AMERICAN SOCIETY OF TRANSPLANTATION

TO: Centers for Medicare & Medicaid Services

FROM: Dr. Dianne McKay, President
American Society of Transplantation

DATE: January 22, 2019

RE: AST Response on "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Last year, CMS proposed a rule change for Medicare C&D programs that would significantly limit access to immunosuppressant medications for the recipients of solid organ transplants. While immunosuppressants would remain designated as one of the six protected classes, the new rule would modify some of the protections that ensure uninterrupted and timely delivery of immunosuppressant medications to our vulnerable population. As such, this comment forms our request to consider important modifications to this proposal. The proposed changes would permit implementation of broader use of prior authorizations, require indication verification, introduce step therapy requirement for immunosuppressants and permit formulary exclusions.

We very much appreciate the effort of CMS to promote cost effective treatment selection when it comes to immunosuppressants that includes use of generic medications and biosimilars. We also understand the need to regulate use of costly immunosuppressive therapies for non-transplant populations, for example their use in rheumatoid arthritis. However, restricting access to life-saving and life-sustaining therapies for transplant recipients, in an effort to regulate use in other patient groups, would introduce imminent and unnecessary harm to this vulnerable patient population. For these reasons, we urge CMS to NOT limit access to medication based simply on a medication class. Rather, medications should have protection based on an indication and based on the level of harm to patient if access is delayed or suddenly withheld. We outline our concerns for the proposed plan below.

**Transplant protocols use a limited repertoire of medications for unique, patient specific criteria*

The Transplant community works with a limited repertoire of medications that are best used in combination to prevent organ rejection (calcineurin inhibitors, antimetabolites, mammalian target of rapamycin inhibitors, corticosteroids and a costimulation blocker). Decision to use these medications is often based on patient specific characteristics such as degree of rejection risk, comorbidities and side effects. The selection of the optimal combination of immunosuppressant medications is not guided by any consensus guideline but often determined by individual patient factors, medication

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tolerance, scientific evidence published by transplant community, provider experience and expertise.

Therapy modification for patients experiencing medication toxicities is done expeditiously to prevent allograft loss. Delaying access to alternative therapies by engaging in cumbersome processes of prior authorization and appeals would expose patients to unnecessary toxicities, risk of non-adherence and allograft rejection. In addition, step therapy requirement and formulary exclusions would significantly impair the ability of transplant providers to swiftly manage patients at the time of their greatest need. We strongly believe that the proposal to prevent or limit accessibility of our patients and providers to ALL currently available immunosuppressive medications in every formulary will profoundly damage the care and health of our transplant patients.

**Immunosuppressants have limited indications for use*
The proposed rule change would permit Medicare C&D plans to determine appropriateness of immunosuppressant medications for certain indications. However, immunosuppressants are often used off label. For example, OPTN/SRTR 2016 Annual Data Report shows that 95% of lung transplant recipients use tacrolimus for rejection prophylaxis. However, tacrolimus does not carry an FDA-approved indication for rejection prophylaxis in this population. Indeed, tacrolimus is the backbone of all modern immunosuppressant protocols today. Despite this real-world use, this fact remains universally under-recognized in leading Pharmacopeia Compendia. Along with tacrolimus, mycophenolate is considered primary adjunct therapy for the vast majority of transplant recipients, yet it has a very limited indication for use in renal, heart and liver transplants only. Moreover, both available mycophenolate formulations are approved for use alongside cyclosporine and corticosteroids – not tacrolimus. Cyclosporine use has fallen to less than 10% across all solid organs we transplant today in adult population. Due to the narrow indications and complicating clinical criteria, Medicare C&D plans would have very limited ability to have significant management input while at the same time placing tremendous clinical and administrative burden on the transplant programs.

**Prior authorization process is cumbersome, limited in scope and duration*
The transplant community has many years of experience handling prior authorizations for our patient population. Despite our collective effort, for the vast majority of patients, the need for prior authorizations is not discovered until patient is OUT of their medication and in need of immediate access to them. This becomes of a particular concern for our patients that are getting further away from their transplant event. Generally, as the time from transplant increases, patient care is shared with non-transplant providers that may not expeditiously assist with prior authorization process. If annual re-approval for immunosuppressants is required or formulary changes are introduced as a universal rule, these requirements would result in dangerous loss of access to medications while putting patients at serious risk for rejection, allograft loss and death.

From our collective experience, we strongly urge you to reconsider this proposal. We are experts in understanding problems the prior authorization process introduces to our patient population. Implementing a universal set of restrictions that include prior approvals, step therapy and formulary restrictions for all Medicare C&D covered transplant patients will introduce undue harm. To ensure safety of solid organ transplant recipients, we urge CMS to guarantee changes to the prior authorization process for organ transplant indications. At minimum, CMS must establish an expedited approval process (under 24 hours), introduce automatic permission for 7-day temporary supply while approval is obtained, and extend approval period to match the life of

transplanted organ. Moreover, protected class indications would have to be completely revised for this class of medications to include unrestricted access to all immunosuppressants for all solid organ transplant types. A creation of specialty council with expertise in the field of transplantation to review formulary decisions would be strongly advised.