NATIONAL QUALITY FORUM

IN-PERSON MEETING
NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PATIENT SAFETY
MEDICATION SAFETY TECHNICAL ADVISORY PANEL

August 10-17, 2010

Measure number: PSM-009-10

Measure name: Medication administration variance

Description: This measure identifies the percentage of ambulatory surgery admissions experiencing a medication administration variance prior to discharge.

Numerator statement: Ambulatory Surgery Center (ASC) admissions experiencing a medication administration variance(s) prior to discharge

Denominator statement: All ambulatory surgery center admissions

Level of analysis: Facility/Agency

Type of measure: Outcome

Data source: Management data, Organization policies and procedures, Paper medical record/flow sheet

Measure developer: ASC Quality Collaboration

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of subcriteria and comments:

<table>
<tr><td colspan="3">IMPORTANCE TO MEASURE AND REPORT</td></tr>
<tr><td>1a Impact</td><td>Completely: 4
Partially: 2
Minimally: 1
Not at all: 0</td><td rowspan="3">A TAP member described the measure as important but was concerned that it may not directly improve patient care. However, the TAP member noted the significance of standardizing medication variances for surgical centers.

The TAP discussed the “Summary of Controversy/Contradictory Evidence” presented in the measure and potential problems with the reporting of medication error rates. The information on the measure submission form indicated, and the TAP members noted, that tracking medication variance for public reporting may encourage gaming of the system.</td></tr>
<tr><td>1b Gap</td><td>Completely: 1
Partially: 6
Minimally: 0
Not at all: 0</td></tr>
<tr><td>1c Relation to outcomes</td><td>Completely: 2
Partially: 3
Minimally: 2
Not at all: 0</td></tr>
<tr><td colspan="3">SCIENTIFIC ACCEPTABILTY</td></tr>
<tr><td>2a Specs</td><td>Completely: 0
Partially: 4
Minimally: 3
Not at all: 0</td><td>The TAP members discussed concerns with the denominator, which includes all admissions. They stated that the variation of procedures conducted at different surgical centers would complicate the comparison of a singular statistic to measure a surgical center’s</td></tr>
</table>

2b Reliability	Completely: 0 Partially: 2 Minimally: 2 Not at all: 3	medication variance. The TAP suggested that a better denominator would be the number of medications or doses used within a surgery. This would allow a comparison across surgical centers for the medication variance of specific surgeries. The measure developer stated that it had considered a denominator that measured the medications or doses used by surgery but decided that it would be too labor-intensive to implement this. The TAP discussed how the numerator would be reported. The measure developer responded that it would be based on internal self- reports from records review. A TAP member asked why the measure includes an exclusion for blood products and radio pharmaceuticals. The measure developer stated that it patterned the exclusion after the AHRQ, which uses this exclusion as a common format in measure development.
2c Validity	Completely: 0 Partially: 1 Minimally: 4 Not at all: 2	
2d Exclusions	Completely: 0 Partially: 2 Minimally: 3 Not at all: 2 NA: 0	
2e Risk-adjustment	Completely: 0 Partially: 0 Minimally: 1 Not at all: 2 NA: 4	
2f Meaningful differences	Completely: 0 Partially: 1 Minimally: 2 Not at all: 4	
2g Comparability	Completely: 0 Partially: 0 Minimally: 1 Not at all: 5 NA: 1	
2h Disparities	Completely: 0 Partially: 0 Minimally: 0 Not at all: 3 NA: 4	
USABILITY		
3a Distinctive	Completely: 1 Partially: 3 Minimally: 3 Not at all: 0	A TAP member stated that this measure would need additional interpretative value to make it useful for public reporting and may be more useful as an internal benchmark.
3b Harmonization	Completely: 1 Partially: 3 Minimally: 3 Not at all: 0 NA: 0	
3c Added value	Completely: 1 Partially: 5 Minimally: 1 Not at all: 0	
FEASIBILITY		

4a Data a byproduct of care	Completely: 1 Partially: 3 Minimally: 2 Not at all: 1	A TAP member noted that not all medications prescribed are recorded on charts. A TAP member followed up on the usability discussion by re-examining the feasibility of self-reporting variances. He/she was concerned that public reporting of the measure and comparison of medication variances across ambulatory surgical centers could create a disincentive to report accurate variances. The measure may be more useful for internal quality reporting. The TAP also decided that the measure would not assist consumers in decisionmaking because reasons for the variance and patient outcomes were not further specified. An additional concern was explored regarding accurately documenting timings on charts.
4b Electronic	Completely: 0 Partially: 2 Minimally: 2 Not at all: 3	
4c Exclusions	Completely: 2 Partially: 3 Minimally: 2 Not at all: 0 NA: 0	
4d Inaccuracies	Completely: 1 Partially: 2 Minimally: 2 Not at all: 2	
4e Implementation	Completely: 1 Partially: 1 Minimally: 5 Not at all: 0	

Measure number: PSM-010-10

Measure name: Querying and counseling about anti-epileptic drug (AED) side-effects

Description: Percentage of patient visits for patients with a diagnosis of epilepsy where the patients were queried and counseled about anti-epileptic drug (AED) side-effects and the querying and counseling was documented in the medical record

Numerator statement: Patient visits with patient queried and counseled about anti-epileptic drug (AED) side-effects and the querying and counseling was documented in the medical record

Denominator statement: All visits for patients with a diagnosis of epilepsy

Level of analysis: Individual, Population: Can be measured at all levels

Type of measure: Process

Data source: Documentation of original self-assessment, Electronic Health/Medical Record, Paper medical record/flow-sheet

Measure developer: ©American Academy of Neurology (AAN)

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of subcriteria and comments:

<table>
<tr><td colspan="3">IMPORTANCE TO MEASURE AND REPORT</td></tr>
<tr><td>1a Impact</td><td>Completely: 1
Partially: 3
Minimally: 0
Not at all: 1</td><td rowspan="3">The TAP discussed whether the measure met the criteria for importance to measure and report. The TAP stated that the measure is important in the care of patients with epilepsy but was concerned that it did not demonstrate that educating patients on the side effects of anti-epileptic (AE) medication has a direct impact on outcomes.

Voting Comments:
• Unclear if screening for possible side effects of anti-epileptic medications would lead to appropriate medication switches and whether these changes would improve the health of patients (might actually result in recurrent seizures).
• Epilepsy is a serious condition but not as prevalent as many other conditions. Documentation of an existing problem is limited.
• The argument for a standard for discussing AEs and their monitoring is reasonable for patients on chronic therapy. Given the possibility for medication interactions, an ongoing assessment is needed. No statistics are provided as to the prevalence of AEs with these medications or their impact on care, but these can be surmised from the work of the AAN, consensus from other organizations, and the evaluation of evidence.</td></tr>
<tr><td>1b Gap</td><td>Completely: 1
Partially: 2
Minimally: 2
Not at all: 0</td></tr>
<tr><td>1c Relation to outcomes</td><td>Completely: 1
Partially: 1
Minimally: 3
Not at all: 0</td></tr>
<tr><td colspan="3">SCIENTIFIC ACCEPTABILTY</td></tr>
</table>

<table>
<tr><td>2a Specs</td><td>Completely: 0
Partially: 0
Minimally: 1
Not at all: 2</td><td rowspan="8">The measure is intended for all medical visits, but the TAP asked whether any doctor seeing a patient on anti-epileptic medication would be responsible for asking the patient about anti-epileptic side effects. The measure developer confirmed that this was the intent of the measure. However, the TAP thought that the measure should have a more narrow focus and advised the developer to specify additional criteria to indicate which doctors should be querying patients about side effects from anti-epileptic medications.

The TAP considered the measure's limitation that it would not measure counseling of patients about the medication.

The measure developer is currently conducting testing on compliance rate.

Currently, the data would be collected through chart abstractions, but ideally they could be submitted through electronic health records. The measure developer intends to further develop the measure in the future for EHR specifications.

The measure partially or minimally meets the criteria. The testing and analysis data has yet to be received.

Voting Comments:
• No testing has been performed. The proposed validity argument is based on a number of assumptions that have not been tested.
• Accuracy will depend heavily on documentation by physicians of the details of their verbal exchanges with patients.
• Many of the items are listed as not applicable, but it is unclear if this is true or if this is because they have not been done.</td></tr>
<tr><td>2b Reliability</td><td>Completely: 0
Partially: 0
Minimally: 1
Not at all: 2</td></tr>
<tr><td>2c Validity</td><td>Completely: 0
Partially: 0
Minimally: 1
Not at all: 2</td></tr>
<tr><td>2d Exclusions</td><td>Completely: 0
Partially: 0
Minimally: 1
Not at all: 2
NA: 4</td></tr>
<tr><td>2e Risk-adjustment</td><td>Completely: 0
Partially: 0
Minimally: 1
Not at all: 2
NA: 4</td></tr>
<tr><td>2f Meaningful differences</td><td>Completely: 0
Partially: 0
Minimally: 1
Not at all: 2</td></tr>
<tr><td>2g Comparability</td><td>Completely: 0
Partially: 0
Minimally: 0
Not at all: 2
NA: 3</td></tr>
<tr><td>2h Disparities</td><td>Completely: 0
Partially: 0
Minimally: 2
Not at all: 1
NA: 2</td></tr>
<tr><td colspan="3">USABILITY</td></tr>
<tr><td>3a Distinctive</td><td>Completely: 0
Partially: 1
Minimally: 2
Not at all: 0
NA: 2</td><td rowspan="3">After discussion, the TAP agreed that the measure sufficiently meets the usability subcriteria.

Voting Comments:
• The intent is for a practice performance module for maintenance of certification as seen with other specialties. It is not clear that this measure is for public reporting except insofar as board certification status is reported.</td></tr>
<tr><td>3b Harmonization</td><td>Completely: 0
Partially: 0
Minimally: 3
Not at all: 1
NA: 1</td></tr>
<tr><td>3c Added value</td><td>Completely: 0
Partially: 1
Minimally: 2
Not at all: 1
NA: 1</td></tr>
<tr><td colspan="3">FEASIBILITY</td></tr>
</table>

<table>
<tr><td>4a Data a byproduct of care</td><td>Completely: 1
Partially: 2
Minimally: 2
Not at all: 0</td><td rowspan="5">The TAP noted that most anti-epileptic drugs are monitored relatively closely and that endorsing the measure may be burdensome to clinicians. The translation into documentation may be challenging. Another complication noted by the TAP was that, in integrated healthcare systems, physicians may refer patients to clinical pharmacists to handle counseling on medications and to follow up on side effects.

Adding this measure may lead physicians to better document their counseling or just counsel more often— will it result in better outcomes? Generally, better patient education leads to better results, as generally proven by randomized controlled trials. There is no way to measure the quality of counseling. The recommendation of this measure may compel physicians to recite the side effects to the patient rather than counsel the patient about the side effects, which does not add benefit. This measure may cause more distraction than help. Because of a lack of specificity, it is left to the physician to define querying and counseling. There was a question as to whether the measure provides an exclusion for cases in which it cannot be determined whether the patient is on anti-epileptic medication, i.e., if the patient does not know or if he/she cannot answer. The measure developer responded that there is a medical exception for such circumstances.

Voting Comments:
Could likely be automated for those with an electronic medical record (EMR). Would likely be quite labor intensive for those with a paper record and would require manual audits.
Would only capture events when the physician documented the education/inquiry and it was translated into a billing code.
Although this data collection could be done by someone within a practice who performs chart review, there is neither a standard manner to record this conversation nor guidance on how to extract this information. Similarly how data could be text-scanned from an EMR is unclear. Physicians who are not the prescriber of an anticonvulsant but are seeing a patient taking such a medication may be unaware of this requirement and may in some way be penalized if the requirement were applicable to physicians beyond neurologists.</td></tr>
<tr><td>4b Electronic</td><td>Completely: 0
Partially: 3
Minimally: 2
Not at all: 0</td></tr>
<tr><td>4c Exclusions</td><td>Completely: 1
Partially: 2
Minimally: 1
Not at all: 0
NA: 1</td></tr>
<tr><td>4d Inaccuracies</td><td>Completely: 0
Partially: 1
Minimally: 2
Not at all: 0
NA: 2</td></tr>
<tr><td>4e Implementation</td><td>Completely: 0
Partially: 1
Minimally: 1
Not at all: 1
NA: 2</td></tr>
</table>

Measure number: PSM-017-10

Measure name: Patient(s) with rheumatoid arthritis taking methotrexate, sulfasalazine or leflunomide that had serum ALT or AST test in last 3 reported months

Description: This measure identifies individuals with rheumatoid arthritis, 2 years of age or older, taking methotrexate, sulfasalazine, or leflunomide that had a serum ALT/AST test in last 3 months of the report period.

Numerator statement: Patients who are diagnosed with rheumatoid arthritis and who are taking methotrexate, sulfasalazine, or leflunomide who have had a serum AST/ALT test during the following time period: last 90 days of the report period through 90 days after the end of the report period

Denominator statement: Patients 2 years of age or older who are diagnosed with rheumatoid arthritis and who are being actively treated with methotrexate, sulfasalazine, or leflunomide

Level of analysis: individual, group, facility/agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of subcriteria and comments:

<table>
<tr><td colspan="3">IMPORTANCE TO MEASURE AND REPORT</td></tr>
<tr><td>1a Impact</td><td>Completely: 2
Partially: 3
Minimally: 1
Not at all: 0</td><td rowspan="3">The TAP identified the weaknesses of the underlying guidelines cited by the measure, which rely on expert opinion and consensus. It discussed whether there was enough evidence to support endorsing the measure and monitoring the medications in the timeframe specified by the measure. The TAP mentioned that mandating the measurement of ALT and AST testing for these medications every three months may impose a burden on the health system.

The TAP noted that measure PSM-020-10: Patient(s) with inflammatory bowel disease taking methotrexate, azathioprine or mercaptopurine that had serum ALT or AST test in last 6 reported months referred to discussions with the American Gastroentological Association (AGA), whereas this measure did not describe any similar combined work with the American College of Rheumatology (ACR). The measure developer stated that there was a preexisting relationship with the AGA, leading to a greater effort to work together between the organizations; however, the measure developer also noted that these measure specifications are consistent with ACR guidelines. Following the TAP's review, the measure developer submitted additional comments stating that it had contacted the ACR and was encouraged to create a measure consistent with ACR guidelines; it took this recommendation into account when the measure was created.

Voting Comments:
• The 3-month time period (and the previous poor performance related to this short period) may have underrepresented actual performance.
• Time frames may not be practical and may be difficult to comply with.</td></tr>
<tr><td>1b Gap</td><td>Completely: 1
Partially: 5
Minimally: 0
Not at all: 0</td></tr>
<tr><td>1c Relation to outcomes</td><td>Completely: 1
Partially: 4
Minimally: 1
Not at all: 0</td></tr>
</table>

		• Although MTX may cause increases in LFTs necessitating dose adjustment or drug discontinuation, the necessary frequency for monitoring is not established and varies by which expert consensus is used. Other drugs may also cause increases in LFTs including leflunomide and sulfasalazine, although whether the same monitoring frequency is appropriate for all drugs is also not based on data. Two of the references provided concerning biologic agents are irrelevant.
SCIENTIFIC ACCEPTABILTY		
2a Specs	Completely: 2 Partially: 3 Minimally: 1 Not at all: 0	The TAP noted that this measure along with measure PSM-020-10 focuses on monitoring methotrexate and related medications. However, this measure specifies monitoring ALT and AST every 3 months, while measure # PSM-020-10 specifies monitoring ALT and AST testing every 6 months. The TAP was concerned that the time windows are not consistent and should be aligned. Additionally, a TAP member noted that although the measure describes monitoring ALT and AST every 3 months, the numerator time window also allows for reporting the last 90 days of the time period through 90 days after, which can be interpreted as measuring ALT and AST levels every 6 months. The measure developer stated that the 90 days after the report period was added to the measure as a grace period but could be taken out of the time window if requested by the TAP. However, the TAP agreed that the measure should include a grace period, although it was uncertain that a 90-day grace period is necessary. The TAP then explored changing the measure description to specify a 6-month period to make it more explicit. Additionally, the TAP was concerned that the measure incorporates monitoring of three separate medications: methotrexate, sulfasalazine, and leflunomide. The TAP stated that the potential liver abnormalities encountered due to the use of these medications are not clearly specified. The TAP discussed the numerous codes included in the denominator details. The measure developer responded that the codes represent its condition confirmation process. The TAP expressed concern over the value of the reliability testing conducted by the measure developer. The measures were tested as a group, rather than separately, and the testing results provided by the developer are not specific to any of the submitted measures. The developer responded that conducting chart review would not be feasible. **Voting Comments:** • The measure should have some tolerance for logistical variation in patient and provider follow-through. The analysis of the measure is relatively small, and it is difficult to know whether the variances identified correlate to actual quality provided. • It is unclear how the 2-year age was chosen. The period of monitoring is unclear: is it 90 days (2a1-3), 120 days (2a7), or is it 180 days (2a1-2a3) during which it will be determined if
2b Reliability	Completely: 2 Partially: 2 Minimally: 2 Not at all: 0	
2c Validity	Completely: 2 Partially: 0 Minimally: 3 Not at all: 1	
2d Exclusions	Completely: 1 Partially: 1 Minimally: 1 Not at all: 1 NA: 2	
2e Risk-adjustment	Completely: 1 Partially: 0 Minimally: 0 Not at all: 1 NA: 4	
2f Meaningful differences	Completely: 1 Partially: 3 Minimally: 1 Not at all: 1	
2g Comparability	Completely: 1 Partially: 0 Minimally: 0 Not at all: 1 NA: 4	
2h Disparities	Completely: 1 Partially: 1 Minimally: 0 Not at all: 1 NA: 3	

		labs are done and whether the prescription is given? The inclusion of concomitant medications (plaquenil, anakinra, rituximab, abatacept, TNF inhibitors) is irrelevant. This measure has not been subject to any form of reliability testing for repeat testing. A process is described for validity testing, but there are no data. The chart comparison testing was not specific to this measure and is thus not relevant or necessarily extrapolatable to this scenario.
USABILITY		
3a Distinctive	Completely: 1 Partially: 1 Minimally: 2 Not at all: 2	The TAP was concerned that NQF had endorsed several related measures focusing on liver function that were not referenced in the measure submission form.
3b Harmonization	Completely: 2 Partially: 1 Minimally: 1 Not at all: 1 NA: 1	
3c Added value	Completely: 2 Partially: 2 Minimally: 0 Not at all: 1 NA: 1	
FEASIBILITY		
4a Data a byproduct of care	Completely: 3 Partially: 2 Minimally: 1 Not at all: 0	After discussion, the TAP agreed that the measure sufficiently meets the feasibility subcriteria. **Voting Comments:** • "I believe that the measure as defined will clearly be easiest to implement for customers of Ingenix, the sponsor of this measure. It will likely be substantially more difficult for others to implement based upon the criteria that have been developed. It is unclear to me how easily this measure as defined could be used by other similar vendors or health systems. I suspect many would require some type of manual process for patient identification and identification of appropriate lab monitoring. This would be quite labor intensive for some." • 4d refers to a 6-month window, but the measure states that it is for 3 months. This measure for rheumatoid arthritis has not been presented or discussed with any similar ACR committee
4b Electronic	Completely: 3 Partially: 3 Minimally: 0 Not at all: 0	
4c Exclusions	Completely: 2 Partially: 1 Minimally: 1 Not at all: 0 NA: 2	
4d Inaccuracies	Completely: 1 Partially: 2 Minimally: 2 Not at all: 1	
4e Implementation	Completely: 2 Partially: 1 Minimally: 1 Not at all: 1 NA: 1	

Measure number: PSM-018-10

Measure name: Patient(s) with rheumatoid arthritis taking methotrexate or sulfasalazine that had a serum creatinine in last 6 reported months.

Description: This measure identifies individuals with rheumatoid arthritis, 2 years of age or older, taking methotrexate or sulfasalazine that had a serum creatinine test in last 6 months of the report period.

Numerator statement: Patients who are diagnosed with rheumatoid arthritis and who are taking methotrexate or sulfasalazine, who have had a serum creatinine test during the following time period: last 180 days of the report period through 90 days after the end of the report period

Denominator statement: Patients 2 years of age or older who are diagnosed with rheumatoid arthritis and who are being actively treated with methotrexate or sulfasalazine

Level of analysis: individual, group, facility/ agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of subcriteria and comments:

<table>
<tr><td colspan="3">IMPORTANCE TO MEASURE AND REPORT</td></tr>
<tr><td>1a Impact</td><td>Completely: 1
Partially: 2
Minimally: 3
Not at all: 0</td><td rowspan="3">The TAP noted that this measure cites minimal evidence to support conducting serum creatinine testing every 6 months for patients taking methotrexate (MTX) or sulfasalazine (SSZ).

The TAP was concerned that patients taking methotrexate or sulfasalazine were not at high risk for nephrotoxicity and that serum creatinine levels do not need to be routinely monitored. The TAP also stated that liver function tests are generally conducted in a comprehensive metabolic panel, which would include a serum creatinine; specifying a measure focused solely on serum creatinine may be unnecessary. It was also discussed that monitoring serum creatinine levels is most critical when disease-modifying anti-rheumatic drugs (DMARDs) are initially prescribed.

The TAP stated that the evidence and importance of this measure are less important and less clear than other measures–the measure minimally meets the importance subcriteria.

Voting Comments:
• There is less direct evidence that these agents are nephrotoxic. This evidence is not included within the</td></tr>
<tr><td>1b Gap</td><td>Completely: 0
Partially: 3
Minimally: 2
Not at all: 1</td></tr>
<tr><td>1c Relation to outcomes</td><td>Completely: 1
Partially: 0
Minimally: 5
Not at all: 0</td></tr>
</table>

		submission. • The presented data demonstrate the effects of 1% of the population compliance rate already at 73.8%. • Evaluating creatinine periodically is important for methotrexate because it may be necessary to adjust the dose. However, it is not clear that SSZ dose adjustment would be needed or that the drug could cause any changes in creatinine. MTX or SSZ themselves are not nephrotoxic. The literature provided for cytopenias, although potentially relevant to an effect of MTX increased in the setting of worsened renal function, is not the appropriate reference. References indicating that creatinine monitoring leads to reduced toxicity from drugs are lacking, indicating the scope of the problem. The references provided for biological agents are irrelevant. There is already a measure to check creatinine before starting a DMARD, which is appropriate. It is unclear why a monitoring period for ALT/AST of 6 months versus 3 months was chosen.
SCIENTIFIC ACCEPTABILTY		
2a Specs	Completely: 2 Partially: 3 Minimally: 0 Not at all: 1	Additionally, the TAP was concerned that the measure incorporates monitoring two separate medications: methotrexate and sulfasalazine. **Voting Comments:** • Reliability was tested only within the measure developer's proprietary database. Validity was tested with a small sample and was broadly applied to several of the submitted measures rather than specifically to this one and is not specifically quantified ("less than 5%"). • The inclusion of concomitant medications (plaquenil, anakinra, rituximab, abatacept, TNF inhibitors) is irrelevant. This measure has not been subject to any form of reliability testing for repeat testing. A process is described for validity testing, but there are no data. The chart comparison testing was not specific to this measure, and is thus not relevant or necessarily extrapolatable to this scenario.
2b Reliability	Completely: 2 Partially: 2 Minimally: 1 Not at all: 1	
2c Validity	Completely: 1 Partially: 1 Minimally: 3 Not at all: 1	
2d Exclusions	Completely: 0 Partially: 2 Minimally: 1 Not at all: 1 NA: 2	
2e Risk-adjustment	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1 NA: 4	
2f Meaningful differences	Completely: 0 Partially: 3 Minimally: 1 Not at all: 1 NA: 1	
2g Comparability	Completely: 0 Partially: 1 Minimally: 0 Not at all: 2 NA: 3	
2h Disparities	Completely: 0 Partially: 1 Minimally: 0 Not at all: 2	

	NA: 3	
USABILITY		
3a Distinctive	Completely: 1 Partially: 3 Minimally: 1 Not at all: 1	After discussion, the TAP agreed that the measure sufficiently meets the usability subcriteria. **Voting Comments:** • It is not clear that this measure would improve healthcare. It is complementary to other measures submitted by Ingenix regarding methotrexate, but it is of lower value. • There is no comment on existing measures (0589: DMARD start Cr check and 0599: MTX Cr check within 12 weeks).
3b Harmonization	Completely: 0 Partially: 3 Minimally: 1 Not at all: 1 NA: 1	
3c Added value	Completely: 1 Partially: 2 Minimally: 1 Not at all: 1 NA: 1	
FEASIBILITY		
4a Data a byproduct of care	Completely: 3 Partially: 2 Minimally: 1 Not at all: 0	The TAP noted that the measure could be burdensome to providers. Potential unintended consequences cited by the TAP included over-ordering of serum creatinine testing and increased costs. **Voting Comments:** • Such a data-collection strategy would be relatively easy for the measure developer and similar companies, whose customers already have live electronic medical record systems that are capable of such data exchange. However, for health systems without these systems in place, laborious manual data collection would be required. • A barrier to success would be connecting the dots between physician and hospital admissions.
4b Electronic	Completely: 3 Partially: 1 Minimally: 1 Not at all: 0 NA: 1	
4c Exclusions	Completely: 3 Partially: 1 Minimally: 1 Not at all: 0 NA: 1	
4d Inaccuracies	Completely: 1 Partially: 3 Minimally: 1 Not at all: 1	
4e Implementation	Completely: 3 Partially: 0 Minimally: 2 Not at all: 1	

Measure number: PSM-019-10

Measure name: Patient(s) with rheumatoid arthritis taking methotrexate, sulfasalazine, gold, or leflunomide that had a CBC in last 3 reported months

Description: This measure identifies individuals with rheumatoid arthritis, 2 years of age or older, taking methotrexate, sulfasalazine, gold, or leflunomide that had a CBC test in last 3 months of the report period.

Numerator statement: Patients who are diagnosed with rheumatoid arthritis and who are taking methotrexate, sulfasalazine, gold, or leflunomide, who have had a CBC test during the following time period: last 90 days of the report period through 90 days after the end of the report period

Denominator statement: Patients 2 years of age or older who are diagnosed with rheumatoid arthritis and who are being actively treated with methotrexate, sulfasalazine, gold, or leflunomide

Level of analysis: individual, group, facility/ agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of subcriteria and comments:

<table>
<tr><th colspan="3">IMPORTANCE TO MEASURE AND REPORT</th></tr>
<tr><td>1a Impact</td><td>Completely: 2
Partially: 4
Minimally: 0
Not at all: 0</td><td rowspan="3">The TAP stated that prior discussions on similar measures had already highlighted general concerns with this measure. The TAP reiterated its previous statements regarding the appropriate frequency for conducting CBCs and the combination of medications included in the measure. It also noted that the medications already had an acceptable compliance rate for CBCs ordered in the past 3 months— are there really meaningful gaps in performance between providers?

Voting Comments:
1% of the population compliance rate is at 66.6%
It is unclear why the age minimum is 2 years (same drugs for IBD start at 12 years). Many DMARDs may cause cytopenias, some more significantly than others, yet this measure has lumped 4 different drugs into the same measure. Although it is true that dose adjustment or drug discontinuation may be needed based on cytopenias, the timing for monitoring is not established. Two of the references provided concerning biologic agents are irrelevant. There are also notes made to drug toxicity in ulcerative colitis, but these references are not included.</td></tr>
<tr><td>1b Gap</td><td>Completely: 1
Partially: 2
Minimally: 2
Not at all: 0</td></tr>
<tr><td>1c Relation to outcomes</td><td>Completely: 1
Partially: 3
Minimally: 1
Not at all: 0</td></tr>
</table>

SCIENTIFIC ACCEPTABILTY		
2a Specs	Completely: 2 Partially: 2 Minimally: 0 Not at all: 1	The TAP revisited its discussion surrounding the grace period included in the denominator time window, which was similar to that for measure PSM-017-10: Patient(s) with rheumatoid arthritis taking methotrexate, sulfasalazine, or leflunomide that had serum ALT or AST test in last 3 reported months. The TAP asked the measure developer to expand the list of medications that should be monitored. Following the TAP's review, the measure developer submitted additional comments. It stated that CBC monitoring is recommended for azathioprine, D-penicillamine, cyclosporine, and cyclophosphamide. However, given the rare use of these DMARD medications, they have been excluded from the measure. CBC monitoring is not recommended for the other DMARD medications. **Voting Comments:** • The inclusion of concomitant medications (plaquenil, anakinra, rituximab, abatacept, TNF inhibitors) is irrelevant. This measure has not been subject to any form of reliability testing for repeat testing. A process is described for validity testing, but there are no data. The chart comparison testing was not specific to this measure and is thus not relevant or necessarily extrapolatable to this scenario.
2b Reliability	Completely: 2 Partially: 1 Minimally: 1 Not at all: 1	
2c Validity	Completely: 1 Partially: 2 Minimally: 1 Not at all: 1	
2d Exclusions	Completely: 0 Partially: 2 Minimally: 0 Not at all: 1 NA: 2	
2e Risk-adjustment	Completely: 0 Partially: 1 Minimally: 0 Not at all: NA: 3	
2f Meaningful differences	Completely: 0 Partially: 2 Minimally: 2 Not at all: 1	
2g Comparability	Completely: 1 Partially: 0 Minimally: 0 Not at all: 1 NA: 3	
2h Disparities	Completely: 0 Partially: 2 Minimally: 0 Not at all: 1 NA: 2	
USABILITY		
3a Distinctive	Completely: 0 Partially: 1 Minimally: 4 Not at all: 0	After discussion, the TAP agreed that the measure meets the usability subcriteria. **Voting Comments:** • Responses to the question of usability are vague and nonspecific. However, this measure has greater face validity than other measures proposed. Some questions arose regarding the nature of the time window to allow for logistical issues associated with patient care. • No comment on related measures for CBC in DMARDS (0591, 0598).
3b Harmonization	Completely: 0 Partially: 3 Minimally: 0 Not at all: 1 NA: 1	
3c Added value	Completely: 0 Partially: 3 Minimally: 0 Not at all: 1	
FEASIBILITY		
4a Data a byproduct of care	Completely: 1 Partially: 3 Minimally: 1	After discussion, the TAP agreed that the measure meets the feasibility subcriteria.

	Not at all: 0	**Voting Comments:** • Per the other Ingenix measures, this measure can be implemented by this commercial vendor with customers that already have this information available electronically. With others, a manual process will be required. • A barrier would be that if a patient were hospitalized, then that data would be missed. • It remains unclear whether the reporting period is 6 months or 3 months.
4b Electronic	Completely: 2 Partially: 2 Minimally: 1 Not at all: 0	
4c Exclusions	Completely: 0 Partially: 3 Minimally: 0 Not at all: 1 NA: 1	
4d Inaccuracies	Completely: 0 Partially: 2 Minimally: 2 Not at all: 1	
4e Implementation	Completely: Partially: 2 Minimally: 1 Not at all: 1	

Measure number: PSM-020-10

Measure name: Patient(s) with inflammatory bowel disease taking methotrexate, azathioprine, or mercaptopurine that had serum ALT or AST test in last 6 reported months

Description: This measure identifies individuals with inflammatory bowel disease, 12 years of age or older, taking methotrexate, azathioprine, or mercaptopurine that had a serum ALT/AST test in last 6 months of the report period.

Numerator statement: Patients who are diagnosed with inflammatory bowel disease and are taking methotrexate, azathioprine, or mercaptopurine, who have had serum ALT or AST testing during the following time period: last 180 days of the report period through 90 days after the end of the report period

Denominator statement: Patients 12 years of age or older who are diagnosed with inflammatory bowel disease and who are being actively treated with methotrexate, azathioprine, or mercaptopurine

Level of analysis: individual, group, facility/ agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of subcriteria and comments:

<table>
<tr><td colspan="3">IMPORTANCE TO MEASURE AND REPORT</td></tr>
<tr><td>1a Impact</td><td>Completely: 0
Partially: 5
Minimally: 0
Not at all: 0</td><td rowspan="3">The TAP stated that the measure was a high-impact measure. It noted that hepatotoxicity has been demonstrated in these drugs. Additionally, the performance rate indicates a gap in care.

The TAP discussed why the compliance rate was 38% for a serum ALT or AST test. It speculated that it may be because a low dose of medication is prescribed, clinician level of comfort with the medication, how often gastroenterologists see patients, or greater monitoring of more patients with more severe inflammatory bowel disease.

Voting Comments:
• The compliance rate is 38.2%.
• Why is the compliance rate for LFTs within 6 months so low (38%)? A current rate for LFT monitoring with the same drugs in RA every 3 months is much higher (66.1%). The different periods of monitoring for liver toxicity that are apparently endorsed by gastroenterologists are more liberal than by rheumatologists. Is there evidence that monitoring every 3 months versus every 6 months improves outcomes? There is also information in 4e that the change to 6 months was made</td></tr>
<tr><td>1b Gap</td><td>Completely: 1
Partially: 4
Minimally: 0
Not at all: 0</td></tr>
<tr><td>1c Relation to outcomes</td><td>Completely: 1
Partially: 2
Minimally: 2
Not at all: 0</td></tr>
</table>

		after an initial review of data that shows that 3 months was potentially even worse in terms of compliance. There is an error of fact: 6MP is the metabolite of azathioprine rather than vice versa as noted in the measure. Is it appropriate to combine MTX and AZA/6MP into a single measure? Is there any indication that lever toxicity is greater with one versus the other?
SCIENTIFIC ACCEPTABILTY		
2a Specs	Completely: 2 Partially: 2 Minimally: 0 Not at all: 1	After discussion, the TAP agreed that the measure meets the scientific acceptability subcriteria. **Voting Comments:** • There are concerns similar to those for other measures submitted by Ingenix. • There is an apparent lack of consensus between rheumatologists and gastroenterologists on the appropriate frequency of monitoring for LFTs for the same drugs. It would seem that the latter would be more conservative to avoid hepatotoxicity. If there is so much disagreement between the two specialties prescribing these drugs, then which guideline is "correct"? Since none of this is based on data but on expert opinion, which experts know best? The testing has not been performed. The appropriate monitoring frequency is not established.
2b Reliability	Completely: 2 Partially: 1 Minimally: 1 Not at all: 1	
2c Validity	Completely: 1 Partially: 2 Minimally: 1 Not at all: 1	
2d Exclusions	Completely: 0 Partially: 2 Minimally: 0 Not at all: 1 NA: 2	
2e Risk-adjustment	Completely: 0 Partially: 0 Minimally: 0 Not at all: 1 NA: 4	
2f Meaningful differences	Completely: 0 Partially: 2 Minimally: 1 Not at all: 2	
2g Comparability	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1 NA: 3	
2h Disparities	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1 NA: 3	
USABILITY		
3a Distinctive	Completely: 0 Partially: 3 Minimally: 2 Not at all: 0	After discussion, the TAP agreed that the measure meets the usability subcriteria. • There are measures for LFT checking when starting MTX and after initiating for RA (0590, 0597), which would arguably be most important before starting a drug. It might be better to have a similar measure for IBD patients starting a drug to ensure that there is an initial thought as to safety issues?
3b Harmonization	Completely: 0 Partially: 3 Minimally: 0 Not at all: 1 NA: 1	
3c Added	Completely: 0	

value	Partially: 3 Minimally: 0 Not at all: 1	
FEASIBILITY		
4a Data a byproduct of care	Completely: 2 Partially: 2 Minimally: 1 Not at all: 0	After discussion, the TAP agreed that the measure meets the feasibility subcriteria. **Voting Comments:** • This measure is similar to other Ingenix measures. This measure may be easily implemented by Ingenix customers, but many others may not have the ability to easily collect these data. • The measure developer has already indicated that monitoring frequency must be adjusted downward because compliance was poor with prior versions of the recommendation. It is difficult to understand why, if the measure has been available since 2006 and used by other organizations, there are not better reliability data related to this particular measure.
4b Electronic	Completely: 2 Partially: 1 Minimally: 2 Not at all: 0	
4c Exclusions	Completely: 1 Partially: 2 Minimally: 0 Not at all: 1 NA: 1	
4d Inaccuracies	Completely: 0 Partially: 3 Minimally: 1 Not at all: 1	
4e Implementation	Completely: 3 Partially: 1 Minimally: 0 Not at all: 1	

Measure number: PSM-021-10

Measure name: Adult patient(s) with multiple sclerosis taking interferon that had a serum ALT/AST test in last 12 reported months

Description: This measure identifies adults with multiple sclerosis taking interferon that had at least one serum ALT/AST test in last 12 months of the report period

Numerator statement: Patients who are diagnosed with multiple sclerosis and are taking interferon, who have had a test for serum ALT or AST during the following time period: last 12 months of the report period through 90 days after the end of the report period

Denominator statement: Patients 18 years of age or older who are diagnosed with multiple sclerosis and who are being actively treated with interferon

Level of analysis: individual, group, facility/ agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of sub criteria and comments:

<table>
<tr><td colspan="3">IMPORTANCE TO MEASURE AND REPORT</td></tr>
<tr><td>1a Impact</td><td>Completely:2
Partially: 1
Minimally: 3
Not at all: 0</td><td rowspan="3">The TAP stated that prior discussions on similar measures had already highlighted general concerns with this measure.

Voting Comments:
• As discussed by the TAP, the measure is based on consensus recommendations, but it may not have validity.
• The compliance rate is 63.4%.
• If current recommendations call for monitoring every 3-6 months, then why is the measure looking at yearly monitoring? The rate of LFT increase is at least as great (if not greater, Grade 3 in 1-2%) as for MTX, in which the monitoring time is 3 months for RA and 6 months for IBD. The measure was evaluated by AAFP, arguably not the most appropriate group to evaluate safety issues related to a drug used by neurologists for MS.</td></tr>
<tr><td>1b Gap</td><td>Completely: 0
Partially: 2
Minimally: 3
Not at all: 0</td></tr>
<tr><td>1c Relation to outcomes</td><td>Completely: 0
Partially: 3
Minimally: 2
Not at all: 0</td></tr>
<tr><td colspan="3">SCIENTIFIC ACCEPTABILTY</td></tr>
<tr><td>2a Specs</td><td>Completely: 1
Partially: 3
Minimally: 0
Not at all: 1</td><td>The TAP recommended shortening the interferon monitoring window from “last 12 months of report period through 90 days after the end of the report period” to “last 6 months of report period through 90 days after the end of the report period, with the</td></tr>
</table>

2b Reliability	Completely: 1 Partially: 2 Minimally: 1 Not at all: 1	consideration of annual monitoring". The TAP stated that interferon-induced flares typically occur at the onset of treatment; the majority would be captured within the shortened 6-9 month monitoring period. Following the TAP's review, the measure developer submitted additional comments. It stated that the measure was designed to apply to all MS patients receiving interferon treatment. It is willing to change the timeframe to 6 months if recommended by the Steering Committee and proposed the following language "to last **6 months** of report period through 90 days after the end of the report period". **Voting Comments:** • Language in this section of the measure submission is very similar to the language used in other Ingenix measure submissions. • Why is mitoxantrone included in drugs?
2c Validity	Completely: 1 Partially: 1 Minimally: 2 Not at all: 1	
2d Exclusions	Completely: 0 Partially: 2 Minimally: 0 Not at all: 1 NA: 2	
2e Risk-adjustment	Completely: 0 Partially: 0 Minimally: 0 Not at all: 1 NA: 4	
2f Meaningful Differences	Completely: 0 Partially: 3 Minimally: 1 Not at all: 1	
2g Comparability	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1 NA: 3	
2h Disparities	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1 NA: 3	
USABILITY		
3a Distinctive	Completely: 1 Partially: 1 Minimally: 3 Not at all: 0	After discussion, the TAP agreed that the measure meets the usability subcriteria. **Voting Comments:** • Again, boilerplate language is used. There are no details about how this measure is being used for genuine quality improvement. • There are no other measures in place for interferon.
3b Harmonization	Minimally: 1 Not at all: 0 NA: 2	
3c Added value	Minimally: 2 Not at all: 0 NA: 2	
FEASIBILITY		
4a Data a byproduct of care	Completely: 2 Partially: 2 Minimally: 1 Not at all: 0	After discussion, the TAP agreed that the measure meets the feasibility subcriteria. **Voting Comments:** • Similar to other Ingenix measures. Ingenix customers may easily gather this information; others will likely need to create new labor intensive, costly systems for implementation.
4b Electronic	Completely: 2 Partially: 1 Minimally: 2 Not at all: 0	

4c Exclusions	Completely: 0 Minimally: 1 Not at all: 1 NA: 1	• A barrier will be that when someone in the target population is hospitalized it may be difficult to connect the dots.
4d Inaccuracies	Completely: 0 Partially: 3 Minimally: 2 Not at all: 0	
4e Implementation	Completely: 2 Minimally: 1 Not at all: 2	

Measure number: PSM-022-10

Measure name: Adult patient(s) with multiple sclerosis taking interferon that had a CBC in last 12 reported months

Description: This measure identifies adults with multiple sclerosis taking interferon that had at least one CBC test in last 12 months of the report period.

Numerator statement: Patients who are diagnosed with multiple sclerosis and are taking interferon, who have had CBC testing during the following time period: last 12 months of the report period through 90 days after the end of the report period

Denominator statement: Patients 18 years of age or older who are diagnosed with multiple sclerosis and who are being actively treated with interferon

Level of analysis: individual, group, facility/ agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of Endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of sub criteria and comments:

IMPORTANCE TO MEASURE AND REPORT		
1a Impact	Completely: 0 Partially: 2 Minimally: 2 Not at all: 0 NA: 0	The TAP stated that prior discussions on similar measures had already highlighted general concerns with this measure. **Voting Comments:** In testing, this measure had a compliance rate of 59.2%.
1b Gap	Completely: 0 Partially: 3 Minimally: 1 Not at all: 0 NA: 0	
1c Relation to outcomes	Completely: 0 Partially: 3 Minimally: 1 Not at all: 0 NA: 0	
SCIENTIFIC ACCEPTABILTY		
2a Specs	Completely: 2 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	The TAP recommended shortening the interferon monitoring window from "last 12 months of report period through 90 days after the end of the report period" to "last **6 months** of the report period through 90 days after the end of the report period, with consideration of annual monitoring". The TAP considered the 12-

2b Reliability	Completely: 2 Partially: 1 Minimally: 1 Not at all: 0 NA: 0	month monitoring period as too infrequent and stated that it was not supported by the data. Following the TAP's review, the measure developer submitted additional comments. The measure developer stated that it was willing to change the timeframe to 6 months, and the evidence supports this change. It proposed changing the wording to "last **6 months** of report period through 90 days after the end of the report period." **Voting Comments:** This measure presents similar strengths and weaknesses as the other Ingenix measures.
2c Validity	Completely: 2 Partially: 1 Minimally: 1 Not at all: 0 NA: 0	
2d Exclusions	Completely: 0 Partially: 2 Minimally: 0 Not at all: 0 NA: 2	
2e Risk-adjustment	Completely: 0 Partially: 0 Minimally: 0 Not at all: 0 NA: 4	
2f Meaningful differences	Completely: 0 Partially: 3 Minimally: 1 Not at all: 0 NA: 0	
2g Comparability	Completely: 0 Partially: 1 Minimally: 0 Not at all: 0 NA: 3	
2h Disparities	Completely: 0 Partially: 1 Minimally: 0 Not at all: 0 NA: 3	
USABILITY		
3a Distinctive	Completely: 0 Partially: 3 Minimally: 1 Not at all: 0 NA: 0	After discussion, the TAP agreed that the measure meets the usability subcriteria.
3b Harmonization	Completely: 0 Partially: 3 Minimally: 0 Not at all: 0 NA: 1	
3c Added value	Completely: 0 Partially: 1 Minimally: 2 Not at all: 0 NA: 1	
FEASIBILITY		
4a Data a byproduct of care	Completely: 1 Partially: 3 Minimally: 0	After discussion, the TAP agreed that the measure meets the feasibility subcriteria.

	Not at all: 0 NA: 0	**Voting Comments:** There are concerns similar to those for other measures submitted by Ingenix. • Ingenix customers may easily gather this information; others will likely need to create new labor intensive, costly systems for implementation. • A barrier will be that when someone in the target population is hospitalized it may be difficult to connect the dots.
4b Electronic	Completely: 2 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	
4c Exclusions	Completely: 0 Partially: 3 Minimally: 0 Not at all: 0 NA: 0	
4d Inaccuracies	Completely: 0 Partially: 3 Minimally: 1 Not at all: 0 NA: 0	
4e Implementation	Completely: 1 Partially: 1 Minimally: 1 Not at all: 1 NA: 0	

Measure number: PSM-023-10

Measure name: Patient(s) with hepatitis C infection taking interferon that had periodic serum ALT monitoring

Description: 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.

Numerator statement: 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

Denominator statement: Patients three years of age or older who are diagnosed with HCV infection and who are being actively treated with an interferon-containing medication

Level of analysis: individual, group, facility/ agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of sub criteria and comments:

<table>
<tr><th colspan="3">IMPORTANCE TO MEASURE AND REPORT</th></tr>
<tr><td>1a Impact</td><td>Completely: 0
Partially: 4
Minimally: 1
Not at all: 0
NA: 0</td><td rowspan="3">The TAP agreed that this measure is relevant for the treatment of patients with hepatitis C. Going 6 months without serum monitoring while on one of these medications would constitute substandard care. The TAP stated that although serum monitoring is not a key safety concern, it may be beneficial, especially if this measure were included as part of a hepatitis C measure set.

One TAP member noted that perhaps the measure should include the medication ribavirin as well as interferon, since this is the standard of care.

Voting Comments:
As discussed in the TAP, hepatic reaction to IFN is rare and idiosyncratic. Screening for this in this way, and in particular using the specifics of the definition of this measure, is unlikely to lead to significant health improvements.

1a. The prevalence of adverse outcomes as a result of not monitoring ALT is not provided to assess the impact although doing so is endorsed by specialty societies as an important goal.
1b. It is quite surprising that LFTs are not monitored more frequently given that the disease under treatment also has</td></tr>
<tr><td>1b Gap</td><td>Completely: 0
Partially: 4
Minimally: 1
Not at all: 0
NA: 0</td></tr>
<tr><td>1c Relation to outcomes</td><td>Completely: 0
Partially: 3
Minimally: 2
Not at all: 0
NA: 0</td></tr>
</table>

		increases in LFTs.
SCIENTIFIC ACCEPTABILTY		
2a Specs	Completely: 1 Partially: 3 Minimally: 1 Not at all: 0 NA: 0	The TAP agreed that this measure has scientific validity. The TAP reviewed the age range proposed in the measure specifications. The measure focuses on people ages 3 years and older and does not have an upper age range. The TAP questioned the need for a minimum age and whether the measure should be applied to people over age 65, because testing was generally focused on people under age 65. The measure developer responded that the measure focuses on people older than age 3 because of the lack of recommendations for treating patients with hepatitis younger than age 3. The TAP concluded that the measure does not need an upper age limit, because people over age 65 would still require serum tests. The TAP discussed how it would be determined whether patients included in the denominator are actively receiving the medication. It stated that the measure is a little vague. Although the measure considers patients who filled the prescription during the past 120 days of the report, if the patient finished his/her treatment within that timeframe then he/she would not have a serum test. A TAP member noted a concern with tracking patients' treatment when they migrate from one care setting to another. Some questioned whether tests during an inpatient admission would be properly captured. To combat this circumstance, the measure developer suggested an exclusion for inpatient admissions. A TAP member also noted that these admissions would be rare and would not affect a substantial number of patients captured by the measure. The TAP discussed the medication compliance rates provided in the measure submission form, which are generic medication compliance rates and not specific to certain medications. It was noted that the accuracy of the medication compliance rate would vary depending on the type of medication. The measure developer stated that the information provided is generic, and it does not have the capacity to collect individualized information by medication. The TAP requested clarification of the meaning of "actively treated with an interferon-containing medication". Following the TAP's review, the measure developer submitted additional comments and described the above statement as referring to a patient who is on interferon treatment. The measure submission form was subsequently changed to further clarify the TAP's question. **Voting Comments:** The measure is somewhat more complex than some of the others and as defined may not be an actual representation of what it is trying to measure.
2b Reliability	Completely: 1 Partially: 2 Minimally: 1 Not at all: 1 NA: 0	
2c Validity	Completely: 1 Partially: 2 Minimally: 1 Not at all: 1 NA: 0	
2d Exclusions	Completely: 1 Partially: 1 Minimally: 0 Not at all: 1 NA: 1	
2e Risk-adjustment	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1 NA: 3	
2f Meaningful differences	Completely: 1 Partially: 2 Minimally: 1 Not at all: 1 NA: 0	
2g Comparability	Completely: 0 Partially: 2 Minimally: 0 Not at all: 1 NA: 2	
2h Disparities	Completely: 1 Partially: 2 Minimally: 0 Not at all: 1 NA: 1	

		Although a prescription may be filled, there is no way to know if the patient remains on the medication or has d/d from other anti-epileptics. The measure developer's own validation of their database indicated an 11% error rate for medications prescribed, which seems to be unacceptable, and a 4% error rate for labs with an addition of 2% for visits. This adds to a 17% error rate, so it is unclear how the measure developer comes up with a 5% error rate overall.
USABILITY		
3a Distinctive	Completely: 1 Partially: 1 Minimally: 2 Not at all: 1 NA: 0	After discussion, the TAP agreed that the measure meets the usability subcriteria.
3b Harmonization	Completely: 1 Partially: 1 Minimally: 2 Not at all: 0 NA: 1	
3c Added value	Completely: 2 Partially: 1 Minimally: 3 Not at all: 0 NA: 0	
FEASIBILITY		
4a Data a byproduct of care	Completely: 2 Partially: 3 Minimally: 0 Not at all: 0 NA: 0	After discussion, the TAP agreed that the measure meets the feasibility subcriteria. **Voting Comments:** The measure is in use now within this system; however, it is unclear how easily this could be implemented by others. This measure requires a significant work requirement for those who are not currently using EMR.
4b Electronic	Completely: 3 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	
4c Exclusions	Completely: 0 Partially: 3 Minimally: 0 Not at all: 1 NA: 1	
4d Inaccuracies	Completely: 2 Partially: 3 Minimally: 0 Not at all: 0 NA: 0	
4e Implementation	Completely: 4 Partially: 0 Minimally: 1 Not at all: 0 NA: 0	

Measure number: PSM-024-10

Measure name: Patient(s) with hepatitis C infection taking interferon that had periodic CBC with differential monitoring

Description: This measure identifies hepatitis C virus (HCV) infected persons, 3 years of age or older, taking interferon that had at least two CBC with differential tests in last 6 months of the report period.

Numerator statement: Patients who are diagnosed with HCV infection and are taking interferon-containing medication, who have had periodic CBC testing during the following time period: last 180 days of the report period through 90 days after the end of the report period

Denominator statement: Patients three years of age or older who are diagnosed with HCV infection and who are being actively treated with an interferon-containing medication

Level of analysis: individual, group, facility/ agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of sub criteria and comments:

IMPORTANCE TO MEASURE AND REPORT		
1a Impact	Completely: 1 Partially: 4 Minimally: 0 Not at all: 0 NA: 0	It was determined that the discussion on this measure had been largely explored during the discussion of measure PSM-023-10: Patient(s) with hepatitis C infection taking interferon that had periodic serum ALT monitoring. It was noted that the measures were similarly specified. There was consensus that this measure is part of the standard of care for patients with hepatitis and that it would improve patient safety. However, it would be most relevant when tracking whether patients received a CBC when they started treatment.
1b Gap	Completely: 1 Partially: 3 Minimally: 1 Not at all: 0 NA: 0	

1c Relation to outcomes	Completely: 1 Partially: 1 Minimally: 3 Not at all: 0 NA: 0	The TAP noted that the guidelines encourage more intensive monitoring than the measure specifies. A TAP member questioned whether the measure is adequate, because it can be achieved and the patient would still be subjected to substantial risk. **Voting Comments:** • The compliance rate was 68%; however, the timeframes for the labs may not be practical in real life. • It is unclear how often significant changes in CBC occur with IFN prescriptions. This information is needed to put the importance in context. The performance gap is based on the measure developer's own internal data.

SCIENTIFIC ACCEPTABILTY		
2a Specs	Completely: 2 Partially: 3 Minimally: 0 Not at all: 0 NA: 0	A TAP member noted that the clinical guidelines do not specify whether the CBC would require the differential to be included. However, it was determined that this was not necessary because the coding for CBC was broader. The TAP suggested that the measure developer provide data about the relationship between laboratory monitoring and improved patient outcomes. Following the TAP's review, the measure developer submitted additional comments indicating that it is unaware of any published data that demonstrate a direct relationship between laboratory monitoring and improved patient outcomes. Routine monitoring is a recommended standard of care, supported by clinical guidelines and expert opinion. The measure excludes people who were not part of a benefit plan for the past 12 months, and a TAP member stated that these patients would also benefit from the measure. The TAP suggested broadening the sample population beyond the 65-year limit. Following the TAP's review, the measure developer submitted additional comments indicating that the comment was aimed at the general age range of the Ingenix database, which is a commercial population in which patients over age 65 are not well represented. **Voting Comments:** • This measure focuses on patients who have a prescription, but it cannot assess whether the patients are taking the medication (e.g., if depression occurs, then the patient stops taking the medication, and monitoring is no longer needed). Even with all the caveats, their own data find that the compliance rate is 68%. Their error rates from their database are 11% for medications used, 4% for labs, and 2% for office visits. This does not seem to be a very good approximation of reality for their results or their system.
2b Reliability	Completely: 1 Partially: 2 Minimally: 1 Not at all: 1 NA: 0	
2c Validity	Completely: 2 Partially: 1 Minimally: 1 Not at all: 1 NA: 0	
2d Exclusions	Completely: 1 Partially: 3 Minimally: 0 Not at all: 1 NA: 0	
2e Risk-adjustment	Completely: 0 Partially: 0 Minimally: 0 Not at all: 1 NA: 4	
2f Meaningful differences	Completely: 0 Partially: 1 Minimally: 2 Not at all: 2 NA: 0	
2g Comparability	Completely: 1 Partially: 0 Minimally: 0 Not at all: 2 NA: 2	
2h Disparities	Completely: 0 Partially: 2 Minimally: 0 Not at all: 2 NA: 1	
USABILITY		
3a Distinctive	Completely: 1 Partially: 3 Minimally: 1 Not at all: 0 NA: 0	After discussion, the TAP agreed that the measure meets the usability subcriteria.
3b Harmonization	Completely: 1 Partially: 1 Minimally: 1 Not at all: 2 NA: 0	

3c Added value	Completely: 1 Partially: 1 Minimally: 1 Not at all: 2 NA: 0	
FEASIBILITY		
4a Data a byproduct of care	Completely: 2 Partially: 3 Minimally: 0 Not at all: 0 NA: 0	After discussion, the TAP agreed that the measure meets the feasibility subcriteria. **Voting Comments:** • Those hospitalized would present challenge to data collection. • Their own internal review shows that there are significant errors in reporting.
4b Electronic	Completely: 2 Partially: 2 Minimally: 1 Not at all: 0 NA: 0	
4c Exclusions	Completely: 1 Partially: 1 Minimally: 0 Not at all: 0 NA:3	
4d Inaccuracies	Completely: 1 Partially: 2 Minimally: 1 Not at all: 0 NA: 0	
4e Implementation	Completely: 2 Partially: 1 Minimally: 0 Not at all: 1 NA: 0	

Measure number: PSM-030-10

Measure name: Patient(s) with inflammatory bowel disease taking methotrexate, sulfasalazine, mercaptopurine, or azathioprine that had a CBC in last 3 reported months

Description: This measure identifies individuals with inflammatory bowel disease, 12 years of age or older, taking methotrexate, sulfasalazine, mercaptopurine, or azathioprine that had a CBC test in last 3 months of the report period.

Numerator statement: Patients who are diagnosed with inflammatory bowel disease and are taking methotrexate, sulfasalazine, mercaptopurine, or azathioprine, who have had a CBC test during the following time period: last 90 days of the report period through 90 days after the end of the report period

Denominator statement: Patients 12 years of age or older who are diagnosed with inflammatory bowel disease and who are being actively treated with methotrexate, sulfasalazine, mercaptopurine, or azathioprine

Level of analysis: individual, group, facility/ agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of sub criteria and comments:

IMPORTANCE TO MEASURE AND REPORT		
1a Impact	Completely: 1 Partially: 3 Minimally: 0 Not at all: 0 NA: 0	The TAP stated that prior discussions on similar measures had already highlighted general concerns with this measure. The TAP stated that monitoring blood counts is appropriate for these medications because they can have a suppressive effect on bone marrow. However, the consequences of monitoring these medications may not change outcomes. The TAP cited recommendations from the ACR that support the measure. The TAP stated that endorsing the measures would improve the compliance rate. The TAP suggested that the measure developer provide data about the relationship between adjusting dosage and improved patient outcomes. The measure developer stated that it is unaware of any published data that demonstrate a direct relationship between dose adjustment of specific medications and
1b Gap	Completely: 1 Partially: 3 Minimally: 0 Not at all: 0 NA: 0	
1c Relation to outcomes	Completely: 1 Partially: 2 Minimally: 1 Not at all: 0 NA: 0	

		improved patient outcomes in IBD management. The laboratory monitoring is designed to reduce adverse events from bone marrow toxicity associated with these medications. Appropriate dose adjustment, based on CBC results, improves safety and has the potential to improve overall compliance by decreasing side effects and improving overall medication adherence. **Voting Comments:** • During testing compliance for this measure was at 41.7%. • Should this measure include TNF inhibitors, 5-ASA drugs, and cyclosporine? The guideline is for patients being treated with the drugs under question and not concomitant medications.
SCIENTIFIC ACCEPTABILTY		
2a Specs	Completely: 2 Partially: 1 Minimally: 1 Not at all: 0 NA: 0	After discussion, the TAP agreed that the measure meets the scientific acceptability subcriteria. **Voting Comments:** Details of testing are not provided. The validation of 100 charts is not relevant to this measure.
2b Reliability	Completely: 2 Partially: 1 Minimally: 0 Not at all: 1 NA: 0	
2c Validity	Completely: 1 Partially: 2 Minimally: 0 Not at all: 1 NA: 0	
2d Exclusions	Completely: 0 Partially: 2 Minimally: 0 Not at all: 1 NA: 1	
2e Risk-adjustment	Completely: 0 Partially: 0 Minimally: 0 Not at all: 1 NA: 3	
2f Meaningful differences	Completely: 0 Partially: 3 Minimally: 0 Not at all: 1 NA: 0	
2g Comparability	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1 NA: 2	
2h Disparities	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1	

	NA: 2	
USABILITY		
3a Distinctive	Completely: 0 Partially: 3 Minimally: 1 Not at all: 0 NA: 0	After discussion, the TAP agreed that the measure meets the usability subcriteria. **Voting Comments:** There is no comment about similar measures (0591, 0598), which are for baseline monitoring for DMARDS and 3-month monitoring of CBC with MTX (albeit in patients with RA).
3b Harmonization	Completely: 0 Partially: 2 Minimally: 0 Not at all: 2 NA: 0	
3c Added value	Completely: 0 Partially: 2 Minimally: 0 Not at all: 2 NA: 0	
FEASIBILITY		
4a Data a byproduct of care	Completely: 2 Partially: 1 Minimally: 1 Not at all: 0 NA: 0	After discussion, the TAP agreed that the measure meets the feasibility subcriteria. **Voting Comments:** • Those hospitalized would create a barrier to data collection because it relates to following up without being able to connect the dots. • This measure has already been used, but no details are provided. This measure is apparently supported by an AGA subcommittee.
4b Electronic	Completely: 3 Partially: 0 Minimally: 1 Not at all: 0 NA: 0	
4c Exclusions	Completely: 1 Partially: 1 Minimally: 0 Not at all: 1 NA: 1	
4d Inaccuracies	Completely: 0 Partially: 3 Minimally: 0 Not at all: 1 NA: 0	
4e Implementation	Completely: 2 Partially: 0 Minimally: 0 Not at all: 2 NA: 0	

Measure number: PSM-031-10

Measure name: Patient(s) with inflammatory bowel disease taking methotrexate that had a serum creatinine in last 6 reported months

Description: This measure identifies individuals with inflammatory bowel disease, 12 years of age or older, taking methotrexate that had a serum creatinine test in last 6 months of the report period.

Numerator statement: Patients who are diagnosed with inflammatory bowel disease and are taking methotrexate who have had serum creatinine testing during the following time period: last 180 days of the report period through 90 days after the end of the report period

Denominator statement: Patients 12 years of age or older who are diagnosed with inflammatory bowel disease and who are being actively treated with methotrexate

Level of analysis: individual, group, facility/ agency, health plan, integrated delivery system, multi-site/ corporate chain, Population: Can be measured at all levels, Population: states, Population: counties or cities, disease management, quality improvement organization (QIO)

Type of measure: Process

Data source: Electronic clinical data, lab data, pharmacy data

Measure developer: © Ingenix, Inc.

Type of endorsement (endorsed or time-limited): Endorsed

Summary table of TAP ratings of sub criteria and comments:

IMPORTANCE TO MEASURE AND REPORT		
1a Impact	Completely: 1 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	The TAP stated that prior discussions on similar measures had already highlighted general concerns with this measure. The TAP noted that the measure does not cite extensive research and that the compliance rate is also low. The recommendations were generally based on ACR guidelines. **Voting Comments:** • Compliance in testing was at 45.4%.
1b Gap	Completely: 1 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	
1c Relation to outcomes	Completely: 1 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	
SCIENTIFIC ACCEPTABILTY		
2a Specs	Completely: 1 Partially: 2 Minimally: 0 Not at all: 0	After discussion, the TAP agreed that the measure meets the scientific acceptability subcriteria.

	NA: 0	
2b Reliability	Completely: 1 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	
2c Validity	Completely: 1 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	
2d Exclusions	Completely: 0 Partially: 2 Minimally: 0 Not at all: 0 NA: 1	
2e Risk-adjustment	Completely: 0 Partially: 0 Minimally: 0 Not at all: 0 NA: 3	
2f Meaningful differences	Completely: 0 Partially: 3 Minimally: 0 Not at all: 0 NA: 0	
2g Comparability	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1 NA: 1	
2h Disparities	Completely: 0 Partially: 1 Minimally: 0 Not at all: 1 NA: 1	
USABILITY		
3a Distinctive	Completely: 1 Partially: 1 Minimally: 1 Not at all: 0 NA: 0	After discussion, the TAP agreed that the measure meets the usability subcriteria.
3b Harmonization	Completely: 0 Partially: 2 Minimally: 0 Not at all: 0 NA: 1	
3c Added value	Completely: 0 Partially: 1 Minimally: 1 Not at all: 1 NA: 1	
FEASIBILITY		
4a Data a byproduct of care	Completely: 3 Partially: 0	After discussion, the TAP agreed that the measure meets the feasibility subcriteria.

	Minimally: 0 Not at all: 0 NA: 0	**Voting Comments:** • Those hospitalized would not be captured by this measure.
4b Electronic	Completely: 3 Partially: 0 Minimally: 0 Not at all: 0 NA: 0	
4c Exclusions	Completely: 1 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	
4d Inaccuracies	Completely: 1 Partially: 2 Minimally: 0 Not at all: 0 NA: 0	
4e Implementation	Completely: 3 Partially: 0 Minimally: 0 Not at all: 0 NA: 0	