Date: October 15, 2008

Topic: CTCAE v3.0 Help Desk Tickets SOC Nervous system disorders

 Working Group # 4: Psychiatric disorders; Nervous system disorders

From: Ann Setser

Issue: **Cerebral edema**

Not listed in CTCAE v3.0. Consider addition in CTCAE v4.0

However, one might report the symptom and not the diagnosis. So if someone has cerebral edema, how did it present?

Tough one, not well covered. unless it is related to lymphatic issues, I would put it in neurology.

I handle these generally by the symptom, and not the DX, so if someone has cerebral edema, how did it present? If it is just an imaging finding without symptoms, perhaps grade it as cerebral edema.  But if presentation is with symptoms, perhaps report the symptoms such as somnolence, seizures, encephalopathy, etc) to determine the AE and then use cerebral edema as the attribution.

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Hemorrhage/Bleeding - CNS Hemorrhage - Grade 3 misspelling 'thombolysis' should be changed to 'thrombolysis'

CTEP Response: YES THIS IS A TYPO AND SHOULD BE THROMBOLYSIS

In the CTCAE version 3, "Depressed level of consciousness" was revised to Somnolence / depressed level of consciousness;" and Grade 1 was deleted. When a very mild sleepiness with the grade less than 2 is observed in a trial and the physician thinks it is caused by a study drug, how we should record it and what grade we should put on it?

Suggestions for addition in CTCAE v4.0: Oncologic emergencies:

* MedDRA: Hypertensive encephalopathy; SOC Nervous system disorders
* MedDRA:Spinal cord compression SOC Nervous system disorders
* MedDRA: Increased intracranial pressure SOC Nervous system disorders
* MedDRA: Hemiparesis
* MedDRA: Migraine
* poor balance – Not in MedDRA
	+ MedDRA LLT Balance difficulty; PT Balance disorder
* smell hypersensitivity – Not in MedDRA
	+ MedDRA options: LLT Smell alteration; Smell perversion; Strange smell sensation; all LLTs for PT Parosmia