U.S. Government Accountability Office

Kidney Transplants: Medicare Coverage of Immunosuppressive Drugs

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Q&A Report to Congressional Committees

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Why This Matters

Over 27,000 kidney transplants were performed in the United States in 2023. A kidney transplant is the preferred method of treatment for patients with end-stage renal disease (ESRD)—a condition of permanent kidney failure requiring regular dialysis or a kidney transplant to maintain life. Compared to dialysis, a functional transplanted kidney may offer patients a better quality of life and increase their chances of living longer. Kidney transplant patients must take daily immunosuppressive drugs for the life of their transplant to prevent kidney rejection. Kidney rejection will result in kidney failure, requiring patients to go on dialysis or undergo another transplant.

Most patients with ESRD, regardless of age, are eligible for Medicare. This Medicare ESRD coverage ends 36 months after patients receive a kidney transplant unless they are otherwise eligible for Medicare. The Consolidated Appropriations Act, 2021 (CAA) extended Medicare coverage of immunosuppressive drugs for certain kidney transplant patients whose Medicare ESRD coverage has ended.

The CAA included a provision for us to report on the implementation of the Medicare immunosuppressive drug benefit, which took effect January 1, 2023. This report provides information on Medicare's immunosuppressive drug benefit, including enrollment and oversight activities taken by the Centers for Medicare & Medicaid Services (CMS).

Key Takeaways

- Medicare's immunosuppressive drug benefit helps certain kidney transplant patients pay for their immunosuppressive drugs. Patients whose Medicare ESRD coverage has ended are eligible for the benefit if they are not enrolled in certain other types of health coverage. The benefit is limited to immunosuppressive drugs and does not cover other Medicare services. Patients are responsible for premiums and other cost sharing, and enroll via attestation of no other health coverage that would make them ineligible for the benefit.
- There were 104 patients enrolled in the benefit as of February 2024. In addition, another 146 patients enrolled and then disenrolled in the benefit from January 2023 through February 2024 for various reasons, such as nonpayment of premiums.
- CMS requires a verbal or written attestation from patients about their eligibility to enroll in the benefit. CMS also reviews enrollment data it receives from the Social Security Administration to check patient eligibility for the benefit. CMS's efforts at the time of our review are consistent with agency statements that CMS will monitor compliance with the benefit's eligibility requirements and address any concerns.

Why do kidney transplant patients need immunosuppressive drugs?

Patients who receive a kidney transplant need immunosuppressive drugs to prevent their immune systems from rejecting their new kidney. Because these drugs only temporarily suppress this response, patients must adhere to a long-term drug regimen to maintain the function of their new kidney. There are several classes of drugs that can be used as part of a long-term immunosuppressive drug regimen for kidney transplant patients, including calcineurin inhibitors, antimetabolites, mammalian target of rapamycin (mTOR) inhibitors, costimulation inhibitors, and corticosteroids. (See table 1.)

Table 1: Examples of Classes of Long-Term Immunosuppressive Drugs for Kidney Transplant Patients

Drug class	Role in suppressing the immune system	Examples of relevant drugs
Calcineurin inhibitors	Inhibits the production of calcineurin, an enzyme that activates the immune system. Acts as the backbone of kidney transplant immunosuppressive therapy.	Cyclosporine, Tacrolimus
Antimetabolites	Inhibits the activation of and rapid increase of cells involved in initiating an immune response.	Azathioprine, Mycophenolate mofetil, Mycophenolate sodium
Mammalian target of rapamycin (mTOR) inhibitors	Inhibits the activity of the immune system response.	Everolimus, Sirolimus
Costimulation inhibitors	Inhibits the activity of the immune system response to prevent it from rejecting a transplanted kidney.	Belatacept[a]
Corticosteroids	Reduces inflammation and suppresses the immune system response.	Prednisone, Prednisolone

Source: GAO summary of academic articles and stakeholder interviews. | GAO-24-107230

Note: There are several classes of drugs that can be used to suppress the immune system response and maintain the function of the new kidney.

[a]Belatacept is administered by intravenous injection. The patient would need to cover injection costs for this medication under the immunosuppressive drug benefit.

Providers generally prescribe a combination of drugs to help achieve high levels of immunosuppression. The combination and dosage of drugs depends on factors, such as the compatibility of the transplanted kidney and the recipient, time since transplantation, condition of the donor kidney, drug interactions, and the health of the recipient, including comorbidities. According to one stakeholder group we interviewed, most kidney transplant patients will be on a regimen of two to three drugs, with each drug coming from a unique drug class.

Over time, providers may adjust or decrease drug dosages; however, most recipients cannot stop an immunosuppressive drug regimen without risk of kidney rejection. Providers typically monitor and adjust patient drug regimens through follow-up visits and other services, including routine laboratory tests to ensure there are no signs of rejection.

Immunosuppressive drugs have side effects that can lead to other conditions, such as hypertension, bone disease, and diabetes. Further, these drugs leave the patient at risk for developing bacterial infections and other conditions, such as cancer. Due to these side effects, kidney transplant patients may be closely monitored for infections and other conditions that require changes to drug regimens and additional medications.

Who is eligible for the immunosuppressive drug benefit?

Patients who had a Medicare-covered kidney transplant are eligible for the immunosuppressive drug benefit once their Medicare ESRD coverage ends and they do not have certain other types of health coverage.[1]

Medicare ESRD coverage (which includes all services, not only those related to kidney failure) ends 36 months, or three years, after patients receive a kidney transplant unless they are otherwise eligible for Medicare based on age or disability status. Once their Medicare ESRD coverage ends, patients are eligible for the immunosuppressive drug benefit if they are not enrolled and do not plan to enroll in certain other types of health coverage, including the following:

- private health coverage, including individual or group health plans, such as employer-sponsored or marketplace coverage;
- Department of Defense coverage for service members and their families;
- Medicaid plans that cover immunosuppressive drugs; and
- Department of Veterans Affairs' coverage that includes immunosuppressive drugs.[2]

Based on these eligibility requirements, CMS projected that roughly 1,800 patients would enroll in 2023 and that 250 would enroll each subsequent year.[3] In particular, CMS based their projections on the number of patients who had a Medicare-covered kidney transplant between 2001 and 2019, and then made adjustments based on those who died or were anticipated to have other coverage that would make them ineligible for the benefit.

To enroll in the benefit, patients must submit a written or verbal attestation to the Social Security Administration that they are not enrolled and do not plan to enroll in any other coverage that would make them ineligible for the benefit. Patients can enroll, disenroll, and reenroll in the benefit anytime, without penalty.

What does the benefit cover?

The immunosuppressive drug benefit covers immunosuppressive drugs and no other Medicare services. See table 2 for more information on benefit coverage.

Table 2: Medicare Immunosuppressive Drug Benefit Coverage, Effective January 1, 2023

Benefit coverage	Scope of coverage
When coverage begins	Coverage begins the month following the month in which a patient submitted their attestation that they are not enrolled (or planning to enroll) in certain other types of health coverage. If disenrolling, coverage ends the last day of the month in which the individual requests disenrollment.
What is covered	The benefit covers immunosuppressive drugs approved to treat and prevent kidney rejection.[a]
What is not covered	The benefit does not cover • drugs to treat conditions that may result from an immunosuppressive drug regimen, such as antibiotics; and • drug administration (e.g., intravenous injection), or any other Medicare services, supplies, or medications.

Source: GAO analysis of information from the Centers for Medicare & Medicaid Services. | GAO-24-107230

[a]Examples of covered drugs include cyclosporine, azathioprine, antithymocyte globulin, tacrolimus, mycophenolate mofetil, cyclophosphamide, prednisone, and prednisolone.

CMS guidance and education materials state that the benefit is not a substitute for more comprehensive coverage of other services and medications a kidney transplant patient may need, such as follow-up visits, laboratory tests, and medications to treat other conditions. In its notices to kidney transplant patients

regarding the benefit, CMS includes contact information for other comprehensive coverage options, such as Medicaid.

How can patients learn about the benefit?

There are three sources of information kidney transplant patients can use to learn about the immunosuppressive drug benefit.

- **Medicare outreach.** Kidney transplant patients can learn about the benefit through direct Medicare outreach. For example, Medicare notifies ESRD patients about the benefit in the pre-termination letter that patients receive prior to the end of their Medicare ESRD coverage (i.e., 36 months after receiving a kidney transplant). The letter notifies patients when their coverage will end and contains information about their coverage options, including the immunosuppressive drug benefit and how to apply for it. According to CMS guidance, this letter is sent to patients several months before their Medicare ESRD coverage terminates. In addition, CMS officials told us that in the fall of 2022, CMS sent a letter to patients who previously had Medicare ESRD coverage and lost it after a transplant to make them aware of the benefit.
- **CMS publications.** Patients can also learn about the benefit through other public CMS resources, such as the *Medicare & You* handbook and the CMS.gov website.
- **Providers and other resources.** Patients can also learn about the benefit through their provider or available state and local resources about health insurance coverage. CMS officials told us that in October 2022, CMS began an outreach campaign to providers, launched a new Medicare webpage to explain the benefit, and issued updated educational resources geared toward providers about the benefit. CMS also included information on the benefit in training materials to state and local entities who help patients with their health coverage decisions. CMS plans to continue to educate providers nationally and provide information about the benefit through future regional training efforts, according to CMS officials.

How much do patients pay for the benefit?

In 2024, patients pay a monthly premium of at least $103 and an annual deductible of $240 for the benefit.[4] Monthly premiums may be higher depending on the patient's income. Once the deductible is met, patients are responsible for paying a portion of the costs for their covered drugs—coinsurance equal to 20 percent of the Medicare-approved amount for each covered immunosuppressive drug. The 20 percent coinsurance amount paid by patients will vary based on their drug regimen and dosages. For example, one stakeholder group we interviewed provided an example of a drug regimen that may result in patients paying $100 per month and another regimen that may result in patients paying over $1,500 per month.

In addition to these costs, patients receiving the benefit will likely have additional costs for services and medications not covered by the benefit, such as follow-up visits with their provider, testing to monitor kidney function (e.g., laboratory work), and medications to treat conditions resulting from the immunosuppressive drug regimen.

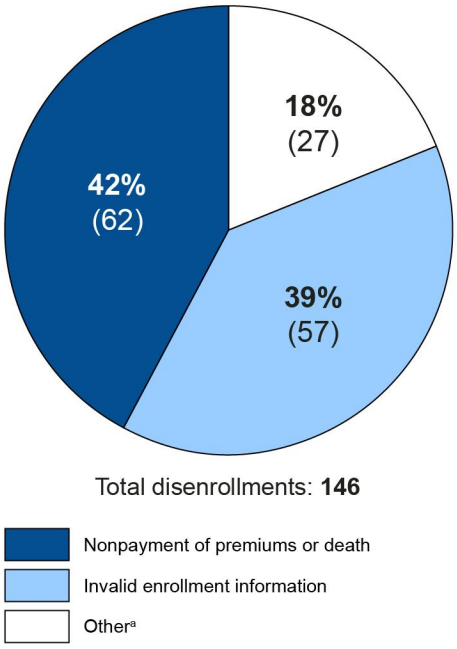
Patients with incomes and resources below a certain limit may qualify for state Medicaid programs that help pay for the benefit's premiums, deductibles, and coinsurance.[5] Patients who qualify for these programs are known as partial-benefit dual-eligible beneficiaries.[6]

How many patients are enrolled in this benefit?

CMS data show there were 104 patients enrolled in the immunosuppressive drug benefit as of February 2024 (the most recent available data at the time of our work). These patients were located in 29 states. Three of those states (Florida, Texas, and Ohio) accounted for 28 percent of all patients enrolled in the benefit. The total number of enrolled patients included five partial-benefit dual-eligible beneficiaries.

In addition, 146 patients enrolled and then disenrolled in the benefit from January 2023 through February 2024 for a variety of reasons. For example, 42 percent of the disenrollments (62) were due to nonpayment of premiums or death and 39 percent (57) were due to invalid enrollment reasons. (See fig. 1.)

Figure 1: Percentage of Disenrollments in the Medicare Immunosuppressive Drug Benefit, by Reason, January 2023–February 2024



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-24-107230

Accessible Data for Figure 1: Percentage of Disenrollments in the Medicare Immunosuppressive Drug Benefit, by Reason, January 2023–February 2024

	Percentage	Total disenrollments: 146
Nonpayment of premiums or death	42%	62
Invalid enrollment information	39%	57
Other	18%	27

Source: GAO analysis of Centers for Medicare & Medicaid Services data. I GAO-24-107230

[a]This group includes patients who voluntarily withdrew from the benefit, some of whom may have obtained another source of health coverage (such as Medicaid or a private group or individual plan). This group also includes patients who enrolled in Medicare due to age or disability status

Of the 146 patients, just over 50 percent disenrolled after being enrolled in the benefit for two months or less. In addition, none of the patients who disenrolled in the benefit from January 2023 through February 2024 have reenrolled.

What might patients consider when deciding whether to enroll in the benefit?

CMS officials and stakeholder groups we interviewed identified several aspects of the immunosuppressive drug benefit that kidney transplant patients may consider when deciding whether to enroll. These include (1) the scope of the

benefit and availability of other health coverage, and (2) the benefit's costs, such as premiums and coinsurance.

Scope of the benefit and availability of other coverage. CMS officials and stakeholder groups told us that benefit enrollment could be affected by the scope of the benefit. They said the benefit was a safety net or last-resort coverage for patients because it only covers immunosuppressive drugs, as mandated by the CAA. As such, some patients, such as those with chronic conditions, may not choose to enroll because the benefit does not cover services unrelated to immunosuppressive drugs, such as physician visits or laboratory tests. For example, a patient with heart disease or hypertension may require additional services and medications. Given the narrowness of the benefit, CMS officials said it was reasonable to assume that patients would choose the most comprehensive coverage available and affordable to meet their health care needs.

However, stakeholder groups also told us that the benefit's safety-net coverage is important. For example, according to stakeholder groups, patients could continue to have coverage for immunosuppressive drugs with this benefit until they find a plan with more comprehensive coverage, such as employer-sponsored coverage or individual plans purchased through the marketplace.[7] In addition, the availability of the benefit may also lessen concerns faced by some patients who are waiting for a kidney transplant and are unsure how they will pay for the immunosuppressive drugs once their Medicare ESRD coverage ends.

Benefit costs. Stakeholder groups also told us that the costs associated with the benefit—such as premiums and coinsurance—may affect a patient's enrollment decision. For example, one stakeholder group told us that, hypothetically, patients may be able to come up with the money to afford more comprehensive plans purchased through the marketplace because some of these plans' premiums are not substantially more expensive than the immunosuppressive drug benefit's premium. Stakeholder groups also said that some patients have been able to obtain immunosuppressive drugs at a reduced cost through coupons and other assistance programs. According to stakeholder groups, using coupons and paying out of pocket to obtain these drugs may be less expensive than paying to enroll in the immunosuppressive drug benefit.

How does CMS monitor eligibility and enrollment in the benefit?

CMS requires an attestation from patients about their eligibility to enroll in the immunosuppressive drug benefit. In addition, CMS officials told us they review enrollment data to check patient eligibility for the benefit.

Attestation. As required by law, patients enroll in the benefit by submitting an attestation to the Social Security Administration.[8] Specifically, patients must (1) attest they do not have and do not plan to have certain other types of health coverage and (2) agree to notify the Social Security Administration within 60 days of enrollment in other health coverage. CMS requires that patients submit their attestation verbally or in writing. According to CMS officials, the Social Security Administration then processes the attestations for enrollment and submits the information to CMS. CMS officials also told us they do not otherwise have a real-time system to check whether a patient has other coverage, such as a group health plan, when they enroll in the benefit.

Enrollment checks. In addition to the required attestation, CMS also reviews enrollment data it receives from the Social Security Administration to check patient eligibility for the benefit. For example, CMS officials told us that they review a daily enrollment report that identifies successful enrollment and disenrollment records processed by the Social Security Administration. For each enrollment record in this report, CMS checks for:

- prior Medicare ESRD coverage, including any overlapping Medicare coverage,
- kidney transplant date, and
- effective date of enrollment in the benefit.

If any enrollment records appear invalid, CMS notifies the Social Security Administration for clarification and corrective action. CMS officials told us they also identified some of the 57 invalid enrollments by checking to see if enrolled patients already had Medicaid coverage. Invalid enrollments were identified through January 31, 2024, and most were identified within a month or two of the coverage start date. CMS officials told us that as of May 2024 they have not identified any other instances of ineligible patients enrolling in the benefit.

CMS officials also told us that they use an annual letter they send to patients enrolled in the benefit to remind patients that they are not allowed to be enrolled in the benefit if they have other health coverage. The letter also contains information on obtaining other comprehensive health coverage. CMS officials also told us that Medicare providers can check for patient eligibility and enrollment in the benefit by using an electronic data system that contains benefit eligibility information.[9]

CMS's efforts at the time of our review are consistent with agency statements that CMS will monitor compliance with the benefit's eligibility requirements and address any concerns, including inaccurate attestations and ineligible patients enrolling and staying enrolled.[10]

Agency Comments

We provided a draft of this report to the Department of Health and Human Services for review and comment. The Department of Health and Human Services provided technical comments, which we incorporated as appropriate.

How GAO Did This Study

We reviewed relevant federal statutes, regulations, documentation, guidance, and academic articles gathered during background research related to the immunosuppressive drug benefit. We interviewed CMS officials about the benefit and the steps taken to monitor compliance with enrollment and eligibility requirements.

We analyzed benefit enrollment data provided by CMS from January 1, 2023, (when the benefit was implemented) through February 29, 2024, (the most recent available data at the time of our review) to describe the level of enrollment and disenrollment, reasons for disenrollment, and the geographic location of enrolled patients. To assess the reliability of these data, we interviewed CMS officials and verified that the data CMS provided were consistent and contained no obvious errors. We found these data to be sufficiently reliable for our reporting purposes.

We also interviewed five stakeholder groups representing kidney transplant patients, providers, and those assisting patients with their coverage options to obtain their views on the benefit. The perspectives from these five stakeholder groups were not generalizable across all stakeholder groups with expertise or experience working with kidney transplant patients.

We conducted this performance audit from December 2023 to August 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence

obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

List of Addressees

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Jason Smith
Chairman
The Honorable Richard E. Neal
Ranking Member
Committee on Ways and Means
House of Representatives

We are sending copies of this report to the appropriate congressional committees and the Secretary of Health and Human Services. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

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Endnotes

[1]42 U.S.C. § 1395o(b).

[2]42 U.S.C. § 1395o(b)(2)(A); 42 C.F.R. § 407.55(b) (2023).

[3]Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules, 87 Fed. Reg. 66,454, 66,496 (Nov. 3, 2022).

Additionally, a 2020 Congressional Budget Office report estimated that 12,000 patients would enroll in the benefit from fiscal years 2023 to 2030 and savings would begin to accumulate around fiscal year 2025 with an estimated reduction of $120 million in direct spending by fiscal year 2030. Congressional Budget Office, *Congressional Budget Office Cost Estimate for H.R. 5534, Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2020* (Washington, D.C.: Nov. 2020).

[4]A premium is a monthly amount patients pay for Medicare coverage, whether they access covered drugs or not. A deductible is the amount patients pay for covered drugs each year before Medicare starts to pay.

[5]These Medicaid programs are called Medicare Savings Programs. Patients who qualify are eligible to receive assistance with their premium expenses through their state Medicaid program. Some may also receive assistance with deductible and coinsurance expenses.

[6]Partial-benefit dual-eligible beneficiaries receive assistance with Medicare premiums and cost sharing through their state Medicaid program. However, they do not qualify for full Medicaid benefits. In the preamble to the final rule implementing the benefit, CMS stated that it anticipated that most kidney transplant patients who enrolled in the benefit would be partial-benefit dual-eligible beneficiaries living in states that did not expand Medicaid. 87 Fed. Reg. at 66,480. This is because all states currently cover immunosuppressive drugs for all full-benefit Medicaid beneficiaries. However, in states that did not expand Medicaid, there are individuals who neither qualify for full Medicaid benefits nor for subsidies in plans offered through state or federal marketplaces; these individuals may not have any source of immunosuppressive drug coverage without the benefit.

[7]The Patient Protection and Affordable Care Act required the establishment of health insurance marketplaces within each state where eligible individuals and small businesses can shop for and purchase qualified health insurance plans. The act requires that non-grandfathered marketplace plans cover 10 categories of essential health benefits, including outpatient care, prescription drugs, laboratory services, and preventive and wellness services and chronic disease management, among others.

[8]42 U.S.C. § 1395o(b)(2)(B)(ii); 42 C.F.R. § 407.59 (2023).

[9]Medicare providers can use the Health Insurance Portability and Accountability Act Eligibility Transaction System to check whether patients are enrolled in the immunosuppressive drug benefit.

[10]87 Fed. Reg. at 66,476-77.