

Dear CMS:

Since 1990 the mission of the Medical Oncology Association of Southern California, Inc. (MOASC) is to "advance and protect the ability of cancer patients to obtain, and the ability of the oncologist to provide optimal cancer care." Our membership has grown to over 350 oncologists in California which increases MOASC's fiscal obligation in providing the exceptional educational programs and media for which the association is recognized nationally.

Below are more comments from the Medical Oncology Association of Southern California regarding NCD on ESA's.

Thank you for your time in reviewing these comments.

1. There is no reason to exclude any solid tumor from treatment, since the mechanism of chemotherapy suppression is the same biologically in all. So for patients with unusual tumors who are anemic on chemotherapy, denying them access to esa therapy when there are no published complications is contrary to the standard care which applies to all solid tumors, even rare ones. The guidelines of ASCO and NCCN do not exclude any solid tumors.

2. Maintenance doses of ESA should continue until hb is over 12, since national guidelines of ASCO and NCCN and the FDA approved package label all indicate that is the standard of care. Stopping before reaching a hb of 12 will eliminate much of the benefit upon which FDA approval was based. This violates the expectation of physicians using FDA approved drugs as directed by the package label, exposing physicians to malpractice claims for failure to treat fatigue and transfusion dependence appropriately.

3. The policy must deal with patients who refuse transfusion for religious or personal reasons, to allow them to maintain ESA therapy, and also to initiate it even in the presence of relative contraindications. A policy which violates their religious beliefs is unconstitutional.

These problems are important enough to urge patients to get restraining order in federal court preventing rule adoption, if the problems are not addressed properly in order to avoid bodily harm to those patients.

One issue was the removal of coverage for CML- at times these patients develop anemias from Gleevec and should be able to be supported with Procrit. Other issues not covered were "anemias of chronic disease" and pre-dialysis anemias. If there is no statement regarding these diagnosis, do we continue" business as usual"?

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