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GENERIC IMMUNOSUPPRESSANTS HAVE REDUCED COSTS AFTER ORGAN TRANSPLANTATION

Both patients and health insurance payers have experienced savings.

Highlights

- Payments by organ transplant recipients and Medicare decreased significantly following the introduction of generic immunosuppressive medications.
- Large differences in out-of-pocket payments for immunosuppressive medications between Part D beneficiaries who did and did not qualify for the Medicare low-income subsidy suggest that recipients with resources just above the threshold to qualify for the subsidy may experience considerable financial strain.

Washington, DC (February 28, 2019) — The introduction of generic versions of immunosuppressive drugs has resulted in substantial cost savings for transplant patients and Medicare, according to a study appearing in an upcoming issue of the *Clinical Journal of the American Society of Nephrology* (*CJASN*).

Individuals who receive organ transplants must take life-long immunosuppressive medications to prevent rejection. Currently, Medicare provides coverage for immunosuppressive medication for the first 3 years following a kidney transplant, and patients can face significant out-of-pocket medication costs after that time. This can prevent some patients from filling necessary prescriptions, potentially leading to poor health outcomes.

About a decade ago, generic formulations of the two most commonly used immunosuppressive medications in the United States, tacrolimus and mycophenolate, became available, providing the potential to reduce costs for transplant recipients and payers.

To investigate the impact of generic introduction on payments for immunosuppressants by patients and Medicare, Margaret E. Helmuth, MA (Arbor Research Collaborative for Health) and her colleagues assessed the cost savings from substitution with generic immunosuppressive medications for organ transplant recipients and the Medicare Part D program. The team reported on the average annualized Medicare Part D plan payments, average annualized payments by the Medicare Part D low-income subsidy program, and average annualized out-of-pocket payments by patients for brand-name and generic tacrolimus and mycophenolate.

The investigators studied immunosuppressant medication costs for transplant recipients who received a kidney, liver, or heart transplant between 1987 and 2013 and filled prescriptions through Medicare Part D for tacrolimus or mycophenolate between 2008 and 2013. Overall, payments decreased for both patients (by 63%–79% for patients not receiving the low-income subsidy and 24%–44% for those receiving the subsidy) and Medicare Part D plans (by 48%–67%) across the 3 organs and 2 drugs over the 5 years studied.

For transplant recipients not receiving the low-income subsidy, the researchers observed declines in average out-of-pocket payments of \$1,000 to \$1,750 per patient per year between 2008 and 2013, depending on the organ type and drug. For the Medicare program, they observed savings of \$1,500 to \$4,500 per patient per year in Part D plan payments between 2008 and 2013, and additional savings to Medicare of \$400 to \$1,500 per low-income subsidy recipient per year over the same time period.

In addition, the investigators observed large differences in average yearly out-of-pocket payments for immunosuppressive medications between Part D beneficiaries who did and did not qualify for the Medicare low-income subsidy. The finding suggests that recipients with resources just above the threshold to qualify for this subsidy may experience considerable financial strain.

"The debate regarding universal coverage of immunosuppressive medications for transplant recipients has been ongoing for more than 30 years," said Helmuth. "We believe that this research will help inform ongoing national discussions about the funding of post-transplant immunosuppressive medication coverage."

In an accompanying Patient Voice editorial, Cher Thomas, RDH, a kidney transplant recipient celebrating her twentieth anniversary after transplantation, noted that in the early months after receiving a kidney, her copay on just 1 medication was \$500, and this was not for an immunosuppressive drug. Now all of her medications are generic, and she is thankful for saving money on her immunosuppressants. She also raised a number of concerns about the study's design and findings, as well as the role of insurance companies in deciding which generic medications can be prescribed to patients.

Study co-authors include Qian Liu, MPH, Marc N. Turenne, PhD, Jeong M. Park, PharmD, Murewa Oguntimein, PhD, Sarah K. Dutcher, PhD, Rajesh Balkrishnan, PhD, Pratima Sharma, MD, MBBS, MS, Jarcy Zee, PhD, Alan B. Leichtman, MD, and Abigail R. Smith, PhD.

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outside the submitted work. MH, QL, MT, JP, RB, PS, JZ, AL, and AS report grants from the US Food and Drug Administration during the conduct of the study. MO and SD report employment by the U.S. Food and Drug Administration during the conduct of the study.

The article, entitled "Secular Trends in the Cost of Immunosuppressants After Solid Organ Transplantation in the United States," will appear online at http://cjasn.asnjournals.org/ on February 28, 2019, doi: 10.2215/CJN.10590918.

The editorial, entitled Cost of Immunosuppressive Drugs and the Patient with a Kidney Transplant," will appear online at http://cjasn.asnjournals.org/ on February 28, 2019.

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