

Dear Dr. ,

I am writing to request a modification in the Indications and Limitations of Coverage and / or Medical Necessity for LCD title Erythropoietin analogues, Epoetin Alpha and Darbepoetin Alpha (LCD ID Number L4835).

Indications of coverage include:

Anemic surgical patients who meet all the following:

*-the surgery is elective, **non-cardiac, non-vascular** and
-hemoglobin level between 10.0 and 13.0 g/dl and
-at risk for perioperative transfusions due to significant,
anticipated blood loss. This includes those patients who are
expected to require > 2 units of blood, and who are **not able
or willing to participate in an autologous blood donation
(PAD) program.***

I will provide information that supports removal of the exclusion for cardiac and vascular surgery, and the requirement that patients be unwilling or unable to participate in preoperative autologous donation.

I. Exclusion for Cardiac and vascular surgery

There is an abundant positive literature in support of preoperative EPO in orthopedic surgery, detailing reduced perioperative transfusion, earlier discharge from hospital, and improved postoperative quality of life. The desirability of avoiding allogeneic transfusion in cardiac surgery is similarly well documented in a robust and growing literature, most recently in a series of articles published this year by the Cleveland Clinic Foundation (abstracts of the two most recent articles are attached) in the Annals of Thoracic Surgery.

To achieve the goal of “bloodless” cardiac surgery, requires the adoption of a combination of blood conservation techniques, including preoperative recombinant human erythropoietin (rHuEPO). Aryeh Shander, et al, reviewed the safety and efficacy of “bloodless” cardiac surgery in a recent review in Seminars in Cardiothoracic and Vascular Anesthesia (Vol 9, March, 2005: 53-63). Dr. Shander states that “multiple trials have shown that the use of rHuEPO preoperatively can effectively increase the patient’s red cell mass, thus decreasing the incidence of perioperative transfusions.” A review and meta-analysis by Alghamdi, et al (J. Card Surgery. 2006 May-

June;21(3): 320-6) concluded that rHuEPO given preoperatively to patients undergoing cardiac surgery, either with or without preoperative autologous donation, significantly reduced allogeneic blood transfusion exposure.

Nearly 20% of transfusions in the United States are associated with cardiac surgery. The efficacy and safety of rHuEPO has been established. The significant deleterious effects of allogeneic transfusion, on outcomes in cardiac surgery, is also well established in the medical literature, punctuated by this year's reports from the Cleveland Clinic Foundation. ***I request that you now consider removing cardiac and vascular surgery as an exception to coverage under L4835.***

II. Exclusion for patient's unwillingness or inability to participate in PAD

While PAD has been used successfully to decrease allogeneic blood exposure, it is not without significant cost, inconvenience to patients, and with at least some risks that are similar to allogeneic transfusions. (There is a similar risk of bacterial contamination as allogeneic blood. Clerical error may lead to transfusion of a unit other than the patient's own). Wastage of autologous units approaches 50% for some procedures. Finally, in older patient populations, the endogenous hematopoietic response to donation is often inadequate to keeping pace with the red cell volume removed, and PAD becomes, in essence a form of chronic hemodilution unless PAD is coupled with EPO and iron therapy. It is logical that unwillingness or inability to participate in PAD no longer be a prerequisite for coverage of EPO in an anemic patient population. ***I request that you now consider removing inability or unwillingness to participate in an autologous blood donation program, as a coverage requirement for L4835.*** I believe this restriction is not in the best interest of patient care and actually has the paradoxical effect of increasing transfusion episodes, and therefore risks and costs. In most instances, PAD works best when combined with EPO.mel

Thank you for your time and consideration. I look forward to your review. If I can be of any help in clarifying my requests, please do not hesitate to contact me. I can be reached at 207.973.7794 or at Igross@emh.org.

Sincerely,

Irwin Gross, M.D., Medical Director
Transfusion Services, Eastern Maine Medical Center