

November 25, 2013

Ms. Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Room 445-G  
Washington, DC 20201

Dear Ms. Tavenner:

On behalf of more than 31,000 members and the 136 million patients seen in the nation's emergency departments, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on new clinical quality measures for potential use by eligible professionals (EPs) in the EHR Incentive Program. ACEP promotes the highest quality emergency care and is the leading advocate for emergency department patients. ACEP also recognizes the need to reduce patient exposures to ionizing radiation and the need for cost-effective emergency care. While ACEP supports the overall direction of the measure, we have grave concerns that the denominator exclusions necessary to adequately differentiate “uncomplicated” headaches from headaches suspect for more serious underlying conditions such as subarachnoid hemorrhage, meningitis, mastoiditis, and other intracranial diseases are sorely lacking.

ACEP appreciates that certain co-morbid conditions such as anticoagulant therapy, HIV status, cancer, and thunderclap headaches have been captured in the value-sets for potential denominator exclusions, and this represents a significant improvement over earlier claims-based measures that fail to capture the clinically meaningful indications for imaging (Schoor et al 2012). However, without additional specifications to make more granular distinctions between “uncomplicated” headaches and more serious underlying disorders, implementing an imaging utilization measure would be irresponsible at best and dangerous at worst because it will label eligible providers inappropriately and place misdirected pressure on “high users” to decrease their imaging use without a clinical rationale for doing so. ACEP is also disappointed that the terms “active diagnosis” are used in the denominator exclusions that are currently specified, noting that even a *history* of HIV or cancer is a red flag even in the absence of an “active diagnosis.” Also, *suspected* stroke, subarachnoid hemorrhage, and the like are also indications for imaging in order to *rule out* an active diagnosis for these conditions.

Similar to any other imaging technique, failure to obtain a necessary diagnostic CT could have serious consequences. A key concern of emergency medicine physicians—and likely motivation in ordering cautionary CTs—is identifying subarachnoid hemorrhage (SAH). Early and accurate diagnosis of SAH leads to improved outcomes. For example, failure to obtain a cranial CT in patients suspected of SAH could result in misdiagnosis of SAH and subsequent permanent neurological deficits or patient mortality. Within the population presenting with headache to the ED, approximately 1 percent of patients have SAH (Ramirez-Lassepas et al. 1997). Of ED patients with acute severe headache and normal neurologic examination, approximately 12 percent (one in 8) have SAH (Linn et al. 1994).

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Research shows that SAH is overlooked in up to 5 percent of cases in the ED (Kowalski et al. 2004). However, misdiagnosis is common on a first physician consultation (not specific to the ED), occurring in 23 to 53 percent of patients with SAH. The most common diagnostic error is failure to obtain a noncontrast cranial CT (Edlow and Caplan 2000).

There are more than 300 headache types and etiologies, making specific diagnoses challenging for physicians. In 1988, with an update in 2005, the International Headache Society (IHS) released a classification system (the ICHD), to assist in diagnosing headaches. The ICHD outlines specific characteristics necessary to confirm a broad range of disorders. Using this system, physicians may classify headache disorders as primary or secondary, and can subdivide primary or secondary headache disorders into specific types. Many patients who present with headache have a primary disorder, such as migraine, tension-type, and cluster headaches that are not associated with an underlying pathology. However, diagnostic tests are unavailable to confirm primary headaches. By contrast, secondary headache disorders are attributable to an underlying pathologic condition, and often require medical attention. Secondary headaches are of infectious, endocrinopathic, neoplastic, vascular, drug-induced, or idiopathic origins, and often require emergent medical care.

Accurate diagnosis of headache in the ED to eliminate the existence of secondary headache disorders can be challenging. In this environment, using the ICHD system may be difficult and time-consuming. In a retrospective study of 480 patients in an urban ED, Friedman et al. (2007) found that more than one third of acute headache patients could not readily be given a specific ICHD diagnosis. Among these patients without a specific ICHD diagnosis, 25 percent were found to have a secondary headache disorder. Another 10 percent had a coexisting primary and secondary headache disorder.

A thorough patient history is crucial to determining the etiology of a headache. The aim of the history is to classify the headache type and screen for secondary headache using red flag indicators. Breen et al. (2008) compiled a list of red flag indicators commonly identified in the literature (adapted from Figure 3 in Breen et al 2008):

- New onset or change in headache in a patient who is over the age of 50
- Time to peak headache intensity < 5 minutes (thunderclap headache)
- Focal neurological symptoms (e.g., limb weakness, aura < 5 minutes or > 1 hour, focal seizure)
- Non-focal neurological symptoms (e.g., cognitive disturbance, generalized seizure)
- Change in headache frequency, characteristics, or associated symptoms
- Abnormal neurological examination
- Headache that changes with posture (e.g., standing up)
- Headache wakening the patient or precipitated by physical activity or the Valsalva maneuver (i.e., coughing/straining)
- Patients with risk factors for cerebral venous thrombosis
- Jaw claudication or visual disturbance
- Neck stiffness
- Fever and rash
- New onset headache in a patient with a history of HIV infection
- New onset headache in a patient with a history of cancer

In addition, several clinical practice guidelines from ACEP, the American College of Radiology, the Institute for Clinical Systems Improvement (ICSI), and others note that imaging may be required depending on the clinical circumstances. For some types of headache or populations at risk, these procedures are more likely to be positive.

***American College of Emergency Physicians Guidelines (ACEP) (2008)***

In October 2008 ACEP updated its 2002 recommendations for patients presenting to the ED with acute nontraumatic headache. The new guideline stated that the outcome measure used in determining the need for neuroimaging in the ED must be “clinically relevant to practice.” ACEP recommends with moderate clinical certainty that patients presenting to the ED with headache and new abnormal findings in a neurologic examination (for example, focal deficit, altered mental status, altered cognitive function) should undergo emergent (that is, immediate), non-contrast head CT. ACEP also recommends that patients presenting with new sudden-onset severe headache should undergo an emergent head CT. HIV-positive patients with a new type of headache should be considered for an emergent neuroimaging study. ACEP also that patients who are older than 50 years and presenting with a new type of headache, but with a normal neurologic examination, should be considered for an urgent (that is, arranged prior to discharge from the ED) neuroimaging study.

***American College of Radiology: Appropriateness Criteria for Headache (2009)***

Appropriateness Criteria for Denominator Exclusions:

Variant	With Contrast	With and Without Contrast
Chronic Headache (No New Features)	4	4
Chronic Headache (New Features)	5	4
Sudden Onset of Severe Headache (ie. Thunderclap)	9	6
Sudden Onset of Unilateral Headache: <ul style="list-style-type: none"> <li>• Suspected Carotid</li> <li>• Vertebral Dissection</li> <li>• Ipsilateral Horner Syndrome</li> </ul>	7	6
Headache with Suspected Intracranial Complication of Sinusitis and/or Mastoiditis	7	6
New Headache in Patients Over Age 60: <ul style="list-style-type: none"> <li>• Sedimentation Rate &gt;55</li> <li>• Temporal Tenderness</li> <li>• Suspected Temporal Arteritis</li> </ul>	6	5
New Headache (HIV+ or Immunocompromised Individual)	5	6
New Headache (Pregnancy)	8	NR
New Headache (Suspected Meningitis/ Encephalitis)	8	6

Notes: ACR Criteria Rating Scale: 1,2,3–Usually not appropriate; 4,5,6–May be appropriate; 7,8,9–Usually appropriate. NR = not rated.

***Institute for Clinical Systems Improvement (2013)***

Warning signs of possible disorder other than primary headache are:

- Subacute and/or progressive headaches that worsen over time (months)
- New or different headache
- Any headache of maximum severity at onset
- Headache of new onset after age 50
- Persistent headache precipitated by a Valsalva maneuver
- Evidence such as fever, hypertension, myalgias, weight loss, or scalp tenderness suggesting a systemic disorder
- Presence of neurological signs that may suggest a secondary cause
- Seizures

Thank you for the opportunity to share our concerns and comments. We look forward to working with your staff on any future revisions. If you have any questions, please do not hesitate to contact, Stacie Schilling Jones, MPH, Director of Quality and HIT at 202-728-0610 ext. 3040 or [sjones@acep.org](mailto:sjones@acep.org).

Sincerely,

Alexander M. Rosenau, DO, CEP, FACEP  
President

### References

- Beithon J, Gallenberg M, Johnson K, Kildahl P, Krenik J, Liebow M, Linbo L, Myers C, Peterson S, Schmidt J, Swanson J. Diagnosis and treatment of headache. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Jan. 90 p.
- Breen DP, Duncan CW, Pope AE, Grays AJ, Al-Shahi Salman R. Emergency department evaluation of sudden, severe headache. *Q J Med.* 2008; 101:435–43.
- Edlow JA, Caplan LR. Avoiding pitfalls in the diagnosis of subarachnoid hemorrhage. *N Engl J Med.* 2000; 342:29–36.
- Edlow JA, Panagos PD, Godwin SA, Thomas TL, Decker WW; American College of Emergency Physicians. Clinical policy: critical issues in the evaluation and management of adult patients presenting to the emergency department with acute headache. *Ann Emerg Med.* 2008 Oct;52(4):407-36.
- Jordan JE, Wippold FJ II, Cornelius RS, Amin-Hanjani S, Brunberg JA, Davis PC, De La Paz RL, Dormont D, Germano I, Gray L, Mukherji SJ, Seidenwurm DJ, Sloan MA, Turski PA, Zimmerman RD, Zipfel GJ, Expert Panel on Neurologic Imaging. ACR Appropriateness Criteria® headache. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 8 p.
- Kowalski RG, Claassen J, Kreiter KT, Bates JE, Ostapovich ND, Connolly ES, Mayer SA. Initial misdiagnosis and outcome after subarachnoid hemorrhage. *JAMA.* 2004; 291:866–9.
- Linn FH, Rinkel GJ, Algra A, van Gijn J. Incidence of subarachnoid hemorrhage: role of region, year, and rate of computed tomography: a meta-analysis. *Stroke.* 1996; 27:625–9.
- Linn FH, Wijdicks EF, van der Graaf Y, Weerdesteyn-van Vliet FA, Bartelds AI, van Gijn J. Prospective study of sentinel headache in aneurysmal subarachnoid hemorrhage. *Lancet.* 1994; 344:590–3.
- Ramirez-Lassepas M, Espinosa CE, Cicero JJ, Johnston KL, Cipolle RJ, Barber DL. Predictors of intracranial pathologic findings in patients who seek emergency care because of headache. *Arch Neurol.* 1997; 54:1506–9.
- Schuur JD, Brown MD, Cheung DS, Graff L, Griffey RT, Hamedani AG, Kelly JJ, Klauer K, Phelan M, Sierzenski PR, Raja AS. Assessment of Medicare's imaging efficiency measure for emergency department patients with atraumatic headache. *Ann Emerg Med.* 2012;60:280-290.
- Ward TN, Leven M, Phillips JM. Evaluation and management of headache in the emergency department. *Med Clin N Am.* 2001; 85(4):971–85.