

Commentary

CMS restricts use of ESAs in cancer patients

Ted Okon | Community Oncology Alliance, Washington, DC

On July 30, 2007, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage decision (NCD) memorandum for the use of erythropoiesis-stimulating agents (ESAs) in the treatment of cancer. According to CMS, “Emerging safety concerns... derived from clinical trials in several cancer and non-cancer populations prompted CMS to review its coverage of ESAs.” As a result, CMS “determined that there is sufficient evidence to conclude that... treatment [with ESAs] is not reasonable and necessary for [Medicare] beneficiaries with certain clinical conditions, either because of a deleterious effect of the ESA on their underlying disease or because the underlying disease increases their risk of adverse effects related to ESA use.”

CMS concluded that ESA use in cancer patients is reasonable and necessary only under these conditions:

- The hemoglobin (Hgb) level immediately prior to initiation or maintenance of ESA therapy is < 10 g/dL.
- The starting dose is ≤ 150 U/kg three times weekly for epoetin alfa (Procrit) or ≤ 2.25 µg/kg weekly for darbepoetin alfa (Aranesp).
- Maintenance therapy at the recommended starting dose may be given only if the Hgb level remains < 10 g/dL 4 weeks after initiation of ESA therapy and rose > 1 g/dL.
- For patients whose Hgb level rose < 1 g/dL from baseline over 4 weeks of ESA treatment and remains below 10 g/dL, the starting dose may be in-

creased once by 25%; continued use is not reasonable and necessary if the Hgb level rises < 1 g/dL from baseline after 8 weeks of ESA therapy.

- Continued use of ESA therapy is not reasonable and necessary if the Hgb level rises > 1 g/dL over 2 weeks, unless it remains or falls to < 10 g/dL; continuation and reinstatement of ESA therapy must include a dose reduction of 25% from the previously administered dose.

- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy.

In a letter sent to CMS, the Community Oncology Alliance (COA) expressed their concern “that there will be significant adverse patient outcomes when the regulations covered by this NCD are fully implemented” and asked that CMS re-examine the NCD and exercise its statutory authority to delay its effective date. COA explained that the NCD places restrictions on the use of ESAs that exceed what is “reasonable and necessary” for cancer patients and ignores well-established clinical guidelines. One of the concerns stated by COA is that, in effect, “CMS has rewritten the FDA requirements for a medication” by issuing an NCD that does not reflect current FDA labeling for ESAs.

In a letter to CMS dated August 3, 2007, the American Society of Clinical Oncology (ASCO) requested that CMS reopen certain portions of the NCD and recommended that CMS delay the effective date for the entire NCD. “The current NCD does not

allow for interpretation consistent with clinical practice, national guidelines, or the FDA-approved labels in this area,” ASCO wrote.

US Oncology, in a letter dated August 7, 2007, supported the concerns raised by ASCO and asked CMS to reopen the NCD on ESAs. Among other points, the letter argued that “CMS should have written a policy that establishes an upper Hgb limit of 12 g/dL and prohibits administration of ESAs above that level.”

Community oncologists have expressed their concerns to COA about the practicality of implementing the NCD published by CMS. Oncologists are worried that, in following the NCD, they risk exactly the thing that CMS purports to protect by issuing the NCD, namely, patient safety. Confusion among community oncology practices and even Medicare carriers has created an uncertain, chaotic situation. Even though the effective date of the NCD was July 30, as of this writing, several carriers have not yet implemented the NCD because of numerous questions regarding it.

In addition to the immediate impact of the NCD in restricting use of ESAs in the treatment of cancer patients is the concern over the precedent established by this particular NCD. Questions have been raised by members of the cancer community about the degree to which CMS, as the largest payer of oncology drugs and services, has overstepped its authority by actually ignoring current FDA labeling in establishing, in effect, its own drug labeling as the basis for Medicare reimbursement. Given that private payers tend to follow Medicare reimbursement policies, this particular NCD is very disconcerting, both in the short term in regard to patient care and in the long term in the separation of sound medical science and payment policy.

Mr. Okon is Executive Director of the Community Oncology Alliance, based in Washington, DC.