AST | AMERICAN SOCIETY OF TRANSPLANTATION

March 25, 2016

Francis J. Crosson, MD
Chairman, Medicare Payment Advisory Commission

RE: Transplant community opposition to the MedPAC suggestion to remove immunosuppressants from the category of "protected drug class" on Medicare Part C and D formularies

Dear Dr. Crosson,

The American Society of Transplantation has serious concerns regarding the MedPAC's suggestion to remove immunosuppressant medications from the category of "protected drug class" on Medicare Part C and D formularies. We opposed this change when it was proposed in 2014, and we again write to confirm our strong opposition.

In the March 2016 report, the MedPAC states that Medicare Part C and D plans' negotiating leverage depends on the presence of competition within each drug class. MedPAC states that removing immunosuppressants as a protected class would allow for negotiation, and would open the opportunity for plans to implement formulary tools. These changes would result in restricted access to life-saving immunosuppressant medications and would be catastrophic for organ transplant recipients.

The key point is that immunosuppressive therapies in transplantation are based on the use of multiple drugs whose mechanisms are complimentary but not necessarily interchangeable. Effective immunosuppression is achieved by leveraging the effects of all medications in the regimen. Individual immunosuppressive agents affect the efficacy and toxicity of the other agents. Consider the therapeutic class of "calcineurin inhibitors" as an example. This class of medications includes multiple tacrolimus and cyclosporine formulations. A plan requirement to substitute cyclosporine, a less potent calcineurin inhibitor, for tacrolimus would result in a reduced efficacy from the calcineurin inhibitor itself, a 40% reduction in mycophenolate exposure and/or a five-fold increase in sirolimus exposure. This change to a single drug in the regimen can derail the overall effectiveness of the regimen and/or result in severe drug toxicity. Furthermore, each change to the immunosuppressive regimen introduces risk for rejection and warrants intense patient education and frequent additional laboratory monitoring. It is impossible to safely switch back and forth between medications within a particular class without completely re-evaluating the whole regimen.

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In addition to the clinical risk to transplant recipients, this change would introduce practical challenges that would be to the detriment of a vulnerable patient population. Each change to an immunosuppressive regimen increases the need for and costs related to drug level monitoring. Each change increases the number of patient visits to evaluate the new therapy. This will not only cost the program and payers, but also patient employers in lost productivity and time. Consider the reality of a single transplant physician trying to constantly monitor which drugs are available to hundreds of individual patients who are typically only seen a few times per year in the transplant center. Consider the impossibility of reasonably managing immunosuppressive therapy over the many years of our patients' lives as they change jobs, move, and change the workflow of their care.

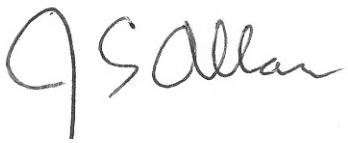
Ironically, there is a significant chance that this proposal could actually increase healthcare costs to the system, including to Medicare. The cost of additional laboratory testing, clinical visits, and treatment arising from over-immunosuppression, under-immunosuppression, and side effects inherent in this well-intended but ultimately misguided plan might very well exceed any savings.

Medicare beneficiaries can change plans annually. Medicare Part C and D plans can renegotiate terms and alter their formularies annually. Immunosuppressive medication decisions must be made based on the characteristics of the drug relative to the patient's medical needs, and not on negotiations between the plan and the manufacturer. The bottom line is that forcing transplant physicians to constantly make fundamental changes to life-saving immunosuppression would dramatically and negatively affect the entire transplant care model.

We strongly support the MedPAC's efforts to identify ways to improve the Medicare drug benefit. The MedPAC has also recommended reducing or eliminating patient copays for generics as a tool to encourage generic medication use, and reducing the out-of-pocket burden with fixed-dollar copays or a complete cap on out-of-pocket costs. We believe these would provide a positive change for transplant recipients. Removing immunosuppressants from protected drug status would be clinically, financially, and administratively detrimental to patients, transplant centers, and payers.

In sum, we strongly urge you to keep immunosuppressants as a "protected class" under Medicare Parts C and D plans.

Sincerely,



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