

FLORIDA SOCIETY OF CLINICAL ONCOLOGY

Questions and Answers related to NCD 000383: ESAs in Cancer and Neoplastic Conditions - 7/31/2007- (Source of Information: CMS Website - http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=12)

QUESTION #1 Will CMS reimburse or provide coverage for ESA treatment once a patient's hemoglobin level exceeds 10 g/dL (or hematocrit exceeds 30%) regardless if it is their first dose or a "maintenance" Dose?

ANSWER #1 The NCD covers the initial use of ESAs for a period of up to 4 weeks when the hemoglobin falls below 10 g/dL. After that period, additional claims for administration of ESAs is covered for the listed indications if a subsequent hemoglobin is < 10 g/dL.

QUESTION #2 Does CMS intend to set a new target range of 10 g/dL as opposed to the labeled 10-12 g/dL deny all reimbursement claims for hemoglobins >10 g/dL (in effect setting a new target range of 10 g/dL)? Or will do the policy relate only to patients who rapidly move above 10 g/dL?

ANSWER #2 In its final NCD, CMS has raised the threshold for coverage of ESAs in cancer patients with anemia due to chemotherapy from the proposed 9 g/dL to 10 g/dL. Neither the proposed nor the final NCD created a target hemoglobin or a hemoglobin range. This is consistent with the current FDA approved label indication "to decrease the need for transfusions in patients who will be receiving concomitant chemotherapy for a minimum of 2 months..." We note that the labeled dosing for this population does not in fact include an explicit numerical target range. Rather "the dose should be titrated for each patient to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for transfusion and not to exceed 12 g/dL"

QUESTION #3 With individual patient hemoglobin levels being widely variable, how might a policy that reimburses below 10 g/dL but not above 10 g/dL be implemented?

ANSWER #3 See #1 above.

QUESTION #4 The decision became effective 7/30/07 according to the CMS site. What is the implementation date for the NCD?

ANSWER #4 The NCD became effective 7/30/07. In regards to claims processing, CMS is developing instructions for its local contractors that process and review Medicare claims. We anticipate that these changes will be implemented by September 30, 2007.

QUESTION #5 Does the NCD override local Medicare contractors' LCDs?

ANSWER #5 Yes, to the extent that an LCD may have been inconsistent with the NCD. Local contractors may continue to make reasonable and necessary determinations for all uses that are not determined in the NCD

QUESTION #6 Is there a requirement to test the hemoglobin at 5th week of ESA administration?

ANSWER #6 CMS did not mandate how frequently a physician monitors their patient's hemoglobin (hematocrit) level. However, continued coverage of ESA therapy is dependent of the beneficiary continuing to meet the coverage requirements.

QUESTION #7 What if in week five the patient's hemoglobin is 11g/dl (whether the doctor knows it or not), does/should ESA coverage continue?

ANSWER #7 Per the final decision, available for viewing at <https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=203> CMS does not provide coverage, that is, will not pay a claim, for the administration of ESAs unless the hemoglobin level immediately prior to initiation or maintenance of ESA treatment is < 10 g/dL (or the hematocrit is < 30%). In accordance with provisions of the Tax Relief and Health Care Act of 2006 and subsequent CMS rulemaking, all claims for ESAs administered in the treatment of anemia related to the treatment of cancer with dates of service on or after January 1, 2008 must include the beneficiary's hemoglobin or hematocrit. Thus we would not expect to pay ESA claims that are not accompanied by a timely hemoglobin or hematocrit.

QUESTION #8 When a course of chemotherapy ends or is completed, does a new "4 week" ESA treatment period start?

ANSWER #8 The 4 week period only applies to the 4 week period following the initiation of ESAs. CMS continues coverage of ESA administration, with the limitations outlined, for up to 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen. We have not limited the number or duration of chemotherapy regimens.

QUESTION #9 Wouldn't the imposition of a ceiling of hemoglobin 10 g/dl (hematocrit 30%) override the physician discretion on an FDA label to use the lowest dose sufficient to avoid transfusions, not to exceed 12g/dl?

ANSWER #9 We are unaware of robust clinical evidence that transfusion is indicated for patients whose hemoglobin is less than 10g/dL. In fact, evidence based reviews of transfusion thresholds generally note 7 or 8 g/dL as the clinically appropriate transfusion threshold. NCDs instruct Medicare contractors on the payment of claims; they do not prohibit a physician from administering any treatment that he or she believes is indicated

QUESTION #10 Did CMS consider that the policy could potentially create more dramatic Hb swings in by allowing ESA use at less than 10 g/dl, followed by discontinuation at 10.1 g/dl despite continued chemotherapy, followed by resumption once the Hb dips below 10g/dl again? Hb variability is suggested to be associated with negative outcomes

ANSWER #10 See #1

QUESTION #11

The elimination of reimbursement at any Hb level above 10 g/dl does not appear to be proposed in the May 14 document. Is it normal or appropriate for a change of policy to be implemented in the final determination that wasn't contained in the proposed NCD, especially given that there was no chance for public to comment on that particular condition for reimbursement?

ANSWER #11

The proposed decision, viewable at <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=203> and in Appendix A of the final decision, proposed that the use of ESAs was reasonable and necessary, that is covered, when the hemoglobin was less than 9 g/dL (hematocrit 27%). The final NCD allows broader coverage in response to public comments.