

# Biomarkers for Assessing and Managing Iron Deficiency Anemia in Late-Stage Chronic Kidney Disease: Comparative Effectiveness Review Number 83

U. S. Department of Health and Human Services, Agency for Healthcare Research and Quality

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Chronic kidney disease (CKD) is the gradual, progressive deterioration of kidney function leading to a toxic accumulation of wastes inside the body, which in turn gives rise to complications such as high blood pressure, decreased bone health, nerve damage, and anemia. The most common causes of CKD are diabetes and hypertension, though others include glomerulonephritis, inherited diseases such as polycystic kidney disease, congenital malformations of the kidney, autoimmune disorders such as lupus, and mechanical obstructions and chronic infections of the urinary tract. CKD patients are classified as having progressed to one of five stages, depending on the severity of their condition (CKD stage 1-5). When CKD progresses to its end stage (stage 5), dialysis or kidney transplantation become necessary. CKD currently affects an estimated 26 million American adults, with a far higher number considered at risk. In addition to the significant detriment to the physical, mental, and social health of patients and their families that it poses, CKD comprises a tremendous individual and global financial burden. A common complication of CKD is anemia, which results from inadequate erythropoietin or from iron deficiency as a result of inadequate absorption or mobilization. The management of anemia in CKD patients must strike an appropriate balance between stimulating generation of erythroblasts (erythropoiesis) and maintaining sufficient iron levels for optimum hemoglobin (Hb) production. Erythropoietic stimulating agents (ESAs) mobilize iron stores in promoting erythropoiesis; however, decreased iron stores or iron availability are the most common reasons for resistance to the effect of ESAs. Thus, most patients who receive ESA treatment will require supplemental (oral or intravenous) iron to ensure an adequate response with erythropoietic agents. Iron management, therefore, is an essential part of the treatment of anemia associated with CKD, as there remain outstanding concerns regarding the adverse effects associated with elevated doses of ESAs and supplemental iron. Assessing iron status is integral to both iron and anemia managements in CKD patients. Bone marrow iron stores are often regarded as the best indicator of iron status (although this is not universally accepted); however, taking a bone marrow sample is invasive and involves risks of infection or bleeding at the biopsy site. Other classical iron status tests, of which ferritin and transferrin saturation (TSAT) are the most widely used, reflect either the level of iron in tissue stores or the adequacy of iron for erythropoiesis. Serum ferritin reflects storage iron-iron that is stored in liver, spleen, and bone marrow reticuloendothelial cells. The TSAT percentage value reflects iron that is readily available for erythropoiesis. Guidelines on monitoring iron status stipulate that hemodialysis (HD) patients receiving erythropoietin should have their iron status monitored every 3 months, and maintain a transferrin saturation (TSAT) >20 percent and a serum ferritin level >100 ng/mL (>200 ng/mL for CKD patients on HD). Although a number of international guidelines have examined the use of both classical and new serum iron biomarkers, their recommendations differ. Across guidelines, it is agreed that the optimal management of anemia in HD patients depends on diagnosis and management of iron deficiency. In view of the considerable clinical uncertainty, the high biological variability associated with laboratory biomarkers, and the need for frequent assessment of iron status to guide treatment for anemia, a systematic review of the relevant literature is a priority. The purpose of this review is to evaluate the impact on patient-centered outcomes of the use of newer versus classical laboratory biomarkers of iron status as part of the management strategy for anemia in patients with CKD stages 3–5, that is, nondialysis or dialysis patients with CKD or kidney-transplant patients.

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