NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** 1505 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Adult patient(s) with atrial fibrillation taking amiodarone that had serum ALT or AST test in last 12 reported months.
De.2 **Brief description of measure**: This measure identifies adults with atrial fibrillation, 18 years of age or older, taking amiodarone that had at least one serum ALT or AST test in last 12 months of the report period.
1.1-2 **Type of Measure:** Process De.3 **If included in a composite or paired with another measure, please identify composite or paired measure**
De.4 **National Priority Partners Priority Area:** Safety De.5 **IOM Quality Domain**: Safety De.6 **Consumer Care Need:**

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** Proprietary measure A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:** Measure Steward Addendum_Ingenix 012010-633997858544138332.doc	**A** **Y** ☒ **N** ☐

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☒ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement Accountability, Payment incentive	**C** Y☒ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☒ N☐
(for NQF staff use**)** **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☒ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:** disparities addressed in separate document;	
Staff Reviewer Name(s): RWinkler	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *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**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**: Patient Safety	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** Amiodarone, one of the most frequently prescribed antiarrhythmic medications in the United States, has been associated with liver abnormalities, including hepatic failure (1, 2). The prevalence of elevated liver enzyme levels ranges from 15 to 30 precent; the prevelance of hepatitis and cirrhosis less than 3 percent (0.6 percent annually)(1). These adverse effects are typically reversible via dose reduction or discontinuation of amiodarone. As such, serum ALT or AST monitoring is recommended at baseline and every 6 months at minimum (1,3). 1a.4 **Citations for Evidence of High Impact:** 1. Vassallo P, Trohman RG. Prescribing amiodarone: an evidence-based review of clinical indications. JAMA 2007;298(11):1312-22. 2.Amiodarone HCl. Drug Facts and Comparisons. eFacts [online]. 2009. Available from Wolters Kluwer Health, Inc. Accessed March 26, 2009. 3. Stelfox HT, Ahmed SB, Fiskio J, Bates DW. Monitoring amiodarone's toxicities: recommendations, evidence and clinical practice. Clin Pharmacol Ther 2004;75:110-22.	**1a** C☐ P☐ M☐ N☐
1b. Opportunity for Improvement	**1b**

Comment [KP1]: 1a. The measure focus addresses:
- a specific national health goal/priority identified by NQF's National Priorities Partners; OR
- a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Serum ALT/AST monitoring allows detection of liver-related adverse events that can be managed with drug discontinuation, dose reductions, or other interventions. This can prevent more serious adverse events and improve treatment outcomes.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Using a geographically diverse 15 million member benchmark database (this database represents predominately a commercial population less than 65 year of age) the compliance rate was 70.0 percent, indicating a clear gap in care and opportunity for care improvement.

1b.3 Citations for data on performance gap:
Ingenix EBM Connect benchmark results, September 2009

1b.4 Summary of Data on disparities by population group:
None

1b.5 Citations for data on Disparities:

C☐ P☐ M☐ N☐

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** This measure will reduce serious adverse events secondary to the absence of recommended amiodarone monitoring.

1c.2-3. Type of Evidence: Systematic synthesis of research, Other, Expert opinion manufacturers recommendations

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
One study found that amiodarone-induced adverse events were documented in 8 percent of patients followed during a one year time period. One third of these adverse events were judged to be preventable had appropriate monitoring occurred (1).

This measure will reduce serious adverse events secondary to the absence of recommended serum ALT/AST monitoring. Routine monitoring is recommended every 6 months at minimum by the North American Society of Pacing and Electrophysiology practice guidelines (2). In addition, serum ALT or AST monitoring is recommended at baseline and every 6 months at minimum by the pharmaceutical manufacturer and in a recent evidence-based review (3,4).

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
No strength of evidence is provided with this monitoring recommendation.

1c.6 Method for rating evidence:

1c.7 Summary of Controversy/Contradictory Evidence: Current standards for amiodarone toxicity monitoring are based on expert opinion and consensus conference with limited evidence to support most recommendations. However, a significant number of sources and published articles support current monitoring recommendation (1).

1c.8 Citations for Evidence (*other than guidelines***):** 1. Stelfox HT, Ahmed SB, Fiskio J, Bates DW. Monitoring amiodarone's toxicities: recommendations, evidence and clinical practice. Clin Pharmacol Ther 2004;75:110-22.
3. Amiodarone HCl. Drug Facts and Comparisons. eFacts [online]. 2009. Available from Wolters Kluwer Health, Inc. Accessed January 21, 2010.

1c
C☐ P☐ M☐ N☐

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

OR
- if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
  - Intermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - Process – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - Structure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - Patient experience – evidence that an association exists between the measure of patient experience of health care and t ... [1]

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a ... [2]

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

4. Vassallo P, Trohman RG. Prescribing amiodarone: an evidence-based review of clinical indications. JAMA 2007;298(11):1312-22.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
Source: Practical Guidelines for Clinicians Who Treat Patients With Amiodarone (see reference in 1c.10), Table 2 - p. 1746

Type of Test	Time When Test Is Performed
Liver function tests	Baseline and every 6 mo

1c.10 Clinical Practice Guideline Citation: 2. Goldschlager N, Epstein AE, Naccarelli G, Olshansky B, Singh B, for the Practice Guidelines Subcommittee, North American Society of Pacing and Electrophysiology. Practical Guidelines for Clinicians Who Treat Patients With Amiodarone. Arch Intern Med 2000;160:1741-1748.

1c.11 National Guideline Clearinghouse or other URL: http://archinte.ama-assn.org.floyd.lib.umn.edu/cgi/reprint/160/12/1741.pdf

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
No strength of evidence is provided with this monitoring recommendation.

1c.13 Method for rating strength of recommendation (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**

1c.14 Rationale for using this guideline over others:
This is the only monitoring guideline developed by a national organization.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?* — **1**

Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met? 1** Y☐ N☐
Rationale:

2. 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) — **Eval Rating**

2a. MEASURE SPECIFICATIONS

S.1 Do you have a web page where current detailed measure specifications can be obtained?
S.2 If yes, provide web page URL:

2a. Precisely Specified

2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):**
Patients who are diagnosed with atrial fibrillation and who are treated with amiodarone, who have had serum a AST/ALT test during the following time period: last 12 months of the report period through 90 days after the end of the report period

2a.2 Numerator Time Window (*The time period in which cases are eligible for inclusion in the numerator***):**
Last 12 months of the report period through 90 days after the end of the report period

2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**

2a-specs C☐ P☐ M☐ N☐

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

Patients that have had a test for serum ALT/SGPT or AST/SGOT (code sets PR0002, LC0051) during the following time period: last 12 months of the report period through 90 days after the end of the report period

Code Set	Code Set Description	Procedure Code
PR0002	ALT/SGPT or AST/SGOT	80050
PR0002	ALT/SGPT or AST/SGOT	80053
PR0002	ALT/SGPT or AST/SGOT	80076
PR0002	ALT/SGPT or AST/SGOT	84450
PR0002	ALT/SGPT or AST/SGOT	84460

Code Set	Code Set Description	LOINC Code
LC0051	ALT/SGPT or AST/SGOT	16325-3
LC0051	ALT/SGPT or AST/SGOT	1742-6
LC0051	ALT/SGPT or AST/SGOT	1743-4
LC0051	ALT/SGPT or AST/SGOT	1744-2
LC0051	ALT/SGPT or AST/SGOT	1916-6
LC0051	ALT/SGPT or AST/SGOT	1920-8
LC0051	ALT/SGPT or AST/SGOT	2325-9
LC0051	ALT/SGPT or AST/SGOT	27344-1
LC0051	ALT/SGPT or AST/SGOT	30239-8
LC0051	ALT/SGPT or AST/SGOT	44785-4
LC0051	ALT/SGPT or AST/SGOT	44786-2
LC0051	ALT/SGPT or AST/SGOT	48134-1
LC0051	ALT/SGPT or AST/SGOT	48136-6

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
All patients 18 years of age or older who have a diagnosis of atrial fibrillation and who are actively being treated with amiodarone

2a.5 Target population gender: Male, Female
2a.6 Target population age range: Patients who are 18 years of age or older at the end of the report period

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
The 24 months prior to the end of the report period for confirmation that the patient had atrial fibrillation; last 120 days of the report period through 90 days after the end of the report period for confirmation that the patient was actively taking amiodarone

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Criteria for inclusion in the denominator are as follows:
1. All male and female patients who are 18 years or older at the end of the report period
2. Patient must have been continuously enrolled in medical benefits throughout the 12 months prior to the end of the report period AND pharmacy benefit plan for 6 months prior to the end of the report period. The standard EBM Connect® enrollment break logic allows unlimited breaks in coverage of no more than 45 days and no breaks greater than 45 days.
3. The patient is listed in the Disease Registry Input File for this condition
   OR
   Patient fulfills both criteria A and B:

A. During the 24 months prior to the end of the report period, the patient has two or more of the following services or events, at least 14 days apart, with a diagnosis of atrial fibrillation (code set DX0014):
-Professional Encounter (code set PR0107, RV0107)
-Professional Supervision (code set PR0108)
-Facility Event – Confinement/Admission (i.e., hospitalization)
-Facility Event – Emergency Room
-Facility Event – Outpatient Surgery

AND
B. During the 12 months prior to the end of the report period, the patient has one or more of the following services or events, with a diagnosis of atrial fibrillation (code set DX0014):
-Professional Encounter (code set PR0107, RV0107)
-Professional Supervision (code set PR0108)
-Facility Event – Confinement/Admission (i.e., hospitalization)
-Facility Event – Emergency Room
-Facility Event – Outpatient Surgery
4. The patient must have filled a prescription for amiodarone (code set RX-9) during the following time period: last 120 days of the report period through 90 days after the end of the report period AND the duration of treatment was greater than 90 days.

Code Set	Code Set Description	Diagnosis Code
DX0014	Atrial Fibrillation	427.3
DX0014	Atrial Fibrillation	427.31
DX0014	Atrial Fibrillation	427.32

Code Set	Code Set Description	Procedure Code
PR0107	Professional encounter	99201
PR0107	Professional encounter	99202
PR0107	Professional encounter	99203
PR0107	Professional encounter	99204
PR0107	Professional encounter	99205
PR0107	Professional encounter	99211
PR0107	Professional encounter	99212
PR0107	Professional encounter	99213
PR0107	Professional encounter	99214
PR0107	Professional encounter	99215
PR0107	Professional encounter	99217
PR0107	Professional encounter	99218
PR0107	Professional encounter	99219
PR0107	Professional encounter	99220
PR0107	Professional encounter	99221
PR0107	Professional encounter	99222
PR0107	Professional encounter	99223
PR0107	Professional encounter	99231
PR0107	Professional encounter	99232
PR0107	Professional encounter	99233
PR0107	Professional encounter	99234
PR0107	Professional encounter	99235
PR0107	Professional encounter	99236
PR0107	Professional encounter	99238
PR0107	Professional encounter	99239
PR0107	Professional encounter	99241
PR0107	Professional encounter	99242
PR0107	Professional encounter	99243
PR0107	Professional encounter	99244
PR0107	Professional encounter	99245
PR0107	Professional encounter	99251
PR0107	Professional encounter	99252
PR0107	Professional encounter	99253
PR0107	Professional encounter	99254
PR0107	Professional encounter	99255
PR0107	Professional encounter	99261
PR0107	Professional encounter	99262
PR0107	Professional encounter	99263
PR0107	Professional encounter	99271
PR0107	Professional encounter	99272

PR0107	Professional encounter	99273
PR0107	Professional encounter	99274
PR0107	Professional encounter	99275
PR0107	Professional encounter	99281
PR0107	Professional encounter	99282
PR0107	Professional encounter	99283
PR0107	Professional encounter	99284
PR0107	Professional encounter	99285
PR0107	Professional encounter	99301
PR0107	Professional encounter	99302
PR0107	Professional encounter	99303
PR0107	Professional encounter	99304
PR0107	Professional encounter	99305
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PR0107	Professional encounter	99391
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PR0107	Professional encounter	99394
PR0107	Professional encounter	99395
PR0107	Professional encounter	99396
PR0107	Professional encounter	99397
PR0107	Professional encounter	99401
PR0107	Professional encounter	99402
PR0107	Professional encounter	99403
PR0107	Professional encounter	99404
PR0107	Professional encounter	99411
PR0107	Professional encounter	99412
PR0107	Professional encounter	99420
PR0107	Professional encounter	99429
PR0107	Professional encounter	S0270
PR0107	Professional encounter	S0271
PR0107	Professional encounter	S0272

PR0107	Professional encounter	S0273

Code Set	Code Set Description	Procedure Code
PR0108	Professional supervision	99321
PR0108	Professional supervision	99322
PR0108	Professional supervision	99323
PR0108	Professional supervision	99324
PR0108	Professional supervision	99325
PR0108	Professional supervision	99326
PR0108	Professional supervision	99327
PR0108	Professional supervision	99328
PR0108	Professional supervision	99331
PR0108	Professional supervision	99332
PR0108	Professional supervision	99333
PR0108	Professional supervision	99334
PR0108	Professional supervision	99335
PR0108	Professional supervision	99336
PR0108	Professional supervision	99337
PR0108	Professional supervision	99339
PR0108	Professional supervision	99340
PR0108	Professional supervision	99371
PR0108	Professional supervision	99372
PR0108	Professional supervision	99373
PR0108	Professional supervision	99374
PR0108	Professional supervision	99375
PR0108	Professional supervision	99377
PR0108	Professional supervision	99378
PR0108	Professional supervision	99379
PR0108	Professional supervision	99380
PR0108	Professional supervision	99441
PR0108	Professional supervision	99442
PR0108	Professional supervision	99443
PR0108	Professional supervision	99444
PR0108	Professional supervision	G0179
PR0108	Professional supervision	G0180
PR0108	Professional supervision	G0181
PR0108	Professional supervision	G0182

Code Set	Code Set Description	Revenue Code
RV0107	Professional encounter	0510
RV0107	Professional encounter	0511
RV0107	Professional encounter	0512
RV0107	Professional encounter	0513
RV0107	Professional encounter	0514
RV0107	Professional encounter	0515
RV0107	Professional encounter	0516
RV0107	Professional encounter	0517
RV0107	Professional encounter	0519
RV0107	Professional encounter	0520
RV0107	Professional encounter	0521
RV0107	Professional encounter	0522
RV0107	Professional encounter	0523
RV0107	Professional encounter	0524
RV0107	Professional encounter	0525
RV0107	Professional encounter	0526
RV0107	Professional encounter	0528
RV0107	Professional encounter	0529
RV0107	Professional encounter	0981

RV0107 Professional encounter 0983

Rx code set	Rx code set description	ndc
9	Amiodarone	00008081401
9	Amiodarone	00008418802
9	Amiodarone	00008418804
9	Amiodarone	00008418806
9	Amiodarone	00074434835
9	Amiodarone	00093913306
9	Amiodarone	00093913352
9	Amiodarone	00093913393
9	Amiodarone	00143987510
9	Amiodarone	00185014405
9	Amiodarone	00185014409
9	Amiodarone	00185014460
9	Amiodarone	00245014001
9	Amiodarone	00245014030
9	Amiodarone	00245014401
9	Amiodarone	00245014430
9	Amiodarone	00245014489
9	Amiodarone	00245014501
9	Amiodarone	00245014510
9	Amiodarone	00245014530
9	Amiodarone	00245014589
9	Amiodarone	00245014701
9	Amiodarone	00245014715
9	Amiodarone	00245014760
9	Amiodarone	00245014789
9	Amiodarone	00245014790
9	Amiodarone	00409434835
9	Amiodarone	00409434849
9	Amiodarone	00548338000
9	Amiodarone	00555091704
9	Amiodarone	00555091709
9	Amiodarone	00703133201
9	Amiodarone	00703133203
9	Amiodarone	00703133501
9	Amiodarone	00703133601
9	Amiodarone	00781120305
9	Amiodarone	00781120360
9	Amiodarone	00781120392
9	Amiodarone	00904590961
9	Amiodarone	10019013101
9	Amiodarone	10019013301
9	Amiodarone	10019013302
9	Amiodarone	10019013304
9	Amiodarone	10019013313
9	Amiodarone	10019013319
9	Amiodarone	10019013389
9	Amiodarone	10139005003
9	Amiodarone	10139005009
9	Amiodarone	10139005010
9	Amiodarone	10139005011
9	Amiodarone	10139005028
9	Amiodarone	13107005605
9	Amiodarone	13107005660
9	Amiodarone	17236007560
9	Amiodarone	23629008610

9	Amiodarone	25021030273
9	Amiodarone	35356000110
9	Amiodarone	38245013325
9	Amiodarone	38245013355
9	Amiodarone	38245013368
9	Amiodarone	49884045802
9	Amiodarone	49884045804
9	Amiodarone	49884045805
9	Amiodarone	51079090601
9	Amiodarone	51079090617
9	Amiodarone	51079090619
9	Amiodarone	51079090620
9	Amiodarone	51672402504
9	Amiodarone	51672405700
9	Amiodarone	51672405706
9	Amiodarone	54569176500
9	Amiodarone	54569514000
9	Amiodarone	54868461800
9	Amiodarone	54868461801
9	Amiodarone	54868461802
9	Amiodarone	54868461803
9	Amiodarone	54868572200
9	Amiodarone	55390005701
9	Amiodarone	55390005710
9	Amiodarone	55390005810
9	Amiodarone	55390009710
9	Amiodarone	55390010501
9	Amiodarone	55887079801
9	Amiodarone	55953021440
9	Amiodarone	55953021441
9	Amiodarone	55953021470
9	Amiodarone	58016030400
9	Amiodarone	58016030430
9	Amiodarone	58016030460
9	Amiodarone	58016030490
9	Amiodarone	60505072200
9	Amiodarone	60505072201
9	Amiodarone	61703024103
9	Amiodarone	62086015303
9	Amiodarone	63323061603
9	Amiodarone	63323061609
9	Amiodarone	63323061613
9	Amiodarone	63323061618
9	Amiodarone	63739038710
9	Amiodarone	67457015303
9	Amiodarone	67457015309
9	Amiodarone	67457015318
9	Amiodarone	67544017630
9	Amiodarone	67544057030
9	Amiodarone	68084037101
9	Amiodarone	68084037111
9	Amiodarone	68382022705
9	Amiodarone	68382022714

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** Does not apply

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Does not apply

2a.11 **Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
Does not apply

2a.12-13 **Risk Adjustment Type:** No risk adjustment necessary

2a.14 **Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**

2a.15-17 **Detailed risk model available Web page URL or attachment:**

2a.18-19 **Type of Score:** Rate/proportion
2a.20 **Interpretation of Score:**
2a.21 **Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**
1. Exclude members who meet denominator exclusion criteria
2. Assign a YES or NO result to remaining members based on numerator response
3. Rate = YES/[YES+NO]

2a.22 **Describe the method for discriminating performance** *(e.g., significance testing)***:**
Over 1000 patients met the denominator from a geographically diverse 15 million member benchmark database. Over 300 patients did not meet numerator compliance, indicating a significant population with patient safety gap in care. The subsequent compliance rate was 70.0 percent.

2a.23 **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)*:
A 15 million patient population sample was chosen to analyze the potential patient safety gap in care. The sample was derived from more than 60 million patients based on criteria including national geographic representation, commercial health coverage and patient age less than 65.

2a.24 **Data Source (***Check the source(s) for which the measure is specified and tested)*
Electronic administrative data/claims, Lab data, Pharmacy data

2a.25 **Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
Our data source is a proprietary Ingenix provider database that includes more than 60 million patients, over multiple years. It includes data from multiple payors. This measure specifically uses the following data from this database: member demographics, ICD-9 codes, revenue codes, CPT codes, place of service, pharmacy claims, and LOINC (lab results) codes.

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:**

2a.29-31 **Data dictionary/code table web page URL or attachment:** Attachment Input Guide_NQF-633994121593092344.doc

2a.32-35 **Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Clinicians: Individual, Clinicians: Group, Facility/Agency, Health Plan, Integrated delivery system, Multi-site/corporate chain, Program: Disease management, Program: QIO, Can be measured at all levels, Population: states, Population: counties or cities

2a.36-37 **Care Settings (***Check the setting(s) for which the measure is specified and tested)*
Ambulatory Care: Clinic, Ambulatory Care: Emergency Dept, Ambulatory Care: Hospital Outpatient, Nursing home (NH) /Skilled Nursing Facility (SNF), Rehabilitation Facility

2a.38-41 **Clinical Services** (*Healthcare services being measured, check all that apply*)
Clinicians: Nurses, Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS	
2b. Reliability testing **2b.1 Data/sample** *(description of data/sample and size)*: Reliability is tested by using multiple databases. There are three primary databases that we use: 1) a customer acceptance (CAT) database that includes approximately 4000 members who satisfy the condition confirmation criteria; 2) a one million member face validity testing (FVT) database that is geographically diverse; and 3) a 15 million member benchmark database that is geographically diverse. All databases represent predominately a commercial population less than 65 year of age. **2b.2 Analytic Method** *(type of reliability & rationale, method for testing)*: Quality assurance of each measure is accomplished through the testing using multiple methods and databases. Types of testing, data samples and volume vary to ensure the integrity of the measure. Rigorous development, analysis and testing processes are deployed for creating measure specifications. Software testing ensures the software is working as designed. Reliability and validity testing of measures is based on differing data samples and volume of members. National benchmarks are created on a large volume set of data representing members throughout the United States. All quality checks for all measure results must have consistent results and meet expected outcomes based on industry knowledge and experience. Customer Acceptance Testing (CAT) is an important quality process. CAT ensures that the clinical measures are functioning as intended and that they generate accurate results for typical billing patterns. Using actual claims data a team of business analysts, nurses, and health services researchers conducts a detailed analysis of the output. For each clinical condition in the product (e.g., Diabetes Mellitus, Coronary Artery Disease, etc.) there is a set of CAT data with at least 4000 members who satisfy the condition confirmation criteria. This data is extracted from a large (50+ million member) multi-payer benchmark database and contains inpatient, outpatient, pharmacy, and laboratory data. The testing team analyzes claims from individual members and compares the creation of denominators (target population), numerators, and exclusions from this manual review process to output results from the quality measure. Regression testing is the part of CAT that verifies the reliability of the product across software releases. For a new release the testing team confirms that every unchanged measure produces the same results as in previous releases, accounting for systematic changes to the software (e.g., code updates, logic changes, etc). Regression testing is conducted at multiple points throughout the software development cycle. **2b.3 Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*: Given the size of our benchmark database, it is the most reliable source for compliance results. Over 1000 members from the benchmark database met the denominator definition for this measure. The overall compliance rate was 70.0 percent.	**2b** C☐ P☐ M☐ N☐
2c. Validity testing **2c.1 Data/sample** *(description of data/sample and size)*: Our data sample for face validity testing includes a geographically diverse one million member database. Our data sample for benchmark testing includes a geographically diverse 15 million member database. Both databases represent predominately a commercial population less than 65 year of age. **2c.2 Analytic Method** *(type of validity & rationale, method for testing)*: Face Validity Testing (FVT) is the final testing step in the software release cycle. One million members are randomly selected from the large multi-payer benchmark database and their claims data is processed through the software. The Medical Director reviews the results to verify that: 1. Prevalence rates for a condition are comparable to nationally published rates 2. Compliance rates for a measure are comparable to the rates reported in the published literature or by other national sources (e.g. HEDIS). If no comparable sources are available, the rates are judged based on what is clinically reasonable. In addition, all results are reviewed for face validity by members of an external physician clinical consultant	**2c** C☐ P☐ M☐ N☐

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

panel.

A similar review of benchmark test results occurs in conjunction with a software release. With benchmark testing, 15 million members are randomly selected from the large multi-payer benchmark database and their claims data is processed through the software.

Our claims-based measures have been validated using a chart review comparison process. This validation project is summarized below:
Goal: evaluate the reliability of claims-based measure results using chart review as the gold standard
Methods:
The charts of 100 members from two clinics in one city were reviewed. Results from our claims-based measures were compared to information present in the chart. During this process, 726 measures were evaluated.
Results:
The overall error rate was less than 5%. The error rate varied depending on the type of claim required for numerator compliance and is summarized as follows:
o The error rate was highest with medications, with an 11 percent error rate (2/18). From chart review, it was difficult to tell if this represented a real error, a medication sample was provided, or the prescription was never filled).
o The error rate was 4 percent (14/318) for measures that required labs for numerator compliance. It was noted that a claims-based measure approach sometimes identified labs that were missing in chart review.
o The error rate for office visit and specialty appointments was 2 percent (8/390). Of note, administrative claims was more likely than chart review to identify relevant office and specialty visits, particularly for appointments that occurred outside the clinic or network.
o Errors were found related to coding in claims data, not due to the claims-based measures or methodology. These errors were not quantified.

2c.3 Testing Results *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
Summarized in 2b3

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):
This measure does not include any exclusions.

2d.2 Citations for Evidence:

2d.3 Data/sample *(description of data/sample and size)*:

2d.4 Analytic Method *(type analysis & rationale)*:

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*:

2d
C☐
P☐
M☐
N☐
NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample *(description of data/sample and size)*: This measure does not include risk adjustment.

2e.2 Analytic Method *(type of risk adjustment, analysis, & rationale)*:

2e.3 Testing Results *(risk model performance metrics)*:

2e
C☐
P☐
M☐
N☐
NA☐

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR
rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	
2f. Identification of Meaningful Differences in Performance **2f.1 Data/sample from Testing or Current Use** *(description of data/sample and size)*: Our benchmark data sample includes a geographically diverse 15 million member benchmark database. The database represents predominately a commercial population less than 65 year of age. **2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*: During benchmark testing, 15 million members are randomly selected from the large multi-payer benchmark database and their claims data is processed through the software. The Medical Director reviews the results to verify that: 1. Prevalence rates for a condition are comparable to nationally published rates 2. Compliance rates for a measure are comparable to the rates reported in the published literature or by other national sources (e.g. HEDIS). If no comparable sources are available, the rates are judged based on what is clinically reasonable. In addition, all results are systematically reviewed for face validity by members of an external physician clinical consultant panel. **2f.3 Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*: Summarized in 2b3	**2f** C☐ P☐ M☐ N☐
2g. Comparability of Multiple Data Sources/Methods **2g.1 Data/sample** *(description of data/sample and size)*: **2g.2 Analytic Method** *(type of analysis & rationale)*: **2g.3 Testing Results** *(e.g., correlation statistics, comparison of rankings)*:	**2g** C☐ P☐ M☐ N☐ NA☐
2h. Disparities in Care **2h.1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: **2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**	**2h** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:**	*2* C☐ P☐ M☐ N☐
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)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information **3a.1 Current Use:** In use **3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used*	**3a** C☐ P☐ M☐ N☐

Comment [KP18]: 2f. 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.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years)**:** Health plans, physicians (individuals and groups), care management, and other vendors/customers are using this measure on a national level. However, we do not know if this specific measure is being used as part of a public reporting initiative. 3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** Health plans, physicians (individuals and groups), care management, and other vendors/customers use many of our measures on a national level for quality improvement, disease management, and physician sharing programs. Customers are able to select their measures depending on their business needs. As such, we do not know which specific measures are used by our customers. **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) 3a.4 **Data/sample** *(description of data/sample and size)***:** Results are summarized and reported by users/customers depending on their business need - we do not have access to this information. Because of us my multiple users/customers, there is no single data sample, methodology, or public reporting format. 3a.5 **Methods** *(e.g., focus group, survey, QI project)***:** 3a.6 **Results** *(qualitative and/or quantitative results and conclusions)***:**	
3b/3c. Relation to other NQF-endorsed measures 3b.1 **NQF # and Title of similar or related measures:**	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): 3b.2 **Are the measure specifications harmonized? If not, why?**	**3b** C☐ P☐ M☐ N☐ NA☐
3c. Distinctive or Additive Value 3c.1 **Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** 5.1 **If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:**	**3c** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*?	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability***, met?** **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	**Eval Rating**

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

4a. Data Generated as a Byproduct of Care Processes

4a.1-2 **How are the data elements that are needed to compute measure scores generated?**
Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)

4a C☐ P☐ M☐ N☐

4b. Electronic Sources

4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*)
No

4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**

4b C☐ P☐ M☐ N☐

4c. Exclusions

4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?**
No

4c.2 **If yes, provide justification.**

4c C☐ P☐ M☐ N☐ NA☐

4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences

4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.**
None anticipated. Of note, the compliance rate for our measure (70.7 percent) was slightly higher than the 61.4 percent liver enzyme monitoring compliance reported by Stelfox, et.al.

4d C☐ P☐ M☐ N☐

4e. Data Collection Strategy/Implementation

4e.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/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:**
Due to the increasing availability of LOINC codes (lab results), a serum ALT/AST LOINC code set was recently added to this measure. Updated face validity and benchmark results that assess the impact of this change will be available September 2010.

4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:**
We do not have access to this information. This would vary based on the customer/vendor, patient population, and programs/interventions associated with measure use.

4e.3 **Evidence for costs:**

4e.4 **Business case documentation:**

4e C☐ P☐ M☐ N☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?

4

Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met?
Rationale:

4 C☐ P☐ M☐ N☐

RECOMMENDATION

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited** ☐
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y** ☐ **N** ☐ **A** ☐

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner)
Co.1 Organization
Ingenix, 12125 Technology Drive, Eden Prairie, Minnesota, 55344

Co.2 Point of Contact
Kay, Schwebke, Medical Director, kay.schwebke@ingenix.com, 952-833-7154-

Measure Developer If different from Measure Steward
Co.3 Organization
Ingenix, 12125 Technology Drive, Eden Prairie, Minnesota, 55344

Co.4 Point of Contact
Kay, Schwebke, Medical Director, kay.schwebke@ingenix.com, 952-833-7154-

Co.5 Submitter If different from Measure Steward POC
Kay, Schwebke, Medical Director, kay.schwebke@ingenix.com, 952-833-7154-, Ingenix

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

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.
We have an external consultant panel that participates in the original literature search process, measure development, code set review, testing review, and maintenance processes. Panel members include the following:

NAME & Title Employer/Position
Alexander, Beth Pharm D, BCPS Assistant Professor, Augsburg College
Ayenew, Woubeshet, MD Hennepin Faculty Associates; Hennepin County Medical Center
Becker, Keith, MD Fairview Medical Center
Betcher, Susan, MD Allina Medical Clinic
Bruer, Paul, MD Comprehensive Ophthamology, LLC
Capecchi, Joseph, MD Allina Medical Clinic
Giesler, Janell, MD Allina Medical Clinic
Grabowski, Carol, MD Allina Medical Clinic
Hansen, Calvin, MD Iowa Health Physicians
Hargrove, Jody, MD Arthritis and Rheumatology Consultants
Hermann, Richard, MD Tufts - New England Medical Center
Jemming, Brian, Pharm D CentraCare Health System
Kohen, Jeffrey, MD Veterans Affairs Medical Center
McCarthy, Teresa, MD University of Minnesota, Department of Family Medicine & Community Health
McEvoy, Charlene, MD, MPH HealthPartners & HealthPartners Research Foundation; Assistant Professor of Medicine, University of Minnesota
McGee, Deanna, Pharm D, BCPS Retail Pharmacy
Ogle, Kathleen, MD Hennepin Faculty Associates; Hennepin County Medical Center: Assistant Professor of Medicine, University of Minnesota Medical School

Peter, Kathleen, MD Park Nicollet Medical Center
Pieper-Bigelow, Christina, MD Allina Medical Clinic
Redmon, Bruce, MD University of Minnesota Physicians
Scharpf, Steven, MD Mountain Valleys Health Centers
Weitz, Carol, MD Independent

Ad.2 If adapted, provide name of original measure:
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 Year the measure was first released: 2005
Ad.7 Month and Year of most recent revision: 03, 2009
Ad.8 What is your frequency for review/update of this measure? every three years at minimum
Ad.9 When is the next scheduled review/update for this measure? 03, 2012

Dental Association.
Ad.11 -13 Additional Information web page URL or attachment:
Date of Submission (*MM/DD/YY*)**:** 11/01/2010

Page 3: [1] Comment [k4] **Karen Pace** **10/5/2009 8:59:00 AM**

1c. The measure focus is:

- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

OR

- if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
  - Intermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - Process – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
    if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - Structure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - Patient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
  - Access – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - Efficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Page 3: [2] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

Amiodarone: Ingenix measure submission
Request for information about disparities
Submitted by Kay Schwebke, M.D., M.P.H.
March 8, 2011

An analysis of our measure results was conducted to look for disparities related to gender or age. Since our database consists of a commercial population less than 65 years of age, the initial age categories were defined as follows: less than 30, 31-40, 41-50, and older than 50. Since atrial fibrillation and amiodarone use is more prevalent in the older population, the sample sizes for the two lower age ranges were too small to make meaningful conclusions. Therefore, the final age range comparison evaluated measure compliance for those patients 50 years and younger versus older than 50. In summary, no disparities were found when comparing men versus women nor when comparing the two age ranges.

We are unable to access disparities related to payer source since our current testing database consists of a commercial population. We are pursuing access to Medicare data and, in the future, anticipate the ability to analyze disparities related to this population.

Our database does not provide access to race/ethnicity. We do not have plans to access this information in the near future. Also, because our database is de-identified, we do not have access to geographic location. If we pursued an analysis related to geographic locations in the future, we could potentially compare four major regions but could not compare other areas (e.g., state comparisons or rural versus urban).