

Dear MOASC Members,

MOASC posed five questions to California NHIC Medical Director, Dr. Bruce Quinn, regarding CMS' NCD on ESA's. Following are his responses.

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**From:** Quinn, Bruce [mailto:bruce.quinn@eds.com]

**Sent:** Thursday, August 02, 2007 9:40 AM

**To:** Pat Tyler

**Cc:** Exec Dir ANCO Online

**Subject:** 5 MOASC questions re LCD/NCD on ESA

**1. (inconsistent with FDA),** NHIC and other carriers need to follow the NCD. Whether the NCD is an appropriate instruction has to be worked about between Amgen and ASCO and CMS. In general, CMS does not have to follow the FDA lockstep, for example, there are numerous devices the FDA approves and CMS does not cover, and that has been the case for years and years. In the case of chemotherapy regimens specifically, under 1861(t)(2) ASCO and others will have to work with CMS, and I am not in a position to disagree with CMS in any way. Aranesp's chemotherapy label is "maintain the lowest level to avoid transfusion AND do not exceed 12 g/dl". CMS assumes via the NCD that the lowest level to avoid transfusion is not stated but could be interpreted at 9 or 10 by CMS, and CMS says 10. However, the next sentence of the FDA Aranesp label says "Reduce dose by 40% when Hg exceeds 11" and this is clearly an entirely different instruction from the CMS instruction to "stop dose when the Hg exceeds 10."

**2. (Hg drops below 10 again).** My understanding is that the patient can get ESA during the period of chemotherapy (say, 20 weeks) and for an additional 8 weeks after the last dose of chemotherapy, when there Hg is below 10. I think the ESA benefit spans the course of chemotherapy and the following 8 weeks, the Hg being below 10 at the time of dosing. CMS seemed to anticipate that in their separate Q&A on the NCD, where Question 10 recognizes that the Hg may go up and down above and below 10.1 over time.

**3. (current ESA patients, with Hg > 10).** The national law regarding NCDs is that they apply at the time they are published. Therefore, say a patient is in week 6 now, of a 12 week course of chemotherapy. And in weeks 1-6, there Hg has been 11. Up to July 30, ESA is covered by Medicare "LCD" as long as the Hg is below 12. As of July 30, ESA is not covered by Medicare by NCD if the Hg is over 10.0.

**4. (effective date)** CMS NCD's are legally effective as of the date of publication. However, there is also a legal principle that the provider had advance notice of coverage conditions. No one has ever said if that means "the next day" or "three days later" or any other specific time, so I can't answer. At the extreme, the NCD was released at the end of 7/30 and providers couldn't possibly have known of it earlier in the day of 7/30.

**5. NHIC edits.** It takes us several weeks to change edits. For one thing, we can't just "change the computer" because there are complicated business processes, work orders, programming time, and error checking. Also, we need to wait for internal CMS instructions on exactly "how" to apply the NCD in the computer. These instructions have not been issued and I can't say exactly when we will receive instructions from CMS - maybe 5 days, maybe 15. Then we would start the computer edit effort. We will be publishing a revised LCD at that point, however, it will be revised only to the extent to exactly mirror the NCD. There will likely also be conference calls among the several dozen Medicare medical directors and/or between us and CMS itself.

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**From:** Pat Tyler [mailto: pat@moasc.org ]  
**Sent:** Thursday, August 02, 2007 6:40 AM  
**To:** Quinn, Bruce  
**Subject:** Decision memo from CMS regarding ESA

Good Morning Dr. Quinn:

Hope all is well with you. As you well know with CMS announcement on Monday July 30, 2007 of their new NCD policy for "ESA" a few questions have arisen?

1. This new policy restricts coverage of ESA's whenever the patient hemoglobin goes above 10. Patients with anemia due to chemotherapy ESA's can be given when the hemoglobin is less than 10. This statement alone is inconsistent with FDA approved guideline and national guidelines?
2. Under the new policy a patient's hemoglobin could repeatedly fall below 10 following termination of coverage at the end of 4 week periods. This is inconsistent with FDA approved guidelines?
3. What about patients who currently are receiving ESA's, who's H&H are above the new guidelines, but below 12 and 36%?
4. We were told that the effective date was July 30, 2007. so effective for dates of service all these new guidelines would apply?
5. Are your edits in place?

Any guidance you can give me regarding these issues would be appreciated

Best Regards  
Pat Tyler