Appendix C

Justification for Adjustments to CMS Sepsis-1 Criteria for End Organ Injury



Systolic blood pressure

Systolic, diastolic, and mean arterial blood pressure decrease during normal pregnancy and reach a nadir in mid-pregnancy with subsequent increases as gestational age increases. $^{1-2}$ A study evaluating frequency of Maternal Early Warning Criteria triggers found that 45 (15%) of healthy women had a SBP < 90 mm Hg. 3 In a study of 32,161 patients reporting vital signs during delivery hospitalization to determine a normal range, it was found that 5% of women had SBP < 90 mm Hg and 2.5% of women had a SBP < 85 mm Hg or lower during the intrapartum and postpartum periods. 4 CMQCC chose the threshold of < 85 mm Hg for diagnosis of sepsis-related end organ injury to reduce frequency of alerts due to physiological changes of pregnancy alone.

Creatinine

Serum creatinine levels decrease during pregnancy due to a rise in glomerular filtration rate. Normal serum creatinine levels during pregnancy range from 0.5 mg/dL to 0.7 mg/dL. It is well established that creatinine $\geq 1.2 \text{ mg/dL}$ or doubling of creatinine are considered diagnostic for renal end organ injury for preeclampsia, and CMQCC chose to adopt these lower levels for diagnosis of sepsis-related end organ injury.

Lactic acid

Lactic acid may be elevated during normal labor and delivery. In a meta-analysis of 2,008 observations of 1,193 normal healthy women during pregnancy, labor, and delivery, assuming a normal distribution, 99.7% of patients had a lactic acid < 2 mmol/L outside of labor. For patients (not in labor with suspected infection) whose Step-1 Initial Sepsis Screen is positive and have a lactic acid > 2 mmol/L, they meet the criteria for diagnosis of sepsis per CMS. However, during all stages of labor and time of delivery, lactic acid levels > 2 mmol/L were reported within the normal range as a result of labor alone. More specifically, out of 10 studies reporting lactic acid levels at the time of delivery, nine reported levels > 2 mmol/L and six reported lactic acid levels > 4 mmol/L due to labor. Due to the wide ranges reported during labor, it is difficult to determine the expected percentage of women with elevated levels as a result of labor. Although there may be some women with elevated lactic acid levels due to anaerobic metabolism during normal labor, there is considerable harm that may occur with untreated worsening infection that may present with rising lactic acid levels. For laboring patients (with suspected infection) whose Step-1 Initial Sepsis Screen is positive and do not meet any end organ injury criteria but have a lactic acid levels over time.

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