January 24, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0938–AT92 Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses (the Proposed Rule)

Dear Administrator Verma:

On behalf of the American Society of Transplant Surgeons (ASTS) we are pleased to have the opportunity to comment on the Proposed Rule. ASTS is a society representing approximately 1,800 professionals dedicated to excellence in transplantation surgery. ASTS advances the art and science of transplant surgery through patient care, research, education, and advocacy.

While we understand and support the Administration's focus on curtailing the increase in drug costs, we strongly object to the provisions of the Proposed Rule that would authorize the imposition of step therapy restrictions ("Fail First" coverage limits) on immunosuppressants provided to Medicare Advantage (MA) enrollees whose immunosuppressants would otherwise by covered by Medicare Part B. Our concerns also extend to immunosuppressants covered under Part D (whether through MA Plans that provide Part D prescription drug coverage (MA-PD Plans) or stand-alone Part D Plans. We believe that these proposals have the potential to endanger the lives and graft survival of our patients and strenuously urge CMS to withdraw these proposals.

While these proposals are of significant concern to all transplant recipients covered under Medicare Parts B or D, we are particularly concerned about the number of kidney transplant recipients who may be impacted if the Proposed Rule is adopted in final form. The 21st Century Cures Act will enable ESRD-eligible Medicare beneficiaries to enroll in MA plans and MA-PD plans for the first time in 2021, and, if the provisions of the Proposed Rule are adopted, the continued lives and graft survival of those ESRD-eligible beneficiaries who opt to enroll in MA or MA-PD Plans may impacted.

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American Transplant Congress
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Boston, Massachusetts

Fail First under Medicare Part B

Under current law, Medicare Part B covers immunosuppressants provided to ESRD-eligible Medicare beneficiaries for three years after transplantation and renal transplant recipients who are eligible for Medicare by reason of age of disability. The former group will be newly eligible to enroll in MA Plans in 2021. The Proposed Rule would authorize MA Plans to require a transplant recipient to fail on one (or more) less costly immunosuppressants before a physician-prescribed Part B immunosuppressant is covered. Thus, CMS' proposal to authorize MA Plans to impose "Fail First" coverage restrictions on the availability of Part B immunosuppressants has the potential to substantially impact our patients.

Based on the analysis conducted by Powers, Pyles, Sutter and Verville (Attachment A), it appears that such a coverage restriction on the availability of physician-prescribed Part B immunosuppressants is illegal.

Moreover, it does not appear that the imposition of Fail First coverage limits is necessary in order to drive adoption of less costly immunosuppressants. A recent article[1] estimated the rate of uptake over time of generic immunosuppressants using US Medicare Part D Prescription Drug Event (PDE) and Colorado pharmacy claims (including both Part D and non-Part D) data from 2008 to 2013. Data from 26,070 kidney, 15,548 liver, and 6,685 heart recipients from Part D, and 1138 kidney and 389 liver recipients from Colorado were analyzed. The proportions of patients with PDEs or claims for generic and brand-name tacrolimus or mycophenolate mofetil were calculated over time by transplanted organ and drug. Among Part D kidney, liver, and heart beneficiaries, the proportion dispensed generic tacrolimus reached 50%-56% at 1 year after first generic approval and 78%-81% by December 2013. The proportion dispensed generic mycophenolate mofetil reached 70%-73% at 1 year after generic market entry and 88%-90% by December 2013. Overall, generic substitution for tacrolimus and mycophenolate mofetil for organ transplant recipients increased rapidly following first availability, and utilization of generic immunosuppressants exceeded that of brand-name products within a year of market entry. The findings of this research were recently confirmed and updated in a study released by Avalere suggesting that 79% of the immunosuppressant prescriptions for 2016 were for generics.[2] There is no reason to believe that the experience with respect to Part B claims for immunosuppressants differs significantly from Part D practice patterns. Thus, while some physicians remain concerned about the use of generic immunosuppressants, the imposition of "Fail First" limitations on coverage for immunosuppressants is not necessary to encourage the transition to generic immunosuppressants or to place pressure on manufacturers of brand name immunosuppressants to lower their costs.

Limitations on Access to Immunosuppressants and other Protected Class Drugs under Part D

Under Medicare Part D, Medicare Part D Plans and MA-PD Plans ("Affected plans") cover immunosuppressants provided to any Age/Disabled Medicare enrollee (a) who is a renal transplant recipient and whose transplant was not covered under Medicare Part A; and (b) who is a non-renal transplant recipient. The Proposed Rule would authorize Affected Plans to limit the availability of immunosuppressants by significantly expanding the authority of these plans to impose Fail First

[1] The adoption of generic immunosuppressant medications in kidney, liver, and heart transplantation among recipients in Colorado or nationally with Medicare part D.; Am J Transplant. 2018 Jul;18(7):1764-1773. doi: 10.1111/ajt.14722. Epub 2018 Mar 31. https://www.ncbi.nlm.nih.gov/pubmed/29603899.

[2] https://avalere.com/insights/patients-use-generics-more-frequently-than-brands-in-medicares-protected-drug-classes.

restrictions and other utilization management rules on immunosuppressants, including those who are already on an effective immunosuppressive drug regimen. In addition, under the Proposed Rule, Affected Plans would be authorized to exclude certain immunosuppressants from their formularies altogether, based on cost considerations.

For the reasons set forth in the attached legal analysis, it appears that these restrictions on access to immunosuppressants prescribed to prevent organ rejection are illegal and that any exclusions from Part D formularies must be based on "scientific evidence and medical standards of practice."

Our primary concern about the Proposed Rule is that it authorizes the use of Fail First coverage limitations even for Medicare beneficiaries who are on a stable immunosuppressant regime already, when they enroll in a new plan. We strongly object to CMS' authorizing MA+ and Part D plans to insist that a Medicare beneficiary who is doing well on an immunosuppressant switch to another lower cost drug. We believe that such a policy is completely inconsistent with the best interests of our patients and has the potential to result in serious health consequences, including potential organ rejection. Transplantation is by far the most clinically and cost effective treatment for ESRD and is often the only available option for other organ recipients. There is a severe and growing organ shortage, and a pressing need to reduce organ wastage. Yet, the Proposed Rule would authorize plans to require transplant recipients to stop an effective and life-sustaining immunosuppressant regimen in order to switch to a less costly alternative, thereby jeopardizing the viability of the transplant.

The sole rationale put forth by the Proposed Rule is that it is necessary to authorize Affected Plans to reduce access to protected class drugs in order for these plans to increase their leverage in negotiating drug prices with manufacturers. But almost 80% of Part D prescriptions for immunosuppressants are for generics already. Whatever incremental "negotiating power" Affected Plans may gain by being authorized to require stable transplant recipients to switch their immunosuppressant regimen is certainly outweighed by the potential harm to patients – and the potential harm to the Medicare program if the change in immunosuppressant regime results in hospitalization, organ rejection, or other serious health consequences.

For these reasons, we strongly urge CMS to withdraw its proposals to authorize Affected Plans to impose Fail First policies on drugs eligible for coverage under Medicare Part B and to limit access to immunosuppressants and other "protected class" drugs under Part D.

Sincerely yours,

Dixon B. Kaufman, MD, PhD
ASTS President

Attachment A:

To: Kim Gifford
ASTS Executive Director

From: Diane Millman, Powers, Pyles, Sutter and Verville PC
Peggy Tighe, Powers, Pyles, Sutter and Verville, PC

Re: Legality of Fail First Restrictions on MA Enrollee Access to Drugs Otherwise Covered under Part B and Restrictions on Access to Protected Class Drugs under Part D, as set forth in RIN 0938–AT92 Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses (the Proposed Rule).

Date: December 31, 2018

This memo sets forth our analysis of the legality of two proposals set forth in the Proposed Rule: The proposal to authorize Medicare Advantage (MA) plans to impose step therapy ("Fail First") coverage limits on drugs that would otherwise be covered under Medicare Part B, and (b) the exceptions to the protections available for "protected class" drugs (including immunosuppressants) in the Proposed Rule. The legality of each of these proposals is examined separately below.

A. Fail First Coverage Limitations on Part B Drugs provided to MA Enrollees

Section 1852(a)(1)(A) of the Medicare Act requires that, except for certain defined exceptions not applicable here, MA Plans provide to MA enrollees the "benefits under the original Medicare fee-for-service program option." These are defined as:

> those items and services (other than hospice care or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B.

Social Security Act Section 1852(a)(1)(B)(i). In fact, the Medicare Act and implementing regulations specifically require that MA plans follow the Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) that are effective in the areas where they do business. (See, e.g. Social Security Act Section 1852 (a)(2)(C)(requiring MA plans with operations in a number of Medicare Administrative Contractor jurisdictions to apply the LCD most favorable to beneficiaries). None of the DME MACs that process Medicare Part B claims for immunosuppressants require a Medicare beneficiary to fail on a lower cost immunosuppressant before coverage is allowed for an immunosuppressant prescribed by the patient's physician. DME MAC LCD L33824, which governs coverage for immunosuppressants includes a number of coverage limitations on immunosuppressants but includes no "Fail First" limitations on coverage. For this reason, the imposition of Fail First coverage limitations on MA enrollees' access to Part B immunosuppressant drugs plainly would be more limited than the coverage available to Medicare beneficiaries who opt to remain in Medicare FFS, and any such Fail First coverage limits would be inconsistent with applicable provisions of the Medicare Act.

B. Limitations on Access to Protected Class Drugs, including Immunosuppressants Prescribed to Prevent Organ Rejection.

The Medicare Act specifically provides that "all" drugs and biologicals in a protected class be offered by Affected Plans. Section 1860D-4(b)(3)(G)(ii) of the Social Security Act states that, unless an exception applies:

> PDP [Physician Drug Plan] sponsors offering prescription drug plans **shall be required** to include all covered part D drugs in [a protected class].

The statute further provides that exceptions are to be authorized only under extremely limited circumstances. Any exception must be adopted under a process that, among other things,

> (I) ensures that any exception to such requirement is based upon scientific evidence and medical standards of practice . . .

Social Security Act, Section 1860D-4(b)(3)(G)(iii)(I).

No provision of the exceptions described in the Proposed Rule require Medicare Part D or Medicare Advantage Plans that provide Part D drug coverage (MA+Plans) to base coverage limits on scientific evidence and medical standards of practice. Rather, two of the new exceptions proposed allow these Plans to exclude an immunosuppressant or other protected class drug from their formularies solely on the basis of cost. Therefore, we believe that it is clear that the Proposed Rule is inconsistent with the governing provisions of the Medicare Act that outline the circumstances under which plans can exclude protected class drugs from their formularies.