DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

OCSQ/Quality Measurement & Health Assessment Group

William L. Roper, MD, MPH
Chair, NQF Board of Directors
National Quality Forum
601 13th Street NW
Suite 500 North
Washington DC 20005

November 30, 2010

Dear Dr. Roper:

On behalf of the Centers for Medicare and Medicaid Services (CMS), I am writing to respectfully appeal the National Quality Forum's decision to not endorse the following two outpatient imaging efficiency (OIE) measures submitted by CMS, and to request reconsideration of this decision:

(1) Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT); and

(2) Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

A recent report in the New England Journal of Medicine[1] raised serious concerns about the use and overuse of CT scanning, stating that for an estimated 62 million CT scans being performed per year, a third are unnecessary, resulting in patient safety issues including unnecessary radiation and contrast material exposure, and the danger associated with "false positive" findings. A CT scan exposes the patient to higher doses of radiation than a conventional x-ray and increases the patient's risk of cancer.

Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)

We believe this is an important area to measure related the use of CT scans, not only in the Medicare population, but likely other population groups as well. Sinus CTs are being ordered in addition to a brain CTs for patients with sinusitis because headache is a common symptom related to sinusitis. However, simultaneous CT sinus and brain imaging for headache without suspected complications is generally considered inappropriate, as the standard anatomic coverage of a CT of the head includes large portions of the paranasal sinuses; thus, ordering both procedures is duplicative and inefficient.

[1] Brenner DJ, Hall EJ. November 29, 2007. Computer Tomography – An Increasing Source of Radiation Exposure. New England J of Medicine: 357(22): 2277-84.

The intent of the Simultaneous Use of Brain CT and Sinus CT measure is to lower the number of potentially unnecessary sinus CTs performed for patients who have already had a brain CT. CMS has substantial concern surrounding this clearly inappropriate radiation exposure from the simultaneous use of these two imaging studies. Literature and consulted technical experts agree that given the specifications of and proposed exclusions for this measure, there is no further instance when use of both Brain CT and Sinus CT is appropriate. In fact the primary reviewer on the NQF Steering Committee reviewing the measure recommended the measure for endorsement. However, the NQF report issued on August 10, 2010 stated:

"The Steering Committee had concerns that a substantial number of facilities would not be able to report the measure because they would have sample sizes that were too small, thus limiting the number of facilities from across the nation that could report the measure. Further, the Committee determined that the measure does not meet the NQF importance criteria because it does not target an imaging practice with a substantial or large magnitude of overutilization. The measure developer stated that approximately five percent of patients who received a brain CT also received a sinus CT on the same day, thus reaffirming the Committee's view that this imaging practice does not have substantial overuse to support measurement endorsement. Given the Steering Committee's concerns with the measure the Committee did not recommend the measure for endorsement."

Our analysis of Medicare data for 2008 found that over 68,000 visits for Medicare patients involved receiving this dual radiation exposure. Although the relative incidence of this duplicative inappropriate imaging is comparatively low, the measure establishes a clear opportunity for improvement and addresses a public health concern related to unnecessary radiation exposure. Based on the Committee's discussion regarding minimum case count requirements, we further reviewed our statistical requirements and increased the minimum case counts needed for this measure (see Attachment A). While the Committee's assessment that many facilities will not have sufficient volume to permit measurement is relevant, our analysis of the Medicare claims data indicate that still over 2,500 facilities will have sufficient volume of denominator cases to permit use of the measure, even after applying more stringent case count requirements.

Because of CMS' concern related to unnecessary radiation exposure, our final Outpatient Prospective Payment (OPPS) Rule for calendar year (CY) 2011 (75 FR 72082) issued on November 2, 2010 adopted the measure among those to be publicly reported starting in CY 2012. Given the limited number of imaging efficiency measures that are available, the public health concern about radiation exposure, and the strong evidence around the inappropriateness of conducting simultaneous CT brain and sinus studies, we are requesting that NQF reconsider its decision and endorse the CMS submitted measure for "*Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).*"

Use of Brain Computed Tomography (CT) in the Emergency Department (ED) for Atraumatic Headache

While we understand that, especially in an aged population, there are instances in which a Brain CT in the ED is necessary, it is important to note that this measure is focused on outliers—hospitals that consistently perform Brain CT scans during ED visits for atraumatic headache. Specifically, our analysis of the data clearly indicates that there are emergency departments at hospitals that have a practice pattern of use of CT brain imaging for patients with atraumatic headache that is very different than the normative pattern for most hospitals. We believe that

identifying outlier practice patterns is consistent with educational and quality improvement efforts for providers, and public reporting related to identifying outlier patterns can play an important role in the quality improvement process.

An analysis of 2007 Medicare claims data found that of the approximately 200,000 Medicare beneficiaries with a visit to an ED with a primary diagnosis of headache, about half received a Brain CT coincident with the ED visit before application of exclusion criteria.[2] Furthermore, after application of exclusion criteria, our analysis of the Medicare data indicates that there are clearly facilities with outlier patterns of care in use of brain CT in the ED for atraumatic headache. Our analysis of 2008 Medicare claims data found that for this measure the national average ratio was 0.336 with half of the hospitals at or below 0.374. However, 5 percent of the hospitals had measure ratios at or above 0.613, and 1 percent of the hospitals had ratios at or above 0.705.

Concern over the inappropriate use of CT Imaging in the ED setting has been driven by three primary factors: false positive interpretations, radiation exposure, and cost. There is generally a lower threshold for ordering neuro-imaging for headache in the ED because of physician time constraints and lack of ED physician familiarity with headache presentation.[3] Because of this lower threshold, the measurement of the use of CT Brain in the ED for patients with a diagnosis of atraumatic headache can help raise the awareness of the need for quality improvement on the appropriate use of CT brain imaging in the ED and, as a result improve patient safety through reduction in unnecessary radiation exposure. The use of brain CT in the emergency department for atraumatic headache underwent a development process that included literature and guideline review, public comment and review by a technical expert panel that supported CMS adoption of the measure.

The NQF Steering Committee originally supported endorsement for this measure (15 votes recommending endorsement and 4 votes not recommending endorsement). However, because there were a number of comments submitted to NQF that did not support the measure, the Committee elected to revote on the measure with the result that the measure was not recommended for endorsement (8 votes recommending the measure and 12 votes not recommending the measure). The Committee during its discussion of comments did not appear to make note that the American College of Radiology and its Neuroradiology Commission submitted comments to NQF in support of this measure.

CMS has undertaken the public reporting work on imaging efficiency as an educational effort, aimed at educating beneficiaries and providers about the appropriate use of and risks associated with imaging services and their respective treatment guidelines. Consequently, as part of the final OPPS rule issued on November 2, 2010, CMS has adopted the measure for public reporting for calendar year 2012. We are requesting that NQF reconsider its decision and endorse the "Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache" measure.

CMS appreciates NQF's consideration of our appeal for endorsement of these two imaging efficiency measures. We believe that both of these measures merit endorsement due to their

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[2] The Lewin Group analysis of Medicare Calendar Year 2007 claims data prepared for the Centers for Medicare & Medicaid Services, HHS Contract No: HHSM-500-2005-0024I, Order No. 0002.

[3] Ward TN, Leven M, Phillips JM. Evaluation and management of headache in the emergency department. Med Clin N Am 2001; 85(4): 971-85.

potential to make a true difference in the quality, and especially, safety of healthcare. Both measures provide an opportunity for improvement and address public health concerns related to unnecessary radiation exposure and the resulting increased risk of cancer—an increased risk that we believe is preventable with the appropriate educational and quality improvement efforts.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Michael T. Rapp, MD JD
Director

Attachment

ATTACHMENT

Alternative Minimum Case Count Methodology for Simultaneous Use of Brain CT and Sinus CT

Based on the discussion at the NQF Steering Committee regarding the minimum case count requirements for the Simultaneous Use of Brain CT and Sinus CT measure, we reexamined the minimum case count criteria for this measure. This measure had an average ratio that was below 0.05 and the 75th percentile was also below 0.05. Our original minimum case count criteria established a case count threshold of 45 cases, which provided a 90 percent confidence level with a precision of +/- 0.05 for ratios below 0.05. Thus, for a hospital with an observed ratio of 0.05 and 45 cases, we were 90 percent confident that the hospital's actual ratio was between 0.00 and 0.10. Because the average ratio for this measure was very low and the variation of ratios across hospitals is small, we could only be confident that the actual ratio for the hospital in the above example is between the first and 99th percentile.

For this measure, we would propose using a methodology similar to the one submitted to NQF, except that we increased the precision that is required. The level of precision was based on the lower of the difference between the median and the 75th percentile (0.047 – 0.034 = 0.013) and the difference between the median and the 25th percentile (0.034 – 0.022 = 0.012). Using this criterion we calculated minimum case counts that would provide a 90 percent confidence interval of the hospital's actual ratio that would not span more than one quartile. For example, a hospital with a ratio at the 75th percentile (0.042) would require 808 cases in order to be confident that the actual ratio is above the median (See *Exhibit 1*).

Hospitals that have high ratios require less precision in order to be confident that the actual ratio is above the average. Thus, the precision and required sample size declines as the ratios increase. For example, a hospital with a ratio of 0.10 would require only 58 cases in order to be confident that the actual ratio is above the median.

Exhibit 1: Table of Required Case Counts for 90 Percent Confidence and Specified Precisions for Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)

Observed Rate	Required Precision	Sample Size Needed to Attain Required Precision
0.0050	0.012	94
0.0100	0.012	187
0.0150	0.012	278
0.0200	0.012	369
0.0250	0.012	458
0.0300	0.012	547
0.0350	0.012	635
0.0400	0.012	722
0.0450	0.012	808
0.0500	0.015	572
0.0550	0.020	352
0.0600	0.025	245
0.0650	0.030	183
0.0700	0.035	144
0.0750	0.040	118
0.0800	0.045	99
0.0850	0.050	85
0.0900	0.055	74
0.0950	0.060	65
0.1000	0.065	58
0.1050	0.070	52
0.1100	0.075	48
0.1150	0.080	44
0.1200	0.085	40
0.1250	0.090	37
0.1300	0.095	34
0.1350	0.100	32
0.1400	0.105	30
0.1450	0.110	28
0.1500	0.115	27
0.1550	0.120	25
0.1600	0.125	24
0.1650	0.130	23
0.1700	0.135	21
0.1750	0.140	20