AMERICAN SOCIETY OF TRANSPLANTATION

August 31, 2022

Submitted electronically via http://regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS-4203-NC: Medicare Program; Request for Information (RFI) on Medicare – Living Organ Donation & Transplantation Provisions and Comments on Expanding Access: Coverage and Care

Dear Administrator Brooks-LaSure:

The American Society of Transplantation (AST), representing a majority of medical professionals engaged in the field of solid organ transplantation, appreciates the opportunity to comment on the Center for Medicare and Medicaid Service's (CMS) recent Medicare Program Request For Information (RFI), CMS-4203-NC. The Society also greatly appreciates your ongoing leadership and partnership with AST to continuously seek to strengthen the nation's organ transplantation system for patients, donors, and their families.

Current Impact on Living Donors

As you may know, the Living Donor Protection Act (LDPA), H.R. 1255 and S. 377, introduced most recently in the 117th Congress, focuses primarily on the protection of living donors against discrimination in the life, disability and long-term insurance policy coverage arenas. If passed, the LDPA anti-discriminatory insurance protections will further remove policy hurdles for individuals seeking to serve as living donors. That said, the LDPA does not, unfortunately, address other key donor patient coverage deficits with regard to medical and psychological care for living donors. More specifically, AST remains concerned regarding the coverage of living organ donors under Medicare Advantage (MA) plans. As you know, living donors make one of the most selfless acts to provide the gift of life to family, friends, and even strangers. As such, AST strongly believes that MA plans should be required to administer and cover the costs for living donors in a manner consistent with the Traditional Medicare Program.

Background & Transplant Patient Concerns:

- Americans with end-stage renal disease (ESRD) are most often covered by Traditional Medicare and increasingly by replacement Medicare Advantage Plans that are administered by private payors. Access to Medicare Advantage Plans for initial ESRD

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enrollees expanded in 2021. While some applauded this change, the nation's transplant center social workers, financial coordinators and nephrologists were alarmed as recipients of living donors have struggled with coverage for their donors both for pre-donation evaluation and for post-donation care.

- Medicare Advantage policies developed the living donor medical and psychological benefits to largely mimic the same benefits in their private insurance offerings, rather than in accordance with Traditional Medicare's benefits. This is not consistent with current CMS rules that already specify that if a private company is selling a Medicare Advantage product, the plan is required to cover, at a minimum, any Medicare covered services, yet no Medicare Advantage policies offers lifetime coverage for medical or psychological complications post donation and may also inhibit the process to evaluate potential donors.

- Most Medicare Advantage plans do not offer extended coverage for donation-related complications after living donation. In fact, some living donors are only entitled to coverage for 10 or 30 days after discharge, while others are limited to just a single visit post operatively.

- Some Medicare Advantage plans have restrictions on initial living donor evaluations that cause barriers to living donation, such as only approving biologically related donors for evaluation testing and not permitting the evaluation of a living donor until after the recipient has been financially cleared to be listed, and thus limiting donor evaluations to only one donor at a time.

- Per the 2020 SRTR Annual Report, Medicare covers 64.8% of all deceased donor transplants and 37.7% of living donor transplants. With over one-third of the country's living donor transplants covered by Medicare, we strongly believe that Medicare Advantage plans should specifically be required to provide the same coverage for all Medicare-approved covered services for living donors.

Living donors directly impact the critical shortage of deceased donor organs, with 6,540 giving the gift of life in 2021 alone. These selfless individuals deserve quality benefits and coverage through pre- and post-donation that is at least equivalent to Traditional Medicare coverage. Their generous decision to donate is saving lives and removing other individuals from the national transplant waiting list.

<u>Organ Transplant Recipients</u>
We offer the following input on Medicare Advantage programs to be considered for future policy development as there are unique implications for solid organ transplant patients and associated medication access that is necessary to prevent rejection of the transplant, maintain transplant function, and ultimately prevent death in this population.

Regarding section B. Expand Access: Coverage and Care

- **B3: How well do MA plans' marketing efforts inform beneficiaries about the details of a given plan? Please provide examples of specific marketing elements or techniques that have either been effective or ineffective at helping beneficiaries navigate their options. How can CMS and MA plans ensure that potential enrollees understand the benefits a plan offers?**

- MA plans are clear at marketing advantages as compared to original Medicare such as routine vision care, hearing aids, routine dental care, and fitness center membership but are less transparent when reviewing disadvantages such as restricted provider network and higher co-payments, co-insurance, and deductibles. In addition, a major disadvantage of MA plans that should be clearly stated in marketing materials is ineligibility to enroll in Medigap (Medicare supplement insurance) to assist with these copayments, coinsurance, and deductibles. Specific to solid organ transplant, when Part B of the MA plan pays for immunosuppressants based on set criteria, enrollees must pay 20% of the immunosuppressant drug(s) cost. Whereas, with original Medicare, patients are eligible to enroll in Medigap (supplemental) plans to assist with coverage of this 20% cost. This is not currently clearly understood by many patients. In addition, the restricted provider networks of some MA plans, can prevent transplant patients from being able to seek care at their transplant center if they enroll in a specific plan after transplant.
- Web based tools to determine coverage of medications are helpful but specific to solid organ transplant should take into account if immunosuppressant drugs will be paid for by Part B or Part D since this depends on set criteria and will ultimately impact cost to the patient.
- MA plans should be required to be transparent with details regarding covered medications including co-payment and covered conditions. MA plans with Part D are currently required to include all immunosuppressant drugs on their formularies as mandated by the Medicare Prescription Drug Benefit Manual. <u>However, presence of a drug on the plan formulary does not mean it will be covered for an individual beneficiary</u>. Unfortunately, when Medicare Part D is the responsible payer for immunosuppressants, coverage is not mandatory despite these medications being necessary to prevent rejection of the transplant, maintain transplant function, and ultimately prevent death. Solid organ transplant recipients that require off-label drug therapy currently may experience coverage denial by Part D if the drug is used for an indication that is not supported by at least one of the two CMS recognized compendia (Micromedex® or AHFS-Drug Information®). <u>It is important for transplant recipients to have transparent details if the immunosuppressant drugs are covered by the plan for the type of solid organ transplant(s) they have received and if there are any conditions or restrictions</u>. Off-label immunosuppressant drug use is frequent in solid organ transplant since clinical trials may only be conducted in one or two of the solid organ transplant types but then used in others. A combination of lifelong immunosuppressant drugs is required to prevent rejection and death with a limited repertoire of medications. These agents may need to be changed to alternative immunosuppressant medications based on adverse effects and transplant complications therefore it would be best for MA plans to be required to cover all maintenance immunosuppressant drugs for all solid organ transplant types to allow adjustment in regimen by specialized transplant providers when necessary.

- **B10: How do MA plans use utilization management techniques, such as prior authorization? What approaches do MA plans use to exempt certain clinicians or**

items and services from prior authorization requirements? What steps could CMS take to ensure utilization management does not adversely affect enrollees' access to medically necessary care?

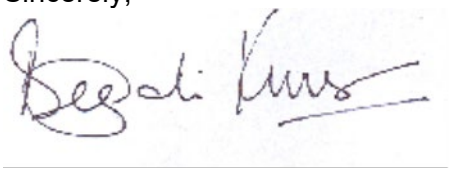
- Prior authorizations requirements by MA plans have increased over time and delay life sustaining medication access as well as add to healthcare administrative costs and clinician inefficiency. Prior authorizations are usually required for most transplant related medications including immunosuppressants and anti-infective agents. MA plan reviewers often do not have clinical knowledge in the subject area and time to review can be detrimental to the patient's health. Expedited review processes typically allow for up to 72 hours and even in that timeframe delayed access can result in deleterious consequences. Specific to solid organ transplant recipients, immunosuppressant medications cannot be missed, or doses delayed, otherwise rejection and graft failure can result. Because of this, ideally CMS should exempt prior authorization requirements of select specialty medications including immunosuppressants which are required to sustain life in solid organ transplant recipients. If prior authorizations continue, real time web-based solutions should be considered, or review time should be decreased to a maximum of 24 hours. Appeal processes are currently cumbersome and add to further delay and inefficiency for clinicians therefore should also be reduced to a maximum of 24 hours. Further, for immunosuppressive drugs in solid organ transplant that are required for the transplant to work properly, there should be a requirement for the MA plan to authorize a short-term supply of the prescribed medication until there is a resolution as to not put the patient at risk for harm. Prior authorization and appeal reviewers should have clinical knowledge in the subject area.
- As previously mentioned, solid organ transplant recipients that require off-label drug therapy currently may experience coverage denial by Part D when it is the payer of an MA plan (after prior authorization) if the drug is used for an indication that is not supported by at least one of the two CMS recognized compendia (Micromedex® or AHFS-Drug Information®). CMS should consider updating the Medicare Prescription Drug Benefit Manual to expand the definition of "medically accepted indication" for immunosuppressant drugs in organ transplantation, similar to what has already been done for anticancer chemotherapeutic regimens. An expanded definition would allow for consideration of peer-reviewed medical literature by MA plans. Additionally, MA and Part D sponsors would also be required to utilize broader Part B recognized compendia, when considering off-label use.

- **B11: What data, whether currently collected by CMS or not, may be most meaningful for enrollees, clinicians, and/or MA plans regarding the applications of specific prior authorization and utilization management techniques? How could MA plans align on data for prior authorization and other utilization management techniques to reduce provider burden and increase efficiency?**
    - Transparency by plans regarding prior authorization requirements, approval/denial metrics for medication prior authorizations, as well as reasons for denial if applicable would be meaningful for enrollees and clinicians.

- MA plans could utilize ICD-10 coding for transplant procedures that have been previously authorized by the plan to exempt requirement for prior authorization of immunosuppressant drugs required to maintain the function of the transplant.
- Currently one type of prior authorization, B versus D determination, requires knowledge of the transplant date as well as Medicare Part A and B active dates to determine which portion pays. A real time solution could be for the transplant date to be entered on the prescription and this information then submitted at the dispensing pharmacy during claim processing rather than clinicians being required to then call or electronically submit this information to the plan after prescriptions are sent. MA plans should have access to Part A and B active dates. This would reduce provider burden for completing prior authorizations for necessary life sustaining medications and increase efficiency.

Thank you in advance for considering our request to improve and strengthen our nation's organ donation and transplantation system. Please do not hesitate to reach out to me directly if you have any questions, concerns or require additional information. Additionally, the AST Director of Government Relations, Bill Applegate, may also be reached at (202) 258-4989 or bapplegate@polsinelli.com.

Sincerely,



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