

## Appendix IV - Specific List

|  | <b>At<br/>Baseline<br/>or Before</b> | <b>New Since<br/>Baseline</b> |
|--|--------------------------------------|-------------------------------|
| <b>Body Mass Index</b><br>- An absolute increase in BMI of more than 8 units (and >24.9 kg/m <sup>2</sup> )  |                                      |                               |
| <b>Blood Pressure</b><br>- Hypertensive emergency (see definition, below)<br>- PRES (Posterior reversible encephalopathy syndrome) (see definition, below)   |                                      |                               |
| <b>Endocrine</b><br>- Symptomatic adrenal insufficiency  |                                      |                               |
| <b>Bone Health</b><br>- Osteonecrosis of one joint<br>- Osteonecrosis of more than one joint<br>- Bone mineral density decrease > 6%<br>- Insufficiency fracture<br>- Insufficiency fracture in more than one bone |                                      |                               |
| <b>Muscle &amp; Tendon</b><br>- Severe glucocorticoid myopathy (see definition)<br>- Tendon rupture<br>- More than one tendon rupture  |                                      |                               |
| <b>Eye</b><br>- Central serous retinopathy<br>- New-onset or worsened elevation of intra-ocular pressure requiring treatment or change in treatment<br>- Posterior subcapsular cataracts (or history of same)      |                                      |                               |

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| <b>Infection</b> <ul style="list-style-type: none"> <li>- Grade 4 infection (see definition, below)</li> <li>- Grade 5 infection (death from infection)</li> </ul>   |  |  |
| <b>Glucose Tolerance</b> <ul style="list-style-type: none"> <li>- Diabetic nephropathy</li> <li>- Diabetic neuropathy</li> <li>- Diabetic retinopathy</li> </ul>   |  |  |
| <b>Gastrointestinal Tract</b> <ul style="list-style-type: none"> <li>- Gastrointestinal perforation (occurring in the absence of regular nonsteroidal anti-inflammatory drug use)</li> <li>- Peptic ulcer disease confirmed by endoscopy (excluding <i>H. pylori</i>)</li> </ul>             |  |  |
| <b>Skin</b> <ul style="list-style-type: none"> <li>- Severe skin toxicity (see definition, below)</li> </ul>   |  |  |
| <b>Neuropsychiatric</b> <ul style="list-style-type: none"> <li>- Psychosis, defined as hallucinations, delusions, or disorganized thought processes (occurring in the absence of mania, delirium, or depression)</li> <li>- Glucocorticoid-induced violence toward self or others</li> </ul> |  |  |
| <b>Other glucocorticoid toxicities</b><br><br>Please specify: _____<br>_____<br>_____  |  |  |

## **DEFINITIONS:**

**Hypertensive emergency:** The blood pressure has reached levels that are damaging organs. Hypertensive emergencies generally occur at blood pressure levels exceeding 180 mmHg systolic OR 120 mmHg diastolic, but can occur at even lower levels in patients whose blood pressure have not been elevated before. Complications can include: stroke, loss of consciousness, memory loss, myocardial infarction, hypertensive retinopathy or nephropathy, aortic dissection, angina, pulmonary edema.

**Posterior reversible leukoencephalopathy syndrome (PRES):** A clinical radiological entity. Clinical features may include headaches, altered mental status, seizures, and visual loss, depending on the affected neuroanatomy. Characteristic Magnetic Resonance Imaging (MRI) findings include vasogenic edema involving the white matter that predominantly affects the posterior occipital and parietal lobes of the brain, although other brain regions may also be affected. Confirmation by MRI is required as is exclusion of other potential causes (including hypertensive emergency).

**Severe glucocorticoid myopathy:** Grade 3 or worse myopathic weakness or respiratory myopathic weakness attributable to glucocorticoid myopathy.

**Central serous retinopathy:** a fluid detachment of macula layers from their supporting tissue. Requires formal ophthalmology examination, typically accompanied by optical coherence tomography and/or fluorescein angiography for diagnostic confirmation.

**Grade 4 infection:** Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis).

**Diabetic nephropathy:** Macroalbuminuria; i.e., a urinary albumin excretion > 300 mg in a 24-hour collection or a urinary protein: creatinine ratio > 300mg/g.

**Diabetic neuropathy:** Any of four types of peripheral neuropathy occurring in the setting of diabetes mellitus, namely: 1) a distal sensory polyneuropathy; 2) autonomic neuropathy (hypoglycemia unawareness, bladder or bowel problems, erectile dysfunction, and other autonomic nervous system issues); 3) diabetic amyotrophy (muscle infarction); or 4) mononeuritis (e.g., foot drop attributed to diabetic neuropathy).

**Diabetic retinopathy:** Any form of retinopathy associated with diabetes mellitus, including both non-proliferative and proliferative forms of diabetic retinopathy as well as diabetic macular edema. These complications must be confirmed by an ophthalmologist.

**Severe skin toxicity:** Any of the three following manifestations:

Grade 4 acneiform lesions - Papules and/or pustules covering any % body surface area (BSA), which may or may not be associated with symptoms of pruritus or tenderness and are associated with extensive superinfection with IV antibiotics indicated or life-threatening consequences

Grade 3 striae - Covering >30% BSA or associated with ulceration

Grade 3 ulcers - Combined area of ulcers >2 cm or full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to fascia

## References

National Cancer Institute Common Terminology Criteria for Adverse Events v4.0 NCI, NIH, DHHS. May 29, 2009 NIH publication # 09-7473.

Medical Research Council of the United Kingdom. Guide to Examination of the Peripheral Nervous System: Memorandum No 45. Palo Alto, Calif: Pedragon House; 1978.

American Heart Association. Hypertensive Crisis. Accessed

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