



Service to those affected by chronic kidney disease

August 27, 2007

Statement from Lori Hartwell – President, Renal Support Network

On the U.S Food and Drug Administration's Decision to change prescribing information on the use of Aranesp[®], Epogen[®], and Procrit[®]

RSN is deeply concerned that patients will suffer tremendously if the FDA limits the hemoglobin to a level that is below what is currently recommended in the National Kidney Foundation's KDOQI™ guidelines and recommendations. This concern was accentuated by the recent National Coverage Decision for oncology, which determined that treatment of anemia could not be initiated until hemoglobin levels fall below 10 g/dL. Unlike patients with cancer, patients with chronic kidney disease are permanently affected by anemia. As a result, effective anemia management is key to a kidney patient's ability to survive and thrive. People who have kidney disease need to continue to receive effective anemia management so they can attain a hemoglobin levels that ensures that they are able to avoid the constant threat of transfusion and combat the debilitating symptoms of anemia.

I represent a nonprofit organization devoted to helping improve the lives of people with chronic kidney disease (abbreviated CKD). I have lived with CKD for the past 39 years; for twelve of those years I was on dialysis. I currently have a transplant, but am taking an Erythropoiesis Stimulating Agent (ESA) since without it my hemoglobin would be extremely low and it would be impossible for me to continue working and performing the normal activities of daily life. I have witnessed firsthand the evolution of anemia management in the kidney patient population and would like the committee to consider how their decision may affect our daily lives.

Impact of Anemia on Patient Quality of Life

Since the introduction of erythropoiesis stimulating agents (ESA) in 1989, hundreds of thousands of people with Chronic Kidney Disease (CKD) have been spared the risks associated with multiple blood transfusions, and their quality of life and general health have improved markedly. These benefits have been demonstrated in many clinical studies and evidenced by the patients themselves.

In my case, I do not feel "normal" and cannot function as well if my hemoglobin level is below 12.0 g/dl. Many studies have shown that treatment outcomes and quality of life suffer when hemoglobin

An illness is too demanding when you don't have hope!

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levels fall below 11.0 g/dl, and my own experience confirms these data. At a hemoglobin of 11.0 g/dl I tire easily. I become short of breath walking up stairs. I have trouble sleeping, and daily activities become difficult or impossible to perform.

Many people who have CKD can relate experiences of how anemia has affected them personally. Symptoms may include chest pain, feeling cold, feeling tired, low energy levels even doing routine activities of daily living, poor appetite, shortness of breath, depression, a poor sense of well-being, and an inability to work, manage a home, or volunteer –in short, loss of a meaningful life.

I would like to share with you representative samples of what fellow patients have told me regarding how anemia management impacts their quality of life:

“When I was first diagnosed I had to have blood transfusions every month in order to fight anemia. ESA’s did not exist at this time. The introduction of Epogen had a huge impact on my life. It improved my energy level which allowed me to get back to living life instead of just surviving. I was healthier, more productive, and much happier. I was able to complete college, work full time and enjoy life.”

--Heather Powell

“Why is quality of life important? Think of a time when you were very sick, maybe with the flu. Your body was weak, and you didn’t have much energy. Would you like to live your whole life feeling like that, or worse? That’s what it feels like to have a low hemoglobin level. You’re frustrated because you don’t have energy to do the things you want to do. When quality of life decreases, physical and emotional health decrease as well.”

--Shari Gilford

“When I was anemic, I could barely get out of bed and walk to the bathroom. One time I passed out in the bathroom. Quality of life is simply being able to walk without the fear of passing out.”

--Julie Glennon

“When I am anemic, I can’t walk as far as the mailbox, grocery shop, do much housework or find the energy to go to work.”

--Kathe LeBeau

“When Epogen wasn’t available, I spent most of my days in bed or on the couch. If it was a school day, I had to push myself to go to classes and to do my dialysis exchanges. Once I started on Epogen, I was able to get to class and was no longer lethargic. I was able to do my dialysis without any help.”

--Leigh Anne Tanzberger

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“My quality of life was greatly impacted when I was anemic. I could barely walk from one side of the house to the other without sitting down because I was out of breath. I went to school during this time but my husband had to drop me off because I did not have the energy to walk from the parking lot to the classroom without the fear of passing out.”

--Mandy Trolinger

“I have been a patient for over thirty-five years and during my first blood transfusion, I contracted Hepatitis C.”

--Roanne Dale

“If quality of life was not present, I probably would have given up and died.”

--Paul Rauch

“Being anemic impacts my livelihood. My job involves numbers and when I am anemic, I cannot concentrate. If you don’t have a job, it definitely impacts your quality of life!”

--Rhonda Brooks

“Before ESAs and mostly because of anemia, my husband's legs would jerk uncontrollably during sleep, the friction actually causing holes in the bed sheets. He also woke up numerous times each night. Frequently he would comment, 'A good night's sleep! It's been so long, I don't remember what that feels like.’”

--Denise Eilers

Patients visit doctors out of what they sense about themselves (i.e. “how we feel”). We simply have no other way to communicate. The goal is to preserve or regain our quality of life. Quality of life is centered on the foundation of hope and the belief that life is still worth living. To not consider quality of life as a major goal in managing anemia is tantamount to ignoring the patient.

Impact of Anemia on the Risk of Blood Transfusions

Prior to the development of ESA’s, patients with CKD often had extremely low hemoglobin levels and required constant blood transfusions. I still remember vividly when my hemoglobin level began to fall. I became very symptomatic and so weak that I had no desire to participate in any activities. My symptoms were so bad that I couldn’t wait to be admitted to the hospital to receive 2 units of blood. For about the next 12 years I received two units of blood approximately every 6 weeks. My life was like a roller coaster dealing with the severe highs and lows in my hemoglobin. It was dreadful! I had to plan events around my hemoglobin level. To say that my quality of life was drastically impacted is an understatement. As a patient, hemoglobin levels are very black and white to me. If I received a blood transfusion I could go out with my friends and resume my life. If I, like many other patients I knew, was unable to get a blood transfusion or if I was at the end of the time when the transfusion was effective, my life was put on hold.

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For almost two decades we have enjoyed a significant decrease in the need for blood transfusions due to the increase in hemoglobin levels. The RSN is concerned that hemoglobin target levels lower than the 11 to 12 g/dL currently recommended by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative will result in a dramatic increase in the number of patients with low hemoglobin levels, and a consequential increase in the need for blood transfusions. Performing a blood transfusion is like playing Russian roulette with our health. Some patients experience only the less serious side effects from transfusions, such as fever and chills or an allergic reaction, such as hives. However, others have much more serious reactions to transfusions that can have a significant and long-lasting impact on their health, and even increase their risk for mortality.

In addition, blood transfusions can severely affect a patient's ability to receive a kidney transplant. The reactive antibodies received from blood transfusions result in fewer potential kidney matches from donors. I would like to share a representative example from a woman who shared her experience with me. This woman has had chronic kidney disease since she was a small child, and received a number of blood transfusions before ESAs were available. Even though she has not received blood transfusions in some time, the effect of those transfusions continues to haunt her, and she currently has a reactive antibody percentage level of 81. As a result, the number of potential kidney donors that are a compatible match is severely limited. The transplant team at her center is not confident that she will ever find a match within her current region. As a result, they have encouraged her to multi-list at other centers to increase the pool of potential donors. However, she does not have the economic resources or the knowledge to work the system and give herself a better chance for finding a compatible kidney. Although she is doing her best, she is confronting an interminable wait for a matched kidney—she may never receive a transplant. There are thousands of other disadvantaged individuals like her across the country who do not have the economic resources to travel around the country and increase their odds of finding a suitable kidney for transplantation.

We believe that any increase in the need for blood transfusions will significantly increase the percent of patients who experience the debilitating symptoms of anemia; increase the number of patients who will have difficulty receiving a matched kidney transplant (especially among economically poorer patients); and represent a severe setback in the care of patients with chronic kidney disease.

RSN Support's the 2006 Centers for Medicare and Medicaid Services Anemia Management Policy

The FDA's decision will undoubtedly be used by the Centers for Medicare and Medicaid Services (CMS) in deciding their reimbursement policy for the use of ESA therapy in patients with CKD. In the past, we have seen the devastating effects of a punitive reimbursement policy for ESAs. Because hemoglobin levels often vary, clinicians were historically forced to resort to keeping patient hemoglobin levels at the lower end to avoid reimbursement penalties. This practice was changed when the CMS implemented a reimbursement policy for ESA therapy that takes into consideration the considerable and ongoing variations in each patient's hemoglobin. This policy allows the physician to order an ESA dose to achieve a target hemoglobin between 11 and 12 g/dl. The policy acknowledges that there is considerable differences in a patient's response to anemia management,

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and contains provisions for appropriate dose reductions when a patient's hemoglobin exceeds this level.

This policy is unique in that it has melded current science with reimbursement policies, thereby encouraging clinicians to gradually reduce ESA doses rather than holding doses or reducing doses dramatically. This prevents the patients' hemoglobin from plummeting, which has been associated with poorer outcomes and may increase the need for blood transfusions. This is consistent with CMS's policy of patient-centered care, for which patients are grateful—CKD treatment is not an exact science, and CMS appears to understand that there is a delicate balance between research and clinical practice.

Anemia management is an individualized treatment. No two patients respond the same way to ESA therapy— whether they have lost their kidney function and are on dialysis, are pre-dialysis, or have a kidney transplant. Many considerations come into play when managing the anemia of patients with CKD. For example, patients with CKD are much more prone to infection, inflammation, cardiovascular disease, and hospitalization than the general public. In addition, patients on dialysis are frequently in need of surgical procedures to revise or repair their life-preserving vascular access. These factors and many others also affect anemia, and our medical teams do a heroic job of constantly monitoring our laboratory values and adjusting doses of intravenous iron and ESA therapies to ensure that we have the best chance of maintaining an optimal hemoglobin level. No two patients are alike or respond the same way to treatment. We must ensure that physicians are able to treat us as individuals and address our symptoms on an individual basis.

The hemoglobin level of 11 to 12 g/dL that is currently recommended by KDOQI™ and supported by the CMS anemia management policy gives patients and clinicians some latitude in the treatment of anemia so that if we experience an infection, need to be hospitalized, or lose additional blood during dialysis we are not as threatened by a poor quality of life or the risk of receiving blood transfusions. It is vital that this policy be continued so that patients with kidney disease are not continually kept on the verge of needing a blood transfusion while experiencing a decrease in our quality of life. In the past, many of us have had the misfortune of living with lower hemoglobin levels and the constant threat of blood transfusions —those of us who remember the “bad old days” know what a blessing (and necessity) it is to live with higher hemoglobin levels.

Recommendations

To conclude, I would like to thank the FDA for constantly monitoring the safety of our drug products and taking patient concerns into consideration. I would like to emphasize that I am not downplaying the safety results of the trials that have been published. All drugs carry risks, and patients deal with these risks everyday in every facet of medicine. We are reminded of the risks of taking medication every time we see or hear a commercial on TV, or talk with our health care team. There are still a lot of questions about anemia management and the effect of ESA therapy, and more studies need to be conducted to clarify these issues.

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However, patients are also acutely aware that the potential risks associated with drug therapy need to be weighed against the benefits. I would like to reiterate that anemia is one of the most devastating conditions that affect those of us who have CKD. As a result, we recommend that the FDA should not mandate an arbitrary hemoglobin level for patients with CKD, and that physicians should retain the ability to individualize ESA therapy in response to an individual patient's needs. If these therapies are restricted, and the patient is consequentially forced to lead a lower quality of life, it begs the question of why that patient is being kept alive in the first place!

Thank you again for considering the patients' perspective in your policy decisions. Please feel free to call upon the Renal Support Network at any time if you have questions.