**The American Society of Transplantation would like to call your attention to an alarming problem with immunosuppressant drug coverage under the Medicare Part D benefit:**

**Immunosuppressant Drug Coverage under Medicare[1]**

- If a transplant recipient has Medicare at the time of transplant, and if Medicare pays for the transplant, his/her immunosuppressant drugs are covered under Medicare Part B. These patients enjoy access to their life-saving immunosuppressants for the duration of their Medicare eligibility.
- If a transplant recipient has any other insurance at the time of transplant (e.g. state Medicaid, private insurance) then later becomes eligible for Medicare (e.g. because they turn 65 years old), his/her immunosuppressant drugs are covered under Medicare Part D. Although the Medicare Part D plan is the appropriate payer for these patients' immunosuppressant drugs, some patients are experiencing denied claims, with those denials upheld through multiple levels of appeal.

**Are Denials of Immunosuppressant Drug Claims by Medicare Part D Plans Appropriate?[2]**

- The Medicare Prescription Drug Benefit Manual mandates that Part D plan sponsors include all or substantially all immunosuppressant drugs on their formularies. However, presence of a drug on a plan formulary does not mean the drug will be approved for coverage for an individual beneficiary.
- The Medicare Prescription Drug Benefit Manual mandates that Part D plan sponsors approve coverage for drugs when they are used for a medically accepted indication. Medically accepted indications are defined as those per FDA-approved indications or as supported by CMS-approved compendia.
- While the FDA-approved indications and CMS-approved compendia mention some transplant indications for immunosuppressant drugs, they do not allow for all clinically appropriate uses.

**What are the Consequences?**

Three key patient populations are currently suffering as a result of these coverage gaps. Affected patients are those who rely on Medicare Part D coverage for their immunosuppressant drugs and:

- Have a lung transplant. Every lung transplant recipient requires immunosuppressant drugs to avoid rejection, maintain lung function, and survive. No immunosuppressant drug is FDA-approved for lung transplant and only tacrolimus and cyclosporine are listed in the CMS-approved compendia as appropriate for off-label use in lung transplant.
- Have a heart transplant complicated by cardiac allograft vasculopathy (CAV; a type of chronic rejection). The International Society for Heart and Lung Transplantation recommends using sirolimus or everolimus for treatment of CAV. Neither of these medications are FDA-approved or listed in the CMS-approved compendia for this use.
- Have a transplant of any type complicated by an inability to take traditional immunosuppressant drugs. Each immunosuppressant drug carries a risk for unique side effects, and patients occasionally cannot tolerate the preferred medication or regimen. Restricting use to indications that are FDA-approved or mentioned in the CMS-approved compendia severely limits treatment options for patients who struggle with immunosuppressant drug toxicities.

**How Many People Are Affected?[3]**

69.6% of liver transplant recipients, 63.6% of heart transplant recipients, and 55.8% of lung transplant recipients have insurance other than Medicare at the time of their transplant. When these patients turn 65 and become eligible for Medicare, they will rely on Medicare Part D Plans for immunosuppressant drug coverage and will be at risk for coverage denials for their life-saving medications.

[1] www.medicare.gov/coverage/prescription-drugs-outpatient.html
[2] www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf
[3] OPTN/SRTR Annual Data Report 2017. *Am J Transplant* 2019; 19(S2):

**How Can We Solve This?**
There are two approaches:

1. File requests for reviews of each affected immunosuppressant drug with the CMS-approved compendia, in the hopes that they will revise their list of appropriate off label uses to include those deemed clinically appropriate by the transplant community. Though this is a reasonable solution, each individual drug review is a long process, our request will not necessarily be a top priority by the compendia, and current transplant literature may not meet the strict criteria required to edit a drug entry. Patients in the vulnerable groups outlined above are suffering from an inability to obtain their life-saving immunosuppressant medications now.
2. Expand the definition of "medically accepted indication" for immunosuppressant drugs in organ transplantation, as it already is for anticancer chemotherapeutic regimens. The expanded definition would allow for consideration of peer reviewed medical literature, from a short list of pre-agreed medical journals. This is a more durable solution and allows for efficient adaptation as the field advances.

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