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**Re: COMMENT ON PROPOSED NATIONAL COVERAGE  
DETERMINATION LANGUAGE ON ESAs**

The Renal Support Network (RSN) is a nonprofit, patient-focused, patient-run organization that strives to help patients develop their personal coping skills, special talents, and employability by educating and empowering them, as well as their family members, to take control of the course and management of the disease.

I am writing to you as the President and Founder of the Renal Support Network and as a patient who has lived with chronic kidney disease (CKD) for over 39 years. Specifically, I would like to provide the patient's perspective on the following statement on erythropoiesis stimulating agents (ESAs) that is proposed in the national coverage language:

Proposed: ESAs have known serious adverse effects in patients who have cancer or pre dialysis chronic kidney disease (CKD). Their long term benefits and harms in the ESRD population are unclear. ESAs are a large cost in current ESRD treatment strategies.

The Renal Support Network respectively contests the statement that the long-term benefits of ESA therapy are unclear. To the contrary, as patients who live with CKD we believe that the clinical literature as well as our own personal experiences refutes this proclamation. Let me begin by discussing how ESA therapy has demonstrated a long-term patient benefit in reducing or eliminating blood transfusions for the vast majority of patients with Stage 5 CKD who are on dialysis.

Prior to the development of ESA's, patients with CKD who were on dialysis often had extremely low hemoglobin levels and required constant blood transfusions. A wide range of significant and potentially serious side effects accompanies blood transfusions, including iron overload and infection. People seem to forget that, when blood transfusions were widely used before the introduction of ESAs, iron levels would often be so high that clinicians were forced to phlebotomize (bleed) patients to drain off excess iron. Transfusions

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

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also cause a tremendous drain on the patient due to many factors, such as: (a) the constant variability (up and down changes) in hemoglobin that occurs between blood transfusions (negatively affecting patient quality of life), (b) the need for extra visits to a doctor's office or clinic to receive a blood transfusion (negatively affecting patient quality of life), and (c) the need to actually suffer through the transfusion process (trust me, not a pleasant experience and negatively affecting patient quality of life). Blood transfusions are 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 had CKD since she was a small child, and received a number of blood transfusions before ESAs were available. Although she had not received blood transfusions in some time, the effect of those transfusions continued to haunt her, and as recently as a few months ago she had a reactive antibody percentage level of 81. As a result, the number of potential kidney donors with which she was a compatible match was severely limited. The transplant team at her center was not confident that she would ever find a match within her region. As a result, they encouraged her to multi-list at other centers to increase the pool of potential donors. However, she did 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 was doing her best, she confronted an interminable wait for a matched kidney. Sadly, this woman's condition continued to deteriorate, and she recently died before being able to receive a compatible kidney 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.

For almost two decades we have enjoyed a significant decrease in the need for blood transfusions due to the benefits that ESAs provide in increasing hemoglobin levels. The RSN is concerned that any change in the policy on how ESAs should be used—and especially a statement discounting all benefits—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. 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 disadvantaged patients); and represent a severe setback in the care of patients with CKD.

One final point on transfusions: Although our organization's focus is on patient's with CKD, we also believe you should consider how the erroneous statement that there are no clear benefits of ESA therapy could negatively affect not only our patient population, but also the country's blood supply. Before ESAs were available patients on dialysis used a significant percentage of the nation's

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blood supply. Over the intervening years, the number of patients on dialysis has more than tripled, and the population is projected to continue to grow in the future. As part of the evaluation CMS should consider how a return to the pre-ESA days of constant blood transfusions may challenge the country's already overtaxed blood supply, including the availability of blood for patients with critical emergencies.

The second benefit of ESA therapy that we would like to address is how these medications have benefited the quality of life for patients with CKD. We realize that there are not many double-blind studies that have addressed this issue. Further, no such studies are likely to be conducted since it would be unethical to withhold ESA treatment from patients just to see how they feel with or without therapy. In this case, we believe that common sense should prevail. There are thousands of reports from patients who have stated that their quality of life improves dramatically following use of ESAs. We strongly believe that if you ask people who had CKD before the availability of ESAs to self-report on whether ESAs have positively affected their quality of life you would hear a resounding—YES.

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. Let me provide you with a few examples, starting with my own. I vividly remember 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. 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.

I believe that my experience is very representative of the patient community, as evidenced by the following quotes from Renal Support Network members:

“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 EPO 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

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frustrated because you don't have energy to do the things you want to do. When quality of life decreases, physical and emotional health decreases 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 EPO 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 EPO, 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

"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

"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

We believe that these brief quotes are representative of hundreds of thousands of patients with CKD who currently enjoy the quality of life benefits provided by higher hemoglobin levels subsequent to ESA therapy. When drafting your policy, please recall that 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 the same as simply ignoring the needs of patients.

RSN is deeply concerned that patients will suffer tremendously if the draft statement on use of ESAs is not altered to more accurately reflect the potential benefits of therapy. As currently worded, the draft statement may inadvertently lead to insurance providers limiting or eliminating

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coverage for ESA therapy. This concern is accentuated by the severe decrease in ESA use that has resulted from the recent National Coverage Decision for oncology.

Unlike patients with cancer, patients with CKD are permanently affected by anemia, and we have experienced first hand the devastating effects of a punitive reimbursement policy for ESAs. When reimbursement policies are not well thought out and tested, it is the patient who suffers. To avoid such a scenario, the Renal Support Network supports the 2006 Centers for Medicare and Medicaid Services Anemia Management Policy, which follows recommendations found in both the prescribing information and the guidelines of the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI™). This policy allows physicians to order an ESA dose to achieve a target hemoglobin between 10 and 12 g/dL. The policy correctly acknowledges that there are considerable differences in how different patients respond to ESAs, and contains provisions for appropriate dose adjustments based on hemoglobin levels.

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 levels 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 has demonstrated an understanding of the fact that there is a delicate balance between research and clinical practice.

We would like to emphasize that we are not downplaying the safety concerns highlighted by clinical trials that have been published on the use of ESAs. However, 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. 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 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, one wonders why that patient is being kept alive in the first place! It is existing, not living.

Finally, the Renal Support Network acknowledges the portion of the draft statement that addresses the expense of ESA therapy, and recognizes the need to conserve healthcare resources whenever possible. However, we urge CMS to review the patient holistically, and not just the cost of a single medication. When viewed from this perspective, we believe that the benefits of ESA therapy are clear. We respectfully request that any policy change does not unintentionally lead to decreased patient access to medications that are crucial to our quality of life.

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Thank you again for considering the patients' perspective. Please feel free to contact me at any time if you would like assistance in developing the final policy from patients who have experienced anemia firsthand.