

NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

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

NQF #: 0584 NQF Project: Infectious Disease Project
(for Endorsement Maintenance Review) Original Endorsement Date: Dec 04, 2009 Most Recent Endorsement Date: Dec 04, 2009 Last Updated Date: Aug 23, 2012
BRIEF MEASURE INFORMATION
De.1 Measure Title: Hepatitis C: Viral Load Test
Co.1.1 Measure Steward: Resolution Health, Inc.
De.2 Brief Description of Measure: This measure identifies the percentage of patients with chronic Hepatitis C (HCV) who began HCV antiviral therapy during the measurement year and had HCV Viral Load testing 6 months prior to initiation of antiviral therapy.
2a1.1 Numerator Statement: Patients in the denominator who had an HCV Viral Load test 6 months prior to the initiation of antiviral therapy.
2a1.4 Denominator Statement: Our denominator is anyone with Hepatitis C diagnosed anytime in the past, based on historical claims on file, who have a new start of peginterferon in the last year, excluding people with documentation of a medical reason(s) for not performing quantitative HCV RNA testing within 6 months prior to initiation of treatment (CPT Category II code 3218F-1P).
2a1.8 Denominator Exclusions: Exclude anyone with a code which states the patient has a medical reason for not having the test done.
1.1 Measure Type: Process 2a1. 25-26 Data Source: Administrative claims 2a1.33 Level of Analysis: Health Plan
1.2-1.4 Is this measure paired with another measure? No
De.3 If included in a composite, please identify the composite measure (<i>title and NQF number if endorsed</i>):

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

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All

three subcriteria must be met to pass this criterion. See [guidance on evidence](#).
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.
[\(evaluation criteria\)](#)

1a. High Impact: H M L I

(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

De.4 Subject/Topic Areas (Check all the areas that apply): Infectious Diseases, Infectious Diseases : Hepatitis

De.5 Cross Cutting Areas (Check all the areas that apply):

1a.1 Demonstrated High Impact Aspect of Healthcare: Other

1a.2 If "Other," please describe: PATIENT-FOCUSED CARE

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

Hepatitis C infects more than 170 million people worldwide, including over 3 million people in the US. Among patients with chronic infection, 15-20% progress to end-stage liver disease and 1-4% of those patients will develop hepatocellular carcinoma. Prevalence is highest among middle-aged patients who have a higher risk of progressing to cirrhosis or cancer (Predicting the Probable Outcome of Treatment in HCV Patients: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3002533/?tool=pubmed>). Hepatitis C causes an estimated 12,000 deaths each year in the US. The direct medical cost of chronic HCV infection is expected to be greater than \$10.7 billion and the cost of premature deaths to be \$54.2 billion, and costs of disability \$21.3 billion, in the 10 year period of 2010-2019 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5943a3.htm>).

The cost of treating HCV infection are substantial (range from \$10,000 to \$40,000), the cost of not treating HCV are estimated to be much higher due to complications, including cirrhosis and hepatocellular cancer. However it is also important to note there are substantial direct and indirect costs associated with drug therapy and a high rate of adverse effects with treatment. These can lead to decreased productivity on the job and also increased utilization of healthcare services by patients. The need to optimize duration of therapy, using measurement of viral load for example, will increase the chances of controlling the infection while minimizing the risk of adverse effects and the economic burden of managing the infection. In conclusion, identification and treatment of HCV is likely to be cost effective (<http://www.njmonline.nl/getpdf.php?id=10000825>).

1a.4 Citations for Evidence of High Impact cited in 1a.3: Navaneethan U, Kemmer, N. et al. Predicting the Probable Outcome of Treatment in HCV Patients. Therap Adv Gastroenterol. September 2009; 2(5): 287-302. Abstract available at:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3002533/?tool=pubmed>

Helsper, CW, Helling HL, et al. Real-life costs of hepatitis C treatment. Netherlands Journal of Medicine. April 2012; 70(3):145-153. Available at <http://www.njmonline.nl/getpdf.php?id=10000825>.

Centers for Disease Control and Prevention. Evaluation of Acute Hepatitis C Infection Surveillance- United States, 2008. MMWR. November 2010; 59(43):1407-1410. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5943a3.htm>.

1b. Opportunity for Improvement: H M L I

(There is a demonstrated performance gap - variability or overall less than optimal performance)

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

By identifying specific patients in whom care is not consistent with the clinical practice guideline underlying the measure, the measure will facilitate improvement in the care for those patients by highlighting the patient-specific QI opportunity for the patient's physician(s).

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers):

[For **Maintenance** – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

The modified measure was tested on three databases of approximately 1.8 million administrative claims total. The databases consisted of 410,000 claims, 700,000 claims and 700,000 claims each, respectively. The results varied from 68.8% to 84.4% compliance with the modified measurement. The number of patients identified in both the denominator and numerators was low with a range of 16 to 55 in the denominator and a range of 11 to 42 in the numerator. This is lower than what was seen with the old

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

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measurement (range of 92-95%), which gave patients credit for a quantitative HCV RNA test anytime in the past. The modified measure is now more closely aligned with the evidence.

1b.3 Citations for Data on Performance Gap: [*For Maintenance* – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included] RHI client experience (this modified measure was tested on three databases of approximately 1.8 million administrative claims total).

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance* –Descriptive statistics for performance results for this measure by population group]

Currently the measure uses claims level data to determine if a viral load was obtained before initiation of antiviral treatment. Since race/ethnicity is not a required data source from patients, it is not possible to determine if disparities in care are happening based on that. CDC has stated that men and intravenous drug users are disproportionately affected by this disease.

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

The data is claims based and population disparities were not assessed.

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

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

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the measure pass subcriterion1c?
Yes IF rationale supports relationship

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

This is a process measure (HCV RNA testing) that leads to improved health/avoidance of harm. HCV RNA testing allows one to establish a baseline level to monitor and assess virologic response to antiviral therapy.

1c.2-3 Type of Evidence (Check all that apply):

Clinical Practice Guideline

1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population):

Central topic- HCV viral load testing prior to initiating antiviral treatment in patients with Hepatitis C.

Population- Patients with chronic Hepatitis C who have initiated drug therapy.

Outcomes addressed- Response to therapy and effectiveness of treatment based on tailoring the regime around the baseline viral load.

1c.5 Quantity of Studies in the Body of Evidence (Total number of studies, not articles): 12 clinical trials were studied in a meta-analysis paper.

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

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1c.6 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): Obtaining a base viral load before initiating antiviral treatment is supported by over 10 clinical trials including 2,275 patients as a way to 1) determine current viral load and 2) use this base measurement to determine treatment efficacy which could result in a shorter therapy duration. The meta-analysis on the 12 studies states that all odds ratios and weighted differences of percentages were statistically significant when splitting patients according to baseline viremia. Those patients with HCV-2 genotype and low viremia HCV-3 patients should have a 24 week therapy duration. HCV-3 patients with a higher viral load will need a longer treatment than the standard 24 weeks. The authors of the meta-analysis excluded studies that had a 48 week duration of therapy and also studies where the patients had acute HCV infection, HIV co-infection, and other comorbidities. High risk patients were excluded which impacts the data- as this group would most likely not respond as well as lower risk patients. The studies themselves varied in the number of patients followed from 70 to 731. This wide range can impact results especially on the lower end with a small sample size. Also the studies used different types of Peg-interferon (alpha or beta) and different doses of ribavirin which could affect comparability across studies. The confidence intervals of the pooled data were for the most part >1.0 showing a significant difference in sustained virological response rates between HCV genotype 2 and 3 for the standard 24 week treatment. The highest CIs were seen high viremic patients supporting the conclusion that high viremic HCV-2 patients have better outcomes on the standard 24 week therapy than high viremic HCV-3 patients.

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): There are similar results across the meta-analysis showing that obtaining a base viral load for HCV patients is beneficial. This measurement serves as a baseline number which can be used to determine treatment efficacy throughout the duration of treatment and it can also be used as a marker to stop treatment early if the virus is cleared. However in these studies the genotype of the virus was as important as the viral load and our measure does not deal with that aspect of treatment. One study of 283 patients concluded that a shorter course of therapy over 12 weeks with peginterferon alfa-2b and ribavirin was as effective as a 24-week course for HCV-2 and HCV-3 patients who showed a response to treatment at 4 weeks. Another study of 53 Japanese patients stated that the amounts of HCV RNA can predict the efficacy of antiviral treatment in patients with HCV-2. In conclusion the viral load is an important first step in the treatment of patients with chronic HCV infection according to most studies.

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms):

The net benefit is better care for patients with HCV infection. By obtaining a viral load measurement before starting antiviral therapy- a baseline number is measured which can be used to determine treatment efficacy throughout the duration of treatment and it can also be used as a marker to stop treatment early if the patient has a rapid virological response. Studies have also concluded that the viral load before treatment begins actually predicts the efficacy of treatment. This baseline measurement provides information to improve patient care.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? **Yes**

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: This was graded by the American Association for the Study of Liver Diseases which uses the American College of Cardiology and American Heart Association Practice Guidelines. Disclosures: Potential conflict of interest: Dr. Nelson receives research support from Vertex, Merck, Phamassett, Genentech/Roche, Gilead, Bristol-Myers Squibb, Tibotec, Bayer/Onyx and serves on advisory boards of Merck, Phamassett, Genentech/Roche, Gilead, Tibotec, and Bayer/Onyx, and is a consultant for Vertex. Dr. Thomas receives research support from Merck, Gilead and serves on a Merck advisory board. Dr. Ghany, Dr. Seeff, and Dr. Strader have nothing to report.

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

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

1c.13 **Grade Assigned to the Body of Evidence:** [Class I](#) - this was assigned by the American Association for the Study of Liver Diseases which based it on the [American College of Cardiology and American Heart Association Practice Guidelines](#).

1c.14 **Summary of Controversy/Contradictory Evidence:** [There is no applicable controversy/contradictory evidence.](#)

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

[Dienstag, JL, McHutchison, JG. American Gastroenterological Association medical position statement on the management of hepatitis C. Gastroenterology. 2006; 130:225.](#)

[Andriulli, A, Mangia, A, et al. Meta-analysis: the outcome of anti-viral therapy in HCV genotype 2 and genotype 3 infected patients with chronic hepatitis. Aliment Pharmacol Ther. 2008; 397-404.](#)

1c.16 **Quote verbatim, the specific guideline recommendation** (*Including guideline # and/or page #*):

[Guideline 5.HCV ribonucleic acid \(RNA\) testing should be performed in:](#)

[b.Patients for whom antiviral treatment is being considered, using a sensitive quantitative assay \(Class I, Level A\)
p. 1339](#)

1c.17 **Clinical Practice Guideline Citation:** [UPDATE: Ghany MG, Nelson DR, Strader DB, Thomas DL, Seeff LB. American Association for Study of Liver Diseases. Diagnosis, management, and treatment of Hepatitis C: An update. Hepatology 2009 April: 1335-74.](#)

[Strader DB, Wright T, Thomas DL, Seeff LB; American Association for the Study of Liver Diseases. Diagnosis, management, and treatment of hepatitis C. Hepatology. 2004;39\(4\):1147-71.](#)

1c.18 **National Guideline Clearinghouse or other URL:**

1c.19 **Grading of Strength of Guideline Recommendation.** Has the recommendation been graded? [Yes](#)

1c.20 **If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:** [Practice Guidelines Committee of the AASLD \(American Association for the Study of Liver Diseases\)](#)

1c.21 **System Used for Grading the Strength of Guideline Recommendation:** [GRADE](#)

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

1c.23 **Grade Assigned to the Recommendation:** [Level A](#)

1c.24 **Rationale for Using this Guideline Over Others:** [It is a clinical guideline promulgated by the American College of Gastroenterology \(the guideline comes from a document - Diagnosis, Management, and Treatment of Hepatitis C: An Update - that is also approved by the Infectious Diseases Society of America and the AASLD\).](#)

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: [High](#) 1c.26 Quality: [Moderate](#) 1c.27 Consistency: [Moderate](#)

1c.28 Attach evidence submission form:

1c.29 Attach appendix for supplemental materials:

Was the threshold criterion, *Importance to Measure and Report*, met?

(*1a & 1b must be rated moderate or high and 1c yes*) Yes No

Provide rationale based on specific subcriteria:

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

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

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **(evaluation criteria)**

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

S.1 Measure Web Page (*In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? **Yes**

S.2 If yes, provide web page URL: <http://www.resolutionhealth.com/558.html>

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

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

2a1.1 Numerator Statement (*Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome*):

Patients in the denominator who had an HCV Viral Load test 6 months prior to the initiation of antiviral therapy.

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

The PCPI measure, 0395, seeks quantitative HCV RNA testing performed within 6 months prior to initiation of antiviral treatment. We have updated our measure to only give credit for viral load testing within 6 months prior to initiation of therapy start because quantitative testing should be conducted in immediate proximity to the initiation of antiviral treatment.

2a1.3 Numerator Details (*All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*):

Any of the following {

- claim for 'HCV viral load test';

- result of 'HCV viral load test';

} during the 6 months preceding RX_START;

'HCV viral load test' procedure:

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p      3218F          rna tstng hep c docd done
p      87522          hepatitis c rna quant    cpt4
```

2a1.4 Denominator Statement (*Brief, narrative description of the target population being measured*):

Our denominator is anyone with Hepatitis C diagnosed anytime in the past, based on historical claims on file, who have a new start of peginterferon in the last year, excluding people with documentation of a medical reason(s) for not performing quantitative HCV RNA testing within 6 months prior to initiation of treatment (CPT Category II code 3218F-1P).

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

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

Past year

2a1.7 Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

- claim for 'Chronic HCV' associated with a procedure in 'Acute & Nonacute IP_ED_OP_E&M', anytime;

- any of the following {

- rx claim for 'Peg-Interferons';

- proc claim for 'Peg-Interferons';

} during the measurement year, saving earliest as RX_START;

-none of the following {

- rx claim for 'Peg-Interferons';

- proc claim for 'Peg-Interferons';

} during the 6 months preceding RX_START;

- no inpatient admission during the 6 months preceding RX_START;

- no proc claim for 'HCV RNA quant exception';

- Age >=18 years;

- health service eligibility for 6 months preceding RX_START;

- prescription drug service eligibility during the 6 months preceding RX_START;

'HCV RNA quant exception' procedure:

p 3218F-1P rna tstng hep c docd done – exclusion modifier

Hepatitis C_chronic (Diagnosis)

Type Code Description

ICD9 07044 CHRONIC HEPATITIS C W/HEPATIC COMA
ICD9 07054 CHRONIC HEP C W/O MENTION HEP COMA
ICD9 07070 UNS VIRAL HEPATITIS C W/O HEP COMA
ICD9 07071 UNS VIRAL HEPATITIS C W/HEP COMA
ICD9 V0262 HEPATITIS C CARRIERGPI

Peg-interferons (Medispan Drug)

12353060052020
Peginterferon alfa-2a Inj 180 MCG/ML
GPI
12353060056440

Peginterferon alfa-2a Inj Kit 180 MCG/0.5ML

GPI

12353060106424

Peginterferon alfa-2b For Inj Kit 120 MCG/0.5ML

GPI

12353060106430

Peginterferon alfa-2b For Inj Kit 150 MCG/0.5ML

GPI

12353060106410

Peginterferon alfa-2b For Inj Kit 50 MCG/0.5ML

GPI

12353060106416

Peginterferon alfa-2b For Inj Kit 80 MCG/0.5ML

Peg-Interferons alpha_P', procedure:

p 4150F pt recvng antivir txmnt hepc
p J9212 inj intrfern alfacon-1 recomb 1 mcg
p J9213 inj interferon alfa-2a recom 3 m u
p J9214 inj interferon alfa-2b recomb 1 m u
p J9215 inj interferon alfa-n3 250,000 iu
p S0145 inj pegylatd ifn alfa-2a 180 mcg ml
p S0146 inj pegyl ifn alfa-2b 10 mcg 0.5 ml
p S0148 inj pegylatd intrfer alfa-2b 10 mcg

2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population):

Exclude anyone with a code which states the patient has a medical reason for not having the test done.

2a1.9 Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

Exclude anyone with 'HCV RNA quant exception' procedure:

p 3218F-1P rna tstng hep c docd done-exclusion modifier

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

No stratification.

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

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

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

2a1.17-18. **Type of Score:** [Rate/proportion](#)

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

2a1.20 **Calculation Algorithm/Measure Logic** (*Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.*):

[Rule Population \(denominator\)](#)

- claim for 'Chronic HCV' associated with a procedure in 'Acute & Nonacute IP_ED_OP_E&M', anytime;

- any of the following {

- rx claim for 'Peg-Interferons';

- proc claim for 'Peg-Interferons';

} during the measurement year, saving earliest as RX_START;

-none of the following {

- rx claim for 'Peg-Interferons';

- proc claim for 'Peg-Interferons';

} during the 6 months preceding RX_START;

- no inpatient admission during the 6 months preceding RX_START;

- no proc claim for 'HCV RNA quant exception';

- Age >=18 years;

- health service eligibility for 6 months preceding RX_START;

- prescription drug service eligibility during the 6 months preceding RX_START;

Yes criteria (numerator)

Any of the following {

- claim for 'HCV viral load test';

- result of 'HCV viral load test';

} during the 6 months preceding RX_START;

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

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

The modified measure was tested on three databases of approximately 1.8 million administrative claims total from 2008 to 2011. The databases consisted of 410,000 claims, 700,000 claims and 700,000 claims each. 50.7% of the population is female with the majority of members over 18 years old (79.4%).

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

2a1.26 Data Source/Data Collection Instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): Data source is administrative claims data (ICD-9 and CPT codes) and laboratory results matched with LOINC codes.

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

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

2a1.33 Level of Analysis (Check the levels of analysis for which the measure is specified and tested): Health Plan

2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested): Ambulatory Care : Clinician Office/Clinic

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

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

The modified measure was tested on three databases of approximately 1.8 million administrative claims total from 2008 to 2011. The databases consisted of 410,000 claims, 700,000 claims and 700,000 claims each. 50.7% of the population is female with the majority of members over 18 years old (79.4%).

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

In the three databases, the measure found the following data:

Out of 410,000 claims: 11/16 members (68.8%)

Out of 1.4 million claims (combined 2 databases): 27/32 members (84.4%)

RHI/WellPoint clinicians reviewed the claims of members who were identified in the measure denominator with an eye toward assessing whether the rule criteria are formulated accurately based on the measure's intent. It was determined that the measure was correctly identifying both numerator and denominator members. While reviewing medical records would have been the best way to ensure the data was correct, we do not have access to members' medical records. We are therefore dependent on providers submitting claims correctly.

2a2.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):

The modified measure has identified members correctly on 3 databases. The compliance rate ranges from 68.8% to 84.4% across these 1.8 million claims. Low number of members are identified in each database which impacts the wide range of compliance rates.

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

2b1.1 Describe how the measure specifications (*measure focus, target population, and exclusions*) **are consistent with the evidence cited in support of the measure focus** (*criterion 1c*) **and identify any differences from the evidence:**
 This measure is consistent with the evidence that HCV RNA quantification is important. HCV RNA quantification determines current viral load and this can be used as a base measurement to determine treatment efficacy which could result in a shorter therapy duration. The key difference between our measure and the meta-analysis is that the meta-analysis removed studies with high-risk patients, while our measure includes all patients with a diagnosis of Hepatitis C.

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

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

The modified measure was tested on three databases of approximately 1.8 million administrative claims total from 2008 to 2011. The databases consisted of 410,000 claims, 700,000 claims and 700,000 claims each. 50.7% of the population is female with the majority of members over 18 years old (79.4%).

2b2.2 Analytic Method (*Describe method of validity testing and rationale; if face validity, describe systematic assessment*):

Our validity testing is face validity. We had 3 board-certified physicians with varied training experiences review the literature and the test results. They then voted that the measure was valid based on the information presented.

2b2.3 Testing Results (*Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment*):

Our validity testing is face validity. We had 3 board-certified physicians with varied training experiences review the literature and the test results. They then voted that the measure was valid based on the information presented. One clinician reviewed the claims history of the individual members and confirmed that the intent of the rule program indeed matched the claims history of the members in the denominator and numerator.

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

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

2b3.1 Data/Sample for analysis of exclusions (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

The modified measure was tested on three databases of approximately 1.8 million administrative claims total from 2008 to 2011. The databases consisted of 410,000 claims, 700,000 claims and 700,000 claims each. 50.7% of the population is female with the majority of members over 18 years old (79.4%).

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

Our validity testing is face validity. We had 3 board-certified physicians with varied training experiences review the literature and the test results. They then voted that the measure was valid based on the information presented. One clinician reviewed the claims history of the individual members and confirmed that the intent of the rule program indeed matched the claims history of the members in the denominator and numerator.

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

Based on our analysis, no patients with the optional CPT Category II code signifying an exclusion were discovered.

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

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

There is no need to risk adjust results from this measure. To the extent that the measure applies only to patients in a particular risk category, that has been taken into account in the specifications for the denominator or exclusions for this measure.

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

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

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment:

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

2b5.1 Data/Sample (*Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

Group Insurance Commission (GIC):

In 2003, the Massachusetts Group Insurance Commission GIC launched the Clinical Performance Improvement initiative, requiring health plans under contract with the GIC to incorporate provider "tiering"—differential payments based on value—into their GIC product. For this initiative, RHI evaluates physician performance on a set of quality measures using administrative claims data from approximately 2.2 million health plan members.

Care Focused Purchasing (CFP)

Care Focused Purchasing, Inc. (CFP) is the largest private or public clinical performance measurement initiative in the nation, representing a coalition of major insurance carriers and more than 50 national self-insured employers. Since CFP's incorporation in 2005, RHI has analyzed medical and pharmacy claims data to assess the quality of care provided by physicians to 29 million CFP employees and members.

Methods to identify statistically significant and practically/meaningfully differences in performance: We have developed a hierarchical logistic regression model with expert biostatisticians at the Johns Hopkins School of Public Health that enables one to produce a probability distribution around a point estimate of the "quality score" for a given physician. This model has shown that there is no minimum sample size that is required to produce a quality score which has a comparatively "tight" probability distribution. Rather, the number of required observations depends on how a given physician performs on particular measures compared to how all other MDs perform on those measures. We recommend that a minimum of 10 observations be required, however, because of the normality assumption that underlies the model and for public "face validity". We have employed this statistical approach in the MD quality profiling we performed on the experience of more than 2 million members of 6 health plans participating in the Massachusetts Group Insurance Commission Clinical Performance Improvement Initiative in 2008.

2b5.2 Analytic Method (*Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance*):

Our validity testing is face validity. We had 3 board-certified physicians with varied training experiences review the literature and the test results. They then voted that the measure was valid based on the information presented. One clinician reviewed the claims history of the individual members and confirmed that the intent of the rule program indeed matched the claims history of the members in the denominator and numerator.

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

The modified measure was tested on three databases of approximately 1.8 million administrative claims total. The databases consisted of 410,000 claims, 700,000 claims and 700,000 claims each. The results varied from 68.8% to 84.4% compliance with the measurement. The number of patients identified in both the denominator and numerators was low with a range of 16 to 55 in the

denominator and a range of 11 to 42 in the numerator. Results are below:

Out of 410,000 claims: 11/16 members (68.8%)

Out of 1.4 million claims (combined 2 databases): 27/32 members (84.4%)

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

2b6.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Not applicable.

2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):

2b6.3 Testing Results (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):

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

2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): Not applicable. We currently do not stratify the measure for disparities.

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

Health disparities exist among individuals with Hepatitis C—such individuals are more likely be intravenous drug users and/or men; however, according to the CDC*(ref), rates of hepatitis C are similar across racial and ethnic groups.

*REF: C. Brooke Steele, Lehida Meléndez-Morales, Richard Campoluci, Nickolas DeLuca, and Hazel D. Dean. Health Disparities in HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis: Issues, Burden, and Response, A Retrospective Review, 2000–2004. Atlanta, GA: Department of Health and Human Services, Centers for Disease Control and Prevention, November 2007. Available at: <http://www.cdc.gov/nchhstp/healthdisparities/>

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?

(Reliability and Validity must be rated moderate or high) Yes No

Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

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

C.1 Intended Actual/Planned Use (Check all the planned uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization)

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

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

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3a. Usefulness for Public Reporting: H M L I

(The measure is meaningful, understandable and useful for public reporting.)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [For **Maintenance** – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.]

Utilized for internal physician performance measurement and not for public reporting at this time.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results:

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

3b. Usefulness for Quality Improvement: H M L I

(The measure is meaningful, understandable and useful for quality improvement.)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):

[For **Maintenance** – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

Utilized for internal physician performance measurement and not for public reporting at this time.

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

The data we have over time is pooled data for the measure prior to revision. As you can see the rate is higher than the rate for the current revised measure (68.8-84.4%).

2009	80/87 = 92.0%
2010	80/84 = 95.2%
2011	83/90 = 92.2%

After harmonizing the measure, we are showing different counts and proportions which are more closely aligned with the evidence. The modified measure was tested on three databases of approximately 1.8 million administrative claims total. The databases consisted of 410,000 claims, 700,000 claims and 700,000 claims each. Our percentages of 68-84% show there is room for improvement.

Overall, to what extent was the criterion, *Usability*, met? H M L I

Provide rationale based on specific subcriteria:

4. FEASIBILITY

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

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

4a.1-2 How are the data elements needed to compute measure scores generated? (Check all that apply).

Data used in the measure are:

Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

4b. Electronic Sources: H M L I

4b.1 Are the data elements needed for the measure as specified available electronically (Elements that are needed to

compute measure scores are in defined, computer-readable fields): [ALL data elements in electronic claims](#)

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

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

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

As with any type of clinical performance measure, and with any source of data used to operationalize the measure, there will be some instances in which the data used to compute the measure are incomplete or inaccurate. We try to minimize the impact of such errors or omissions through the way we have constructed the technical specifications for the measure. There is no data source for performance measurement that is completely accurate.

Potential data errors of omission or commission could be audited through chart abstraction, or feedback from physicians and patients. However, as mentioned above, each of these alternative sources of information also are susceptible to error and thus are not true gold standards. Audits included obtaining feedback from physicians whose performance had been evaluated.

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

A.2 Please check if either of the following apply (regarding proprietary measures):

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., fees for use of proprietary measures):

Overall, to what extent was the criterion, *Feasibility*, met? H M L I

Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

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

Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

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

0395 : Paired Measure: Hepatitis C Ribonucleic Acid (RNA) Testing Before Initiating Treatment (paired with 0396)

5a. Harmonization

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

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

5b. Competing Measure(s)

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

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5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):
 This measure, 0395, only allows patients to be identified in the numerator with CPT Category II codes while our measure uses billing claims and lab results for HCV RNA quantification in the numerator. Since CPT Category II codes are optional- this code may not be submitted by providers.

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Resolution Health, Inc., 10490 Little Patuxent Parkway, Suite 610, Columbia, Maryland, 21044

Co.2 Point of Contact: Jeffrey, Clyman, MD, MPH, Jeffrey.Clyman@anthem.com, 240-295-5983-

Co.3 Measure Developer if different from Measure Steward: Resolution Health, Inc., 10490 Little Patuxent Parkway, Suite 610, Columbia, Maryland, 21044

Co.4 Point of Contact: Jeffrey, Clyman, MD, MPH, Jeffrey.Clyman@anthem.com, 240-295-5983-

Co.5 Submitter: Jeffrey, Clyman, MD, MPH, Jeffrey.Clyman@anthem.com, 240-295-5983-, Resolution Health, Inc.

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

Co.7 Public Contact: Reynita, Taylor, Reynita.Taylor@anthem.com, 240-295-5837-, Resolution Health, Inc.

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.

Over the past several years, two formal workgroups -- one organized by the Care Focused Purchasing initiative and one organized by the Massachusetts Group Insurance Commission Clinical Performance Improvement Initiative -- and several ad hoc experts have provided useful input to our measure development and refinement processes. In each case, we have provided the Work Group Members with details regarding each of our performance measures and members of the work group (not always all members) have provided feedback on the validity of the clinical practice guideline underlying the measure and suggestions regarding potential ways to improve the technical specifications for the measure. In some instances, we have eliminated measures based on feedback from the work groups. In other instances, work group members have proposed new measures. We try to get feedback from work group members and selected clinical experts on an annual basis.

Care Focused Purchasing Clinical Advisory Panel

Bobbie Berg -BCBS -IL

Dow Briggs - BCBS- AL

Joe Calderella - Cigna

Carl Cameron - Preferred Care

Steven Goldberg – Humana

Tom James – Humana

Don Liss – Aetna

Catherine MacLean – WellPoint

Zak Ramadan–Jradi – Regence

Fred Volkman – Avidyn Health

Constance Hwang – Resolution Health

Darren Schulte - Resolution Health

<p>Earl Steinberg – Resolution Health</p> <p>Massachusetts Group Insurance Commission Physician Advisory Panel</p> <p>Jim Glauber – Neighborhood Health Plan</p> <p>Lyn Laurenco - Neighborhood Health Plan</p> <p>Anton Dodek - Tufts</p> <p>Barbara Chase - Fallon</p> <p>Jonathan Scott Coblyn – Brigham and Women's Hospital</p> <p>Tom Ebert - Health New England</p> <p>Elaine Wilson - Harvard Pilgrim Health Care</p> <p>Jennifer St. Thomas – Tufts</p> <p>Jennifer Lavigne – Fallon</p> <p>Michael O'Shea - Baycare Health</p> <p>Neil Minkoff - Harvard Pilgrim Health Care</p> <p>Paul Mendis- Neighborhood Health Plan</p> <p>Bob Jordan - Neighborhood Health Plan</p> <p>Bob Sorrenti – Unicare</p> <p>Constance Williams – Unicare</p> <p>Laura Syron - Neighborhood Health Plan</p> <p>Susan Tiffany – Unicare</p> <p>Constance Hwang – Resolution Health</p> <p>Darren Schulte - Resolution Health</p> <p>Earl Steinberg – Resolution Health</p> <p>David Gregg – Mercer</p> <p>Russ Robinson - Mercer</p>
<p>Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:</p>
<p>Measure Developer/Steward Updates and Ongoing Maintenance</p> <p>Ad.3 Year the measure was first released: 2006</p> <p>Ad.4 Month and Year of most recent revision: 10, 2008</p> <p>Ad.5 What is your frequency for review/update of this measure? Annual Review</p> <p>Ad.6 When is the next scheduled review/update for this measure? 08, 2009</p>
<p>Ad.7 Copyright statement: Copyright © 2008 – Resolution Health, Inc. All rights reserved. The material submitted is confidential and proprietary. No use of this material is permitted other than in accordance with the Agreement with Measure Stewards between National Quality Forum and Resolution Health, Inc.</p>
<p>Ad.8 Disclaimers:</p>
<p>Ad.9 Additional Information/Comments:</p>
<p>Date of Submission (MM/DD/YY): 05/29/2012</p>