

# Chronic Kidney Disease and Medicare

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## ABSTRACT

**BACKGROUND:** Since 1972, Medicare has covered the cost of end-stage renal disease (ESRD). Consequently, Medicare pays a large proportion of ESRD's costs. However, before implementation of Medicare Part D, employer health plans paid most ESRD-associated prescription costs. The ESRD population faces significant hurdles when using the new Part D benefit. To understand those challenges, a basic understanding of Part D is needed.

**SUMMARY:** Medicare Part D has unique implications for chronic kidney disease (CKD) populations (dialysis, kidney transplant, and CKD patients not on dialysis). Approximately 405,000 ESRD patients were eligible for Part D coverage in 2006. Drug coverage is available for many drugs via Medicare Part B or Part D; however, the Medicare Part B and Part D medication coverage divide is confusing to most clinicians, including pharmacists. Many ESRD patients fall into the dual-eligible category—they are covered by both Medicare and Medicaid. These patients now receive their medications through Part D and must enroll in a prescription drug plan (PDP). However, many PDP plans may not have the drugs that were covered in state-sponsored Medicaid programs. Dialysis-specific issues also abound because of the high-cost, high-use medications needed to treat the numerous comorbid conditions (diabetes, hypertension, anemia, bone and mineral metabolism disorders, and cardiovascular disorders) that flourish in the ESRD population.

**CONCLUSION:** Managed care demonstration projects are underway to better understand if enrolling these patients into managed care plans with disease management models (i.e., special needs plans) can provide quality care in an effective and efficient manner. Screening patients at high risk for kidney disease, identifying patients with early kidney disease, preventing progression to ESRD, and effectively managing comorbid conditions may reduce long-term medical costs and maintain work productivity. Health care providers need to make an active effort to help CKD patients select kidney-friendly formularies. Medicare requires medication therapy management (MTM) services for certain beneficiaries (called "targeted beneficiaries") enrolled in PDP plans to improve medication optimization. Approximately 80% of the typical ESRD population has more than 2 targeted comorbidities. Thus, many ESRD patients should be targeted for MTM services, a task that represents an opportunity for pharmacists.

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Since 1972, Medicare has covered the cost of end-stage renal disease (ESRD). Regardless of age or disability, most patients who have ESRD, including dialysis and transplant patients, are eligible for Medicare benefits beginning in the 4th month after diagnosis. The exception is patients who undergo home (peritoneal) dialysis; patients who begin training for peritoneal dialysis can enroll in Medicare in the first month after ESRD diagnosis. Consequently, Medicare pays a large proportion of ESRD's costs.<sup>1,2</sup>

Employer group health plans (EGHPs) are paying an increasing proportion of ESRD costs. In 1997, the 18-month Medicare coordination period for ESRD patients enrolled in EGHPs was extended to 30 months. During the first 3 months (waiting period), the EGHP is typically the primary payer for these ESRD patients. Starting in the 4th month, Medicare becomes the secondary payer. Thus, for 30 months, coverage overlaps and is coordinated. If the patient is still employed, the situation reverses; Medicare becomes the primary payer, and the EGHP becomes the secondary payer.<sup>1,2</sup>

The kidney transplant population (patients who do not receive hemodialysis or peritoneal dialysis as their first option) is addressed differently. In transplant patients, Medicare coverage can begin during the month that the patient's kidney is transplanted. However, Medicare coverage ends 36 months after a successful transplant, and the patient's employer group health insurance resumes if the patient is employed. Medicaid or other medical assistance programs cover patients who are unemployed unless they qualify for Medicare benefits by virtue of age or disability.<sup>1,2</sup>

Medicare Part D has unique implications for chronic kidney disease (CKD) populations (dialysis, kidney transplant, and CKD patients not on dialysis). Beginning January 1, 2006, a plan covering prescription drugs, Medicare Part D, has been available for all beneficiaries who have either Medicare Part A (hospital insurance) or Part B (medical insurance). This prescription drug coverage differs from discounts that were offered by the Medicare-approved drug discount cards in 2004 and 2005. In 2005, approximately 90% (N=306,860) of dialysis patients and 69% (N=98,717) of transplant patients were covered by Medicare, either as a primary or secondary insurer. Thus, approximately 405,000 ESRD patients were eligible for Part D coverage in 2006.<sup>3</sup>

## Part D's Drug Expenditure Impact

Before implementation of Medicare Part D, employer health plans paid most ESRD-associated prescription costs. Annually, the Centers for Medicare & Medicaid Services (CMS) conducts a Medicare Beneficiary Survey, examining about 12,000 Medicare patients; a small segment of those patients have ESRD. Patel and colleagues looked at this data to estimate the impact of the standard Part D benefit on drug expenditures.<sup>4</sup> They excluded

adults who were dually enrolled in Medicaid, resulting in 41,617 study subjects, of whom 256 had ESRD. They projected that in 2006, ESRD beneficiaries would have mean annual total and out-of-pocket expenditures approximately twice that of their Medicare peers. Of note, about 28% of ESRD patients (n = 134,412) in 2005 were dually eligible for both Medicare and Medicaid, and all of these patients should have been enrolled in a Part D plan automatically if they had not chosen a plan.<sup>3</sup>

In terms of Medicare Part D, Medicare has specific rules for ESRD patients. There are 2 types of Medicare Part D plans: a Medicare Advantage Part D plan (called a MAPD) and a stand-alone prescription drug plan (called a PDP). In most cases, dialysis-dependent patients are allowed to join only a PDP. The only exception is if a Medicare Advantage (MA) plan (also called a Medicare health plan) is called a “special needs plan” and accepts people on dialysis. Patients who are already enrolled in an MAPD when diagnosed with CKD can remain in their plan. Several studies are underway to scrutinize this situation, with an eye toward policy change in the future. New kidney transplant patients can enroll in MA plans as long as they do not need dialysis and they meet Medicare eligibility criteria.<sup>1</sup>

A recent survey conducted by the American Kidney Fund estimates that about 51% of ESRD patients have enrolled in Part D, and the data suggest that the ESRD population faces significant hurdles when using this benefit.<sup>5</sup> To appreciate those challenges, a basic understanding of Part D is needed.

Under a standard Part D plan in 2007, patients pay a deductible of about \$265. Once they have reached the deductible for prescription drugs, they pay as follows:

- Twenty-five percent of yearly costs for covered drugs from \$265 to \$2,400. Part D pays 75%.
- One hundred percent of costs for covered drugs from \$2,401 to \$5,451.25 (i.e., beneficiaries pay up to \$3,850 in out-of-pocket costs [“donut hole” or coverage gap]).
- Five percent of costs for covered drugs (or a copayment of \$2 or \$5), whichever is more, for the remainder of the calendar year (catastrophic coverage).

In the donut hole, patients become responsible for up to \$3,850 in out-of-pocket expenses. Medicare Part D covers mainly oral prescription drug costs.<sup>6</sup> CMS has identified 6 categories of special drugs for which PDPs must cover “all or substantially all” drugs (Table 1).

Medicare also excludes some drugs for anorexia; weight loss; weight gain; infertility; cosmetic purposes, like hair growth; cold and cough medicines; nonprescription or over-the-counter products; barbiturates; benzodiazepines; and vitamins and minerals (except prenatal vitamins and fluoride preparations). The National Kidney Foundation (NKF) helped successfully lobby CMS to recognize that active vitamin D analogs are essential to treat bone disease in these patients. Active vitamin D analogs (those that do not rely on activation by the kidney, such as calcitriol, doxercalciferol, and paricalcitol)

**TABLE 1 Medicare Part D Covered Drugs**

A PDP must cover “all or substantially all” of the following:

- Cancer medicines
- HIV/AIDS drugs
- Antidepressants
- Antipsychotics
- Anticonvulsants
- Immunosuppressants (unless covered by Part B)

Note: The PDP may not cover every brand name or all doses.  
PDP = prescription drug plan.

are now also covered under Part D plans. Kidney-related vitamins (special blends of vitamins that have been formulated specifically for dialysis patients) and oral iron are not covered under Part D. Unfortunately, benzodiazepines are also not covered, although dialysis patients often need benzodiazepines for anxiety or restless leg syndrome, which are pervasive problems.<sup>7</sup> The so-called “enhanced plans” may cover some excluded drugs, but the premiums are higher for these plans compared with standard plans. It is important to understand that many PDPs do not follow the standard plan template. For instance, many PDP plans waive premiums; others provide generic products during the gap period.

**Specific Medication-Related Issues in CKD Patients Under Part D**

**Erythropoiesis-Stimulating Agents, Vitamin D, and Iron**

Erythropoiesis-stimulating agents (ESAs) are the most costly drugs paid by Medicare in the ESRD population. Most dialysis patients are covered by Medicare Part A and B and thus are eligible for Medicare Part D. However, Medicare Part D does not cover ESAs for ESRD patients; ESAs are covered by Medicare Part B. This coverage divide is confusing to most clinicians, including pharmacists. Medicare Part B covers separately reimbursable medications given during dialysis, including ESAs, intravenous active vitamin D, or intravenous iron products. Part D also does not cover oral iron products that are used to manage anemia along with ESAs in peritoneal dialysis patients.<sup>8</sup>

In CKD patients who are not yet on dialysis, Part B may pay for ESAs if the CKD patient is Medicare-eligible due to age or disability. Unlike ESRD, CKD alone is not a condition that creates Medicare eligibility. Medicare beneficiaries may have Part B coverage, but the coverage depends on the fiscal intermediary and the criteria it establishes. Many fiscal intermediaries require a diagnosis of anemia or CKD ICD-9-CM (*International Classification of Diseases, Ninth Revision, Clinical Modification*) codes for patients to be eligible. In addition, they generally will stipulate a certain hemoglobin level. Some also require specific

serum creatinine or glomerular filtration rate cutoffs for ESA coverage. If Medicare Part B does not cover ESAs, a Part D plan could cover ESAs; in fact, most PDPs include ESAs on their formularies, but they may place them in their formularies' more costly tiers and require prior authorization.<sup>8</sup>

Medications excluded from Part D can be problematic for CKD patients. Although oral active vitamin D products are covered, precursor vitamin D products are not. In CKD patients who have enough kidney function to activate vitamin D, precursor products are appropriate and less costly to treat bone disease. Ergocalciferol, which is recommended by Kidney Disease Outcomes Quality Initiative (KDOQI) practice guidelines, is not covered by Part D. This is also true for oral iron products, such as ferrous sulfate, which are used along with ESA therapy to treat anemia in peritoneal dialysis patients and in CKD patients who are not on dialysis.<sup>9</sup>

### Dual-Eligible Issues

Many ESRD patients fall into the dual-eligible category; that is, they are covered by both Medicare and Medicaid. About 28% of ESRD patients (transplant and dialysis) were dually enrolled in 2005; the number of dual eligibles has risen substantially from approximately 100,000 patients in 1999 to nearly 135,000 patients in 2005. Before 2006, patients who were dual eligible received their medications through state-funded Medicaid programs. Following Part D implementation, these patients now receive their medications through Part D and must enroll in a PDP plan. However, many PDP plans may not have the drugs that were covered in patients' state-sponsored Medicaid programs. Dialysis providers need to make an active effort to help patients select kidney-friendly formularies.<sup>3</sup>

### Kidney Transplant-Specific Issues

The majority of kidney transplant patients are Medicare beneficiaries. If the patient has a Medicare-covered transplant, immunosuppressants are covered under Part B for at least 36 months. After 36 months, Part B will continue to pay if the patient has age- or disability-based Medicare coverage. In the circumstance where the patient does not have a Medicare-covered transplant but then becomes eligible for Medicare due to age or disability, immunosuppressants will be covered under Part D, and Part D formularies are required to cover "substantially all" immunosuppressants.<sup>2</sup>

Consider the case example of a transplant patient who resides in Minnesota. He had 2 Medicare-covered transplants in the 1980s. He shifted out of Medicare to employer group health insurance 36 months after his second successful kidney transplant. About 3 years later, he became a Medicare beneficiary again when he became disabled. He recently reached his 65th birthday, and his wife wonders if he should sign up for Medicare Part D. To determine the best course of action, his pharmacist helped his wife enter his medications with com-

plete dosing information into Medicare's Compare Medicare Prescription Drug Plans at [www.Medicare.gov](http://www.Medicare.gov) (also called the Formulary Finder for Prescription Drug Plans, available at <http://formularyfinder.medicare.gov/formularyfinder/selectstate.asp>). For immunosuppressants, he was prescribed Cellcept, 500 milligrams, twice a day (which is a proprietary drug) and generic cyclosporine.

The Medicare Prescription Drug Plan Finder identified 51 plans in Minnesota that would match this patient's need. Table 2 compares Option 3, a low-cost plan costing \$4,300 a year, with 2 other plans that also cover generics in the donut hole period. The monthly costs range from a high of \$110 a month to a low of \$39.50 a month, and none of the 3 have deductibles.

This patient's medication costs in the initial coverage period before reaching the gap will be considerable, and the Cellcept will account for a large portion of the cost in 2 of the plans. The variability from plan to plan can be significant, and patients must analyze these differences and nuances. Once they enter the gap and become responsible for most of their medication payment, their costs stay about the same in the enhanced plan (which has the highest premium). In the other plans, out-of-pocket expense escalates to more than \$430 per month. Once patients pass through the donut hole, catastrophic coverage begins and all 3 plans have about the same copayment amounts. So although some plans have low copayments initially, in later months costs can be unmanageable for many patients. For transplant patients in particular, many PDPs' elevation of the tier status of immunosuppressants in 2006-2007 to a specialty tier in which a higher cost is borne by the patient seems to have caused a problem. When these patients enter the gap and become responsible for what is to them a staggering cost, they may become nonadherent. They may eliminate doses to try to stretch their prescriptions. Transplant patients who stop taking immunosuppressants or lengthen the dosage interval could experience a rejection. Clinicians' time is frequently wasted dealing with barriers like prior authorization, step-therapy, or quantity limits, especially for higher-tier drugs. There are patient assistance programs but in the gap period, patients who have any income at all rarely qualify for assistance.

Multiple options for immunosuppressants are important for those kidney transplant patients who have their immunosuppressants covered under Part D instead of Part B.

### Dialysis

Dialysis-specific issues also abound because of the high-cost, high-use medications needed to treat the numerous comorbid conditions (diabetes, hypertension, anemia, bone and mineral metabolism disorders, and cardiovascular disorders) that abound in the ESRD population. In fact, the number of medications taken by dialysis patients range from 10 to 12.<sup>10</sup> Data from 3,768 dialysis patients in the 2003 Medstat MarketScan

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**TABLE 2 Medicare Prescription Drug Finder**

	Medicare BlueRx Option 3	WellCare Complete	AARP MedicareRx Plan Enhanced
Your total annual drug plan cost	\$4,314	\$5,161	\$4,629
Your total drug cost for the rest of 2007 (8 months left)	\$2,876	\$3,095	\$3,089
Prescription premium per month	\$110.30	\$39.50	\$46.50
Deductible	\$0	\$0	\$0
Initial coverage limit (amount you have to spend before your copay or coinsurance changes)	\$0	\$2,100	\$2,400
Your total drug costs after you have met your deductible but before your total drug costs reach the initial coverage limit.			
allopurinol tablet 300 mg	\$1.74	\$0	\$5.71
Cellcept tablet 500 mg	\$104.48	\$20.00	\$115.01
Coumadin tablet 7.5 mg	\$10.91	\$35.30	\$28.00
cyclosporine capsule 500 mg	\$95.98	\$0	\$6.00
lisinopril tablet 5 mg	\$2.24	\$0	\$6.00
Mytussin AC 100 mg/5 mL	\$12.58	\$12.33	\$12.83
prednisone tablet 5 mg	\$0.80	\$0	\$2.76
verapamil capsule 240 mg	\$13.58	\$41.72	\$6.00
pravastatin tablet 20 mg	\$7.01	\$22.06	\$6.00
Total monthly cost	\$249.22	\$131.41	\$188.31
Your monthly drug costs after your total drug costs reach the initial coverage limit but before your total out-of-pocket expense equals \$3,850.00.			
allopurinol tablet 300 mg	\$1.74	\$4.20	\$5.71
Cellcept tablet 500 mg	\$104.48	\$339.88	\$348.73
Coumadin tablet 7.5 mg	\$10.91	\$35.30	\$36.61
cyclosporine capsule 500 mg	\$95.98	\$10.00	\$6.00
lisinopril tablet 5 mg	\$2.24	\$6.60	\$6.00
Mytussin AC 100 mg/5 mL	\$12.58	\$12.33	\$12.83
prednisone tablet 5 mg	\$0.80	\$4.90	\$2.76
verapamil capsule 240 mg	\$13.58	\$41.72	\$6.00
pravastatin tablet 20 mg	\$7.01	\$22.06	\$6.00
Total monthly cost	\$249.22	\$476.99	\$430.44
Your monthly drug costs after your total out-of-pocket expense equals \$3,850.00.			
allopurinol tablet 300 mg	\$2.15	\$2.15	\$2.15
Cellcept tablet 500 mg	\$17.41	\$16.99	\$17.43
Coumadin tablet 7.5 mg	\$5.45	\$5.45	\$5.45
cyclosporine capsule 500 mg	\$15.98	\$15.59	\$15.99
lisinopril tablet 5 mg	\$2.15	\$2.15	\$2.15
Mytussin AC 100 mg/5 mL	\$12.58	\$12.33	\$12.83
prednisone tablet 5 mg	\$2.15	\$2.15	\$2.15
verapamil capsule 240 mg	\$2.26	\$41.72	\$2.44
pravastatin tablet 20 mg	\$2.15	\$22.06	\$2.15
Total monthly cost	\$62.18	\$120.40	\$62.24
Drug coverage information			
allopurinol tablet 300 mg	Generic	Tier 1	Tier 1
Cellcept tablet 500 mg	Specialty	Tier 2*	Tier 4 specialty*
Coumadin tablet 7.5 mg	Brand	Tier 3	Tier 2
cyclosporine capsule 500 mg	Generic	Tier 1*	Tier 1*
lisinopril tablet 5 mg	Generic	Tier 1	Tier 1
Mytussin AC syrup 100 mg/5 mL	Not formulary	Not formulary	Not formulary
prednisone tablet 5 mg	Generic	Tier 1	Tier 1
verapamil capsule 240 mg	Generic	Not formulary	Tier 1
pravastatin tablet 20 mg	Generic	Not formulary	Tier 1

\* These drugs may be subject to prior authorization, step therapy, or quantity limits.

Commercial Claims and Encounters Database and the Medicare Supplemental and Coordination of Benefits Database (Medstat Group, Inc., Ann Arbor, MI) showed that the average number of Part D medications received by dialysis patients is 8.3+4.4 (Median 8). This number excluded ESAs as well as intravenous vitamin D, iron, and antibiotics, as these medications are covered by Medicare Part B and include diabetic supplies to administer insulin, which are covered under Part D.

Extrapolation of 4th-quarter data to 12 months revealed that about 33% of dialysis patients with EGHP insurance spend less than \$2,251 on Part D medications per year. These data suggest that about 68% of dialysis patients will reach the donut hole, where patients are responsible for paying the entire cost of their medications. This is an issue, as some patients may discontinue medications at this point if they cannot afford the full price. Of note, some plans will cover generics during this period. In addition, patients who are dual eligible or who receive extra help will continue to receive medications during this period for lower costs. About 32% will go past the donut hole and into catastrophic coverage (more than \$5,100 in covered drug costs, \$3,600 in out-of-pocket spending).<sup>11</sup> A limitation of this analysis is that it did not include either cinacalcet or lanthanum carbonate, 2 costly drugs that the U.S. Food and Drug Administration approved after these data were presented. The inclusion of these 2 drugs would be expected to increase the percentage of patients who fell into the donut hole and reached the catastrophic coverage period.

Patel's Medicare Current Beneficiary Survey (which, again, excluded dual-eligible patients) attempted to clarify total annual and out-of-pocket drug spending projected if patients enrolled in a Part D plan. In the population of 256 patients with ESRD and 41,000 patients without ESRD, dialysis patients tended to be much younger, with about half of them being younger than 65 years. Again, dialysis is a covered entity, but patients without ESRD must be at least 65 years old to receive Medicare benefits.<sup>4</sup> In this analysis, almost 54% of patients were taking more than 10 medications compared with slightly less than 24% of patients in the general Medicare population. In terms of drug spending, ESRD medications averaged \$6,488+\$765 annually, compared with \$2,705+\$35 in the population without ESRD. On average, predicted out-of-pocket spending by patients with ESRD under Medicare Part D was \$2,329+\$133 compared with \$1,311+\$16 in patients without ESRD.<sup>4</sup>

Patel also predicted that 70% of ESRD patients would reach the gap, with June being the month when this would happen most often compared with 43% of the general Medicare population (the mean month for this group was July). Thirty-nine percent of ESRD patients would qualify for catastrophic coverage (mean month, July), compared with only 14% of the general population (mean month, September).<sup>4</sup> These figures are congruent with those produced using Medstat Markets data (above).



Analyzing further to look at drug cost variability, Patel found the cost variability from month to month was even greater among ESRD patients than non-ESRD patients, suggesting that ESRD patients with moderate to high drug costs will be more vulnerable to cost swings that may increase their risk of reducing or stopping essential chronic medications.

### The MTM Requirement

Medicare requires medication therapy management (MTM) services for certain beneficiaries (called “targeted beneficiaries”) enrolled in PDP plans to improve medication optimization. Each PDP defines its own targeted beneficiaries; in general, targeted beneficiaries must have multiple chronic conditions (such as diabetes, asthma, congestive heart failure, dyslipidemia, and hypertension); be taking multiple Part D medications; and have annual Part D medication costs greater than \$4,000.

Approximately 80% of the typical ESRD population has more than 2 targeted comorbidities. In terms of costs, almost half spent more than \$4,000 in 2006.<sup>11</sup> Thus, many ESRD patients should be targeted for MTM services, and this task represents an opportunity for pharmacists.

Although the data are sparse and not very robust, some indicators support concerns that CKD patients, in general, are experiencing a multitude of problems under Part D. The NKF established the Kidney Medicare Drugs Awareness and Education program to help CKD patients understand Part D.<sup>12</sup> Subsequently, many CKD patients, their health care providers, and patient caregivers submitted issues regarding Part D to the NKF. Although the NKF did not systematically collect or analyze information, several recurrent themes were expressed, including (1) dual-eligible patients were either automatically or unintentionally enrolled in plans that required premiums (enhanced plans), rather than standard plans that did not have premiums; (2) Part D’s copayment amounts exceeded those that the dual-eligible patient was accustomed to under Medicaid; (3) a lack of understanding by patients, caregivers, providers, and pharmacists about Medicare Part B versus Part D coverage of immunosuppressant medications, which led to immunosuppressant prescriptions not being filled in a timely manner; and (4) problems paying for medications when the donut hole was reached.

A recent survey of ESRD social workers by the American Kidney Fund supports these findings. Social workers reported that many ESRD patients experienced administrative difficulties both during the enrollment phase and when seeking an appeal; 92% experienced problems with their plan’s formulary. Of those experiencing formulary problems, 32% reported that their plan did not include some of their medications, 35% said that they needed to get prior authorization for formulary medications, and 20% of patients had medications that were excluded by Part D and had difficulties paying their premiums or deductibles. More than 40% of ESRD patients (excluding non-dual-

eligible and low-income subsidy patients) had difficulty paying premiums or deductibles. More than half of dual-eligible or low-income subsidy patients had a “few difficulties” meeting their \$1 to \$5 copayment amounts. This survey also pointed out that a good portion of ESRD patients weren’t even aware that the Part D program existed.<sup>5</sup>

### Conclusion

Medicare Part D has unique implications for the CKD populations. Drug coverage is available for many drugs via Medicare Part B or Part D; the Medicare Part B and Part D medication coverage divide is confusing to most clinicians, pharmacists, and patients. Many ESRD patients fall into the dual-eligible category—they are covered by both Medicare and Medicaid.

ESRD is a costly condition. From the diagnosis of CKD to the time ESRD develops, the costs grow and patients’ energy and productivity decline. EGHPs are paying an increasing proportion of costs for ESRD patients. Managed care demonstration projects are underway to better understand if enrolling these patients into managed care plans with disease management models (i.e., special needs plans) can provide quality care in an effective and efficient manner. Screening patients at high risk for kidney disease, identifying patients with early kidney disease, preventing progression to ESRD, and effectively managing comorbid conditions may reduce long-term medical costs and maintain work productivity. Available data suggest that CKD patients are experiencing a variety of problems under Medicare Part D. Adequate access to essential chronic medications under Medicare Part D or within managed health plans is critical to prevent progression of kidney disease, prevent rejection of kidney transplants, and maintain health in dialysis patients.

### DISCLOSURES

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