



National
Kidney
Foundation®

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Leland E. Garrett M.D
Palmetto GBA, LLC
17 Technology Circle
Columbia, South Carolina 29203

April 21, 2020

Dear Dr. Garrett,

The National Kidney Foundation (NKF) appreciates the unprecedented flexibilities that the Centers for Medicare and Medicaid Services (CMS) has offered patients during this national public health emergency. Patients affected by kidney disease are at special risk of morbidity and mortality secondary to Covid-19 infection due to underlying vulnerabilities and the settings in which they receive care. We encourage Palmetto GBA to exercise every possible flexibility during the PHE to ensure the safety of some of our society's most vulnerable patients.

Immunosuppressive Coverage

We were heartened to see the guidance of March 5, 2020 that gives Medicare Administrative Contractors or MACs the flexibility to pay for greater-than-30-day supply of Part B drugs. According to the guidance, these decisions should consider relevant factors associated with determining whether an extended supply of a drug is "reasonable and necessary," such as a patient's diagnosis and the nature of the Part B drug.¹ We are writing to express our concern that not all kidney transplant recipients, the majority of whom receive their immunosuppressive drugs through Part B, are being granted access to 90-day supplies of these vital prescriptions. Improved access to immunosuppressive drugs is an example of a Medicare service that is "reasonable and necessary" to protect patients during the Covid-19 crisis and that is aligned with CMS' intent for the guidance. NKF is disappointed to learn that greater-than-30-day supply requests are not always being granted by the MACs. It is critically important that transplant recipients can access a 90-day supply of their immunosuppressive medications during this public health crisis. We strongly encourage your organization to ensure that transplant recipients have access to multiple months' supply of the drugs needed to maintain the health of their kidney transplants.

Virtually all kidney transplant recipients rely on immunosuppression to maintain their transplants and so are at especially high risk of contracting Covid-19. The ability of these patients to social distance and avoid areas where transmission of Covid-19 is especially likely, such as hospitals and pharmacies, is paramount. Access to their immunosuppressive regimen is non-negotiable for transplant recipients who

¹ https://www.cms.gov/files/document/03052020-medicare-covid-19-fact-sheet.pdf?fbclid=IwAR3NifSYLLtev-KflpFvnEy0BZhjKevJ-HOTU6eQApbMd_mNSAZ76YCLoZE

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rely on a specific combination of glucocorticoids (primarily oral prednisone), azathioprine, mycophenolate mofetil (MMF), enteric-coated mycophenolate sodium (EC-MPS), cyclosporine (in nonmodified or modified [microemulsion] form), tacrolimus, everolimus, rapamycin (sirolimus), and belatacept to preserve their transplants and their lives.

NKF acknowledges that some pharmacies are reticent to fill multiple months of supply due to concerns about drug shortages. We encourage Palmetto GBA to allow for payment of multiple months of supply, understanding that not all pharmacies will request it, though NKF is engaged in conversations with federal government stakeholders to ensure there is confidence in the global drug supply chain. We also acknowledge that while some Medicare beneficiaries who rely on immunosuppressive medications may be able to access them by mail order, this is not possible for all patients. The ideal solution is simply to ensure that transplant recipients do not need to visit a pharmacy or manage the vagaries of monthly mail order deliveries for these lifesaving drugs during a pandemic where they are at special risk.

Transportation

Even in times where the healthcare system is not under exceptional strain, transportation is a significant concern for patients with end-stage renal disease (ESRD) who rely on outpatient dialysis to stay alive. Many, though not all, ESRD patients are “dual eligible” meaning that they can access non-emergency medical transport (NEMT) through their state Medicaid program. Unfortunately, during the Covid-19 crisis, NEMT providers are declining to transport patients who are Covid-19 positive or who are displaying respiratory symptoms due to fears about transmission. MACs do have the authority to pay for ground ambulance transport when it is “medically necessary and reasonable.” We strenuously believe that Palmetto GBA should consider temporarily interpreting this language to include Covid-19 positive dialysis patients and patients under investigation. For the small number of dialysis patients who will be able to access ground ambulance transport as a last resort during the PHE, it will be live saving.

NKF would be pleased to discuss these issues further at your convenience. If there are concerns about filling 90-day prescriptions of immunosuppressive drugs or about temporarily reimbursing for ambulance transport for dialysis patients, we would welcome the opportunity to share our perspective on why the benefits to patients affected by kidney disease during this time dramatically outweigh the risks to patients and the Medicare program. Please contact Miriam Godwin (miriam.godwin@kidney.org).

Sincerely,

Kevin Longino

Kevin Longino
CEO and transplant patient

Holly Mattix Kramer

Holly Mattix Kramer, MD, MPH
President