Medication Safety Basics, 2010. http://www.cdc.gov/MedicationSafety/basics.html#ref
1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐ (*There is a demonstrated performance gap - variability or overall less than optimal performance*)

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

1b.2 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*: [*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]

MEDICARE Reported Rates:

ACE inhibitors or ARBs	2009	2008	2007
N	294	277	242
MEAN	89.6	86.7	84.8
STDEV	6.78	11.6	12.6
STDERR	0.4	0.7	0.81
MIN	38.4	5.53	25.4
MAX	99.2	99.1	99
P10	84.7	77.6	74.4
P25	88.7	86	84.2
P50	91.1	89.6	88.7
P75	92.8	92.1	91.1
P90	94.4	93.5	92.7

Digoxin	2009	2008	2007
N	245	223	205
MEAN	92	90.4	87.9
STDEV	6.33	10.1	11
STDERR	0.4	0.68	0.77
MIN	39.1	11.9	34.7
MAX	100	100	100
P10	87.5	85.7	80.3
P25	90.5	89.4	87
P50	93.4	92.6	90.8
P75	94.9	94.6	93.4
P90	96.6	96	95.4

Diuretics	2009	2008	2007
N	294	276	241
MEAN	89.8	87.1	84.8
STDEV	6.86	11.6	13
STDERR	0.4	0.7	0.83
MIN	39	7.09	24
MAX	99.3	99.3	98.
P10	84.6	79.1	74.6
P25	88.8	86.5	84.6
P50	91.4	90.2	89
P75	93.1	92.3	91.2
P90	94.6	93.8	93.3

Anticonvulsants	2009	2008	2007
N	243	215	195
MEAN	69.7	67.5	65.1
STDEV	11.6	12.8	14.1
STDERR	0.74	0.87	1.01
MIN	28.6	13	11.8
MAX	98.9	98.7	98.7
P10	56.8	53.6	47
P25	64.5	62.4	60

P50	69.3	68.2	66.9
P75	75.9	74.5	73.5
P90	83.9	82	80

Total	2009	2008	2007
N	294	277	242
MEAN	89.2	86.3	84.3
STDEV	6.83	11.5	12.7
STDERR	0.4	0.69	0.81
MIN	38.6	6.48	24.8
MAX	99	99	98.6
P10	84.3	77.1	73.9
P25	88	85.6	83.8
P50	90.7	89.4	88.3
P75	92.5	91.6	90.7
P90	93.9	93.1	92.3

COMMERCIAL Reported Rates:

ACE inhibitors or ARBs	2009	2008	2007
N	235	244	245
STDEV	4.64	4.49	7.36
STDERR	0.3	0.29	0.47
MIN	61.8	61.2	25.3
MAX	93.7	93.8	92.5
P10	75.3	73.3	68.8
P25	78.3	77.2	75.3
P50	81.4	80	78.9
P75	83.6	82	81.2
P90	85.8	83.9	83.9

MEAN 80.8 79.4 77.2

Digoxin	2009	2008	2007
N	168	178	185
MEAN	83.6	81.9	79.7
STDEV	6.86	6.56	7.36
STDERR	0.53	0.49	0.54
MIN	52.7	55.3	46.8
MAX	97.8	95	97.7
P10	76.6	75	70.3
P25	80.6	78.9	75.8
P50	84.4	82.4	80.6
P75	87.8	85.7	85
P90	90.9	90	87.2

Diuretics	2009	2008	2007
N	235	244	245
MEAN	80.4	79.1	76.8
STDEV	4.78	4.63	7.42
STDERR	0.31	0.3	0.47
MIN	58.1	61.9	26.3
MAX	93.1	93	90.3
P10	75	72.8	68.4
P25	78.1	77.2	74.8
P50	81	79.8	78.3
P75	83.1	82.1	81.1

P90	86	83.9	83.1

Anticonvulsants	2009	2008	2007
N	214	221	225
MEAN	62	61.7	59.6
STDEV	7.58	7.16	10.1
STDERR	0.52	0.48	0.67
MIN	33.1	41	20
MAX	93.3	93.5	88.5
P10	53.6	53.8	48.3
P25	57.1	57.2	55.4
P50	62.2	61.6	61
P75	65.8	65.3	65.1
P90	71.1	70.4	69.6

Total	2009	2008	2007
N	235	244	245
MEAN	80.3	78.9	76.6
STDEV	4.67	4.46	7.29
STDERR	0.3	0.29	0.47
MIN	59.7	61.8	25.4
MAX	93.1	93.4	90.3
P10	74.8	72.6	68.7
P25	77.9	76.7	74.6
P50	80.8	79.6	78.4
P75	83.1	81.6	80.6
P90	85.2	83.5	82.8

MEDICAID Reported Rates:

ACE inhibitors or ARBs	2009	2008	2007
N	111	97	103
MEAN	85.9	84.8	82.5
STDEV	4.76	7.28	7.62
STDERR	0.45	0.74	0.75
MIN	70	32.2	38.1
MAX	98.3	98.9	98.4
P10	80	78	77.3
P25	84.1	83.3	79.9
P50	86.3	86.3	84.2
P75	89.2	88.1	87
P90	90.5	90.1	88.8

Digoxin	2009	2008	2007
N	59	56	57
MEAN	88.9	88.5	84.9
STDEV	5.23	5.86	9.78
STDERR	0.68	0.78	1.3
MIN	72.7	67.3	39
MAX	97.2	98.3	96.3
P10	82	81.1	79.4
P25	86	86.6	82.1
P50	90	90.1	86.6
P75	92.7	92.3	90.9
P90	95.2	93.8	92.5

Diuretics	2009	2008	2007
N	111	97	103
MEAN	85.4	84.2	81.3
STDEV	4.45	7.8	7.76
STDERR	0.42	0.79	0.76
MIN	72.6	27.8	39.7
MAX	96.5	97.6	97
P10	79.4	77.1	74.3
P25	82.6	81.9	78.4
P50	86.1	85.7	82.6
P75	88.4	87.8	86
P90	90.6	89.9	88.6

Anticonvulsants	2009	2008	2007
N	98	88	92
MEAN	68.7	68.7	65.9
STDEV	7.51	9.11	9.19
STDERR	0.76	0.97	0.96
MIN	43.3	18.2	32.3
MAX	88.9	86.8	81.8
P10	60.4	59.2	55.2
P25	64.5	65	61.8
P50	68.6	69.2	67.5
P75	72.7	73.5	71.4
P90	78.1	78.5	76.3

Rate	2009	2008	2007
N	115	97	103
MEAN	83.2	82.6	80.1
STDEV	6.42	7.31	7.34
STDERR	0.6	0.74	0.72
MIN	38.2	29.3	38
MAX	95.7	96.9	96.1
P10	77.2	76.2	73.5
P25	81.2	80.1	77.2
P50	84.3	83.5	81.6
P75	86.8	86	84
P90	88.5	88.5	86.5

1b.3 Citations for Data on Performance Gap: [*For **Maintenance** – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
Section 1b.2 references data from the most recent three years of measurement for this measure. The data in section 1b.2 includes percentiles, mean, min, max, standard deviations and standard errors. There were 813 Medicare, 724 Commercial, and 315 Medicaid submissions for total rate portion of this measure.

NCQA collects data directly from Health Plan Organizations and Preferred Provider Organizations via a data submission portal - the Interactive Data Submission System (IDSS). NCQA assigns a sub-ID by an accreditible identity based on the legal entity and management structure that supports the product lines/products that NCQA accredits. Each accreditation is legally accountable entity provides to members and representation of an organization and delivery structure that is meaningful to members.

1b.4 Summary of Data on Disparities by Population Group: [*For **Maintenance** –Descriptive statistics for performance results for this measure by population group*]
This measure is not stratified for disparities.

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

This measure is not stratified for disparities.

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

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

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

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

The elderly population is one that is often prone to medication errors, primarily due to multiple medications prescribed for their various health conditions. Thus, polypharmacy causes even more problems, with drug interactions going undetected. Some of the other factors that lead to medication errors in the elderly in their homes are the following:

1. Poor lighting and poor vision
2. Cluttered medicine cabinets that hold expired medications
3. Duplicate therapy as a result of self-medicating
4. Consulting multiple physicians and not providing a complete medication history
5. Dementia or confusion
6. Overuse of “as needed” medications
7. Sharing medications with other family members (John, 2005).

ABOUT PERSISTENT MEDICATIONS MONITORING

- Up to half of patients on persistent medications receive no drug monitoring in one year (Raebel, et al., 2006; Stelfox, 2004).
- Among those aged 65 and older, 87 percent of all hospitalizations from unintentional drug overdose were due to drugs that commonly require outpatient monitoring (Budnitz, 2006).

From 2004 through 2005, adverse drug events accounted for 2.5% of estimated emergency department visits for all unintentional injuries and 6.7% of those leading to hospitalization and accounted for0.6%of estimated emergency department visits for all causes. Drugs for which regular outpatient monitoring is used to prevent acute toxicity accounted for 41.5%of estimated hospitalizations overall and 54.4% of estimated hospitalizations among individuals aged 65 years or older (Budnitz, 2006).

KEY FINDINGS – Adults

- In a given week, an average of 82% of adults in the U.S. are taking at least one medication (prescription or nonprescription drug, vitamin/mineral, herbal/natural supplement); 29% are taking five or more.
- Men and women aged 65 years or older continue to be the biggest consumers of medications: 17-19% in this age group take at least ten in a given week.

The prevalence of use of medications overall and prescription drugs has not changed materially since the Survey began in 1998. However, polypharmacy has increased since 2000, from 23% to 29% for use of five or more medications and from 6.3% to 12% for use of at least five prescription drugs (Slone Survey, 2006).

For overall medications, prevalence of use increased with age among both males and females. The highest overall prevalence was in older men (93%) and older women (94%). Polypharmacy was particularly common in these subjects: 57-59% took at least five medications and 17-19% at least ten (Slone Survey, 2006).

Since 2000, use of at least five medications has increased from 23% to 29%. Use of at least ten medications has also increased, from 4.4% in 2000 to 7.5% in 2006. A larger proportional increase in prevalence over the same time period was seen for use of at least five prescription drugs: 6.3% to 12% (Slone Survey, 2006).
In a list of the thirty Most Commonly Used Prescription and Over-the-Counter Drugs Taken by U.S. Adults in 2006, hydrochlorothiazide (diuretic) ranked 5th and lisinopril (ACE-inhibitor) ranked 7th (Slone Survey, 2006).
Individual patients hold different beliefs about medications to which they persist vs nonpersist or nonfulfill. Patients exhibit different medication-taking behaviors for different medications because they weigh the perceived risks and benefits for each medication separately (McHorney & Gadkari, 2010). Adverse drug events cause clinically significant morbidity and mortality and are associated with large economic costs. They are common in older adults, regardless of whether they live in the community, reside in long-term care facilities, or are hospitalized. Most physicians recognize that prescribing medications to older patients requires special considerations, but nongeriatricians are typically unfamiliar with the most commonly used measure of medication appropriateness for older patients. (Bunditz, et al., 2007)
Several studies carried out in the US have investigated adverse drug effects experienced by hospitalized patients and their impact on hospital costs. Patients who developed adverse effects were hospitalized an average of 1.2–3.8 days longer than patients who did not, with additional hospital costs of $US2284–5640 per patient. A recent estimation revealed that in the US the cost of problems linked to drug use in the ambulatory setting exceeded $US177 billion in the year 2000 (Rodriguez-Monguio, Otero, & Roviro, 2003).

1c.2-3 Type of Evidence *(Check all that apply)*:
Selected individual studies (rather than entire body of evidence)

1c.4 Directness of Evidence to the Specified Measure *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:
This measure seeks to monitor the use of persistent medications in the elderly. The measure intent and the body of evidence are congruent.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: 8

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): These studies are consistent in their conclusions

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):*

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
With monitoring, clinicians can adjust the patient's dosage to prevent avoidable adverse events.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: N/A

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

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

1c.13 Grade Assigned to the Body of Evidence: N/A

1c.14 Summary of Controversy/Contradictory Evidence: There is no controversy concerning monitoring of persistent medications.

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

Budnitz, D et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006;296:1858-1866.

Budnitz DS, Shehab N, Kegler SR, Richards CL. Emergency department visits for adverse drug events in older adults: the contribution of potentially inappropriate medication use. Ann Intern Med 2007;147:755-765.

John, JM. (2005). Preventing Medication Errors at Home. Journal of Pharmacy Practive;18(3):141-4.

Raebel MA et al. Monitoring of drugs with a narrow therapeutic range in ambulatory care. Am J Manag Care. 2006 May;12(5):268-74

Rodriguez-Monguio R, Otero M, & Rovira J. Assessing the economic impact of adverse drug effects. Pharmacoeconomics 2003;21:623-50.

Slone Epidemiology Center. Patterns of medication use in the United States, 2006: a report from the Slone Survey. http://www.bu.edu/slone/SloneSurvey/AnnualRpt/SloneSurveyWebReport2006.pdf. Accessed August 2011.

Stelfox, HT et al. An evaluation of the adequacy of outpatient monitoring of thyroid replacement therapy. J Eval Clin Pract. 2004 Nov;10(4):525-30

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
Although there are no clinical guideline recommendations on the frequency of monitoring, annual monitoring represents a conservative standard of care and is supported by FDA drug labeling recommendations for each drug.

The denominator for this measure is specified by defining patients on persistent medications throughout the year as those who require monitoring. In addition, medical record concordance results demonstrate that administrative data captures monitoring events performed with fairly high reliability and accuracy.

1c.17 Clinical Practice Guideline Citation: N/A

1c.18 National Guideline Clearinghouse or other URL: N/A

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? No

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

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

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

1c.23 Grade Assigned to the Recommendation: N/A

1c.24 Rationale for Using this Guideline Over Others: N/A

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High 1c.26 Quality: High1c.27 Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐
Provide rationale based on specific subcriteria:

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

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

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? No

S.2 If yes, provide web page URL:

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

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

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
For annual monitoring for members on ACE inhibitors or ARBs, digoxin, and diuretics:

The number of patients with at least one serum potassium and either a serum creatinine or a blood urea nitrogen therapeutic monitoring test in the measurement year.

For annual monitoring for members on anticonvulsants:

At least one drug serum concentration level monitoring test for the prescribed drug in the measurement year.

Sum of the 4 numerators.

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

2a1.3 Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*:
For annual monitoring for members on ACE inhibitors or ARBs, digoxin, and diuretics:
The member must meet one of the following criteria to be compliant.
• A code for a lab panel test during the measurement year
• A code for a serum potassium and a code for serum creatinine during the measurement year
• A code for serum potassium and a code for blood urea nitrogen during the measurement year

For annual monitoring for members on anticonvulsants:
If a member received only one type of anticonvulsant, the drug serum concentration level test must be for the specific drug taken as a persistent medication (i.e., a member on phenytoin received a drug serum test for phenytoin).

If a member persistently received multiple types of anticonvulsants, each anticonvulsant medication and drug monitoring test combination is counted as a unique event (i.e., a member on both phenytoin and valproic acid with at least 180 treatment days for each drug in the measurement year must separately show evidence of receiving drug serum concentration tests for each drug.

Codes to identify physiologic monitoring tests:
Lab panel- CPT: 80047, 80048, 80050, 80053, 80069
Serum potassium (K+)- CPT:80051, 84132; LOINC: 2824-1, 2823-3, 6298-4, 12812-4, 12813-2, 22760-3, 29349-8, 32713-0,

39789-3, 39790-1, 41656-0, 51618-7
Serum creatinine (SCr)- CPT: 82565, 82575; LOINC: 2160-0, 2163-4, 2164-2, 11041-1, 11042-9, 12195-4, 13441-1, 13442-9, 13443-7, 13446-0, 13447-8, 13449-4, 13450-2, 14682-9, 16188-5, 16189-3, 21232-4, 26752-6, 31045-8, 33558-8, 35203-9, 35591-7, 35592-5, 35593-3, 35594-1, 38483-4, 39955-0, 39956-8, 39957-6, 39958-4, 39959-2, 39960-0, 39961-8, 39962-6, 39963-4, 39964-2, 39965-9, 39966-7, 39967-5, 39968-3, 39969-1, 39970-9, 39971-7, 39972-5, 39973-3, 39974-1, 39975-8, 39976-6, 40112-5, 40113-3, 40114-1, 40115-8, 40116-6, 40117-4, 40118-2, 40119-0, 40120-8, 40121-6, 40122-4, 40123-2, 40124-0, 40125-7, 40126-5, 40127-3, 40128-1, 40248-7, 40249-5, 40250-3, 40251-1, 40252-9, 40253-7, 40254-5, 40255-2, 40256-0, 40257-8, 40258-6, 40264-4, 40265-1, 40266-9, 40267-7, 40268-5, 40269-3, 40270-1, 40271-9, 40272-7, 40273-5, 44784-7, 50380-5, 50381-3, 51619-5, 51620-3
Blood urea nitrogen (BUN)- CPT: 84520, 84525; LOINC: 3094-0, 6299-2, 11064-3, 11065-0, 12964-3, 12965-0, 12966-8, 14937-7, 44734-2, 49071-4

Codes to identify Drug Serum Concentration Monitoring Tests:
Drug serum concentration for phenobarbital- CPT: 80184; LOINC: 3948-7, 3951-1, 10547-8, 14874-2, 34365-7, 60468-6
Drug serum concentration for phenytoin- CPT: 80185, 80186; LOINC: 3968-5, 3969-3, 14877-5, 32109-1, 40460-8
Drug serum concentration for valproic acid or divalproex sodium- CPT: 80164; LOINC: 4086-5, 4087-3, 4088-1, 14946-8, 18489-5, 21590-5, 32119-0, 32283-4
Drug serum concentration for carbamazepine- CPT: 80156, 80157; LOINC: 3432-2, 3433-0, 9415-1, 14056-6, 14639-9, 18270-9, 29147-6, 29148-4, 32058-0, 32852-6, 47097-1

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
Members on persistent medications—defined as members who received at least 180 treatment days of ambulatory medication in the measurement year.

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

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

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
Drugs to identify members on ACE inhibitors or ARBs:
Angiotensin converting enzyme inhibitors: benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, quinapril, ramipril, trandolapril

Angiotensin II inhibitors
Candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan , valsartan

Antihypertensive combinations
amlodipine-benazepril, amlodipine-olmesartan, amlodipine-valsartan, benazepril-hydrochlorothiazide, candesartan-hydrochlorothiazide, captopril-hydrochlorothiazide , enalapril-hydrochlorothiazide, eprosartan-hydrochlorothiazide, fosinopril-hydrochlorothiazide, hydrochlorothiazide-irbesartan, hydrochlorothiazide-lisinopril, hydrochlorothiazide-losartan, hydrochlorothiazide-moexipril, hydrochlorothiazide-olmesartan. hydrochlorothiazide-quinapril, hydrochlorothiazide-telmisartan . hydrochlorothiazide-valsartan, trandolapril-verapamil, amiloride-hydrochlorothiazide-olmesartan and aliskiren-hydrochlorothiazide-amlodipine

Drugs to identify members on digoxin:
Inotropic agents: digoxin

Drugs to identify members on diuretics:
Antihypertensive combinations
Prescription: aliskiren-hydrochlorothiazide, amiloride-hydrochlorothiazide, amlodipine-hydrochlorothiazide-valsartan, atenolol-chlorthalidone, benazepril-hydrochlorothiazide, bendroflumethiazide-nadolol, bisoprolol-hydrochlorothiazide, candesartan-

hydrochlorothiazide, captopril-hydrochlorothiazide, chlorthalidone-clonidine, enalapril-hydrochlorothiazide, eprosartan-hydrochlorothiazide, fosinopril-hydrochlorothiazide, hydrochlorothiazide-irbesartan, hydrochlorothiazide-lisinopril, hydrochlorothiazide-losartan, hydrochlorothiazide-methyldopa, hydrochlorothiazide-metoprolol, hydrochlorothiazide-moexipril, hydrochlorothiazide-olmesartan, hydrochlorothiazide-propranolol, hydrochlorothiazide-quinapril, hydrochlorothiazide-spironolactone, hydrochlorothiazide-telmisartan, hydrochlorothiazide-timolol, hydrochlorothiazide-triamterene, hydrochlorothiazide-valsartan

Loop diuretics
Prescription: bumetanide, ethacrynic acid, furosemide, torsemide

Potassium-sparing diuretics
Prescription: amiloride, eplerenone, spironolactone, triamterene

Thiazide diuretics
Prescription: chlorothiazide, chlorthalidone, hydrochlorothiazide, hydroflumethiazide, indapamide, methyclothiazide, metolazone,

Drugs to identify members on anticonvulsants:
Barbiturate anticonvulsants: phenobarbital
Dibenzazepine anticonvulsants: carbamazepine
Hydantoin anticonvulsants: phenytoin
Miscellaneous anticonvulsants: divalproex sodium, valproic acid

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
For Annual Monitoring for Members on Anticonvulsants:
(optional) Members from each eligible population rate who had an inpatient (acute or nonacute) claim/encounter during the measurement year.

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
Specifications do not include codes or definitions to identify acute or nonacute inpatient claims and encounters.

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

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

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

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

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

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

2a1.20 Calculation Algorithm/Measure Logic*(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
Step 1. Determine the eligible population. The eligible population is all members who satisfy all specified criteria, including any age, continuous enrollment, benefit, event, or anchor date enrollement requirement.

Step 2. Search administrative systems to identify numerator events for all members in the eligible population.

Step 3. If applicable, for members for whom administrative data do not show a positive numerator event, search administrative data for an exclusion to the service/procedure being measured. Note: This step applies only to measures for which optional exclusions are specified and for which the organization has chosen to search for exclusions. The organization is not required to search for optional exclusions.

Step 4. Exclude from the eligible population members from step 3 for whom administrative system data identified an exclusion to the service/procedure being measured.

Step 5. Calculate the rate.

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

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

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

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): Healthcare Effectiveness Data Information Set (HEDIS)

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

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

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

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinic/Urgent Care, Ambulatory Care : Clinician Office, Laboratory, Pharmacy

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

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
HEDIS Health Plan performance data for 2010

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

Reliability was estimated by using the beta-binomial model. Beta-binomial is a better fit when estimating the reliability of simple pass/fail rate measures as is the case with most HEDIS® health plan measures. The beta-binomial model assumes the plan score is a binomial random variable conditional on the plan´s true value that comes from the beta distribution. The beta distribution is usually defined by two parameters, alpha and beta. Alpha and beta can be thought of as intermediate calculations to get to the needed variance estimates. The beta distribution can be symmetric, skewed or even U-shaped.

Reliability used here is the ratio of signal to noise. The signal in this case is the proportion of the variability in measured performance that can be explained by real differences in performance. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one plan from another. A reliability score greater than or equal to 0.7 is considered very good.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Reliability for this measure was calculated as 0.99775 for the total rate, 0.99566 for the ACE inhibitor or ARB rate, 0.93766 for the Digoxin rate, 0.99464 for the Diuretics rate, and 0.95919 for the Anticonvulsants rate.

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

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* are consistent with the evidence cited in support of the measure focus (*criterion 1c)* and identify any differences from the evidence:
The measure monitors the use of persistent medications in the elderly. The evidence is consistent with the focus and scope of this measure.

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

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

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
NCQA tested the measure for face validity using a panel of stakeholders with specific expertise in measurement and women's health. This panel included representatives from key stakeholder groups geriatricians, health plans, Medicare officials and researchers. Experts reviewed the results of the field test and assessed whether the results were consistent with expectations, whether the measure represented quality care, and whether we were measuring the most important aspect of care in this area.

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
This measure was deemed valid by the expert panel.

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

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

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
NCQA currently allows health plans for optional exclusions to their results. NCQA does not conduct the annual analysis applied to a sample. In measure development, field testing and any re-analysis for update, we investigate and validate the effect reliability exclusion applied to the eligible denominator.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
N/A

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
N/A

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured*

entities was appropriately tested with adequate results.)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
N/A

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
N/A

2b4.3 Testing Results *(Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata)*:
N/A

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: The measure assesses the monitoring of persistent medications a general population of all adult and elderly persistent medication users; risk adjustment is not indicated.

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

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
Comparison of means and percentiles; analysis of variance against established benchmarks; if sample size is >400, we would use an analysis of variance

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
MEDICARE Reported Rates:

ACE inhibitors or ARBs	2009	2008	2007
N	294	277	242
MEAN	89.6	86.7	84.8
STDEV	6.78	11.6	12.6
STDERR	0.4	0.7	0.81
MIN	38.4	5.53	25.4
MAX	99.2	99.1	99
P10	84.7	77.6	74.4
P25	88.7	86	84.2
P50	91.1	89.6	88.7
P75	92.8	92.1	91.1
P90	94.4	93.5	92.7

Digoxin	2009	2008	2007
N	245	223	205
MEAN	92	90.4	87.9
STDEV	6.33	10.1	11
STDERR	0.4	0.68	0.77
MIN	39.1	11.9	34.7

MAX	100	100	100
P10	87.5	85.7	80.3
P25	90.5	89.4	87
P50	93.4	92.6	90.8
P75	94.9	94.6	93.4
P90	96.6	96	95.4

Diuretics	2009	2008	2007
N	294	276	241
MEAN	89.8	87.1	84.8
STDEV	6.86	11.6	13
STDERR	0.4	0.7	0.83
MIN	39	7.09	24
MAX	99.3	99.3	98.
P10	84.6	79.1	74.6
P25	88.8	86.5	84.6
P50	91.4	90.2	89
P75	93.1	92.3	91.2
P90	94.6	93.8	93.3

Anticonvulsants	2009	2008	2007
N	243	215	195
MEAN	69.7	67.5	65.1
STDEV	11.6	12.8	14.1 STDERR 0.74 0.87 1.01
MIN	28.6	13	11.8
MAX	98.9	98.7	98.7
P10	56.8	53.6	47
P25	64.5	62.4	60
P50	69.3	68.2	66.9
P75	75.9	74.5	73.5
P90	83.9	82	80

Total	2009	2008	2007
N	294	277	242
MEAN	89.2	86.3	84.3
STDEV	6.83	11.5	12.7
STDERR	0.4	0.69	0.81
MIN	38.6	6.48	24.8
MAX	99	99	98.6
P10	84.3	77.1	73.9
P25	88	85.6	83.8
P50	90.7	89.4	88.3
P75	92.5	91.6	90.7
P90	93.9	93.1	92.3

COMMERCIAL Reported Rates:

ACE inhibitors or ARBs	2009	2008	2007
N	235	244	245 MEAN 80.8 79.4 77.2
STDEV	4.64	4.49	7.36
STDERR	0.3	0.29	0.47
MIN	61.8	61.2	25.3
MAX	93.7	93.8	92.5
P10	75.3	73.3	68.8
P25	78.3	77.2	75.3

P50	81.4	80	78.9
P75	83.6	82	81.2
P90	85.8	83.9	83.9

Digoxin	2009	2008	2007
N	168	178	185
MEAN	83.6	81.9	79.7
STDEV	6.86	6.56	7.36
STDERR	0.53	0.49	0.54
MIN	52.7	55.3	46.8
MAX	97.8	95	97.7
P10	76.6	75	70.3
P25	80.6	78.9	75.8
P50	84.4	82.4	80.6
P75	87.8	85.7	85
P90	90.9	90	87.2

Diuretics	2009	2008	2007
N	235	244	245
MEAN	80.4	79.1	76.8
STDEV	4.78	4.63	7.42
STDERR	0.31	0.3	0.47
MIN	58.1	61.9	26.3
MAX	93.1	93	90.3
P10	75	72.8	68.4
P25	78.1	77.2	74.8
P50	81	79.8	78.3
P75	83.1	82.1	81.1
P90	86	83.9	83.1

Anticonvulsants	2009	2008	2007
N	214	221	225
MEAN	62	61.7	59.6
STDEV	7.58	7.16	10.1
STDERR	0.52	0.48	0.67
MIN	33.1	41	20
MAX	93.3	93.5	88.5
P10	53.6	53.8	48.3
P25	57.1	57.2	55.4
P50	62.2	61.6	61
P75	65.8	65.3	65.1
P90	71.1	70.4	69.6

Total	2009	2008	2007
N	235	244	245
MEAN	80.3	78.9	76.6
STDEV	4.67	4.46	7.29
STDERR	0.3	0.29	0.47
MIN	59.7	61.8	25.4
MAX	93.1	93.4	90.3
P10	74.8	72.6	68.7
P25	77.9	76.7	74.6
P50	80.8	79.6	78.4
P75	83.1	81.6	80.6

P90	85.2	83.5	82.8

MEDICAID Reported Rates:

ACE inhibitors or ARBs	2009	2008	2007
N	111	97	103
MEAN	85.9	84.8	82.5
STDEV	4.76	7.28	7.62
STDERR	0.45	0.74	0.75
MIN	70	32.2	38.1
MAX	98.3	98.9	98.4
P10	80	78	77.3
P25	84.1	83.3	79.9
P50	86.3	86.3	84.2
P75	89.2	88.1	87
P90	90.5	90.1	88.8

Digoxin	2009	2008	2007
N	59	56	57
MEAN	88.9	88.5	84.9
STDEV	5.23	5.86	9.78
STDERR	0.68	0.78	1.3
MIN	72.7	67.3	39
MAX	97.2	98.3	96.3
P10	82	81.1	79.4
P25	86	86.6	82.1
P50	90	90.1	86.6
P75	92.7	92.3	90.9
P90	95.2	93.8	92.5

Diuretics	2009	2008	2007
N	111	97	103
MEAN	85.4	84.2	81.3
STDEV	4.45	7.8	7.76
STDERR	0.42	0.79	0.76
MIN	72.6	27.8	39.7
MAX	96.5	97.6	97
P10	79.4	77.1	74.3
P25	82.6	81.9	78.4
P50	86.1	85.7	82.6
P75	88.4	87.8	86
P90	90.6	89.9	88.6

Anticonvulsants	2009	2008	2007	N	98	88	92
MEAN	68.7	68.7	65.9				
STDEV	7.51	9.11	9.19				
STDERR	0.76	0.97	0.96				
MIN	43.3	18.2	32.3				
MAX	88.9	86.8	81.8				
P10	60.4	59.2	55.2				
P25	64.5	65	61.8				
P50	68.6	69.2	67.5				
P75	72.7	73.5	71.4				
P90	78.1	78.5	76.3				

Rate	2009	2008	2007
N	115	97	103
MEAN	83.2	82.6	80.1
STDEV	6.42	7.31	7.34
STDERR	0.6	0.74	0.72
MIN	38.2	29.3	38
MAX	95.7	96.9	96.1
P10	77.2	76.2	73.5
P25	81.2	80.1	77.2
P50	84.3	83.5	81.6
P75	86.8	86	84
P90	88.5	88.5	86.5

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

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Three Medicare Advantage Plans representing a variety of models, performance and geographic regions are recruited and selected to participate in each NCQA field test. Medicare enrollment must be greater than 15,000, and the field testing included an administrative data pull and medical record review (200 charts).

Plans may have been asked to provide additional plan demographic information to assist in evaluating the field-test results. Unless agreed upon by all plans participating in the testing of a measure, plan names were kept confidential. NCQA does not release field-test site names in conjunction with field-test data.

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
The purpose of field testing is to determine:
- The validity of the administrative algorithm to identify the target population (denominator) based upon the measurement period, continuous enrollment /exclusionary criteria
- The validity of administrative data to accurately capture medical processes delivered (i.e. tests) or diagnoses by comparing administrative results with data from a sample of medical records
- The feasibility of the measure specifications to identify the quality problem and to discriminate performance between health plans for the purposes of HEDIS public reporting.
- The reliability and feasibility of the measure specifications so that all health plans can capture the required data elements and can conduct programming

Based upon the field test results, NCQA made necessary revisions to the measure specifications so that it meets the Desirable Attributes of a HEDIS measure.

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
Rate #1 – annual monitoring (serum potassium and creatine/blood urea nitrogen) for patients on ACE Inhibitors, ARBs, Digoxin and Diuretics.
- Plan performance: Average rates of monitoring for serum potassium and creatine/blood urea nitrogen are similar across drugs (66-71%) and show room for improvement in plans
- Variation between plans was evident for each drug/monitoring combination (including combination products) and the clinical differences in the patient populations also supports plans drilling down to look at rates for each drug and within diuretics for QI purposes:
- ACE Inhibitors – average 66%, (58.9% - 68.3%), ARBS – average 70.7% , (63.1- 85.8%), Digoxin – average 71.2%, (60.3% - 80.2%), Diuretics – average 69.3% , (59.9% - 79.6%). Potassium sparing diuretics, Potassium wasting diuretics, and Combination potassium sparing/wasting diuretics

Denominator feasibility: These drugs are highly prevalence in health plans (field test plans had 190 -5133 Medicare members and

78-4400 commercial members in the denominator for each of the drugs) and therefore the eligible populations are large enough to support valid rates.
Data Validity – Medical Record Concordance: Medical record concordance shows positive predictive value (85-95%), sensitivity (89-93%) and specificity (62-91%) are fairly high and consistent for these monitoring tests across the drugs.

Rate #2 – annual drug level monitoring for patients on anticonvulsants
- Plan performance: Average rates of monitoring patients on anticonvulsants for drug serum concentration is low (54.1%) for phenytoin and phenobarbital, and slightly higher for valproic acid (71%). Note carbamazepine was subsequently added to the indicator and was not investigated in the field test; however similar results are expected.
- Room for improvement: Monitoring rates are lower for anticonvulsants than for indicator #1 and show great room for improvement.
- Denominator feasibility: Small numbers of patients use valproic acid (between 3-42 Medicare members and 60-302 commercial members in each plan met the denominator criteria). Although they have slightly higher monitoring rates this is not expected to impact overall monitoring rates for anticonvulsants. Field test plans had between 29 to 191 Medicare members and 126-660 commercial members on phenytoin and phenobarbitol in the measure denominator; combined with members on valproic acid and carbamazepine, the denominator should be sufficient to support valid rates which for HEDIS is a minimum of 30.
- Data Validity – Medical Record Concordance: Medical record concordance - positive predictive value (97%), sensitivity (79%, range 14-100%) and specificity (92%) shows administrative data are fairly reliable to capture monitoring tests that were performed (and may be better than the medical record). Specificity differs by drug - valproic acid (69%), phenytoin/phenobarbital (92%).
- Rationale: Monitoring is a patient safety issue for drugs with high toxicity. Including this set of drugs in the indicator will help health plans to target quality improvement efforts for these drugs.

Rate #3: Combined rate
- Plan performance: Performance on the overall field-test was about 70%, plan rates ranged from 64% and 69%. For the fourth rate, average performance was 21%, plan rates ranged from a low of 18.2% to 37.8% for monitoring within 12 months.
- Room for Improvement: Based on field-test results, the potential for improvement seems to be moderate to high. There is at least 30% room for improvement for the first three monitoring rates, and over 60% room for improvement on the fourth monitoring rate. Monitoring for patients on ACE or ARBs was lower among commercial than Medicare members (54% vs. 75%) and suggests room for improvement in younger populations. Clinical literature document the potential harms from long-term use of these drugs which warrants monitoring and follow-up by prescribing physicians to assess for side-effects such as drug toxicity or electrolyte imbalances and to adjust drug dosages/therapeutic decisions accordingly. Drug labeling also recommends periodic monitoring of these patients.
- Denominator feasibility: Health plan eligible populations are large enough to support valid rates, which for HEDIS is a minimum of 30 in the denominator.
- Data Validity- Medical Record Concordance: Medical record confirmation of monitoring tests performed when indicated in the administrative data was quite high, with average specificity and positive predictive value (PPV) of administrative data in the 90th percentile or above.. The reliability of health plan's administrative data did vary by plan. Across all drugs and monitoring tests, the positive predictive value of plans' administrative data to capture tests ranged from 74% to 100%, sensitivity ranged from 76% to 99% and specificity range from 63% to 99%.

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

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)*: The measure is not stratified to detect disparities. NCQA has participated with IOM and others in attempting to include information on disparities in measure data collection. However, at the present time, this data, at all levels (claims data, paper chart review, and electronic records), is not coded in a standard manner, and is incompletely captured. There are no consistent standards for what entity (physician, group, plan, employer) should capture and report this data. While "requiring" reporting of the data could push the field forward, it has been our position that doing so would create substantial burden with inability to use the data because of its inconsistency. At the present time, we agree with the IOM report that disparities are best considered by the use of zip code analysis which has limited applicability in most reporting situations. At the health plan level, for HEDIS health plan data collection, NCQA does have extensive data related to our use of stratification by insurance status (Medicare, Medicaid and private-commercial) and would strongly recommend this process where the data base supporting the measurement includes this information. However, we believe that the measure specifications should NOT require this since the measure is still useful where the data needed to determine disparities cannot be ascertained from the data available.

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

explain:
N/A

2.1-2.3 Supplemental Testing Methodology Information:

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

If the Committee votes No, STOP

3. USABILITY

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

C.1 Intended Purpose/ Use *(Check all the purposes and/or uses for which the measure is intended)*: Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Public Reporting, Regulatory and Accreditation Programs, Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
This measure is used in public reporting through Healthcare Effectiveness Data and Information Set (HEDIS) and is reported through venues such as the annual State of Healthcare Quality report, Quality Compass, America's Best Health Plans.

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: HEDIS measures adhere to the desirable attributes of scientific acceptability, feasibility and usability. The measures provide performance rates that are audited for consistency and accuracy.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): It is used in NCQA's Health Plan Accreditation program.

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
This measure is a measure in the Healthcare Effectiveness Data and Information Set (HEDIS), and is used in NCQA's Health Plan Accreditation program.

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

Upon review of public comment results, the Committee on Performance Measurement approved the NCQA staff recommendation to add the measure to HEDIS. After reviewing first-year analysis results, the CPM approved the staff recommendation to publicly report the measure. The measure was deemed usable and feasible.

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

4. FEASIBILITY

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

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

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition,
Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H☐ M☐ L☐ I ☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements are in a combination of electronic sources

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

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

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

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

A.2 Please check if either of the following apply (*regarding proprietary measures*): Proprietary measure
4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues *(e.g., fees for use of proprietary measures)*:
NCQA´s multi-stakeholder advisory panels examined an analysis of the measure after its first year of reporting. The measure was deemed appropriate for public reporting. NCQA has processes to ensure coding and specifications are clear and updated when needed.

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

OVERALL SUITABILITY FOR ENDORSEMENT

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

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

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the

same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?

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

5b. Competing Measure(s)

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

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): National Committee for Quality Assurance, 1100 13th Street NW, Suite 1000, Washington, District Of Columbia, 20005

Co.2 Point of Contact: Bob, Rehm, Assistant Vice President, Performance Measurement, Rehm@ncqa.org, 202-955-1728-

Co.3 Measure Developer if different from Measure Steward: National Committee for Quality Assurance, 1100 13th Street NW, Suite 1000, Washington, District Of Columbia, 20005

Co.4 Point of Contact: Bob, Rehm, Assistant Vice President, Performance Measurement, Rehm@ncqa.org, 202-955-1728-

Co.5 Submitter: Dawn, Alayon, MPH, CPH, Senior Health Care Analyst, alayon@ncqa.org, 202-955-3533-, National Committee for Quality Assurance

Co.6 Additional organizations that sponsored/participated in measure development:

Co.7 Public Contact: Bob, Rehm, Assistant Vice President, Performance Measurement, Rehm@ncqa.org, 202-955-1728-, National Committee for Quality Assurance

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Geriatric Measurement Advisory Panel
Wade Aubry, MD, National Medical Consultant, BCBS Association
Arlene Bierman, MD, MS, Chair in Women´s Health Research, University of Toronto and St. Michael's Hospital
Joyce Dubow, MUP, Senior Advisor, AARP
Peter Hollmann, MD, Medical Director, BCBS of Rhode Island
Jerry Johnson, MD, Chief of the Geriatric Medical Division,University of Pennsylvania
David Martin, MD, National Medical Director, Ovations
Adrienne Mims, MD, MPH, Medical Director, Medicare Quality Improvement, Alliant Health Solutions

Steven Phillips, MD, CMD, Medical Director, Sierra Health Services, Inc.
Scott Sarran, MD, MM, VP and Chief Medical Officer, BCBS of Illinois
Eric G Tangalos, MD, FACP, AGSF, CMD, Professor of Medicine, Mayo Clinic
Joan Weiss, PhD, RN, CRNP, Chief Allied, Geriatrics, and Rural Health Branch, Health Resources and Services Administration
Neil Wenger, MD, Professor, UCLA Division of General Internal Medicine and RAND

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Jeffrey Kelman
Elizabeth Goldstein
Morgot Blige Holloway
Rosemary Lee
Alice Lee Martin
Sonya Bowen

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Mark Brueckl, RPh, MBA, Academy of Managed Care Pharmacy
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Linda DeLaet, PharmD, Kaiser Permanente
Gerry Hobson, RPh, Cerner Multum
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Kevin Park, MD, CHCA, Attest Health Care Advisors, LLC

Technical Advisory Group
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Darryl Gray, MD, ScD, Agency for Healthcare Research and Quality
Carlos Hernandez, CHCA, CenCal Health
Harmon Jordan, ScD, Research Triangle Institute
William Munier, MD, Agency for Healthcare Research and Quality (AHRQ)
James Murray, PhD, Eli Lilly & Co.
Patrick Roohan, New York State Department of Health (NYSDOH)
Lynne Rothney-Kozlak, MPH, Independent Consultant
Natan Szapiro, Independence Blue Cross

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.3 Year the measure was first released: 2006
Ad.4 Month and Year of most recent revision: 05, 2010
Ad.5 What is your frequency for review/update of this measure? Approximately every 3 years, sooner if the clinical guidelines have changed significantly.
Ad.6 When is the next scheduled review/update for this measure?

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (*MM/DD/YY*): 09/14/2011