NATIONAL QUALITY FORUM

Measure Evaluation 4.1
January 2010

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 sub-criteria and most of the footnotes from the evaluation criteria are provided in Word comments and will appear if your cursor is over the highlighted area (or in the margin if your Word program is set to show revisions in balloons). 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 sub-criterion 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* sub-criteria *(yellow highlighted areas)*.

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the sub-criterion, 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 sub-criteria as indicated)

(for NQF staff use) **NQF Review** #: PSM-023-10 **NQF Project:** Patient Safety Measures

MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Patient(s) with hepatitis C infection taking interferon that had periodic serum ALT monitoring.
De.2 **Brief description of measure***:* This measure identifies hepatitis C virus (HCV) infected persons, 3 years of age or older, taking interferon that had at least two serum tests in last 6 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** Does not apply
De.4 **National Priority Partners Priority Area:** safety De.5 **IOM Quality Domain**: safety De.6 **Consumer Care Need:** Staying Healthy

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 signed and submitted A.4 **Measure Steward Agreement attached:** Measure Steward Addendum_Ingenix 012010-633997883005544278.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, quality improvement Payment Incentive, Accountability	**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*)**:**	
Staff Reviewer Name(s):	

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**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** Hepatitis C, a viral disease, is the most common blood-borne infection in the United States. Approximately 4 million Americans are positive for the antibody to hepatitis C (1.6 percent seroprevalence); it's estimated that 80 percent are chronically infected with HCV (1). The recommended treatment is combination pegylated interferon and ribavirin. Given the serious adverse events associated with treatment, patients must be carefully monitored during treatment. Since these adverse events can be addressed through drug discontinuation, dose reduction, or other interventions, routine laboratory monitoring is recommended. This includes monitoring of the CBC and serum ALT levels (1,2). 1a.4 **Citations for Evidence of High Impact:** 1. Ghany MG, Strader DB, Thomas DL, Seeff LB. AASLD Practice Guidelines. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology 2009;49(4):1335-74. 2. Peginterferon alpha-2a. Drug Facts and Comparisons. eFacts [online]. 2009. Available from Wolters Kluwer Health, Inc. Accessed January 13, 2010	**1a** C☐ P☐ M☐ N☐
1b. Opportunity for Improvement 1b.1 **Benefits (improvements in quality) envisioned by use of this measure:** Serum ALT monitoring allows detection of liver-related adverse events that can be managed with drug discontinuation, dose reductions, or	**1b** C☐ P☐ M☐

other interventions. This can prevent more serious adverse events and improve treatment outcomes.

N☐

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 65.8 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:

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*)**:** The primary outcome is to improve the safety and efficacy of HCV treatment. Serum ALT 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 (i.e., viral eradication).

Per the pharmaceutical manufacturer, 1 percent of patients in the hepatitis C trials experienced marked elevations in ALT levels during treatment. On occasion, these transaminase elevations were associated with hyperbilirubinemia and were managed by dose reduction or treatment discontinuation.

1c.2-3. Type of Evidence: evidence based guideline, other (specify) manufacturer's recommendations

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
The 2009 AASLD hepatitis C virus (HCV) guidelines address the diagnosis, management and treatment of patients infected with HCV. These guidelines have been approved by the AASLD, the Infectious Diseases Society of America, and the American College of Gastroenterology. The guidelines include specific laboratory monitoring recommendations for patients on anti-HCV treatment. These recommendations are consistent with the pharmaceutical manufacturer's monitoring recommedations.

The AASLD guidelines recommend a serum ALT monthly at minimum during the first 12 weeks of treatment and subsequently every 8 - 12 weeks. The rationale is that monitoring will reduce preventable adverse events, improve treatment compliance, and ultimately improve outcomes such as quality of life and viral eradication. Since laboratory adverse events can be serious (e.g., liver failure, death), monitoring is an essential component of treatment.

The AASLD guideline monitoring recommendations are consistent with the manufacturer's recommendations. The manufacturer recommends "liver function tests" at initiation of treatment, at 2 and 4 weeks, and the "periodically during therapy". In the clinical studies, the CBC was measured at 1, 2, 4, 6, and 8, and then every 4 to 6 weeks, or more frequently if abnormalities were found.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
There is no strength of evidence provided with this recommendation. This recommendation is baesd on consensus expert opinion.

1c.6 Method for rating evidence:

1c.7 Summary of Controversy/Contradictory Evidence: There is no controversial evidence related to this recommendation.

1c
C☐
P☐
M☐
N☐

1c.8 Citations for Evidence (*other than guidelines***):** manufacturer's recommendations: Peginterferon alpha-2a. Drug Facts and Comparisons. eFacts [online]. 2009. Available from Wolters Kluwer Health, Inc. Accessed January 13, 2010 **1c.9 Quote the Specific guideline recommendation (***including guideline number and/or page number***):** Patients should be monitored during therapy to assess the response to treatment and for the occurrence of side effects. A reasonable schedule would be monthly visits during the first 12 weeks of treatment followed by visits at 8 to 12 week intervals thereafter until the end of therapy. At each visit the patient should be questioned regarding the presence of side effects and depression. They should also be queried about adherence to treatment. Laboratory monitoring should include measurement of the complete blood count, serum creatinine and ALT levels, and HCV RNA by a sensitive assay at weeks 4, 12, 24, 4 to 12 week intervals thereafter, the end of treatment, and 24 weeks after stopping treatment. This recommendation is on page 1347 of the guideline. **1c.10 Clinical Practice Guideline Citation:** Ghany MG, Strader DB, Thomas DL, Seeff LB. AASLD Practice Guidelines. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology 2009;49(4):1335-74. **1c.11 National Guideline Clearinghouse or other URL:** http://www.aasld.org/practiceguidelines/Documents/Bookmarked%20Practice%20Guidelines/Diagnosis_of_HEP_C_Update.Aug%20_09pdf.pdf **1c.12 Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):** There is no strength of evidence provided with this recommendation. This recommendation is baesd on consensus expert opinion. **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 document represents the most recent HCV management and treatment guideline. It has been approved by three national specialty organizations most involved with hepatitis C care - the AASLD, the Infectious Diseases Society of America, and the American College of Gastroenterology.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **for** *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
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-specs** **C☐** **P☐** **M☐** **N☐**
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 HCV infection and are taking interferon-containing medication, who have had periodic tests for serum ALT during the following time period: last 180 days 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 180 days 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***):**
Patients who have had two or more tests for serum ALT/SGPT (code set PR0001), at least 14 days apart, during the following time period: last 180 days of the report period through 90 days after the end of the report period

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Patients three years of age or older who are diagnosed with HCV infection and who are being actively treated with an interferon-containing medication

2a.5 Target population gender: Female, Male
2a.6 Target population age range: Patients three 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 HCV infection; 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 interferon-containing medication

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 males or females that are three years of age 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

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 HCV infection (code set DX0060):
- Professional Encounter code set (PR0107 or RV0107)
- Professional Supervision code set (PR0108)
- Facility Event – Confinement/Admission (i.e., hospital admission)
- Facility Event – Emergency Room
- Facility Event – Outpatient Surgery

4. The patient must have filled a prescription for an interferon-containing medication (code set RX-61) during the last 120 days of the report period through 90 days after the end of the report period, with a duration of treatment greater than 120 days

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***):**
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: better quality = higher 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 550 patients met the denominator from a geographically diverse 15 million member benchmark database. Approximately 190 patients did not meet numerator compliance, indicating a significant population with patient safety gap in care. The subsequent compliance rate was 65.8 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 clinical data, 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 codes, pharmacy claims, and LOINC (laboratory 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-633991700136736750.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: counties or cities, Population: states

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: PA/NP/Advanced Practice Nurse, 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

2b
C☐
P☐
M☐
N☐

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 550 members from the benchmark database met the denominator definition for this measure. The overall compliance rate was 65.8 percent.

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 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

2c
C☐
P☐
M☐
N☐

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.4 **If outcome or resource use measure is not risk adjusted, provide rationale:**	**2e** C☐ P☐ M☐ N☐ NA☐
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	**2f** C☐ P☐ M☐ N☐

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	
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 sub-criteria **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 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	**3a** C☐ P☐ M☐ N☐

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 **Competing Measures 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☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **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
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,	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources	**4b**

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*) Yes 4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**	**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.** It is possible that some serum ALT claims could be missed if obtained during a hospitalization. However, the guideline recommendation is for serum ALT testing every 4-12 weeks at minimum and numerator compliance for our measure will be met if at least two tests were done during the last 6 months of the report period through 90 days after the report period (a 9 month total time period). We believe that our 9 month timeframe minimizes the likelihood that this error would impact the compliance results.	**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 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 sub-criteria **for** *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility***, met?** **Rationale:**	**4** **C☐ P☐ M☐ N☐**
RECOMMENDATION	
(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
This measure was reviewed and supported by an American Gastroenterological Association subcomittee.

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: 2006
Ad.7 Month and Year of most recent revision: 2007-08
Ad.8 What is your frequency for review/update of this measure? every three year at minimum
Ad.9 When is the next scheduled review/update for this measure? 2010-05

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment:

Date of Submission (*MM/DD/YY*)**:** 01/22/2010

INGENIX®

Input Guide

Release 7.0, Technical Guide for Windows, February 2008

Ingenix
950 Winter Street, Suite 3800
Waltham, MA 02451
Customer Support:
Tel: 866.818.7424
Fax: 781.895.9951
SymmetrySuite.Support@ingenix.com

What Input Files to Prepare

The following list specifies what input files you prepare for processing:

- The claims data file (required)
- The member data file (required)
- The member term data file (required)

Field Type Definitions and Input File Requirements

This chapter lists the field requirements for your input files. One of the attributes listed among the requirements is defined as "Type". There are four field types used to describe a field's value, and they are defined below.

Field Type	Definition
AlphaNum	A value made of letters and/or numbers. If a value of this type is made of numbers only, it will not be a value that can be operated on mathematically. For example, it would be inappropriate to subtract one procedure code from another procedure code even though both values may contain only numbers.
Num	A value made of numbers only, and which can logically be operated on mathematically. Age is an example of this type. One particular field, while not used in mathematical calculations, is defined in the EBM Connect software as such that it accepts only numeric values. (To enter a non-numeric value would cause EBM Connect processing to stop.) Therefore, this field is defined as Num. It is the Case ID field in the optional disease registry input file.
Date	A value which can be interpreted as a date value. Values should always use four-digit years but the format may vary otherwise.
DecNum	A value made of numbers and a decimal point. These values can also logically be operated on mathematically.

Claims Input File

The claims file contains detailed information on services that were billed or performed or otherwise rendered. The claims file includes:

- Medical claims, including medical services, facility services and clinic services
- Pharmacy claims, including billed prescriptions and drugs
- Lab claims, including lab test and results information

Field Name	Type	Length	Required or Optional
Family ID	AlphaNum	1-30	Always required for all claims
Patient ID	AlphaNum	0-2	Optional
Amount Paid	DecNum	1-11	Required for all claims
Amount Allowed	DecNum	0-11	Required for all claims
Procedure Code	AlphaNum	5	Required if there is no revenue code, NDC, or LOINC® code
Procedure Code Modifier	AlphaNum	2	Required for medical claims
Revenue Code	AlphaNum	0 or 4	Optional (applies to medical claims when used)
First Diagnosis Code	AlphaNum	5 or 6	Required for medical claims
Second Diagnosis Code	AlphaNum	0, 5 or 6	Optional (applies to medical claims when used)
Third Diagnosis Code	AlphaNum	0, 5 or 6	Optional (applies to medical claims when used)
Fourth Diagnosis Code	AlphaNum	0, 5 or 6	Optional (applies to medical claims when used)
First Date of Service	Date	8 or 10	Always required for all claims
Last Date of Service	Date	8 or 10	Required for all claims

Paid Date	Date	0, 8 or 10	Optional
Type of Service	AlphaNum	0-10	Optional
Provider ID	AlphaNum	1-20	Required for medical claims
Ordering Provider ID	AlphaNum	0-20	Optional
Provider Type	AlphaNum	1-10	Required for medical claims
Provider Specialty Type	AlphaNum	1-10	Required for medical claims
Provider Key	AlphaNum	1-20	Required for medical claims
NDC	AlphaNum	0 or 11	Required for Rx claims
Day Supply	Num	0-4	Required for Rx claims
Quantity Count	DecNum	0-10	Required for Rx claims
LOINC®	AlphaNum	0 or 7	Required for lab claims
Lab Test Result	AlphaNum	0-18	Required for lab claims
Place of Service	AlphaNum	1-10	Required for medical claims
Unique Record ID	AlphaNum	1-28	Required for all claims
Claim Number	AlphaNum	1-28	Required for all claims
Bill Type Frequency Indicator	Num	0 or 1	Optional
Patient Status	AlphaNum	1-2	Required for facility claims (involving admission or confinement).
Facility Type	AlphaNum	0-2	Optional
Bed Type	AlphaNum	0-1	Optional
First ICD-9 Procedure Code	AlphaNum	0, 4 or 5	Optional, but will impact results (applies to medical claims when used)
Second ICD-9 Procedure Code	AlphaNum	0, 4 or 5	Optional (see above)
Third ICD-9 Procedure Code	AlphaNum	0, 4 or 5	Optional (see above)
Fourth ICD-9 Procedure Code	AlphaNum	0, 4 or 5	Optional (see above)

Field Descriptions

Instructions for each input field are as follows:

Family ID

This field identifies all members of a family and can be any alphanumeric string.

Note: Remember that each Family ID (and Patient ID) listed in your claims input file must have a corresponding record in your member input data file and your member term data file.

Patient ID

This field identifies individual members within a family. If present, this field must be sorted within Family ID, so that all records for an individual are contiguous. If the Family ID uniquely identifies an individual, this field need not be specified (that is, its length in the dictionary will be zero).

Amount Paid

The amount paid for this claim line.

Amount Allowed

The allowed amount for this claim line. This amount typically represents the total amount reimbursed including deductibles, copays, coinsurance, insurer paid, etc.

Procedure Code

The procedure code must be one of:

- A procedure code specified in the Physician's Current Procedure Terminology, 4th Edition (CPT®-4 codes) defined by the American Medical Association, for the years 1997 and later.
- A procedure code specified by the HCFA Common Procedure Coding System, Level II code (HCPCS) defined by the Centers for Medicare and Medicaid Services (CMS) for the years 1999 and later.
- A National Uniform Billing Committee (NUBC) revenue code.

Note: When the NUBC code is entered in the Procedure Code field, it should be padded to the right with blanks because the Procedure Code field always occupies five characters.

- If your organization defines its own procedure codes and/or revenue codes, they must be mapped to standard procedure and revenue codes.

Procedure Code Modifier

Use this field to specify any procedure code modifier that accompanies the procedure code.

Revenue Code

The revenue code, if one was entered for the claim. Supported values in this field are NUBC revenue codes. If your organization defines its own revenue codes, they must be mapped to standard revenue codes.

The revenue code is an optional field, allowing you to define your input records so that you can place an NUBC revenue code and a CPT/HCPCS procedure code on a single record line.

For claim records that do not have a revenue code, leave the revenue code field blank.

First Diagnosis Code Through Fourth Diagnosis Code

Up to four diagnoses may be entered for each claim, but only the first is required.

If your organization defines its own diagnosis codes, they must be mapped to standard ICD-9 diagnosis codes.

First Date of Service and Last Date of Service

The first date and last date represented by the claim line. If you choose to use a date format with separators (such as YYYY/MM/DD or YYYY-MM-DD), the separators are ignored on input, so you can use any character as a separator. Valid formats include: YYYYMMDD, MMDDYYYY, DDMMYYYY, YYYY/MM/DD, MM/DD/ YYYY, and DD/MM/YYYY, where the separator can be any character.

Paid Date

This field is optional. This is the date the claim was paid. The format of the paid date must be the same as that used in the First and Last Date of Service.

Type of Service

This is an optional code which represents the type of service (TOS) performed for this claim. If no specific value is available for this field, it should be filled with blanks. If this field is not used (i.e., its length is set to zero in the configuration), non-pharmaceutical claims with no procedure code will be treated as ancillary records.

Provider ID

Provider identification number from the claim. Used to identify who performed the service.

Ordering Provider ID

This is an optional field. This is the identification number of the provider who ordered the service.

Provider Type

This code represents the type of provider who performed the service. Examples of provider types would be chiropractor, nurse practitioner, medical doctor, counselor, pharmacy, hospital or treatment facility.

Provider Specialty Type

This code represents the specialty of the provider who performed the service.

Provider Key

Unique number or code for a physician who has multiple provider IDs or specialties. A single health care provider may have multiple provider IDs in your input claims data, but this person or entity should have only one provider key.

NDC

If this is a pharmaceutical claim, this field should contain the drug's NDC code. For non-pharmaceutical claim records, the NDC field should be filled with blanks.

Day Supply

For pharmacy records, the number of days a filled prescription is expected to last. If you have no pharmacy records, the Days Supply is an optional field.

Quantity Count

Quantity of drug dispensed in metric units:

Each - solid oral dosage forms (tablet, capsule), powder filled (dry) vials, packets, patches, units of use packages, suppositories, bars.

Milliliter - (cc) liquid oral dosage forms, liquid filled vials, ampules, reconstituted oral products.

Grams - ointments, bulk powders (not IV).
If you have no pharmacy records, the Quantity Count is an optional field.

LOINC®

Logical Observation Identifiers Names and Codes (LOINC®). The LOINC Code is a universal identifier for a lab test for a particular analyte. The LOINC User's Guide and database can be found at www.regenstrief.org.

Enter a LOINC code if the record is a lab record. For non-lab records, leave the LOINC field blank.

If you have no lab records in your claims input, the LOINC code is optional.

Notes:

(1) When using lab results data that has not been mapped to a LOINC code, map the comparable vendor-specific test number provided by the laboratory vendor(s) to one of these default codes.

(2) This is a retired code which may be present on historical data, or which some laboratories may be continuing to use. Input record data with this code is included in the definition of this test.

Lab Test Result

If the record is a lab record, use this field to enter the result value of lab test. For non-lab records, this field should be blank.

If you have no lab records in your claims input, the Lab Test Result is optional.

Place of Service

Place of service (POS). You must map your internal POS codes to Centers for Medicare and Medicaid Services (CMS) standard POS codes.

Unique Record ID

This required field contains a unique identifier representing the service line from the claim. For medical services, this ID typically represents the service row from the CMS 1500 or CMS 1450/UB92 claim form.

Claim Number

A unique identifier used to link service lines for a specific claim submitted for a member. If a claim has multiple service lines, each service will have a unique record ID and the same claim number to represent the claim.

Bill Type Frequency Indicator

This optional field is used to indicate the disposition of confinements.

Patient Status

This field is required for facility claims. The contents will be the patient status indicator field from the NUBC UB-92 form. This field can denote whether the member died during a confinement.

Facility Type

This field is optional. Space for it is provided to allow for additional post grouping analysis. The contents will typically be the UB-92 facility type data value. This would allow records to be easily selected for diagnosis related grouping (DRG) based on the facility type.

Bed Type

If a value is present, this field acts as an additional discriminator in determining whether a Facility record extends an existing confinement or starts a new confinement.

First ICD-9 Procedure Code Through Fourth ICD-9 Procedure Code

If your claims have ICD-9 procedure codes, include them in your claims input file.

If a decimal point will appear in this field in your claim records, the length should be given as 5. If the decimal separator is not used, the length is 4. If these fields are unused, the length is zero.

Member Input File

The member data file contains the most current information about the member.

Field Descriptions

Field	Type	Length	Required or Optional
Family ID	AlphaNum	1-30	Required
Patient ID	AlphaNum	0-2	Optional
Patient Gender	AlphaNum	1	Required
Date of Birth	Date	8 or 10	Required
Member Beginning Eligibility Date	Date	0, 8 or 10	Optional
Member Ending Eligibility Date	Date	0, 8 or 10	Optional

Instructions for each input field are as follows:

Family ID

This field identifies all members of a family and can be any alphanumeric string. The records in the member file must be sorted first on the Family ID (together with Patient ID, if available) so that all records for an individual are contiguous.

Patient ID

This field identifies individual members within a family. If present, this field must be sorted within Family ID, so that all records for an individual are contiguous. If the Family ID uniquely identifies an individual, this field need not be specified (that is, its length in the dictionary will be zero).

Patient Gender and Date of Birth

The member's gender (F or M) and date of birth. If you choose to use a date format with separators (such as YYYY/MM/DD or YYYY-MM-DD), the separators are ignored on input, so you can use any character as a separator. Valid date formats include: YYYYMMDD, MMDDYYYY, DDMMYYYY, YYYY/MM/DD, MM/DD/YYYY, and DD/MM/YYYY, where the separator can be any character.

Member Beginning Eligibility Date and Ending Eligibility Date

The first date on which the member became covered under the plan and the last date of the member's coverage. If you choose to use a date format with separators (such as YYYY/MM/DD or YYYY-MM-DD), the separators are ignored on input, so you can use any character as a separator. Valid formats include: YYYYMMDD, MMDDYYYY, DDMMYYYY, YYYY/MM/DD, MM/DD/YYYY, and DD/MM/YYYY, where the separator can be any character.

Member Term Input File

The member term data file contains member coverage and term activity information. Plan coverage begin and end dates are required in order to correctly calculate the other fields in the member term file. There may be more than one record per individual member.

Field Descriptions

Field	Type	Length	Required or Optional
Family ID	AlphaNum	1-30	Required
Patient ID	AlphaNum	0-2	Optional
Member Beginning Eligibility Date	Date	8 or 10	Required
Member Ending Eligibility Date	Date	8 or 10	Required
Primary Care Provider	AlphaNum	20	Required
Provider Specialty Type	AlphaNum	1-10	Required
Medical Flag	AlphaNum	1	Required
Pharmacy Flag	AlphaNum	1	Required

Instructions for each input field are as follows:

Family ID

This field identifies all members of a family and can be any alphanumeric string. The records in the member term file must be sorted first on the Family ID (together with Patient ID, if available) so that all records for an individual are contiguous.

Patient ID

This field identifies individual members within a family.

Member Beginning Eligibility Date and Member Ending Eligibility Date

The first date on which the member became covered under the plan and the last date of the member's coverage. If you choose to use a date format with separators (such as YYYY/MM/DD or YYYY-MM-DD), the separators are ignored on input, so you can use any character as a separator. Valid formats include: YYYYMMDD, MMDDYYYY, DDMMYYYY, YYYY/MM/DD, MM/DD/YYYY, and DD/MM/YYYY, where the separator can be any character.

Primary Care Provider

The provider key for the member's primary care physician. A single health care physician may have multiple provider IDs in your input claims data, but this person should have only one provider key.

Provider Specialty Type

This code represents the specialty of the primary care physician.

Medical Flag

Identifies whether the member has medical coverage (Y or N).

Pharmacy Flag

Identifies whether the member has pharmacy coverage (Y or N).