National Kidney Foundation®

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October 26, 2018

Kimberly Canady, RN
North Carolina Department of Health and Human Services
1985 Umstead Drive, Kirby Building
Raleigh NC 27603

Via email: kimberly.canady@dhhs.nc.gov

RE: Medicaid and Health Choice Clinical Coverage Policy No: 1A-34, End Stage Renal Disease (ESRD) Services

Dear Ms. Canady,

Thank you for the opportunity to provide input on Medicaid and Health Choice Clinical Coverage Policy No: 1A-34, End Stage Renal Disease (ESRD) Services in advanced of proposed changes. The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI). In North Carolina, we reached over 900 current patients and members of the public through free education and screening opportunities last year and gathered to celebrate kidney health with another 1,500+ patients, caregivers, friends, family, and healthcare professionals at Kidney Walk events across the state.

Innovation and Access to New Therapies

Important in any regulatory policy is ensuring that patients have access to the care and medications they need and that allow them to live high-quality lives. As new medications become available for dialysis patients it is important that North Carolina Medicaid and NCHC have a pathway to include coverage of those medications. As an example, late last year etelcalcetid (J0606) was approved to treat hyperparathyroidism (HPT) in dialysis patients, but is not included in this current coverage policy. Innovation in new medication for ESRD patients has been slow, when compared to other conditions. It is critical to spurring innovation and ensuring that patients have access to breakthrough therapies that coverage policies have a process built in that allows for timely review and coverage of new therapies.

Transportation

For patients who receive treatment in a dialysis clinic access to transportation is critical and helps ensure that patients do not miss treatments. Other states provide coverage for transportation to dialysis under Medicaid and we suggest the Department of Health and Human Services (DHHS) also consider revising the ESRD coverage policy to allow for coverage of transportation to dialysis. If dialysis patients encounter problems keeping appointments because of transit demands, missed or shortened treatments may result.

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Compared with other dialysis patients, those who missed one or more dialysis sessions in a month had a 25% higher risk of death. Patients who shortened three or more dialysis treatments in a month had a 20% higher risk of death than those who received the prescribed treatment.[1] Additionally, patients who miss dialysis treatments may need to seek expensive care in hospital emergency departments. DHHS may also want to consider revising the coverage policy to allow for coverage of caregiver assisted home dialysis to create greater opportunities for patients to receive dialysis at home.

Access to Home Dialysis and Reimbursement for More Frequent Dialysis

The National Kidney Foundation believes more is needed to encourage access to home dialysis and alternative frequencies of dialysis delivered. We appreciate that DHHS allows for coverage of training and retraining for home dialysis modalities separately from the composite rate as appropriate training is critical to improving patients' confidence and persistence on a home modality. Additional steps could be taken to remove barriers to home dialysis. In late 2017 the National Kidney Foundation held a KDOQI Home Dialysis Controversies conference that culminated in the development of workgroups to establish recommendations to address barriers that hinder increased home dialysis use. Barriers noted at the conference included lack of coverage for caregiver assisted home dialysis and lack of availability and training to start patients on peritoneal dialysis when patients present to the hospital in need of urgent dialysis. These are areas where DHHS could adopt coverage policies that would promote greater use of home dialysis.

The National Kidney Foundation also requests that DHHS allow for the reimbursement of more than three times per week hemodialysis when necessary. The 2015 updated KDOQI Hemodialysis Adequacy Guideline, promoted shared decision-making as many of the recommendations call for considering different durations of dialysis, including more frequent dialysis, and informing patients of the risks and benefits of the different types of dialysis available. There are also clinical reasons as to why more frequent dialysis may be necessary for some patients[2] and the coverage policies should allow for this. However, we recognize that reasonable limitations are needed to ensure appropriate payments are made. The National Kidney Foundation and the KDOQI steering committee would be happy to work with DHHS to help define reasonable parameters around conditions where reimbursement for extra dialysis treatments is necessary.

Additionally, some innovative CKD care management programs are showing that patients who receive earlier diagnosis, appropriately timed referral and care by nephrologist, and education that promotes shared decision making about their treatment options are more likely to select and persist with home dialysis over in-center therapy.[3,4] The National Kidney Foundation believes an increased focus on early CKD payment reform is necessary to encourage cost-effective and improved ESRD care. Unfortunately, the current payment system does not adequately support the earlier care needs of patients.

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[1] J.E. Leggat, et al, Noncompliance in Hemodialysis: Predictors and Survival Analysis, *Am J. Kidney Dis*. 1998 Jul;32(1):139-45.
[2] KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update Am J Kidney Dis. 2015;66(5):884-930.
[3] Fishbane, Steven, et.al, Augmented Nurse Care Management in CKD Stages 4 to 5: A Randomized Trial, Am J Kidney Dis. 2017;70(4):498-505.
[4] Johnson, Douglas, et.al, Going Upstream: Coordination to Improve CKD Care, Seminars in Dialysis, published online January 14, 2016 https://onlinelibrary.wiley.com/doi/full/10.1111/sdi.12461.

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Innovation in Payment Models to encourage earlier kidney care

As North Carolina DHHS is an innovator in testing new Medicaid reforms, we offer the following recommendations on how to improve the care of individuals with CKD who are not on renal replacement therapy. The National Kidney Foundation has developed an alternative payment model to improve earlier detection of CKD and care of patients. The final recommendations presented to the Center for Medicare and Medicaid Innovation (CMMI) at the end of September 2018 would allow PCPs and nephrology practitioners to form physician-led and patient-focused CKD seamless care organizations. Named after the National Kidney Foundation's CKDintercept initiative, the CKDintercept organizations (CKDI-O) would receive per-beneficiary per-month payments (PBPM) for the management of CKD stages 3 through the transition to ESRD. This fee is intended to help support implementation of a multi-disciplinary care team to help with care coordination, remote monitoring, nutrition, medication management, and care transitions. A Performance-based Incentive Payment (PBIP) would also be available, contingent on performance of CKD-related quality measures and lowering CKD-related expenditures.

In alignment with the Centers for Medicare & Medicaid Services' (CMS) goals to provide practitioners with opportunities to receive credit and bonuses for participating in advanced APMs (AAPMs), CKDI-Os would take on downside risk beginning in year two of the model. Patient attribution in the model would be prospective assignment of beneficiaries based on plurality of primary care or nephrology claims to providers in the CKDI-O. Beneficiaries would also be allowed to voluntarily opt in by self-selecting a participating provider. Participation would be contingent on an appropriate percentage of the practitioner's attributed diabetic and hypertension population receiving testing for both eGFR and Albumin to Creatine Ration (ACR) in alignment with the KDOQI guidelines.

CKDI-O providers would also need to participate in practice transformation activities, which is common for other AAPMs. Recommended activities include integrated mental health, nutrition counseling, advanced care planning, development of patient and family advisory councils, and use of shared decision-making tools.

As DHHS is already exploring new models of care for special populations, we believe testing this model in CKD care would produce improved quality of care for patients, slow progression to ESRD, promote early wait-listing and kidney transplantation in those who progress, and substantially lower healthcare costs. We would be happy to further discuss this model with the Department and Physician Advisory Group.

The National Kidney Foundation greatly appreciates the opportunity to provide early comments as DHHS considers updates to its coverage policy for ESRD services. If you have any questions please contact Tonya Saffer, Vice President, Health Policy at tonya.saffer@kidney.org.

Sincerely,

Rob Hayden
Executive Director
NKF Serving North Carolina