



Service to those affected by chronic kidney disease

Lori Hartwell  
*Founder/President*

December 6, 2021

Wendy Rodgers, M.Ed, MPH  
*Chairman of the Board*

The Honorable Xavier Becerra  
Secretary, Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Lana Kacherova, RN  
*Treasurer*

**Re: Patient Access to and Adequate Reimbursement for Innovative ESRD Treatment, KORSUVA**

Joanna Galeas Lee  
*Secretary*

Dear Secretary Becerra,

**Board Members:**

Lubna Akbany, RD  
Kathleen Baldwin, PhD  
Marlene De Vera, RN  
Joanna Galeas Lee  
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Dean Hartwell, JD  
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Wendy Rodgers, M.Ed, MPH  
James Troyer, MS, EMBA, MPA  
Rafael Villicana, MD  
Susan Vogel, MHA, RN, CNN

Renal Support Network (RSN) is a nonprofit patient organization dedicated to helping improve the lives of people living with kidney disease. As RSN President / Founder, it is my goal to give people living with chronic kidney disease (CKD) tools to take control of the course and management of this life-threatening illness. I have lived with CKD since 1968 (when I was two years old) and have witnessed firsthand the evolution of the End Stage Renal Disease (ESRD) program. I was on dialysis for 13 years and now am doing well with my 4<sup>th</sup> kidney transplant.

Innovation has been the cornerstone of my survival and well-being. I, along with our members, have greatly benefited from the Medicare End-Stage Renal Disease Program. We are elated that innovation is a priority of this administration, with the Center for Medicare and Medicaid Innovation to the NIH funding that has stimulated new products to come to market to help people who have kidney disease.

I am writing in hopes that the reimbursement pathway system can be corrected to help people on dialysis have access to a new product. Specifically, there is now a breakthrough product for people who have CKD-associated pruritus. Itching is a very serious problem and people suffer greatly from this condition. It's an inside itch from which there is no relief, and it can lead to sleep disturbances and skin injury and infection due to scratching. The FDA recently fast-tracked and approved the drug KORSUVA which is the first and only FDA-approved product to treat chronic kidney disease associated pruritus.

KORSUVA, an FDA-designated breakthrough product, is the first to effectively treat CKD-associated pruritus, which affects up to 40% of CKD patients. Without access to KORSUVA, patients, if treated at all, are given primarily antihistamines like Benadryl. Antihistamines, however, are not effective since this type of itching is not histamine mediated. For me, Benadryl just made me very tired and my skin drier, which didn't help the problem.

An illness is too demanding when you don't have hope!  
– Lori Hartwell, RSN Founder and President

## Renal Support Network

Since the ESRD payment system is bundled, the Center for Medicare and Medicaid Services recognizes the importance of incentivizing new therapies so companies will invest and bring products to market to improve lives and outcomes.

The Medicare ESRD transitional drug add-on payment adjustment (TDAPA) was created to help patients have access to new therapies. Our members were thrilled when the CMS recognized the need to address this serious gap, as payment drives practice. There are a few issues that need to be addressed with CMS to ensure the payment policy is transparent and allows people to have access to this new therapy:

- CMS needs to commit when it awards TDAPA to assessing the value of this drug for the treatment of ESRD patients, and if appropriate, adjust the base rate once the TDAPA period ends.
- The current functional category for anti-pruritics does not include a drug like KORSUVA and is instead based on antihistamines and corticosteroids. There is effectively no money in the base rate for this category based on CMS's own data. Benadryl is an antihistamine and only pennies per treatment.
- CMS also needs to clearly communicate how it intends to assess the ESRD payment base rate once the TDAPA period for KORSUVA ends. Only in this way can we be assured that there will be sufficient money in the bundle for facilities to provide appropriate patient access to the product during and after the TDAPA period.
- CMS should follow the FDA's lead and make sure that it expedites review of KORSUVA. It should not delay awarding TDAPA or signaling the post-TDAPA assessment. Patients need access to this product.

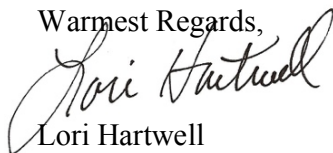
We need your help to make sure that CMS payment policy does not create barriers to patient access.

KORSUVA is the first new product to test the TDAPA payment method. We need to get it right. Companies will not invest in this space if a product that is truly innovative for people who have CKD does not make it as the payment policy falls short.

We ask that KORSUVA receives the ESRD transitional drug add-on payment adjustment, and TDAPA payment policy is adjusted to allow new innovations a pathway so people who need new treatment options have access to them.

Please let me know if you have any questions. Thank you.

Warmest Regards,



Lori Hartwell  
President/Founder

cc: The Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services  
The Honorable Jonathan Blum, Principal Deputy Administrator  
The Honorable Meena Seshamani, Deputy Administrator and Director of the Center for Medicare