

Dear Dr. Gross,

The six other NGS Medical directors and I discussed your request to remove the exclusion for cardiac and vascular surgery and the requirement that patients be unwilling or unable to participate in preoperative autologous donation from LCD L4835. We decided that the available published evidence did not support removing these restrictions. Our major concern related to patient safety issues summarized by recent FDA warnings and the FDA label warnings. Should new evidence become available we will be pleased to reconsider this issue. Our decision was based on the following publications:

#### Reference List

- (1) EPOGEN FOR INJECTION. Physicians' Desk Reference. 61 ed. Montvale: Thomson PDR; 2006: 591-97.
- (2) Alghamdi AA, Albanna MJ, Guru V, Brister SJ. Does the use of erythropoietin reduce the risk of exposure to allogeneic blood transfusion in cardiac surgery? A systematic review and meta-analysis. *J Card Surg.* 2006;21:320-326.
- (3) D'Ambra MN, Gray RJ, Hillman R, Jones JW, Kim HC, Rawitscher R et al. Effect of recombinant human erythropoietin on transfusion risk in coronary bypass patients. *Ann Thorac Surg.* 1997;64:1686-93.
- (4) Drueke TB, Locatelli F, Clyne N, Eckardt KU, Macdougall IC, Tsakiris D et al. Normalization of hemoglobin level in patients with chronic kidney disease and anemia. *N Engl J Med.* 2006;355:2071-84.
- (5) Koch CG, Li L, Van Wagoner DR, Duncan AI, Gillinov AM, Blackstone EH. Red cell transfusion is associated with an increased risk for postoperative atrial fibrillation. *Ann Thorac Surg.* 2006;82:1747-56.
- (6) Koch CG, Khandwala F, Li L, Estafanous FG, Loop FD, Blackstone EH. Persistent effect of red cell transfusion on health-related quality of life after cardiac surgery. *Ann Thorac Surg.* 2006;82:13-20.
- (7) Koch CG, Li L, Duncan AI, Mihaljevic T, Loop FD, Starr NJ et al. Transfusion in coronary artery bypass grafting is associated with reduced long-term survival. *Ann Thorac Surg.* 2006;81:1650-1657.
- (8) Koch CG, Li L, Duncan AI, Mihaljevic T, Cosgrove DM, Loop FD et al. Morbidity and mortality risk associated with red blood cell and blood-component transfusion in isolated coronary artery bypass grafting. *Crit Care Med.* 2006;34:1608-16.
- (9) Remuzzi G, Ingelfinger JR. Correction of anemia--payoffs and problems. *N Engl J Med.* 2006;355:2144-46.
- (10) Singh AK, Szczech L, Tang KL, Barnhart H, Sapp S, Wolfson M et al. Correction of anemia with epoetin alfa in chronic kidney disease. *N Engl J Med.* 2006;355:2085-98.

**Gary**

Gary Weaver, MD, FACP  
Medicare Part A Medical Director  
National Government Services  
Phone: (207) 253-3626  
Fax: (207) 253-3646