



Saving and improving lives with transplantation.

American Society of Transplant Surgeons®

August 30, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: [CMS-4203-NC] RIN 0938-AV01 Medicare Program; Request for Information on Medicare Advantage (MA RFI)

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to comment on the MA RFI. ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS very much appreciates CMS' focus on assuring the equity, transparency and access of services provided by MA plans to Medicare enrollees. These issues are of particular interest to ASTS because kidney transplantation is the treatment of choice for End Stage Renal Disease (ESRD), and ESRD-eligible Medicare beneficiaries became eligible to enroll in MA plans for the first time in 2021.¹ A new analysis conducted by Avalere recently found that just over 40,000 Medicare Fee-for-Service (FFS) patients with end-stage renal disease (ESRD) elected to enroll in Medicare Advantage (MA) during the 2021 open enrollment period. This enrollment shift increased the proportion of ESRD patients enrolled in MA from 23% to 30%. In light of the growing proportion of ESRD-eligible Medicare beneficiaries enrolled in MA plans, ASTS believes that it is critical for MA plans to provide access to kidney transplantation that is at least comparable to that provided to ESRD-eligible beneficiaries who are covered under traditional Medicare FFS.

In fact, the ESRD-eligible beneficiaries who are newly eligible for enrollment in MA plans may be somewhat more appropriate for transplantation than those eligible for Medicare coverage due to age/disability, since the former group may be somewhat younger and less likely to have multiple other chronic and other serious clinical conditions. Generally, ESRD patients who are clinically appropriate for transplantation are those who are in relatively better health than those who remain on dialysis, and transplantation is more commonly performed among those who are younger than 65. For this reason, the extension of MA eligibility to the ESRD-eligible patient population is of particular interest to the transplant community.

The Benefits of Renal Transplantation

Kidney transplantation is often the best treatment option for Medicare patients with ESRD. The average kidney transplant recipient lives more than twice as long as the average dialysis patient and enjoys markedly improved quality of life.

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Furthermore, transplantation is the most cost-effective long-term treatment for such patients: The cost difference between a patient on dialysis and a patient who has been transplanted successfully is in the range of \$50,000 per patient per year. Therefore, transplantation is not only the preferred clinical option for those ESRD patients who meet applicable clinical criteria but is also the most cost-effective option for the Medicare Program.

Renal Transplantation in the Context of MA

Significantly, the cost benefits of kidney transplantation accrue in the post-transplant period. For this reason, these savings may not accrue to MA plans that encourage the transplantation of either ESRD-eligible or Age/Disability-eligible beneficiaries. Age/Disability-eligible and ESRD-eligible Medicare enrollees have the option to switch MA plans or opt for Medicare FFS coverage in the post-transplant period, and Medicare coverage for ESRD-eligible beneficiaries in the post-transplant period is limited to three years, which is approximately the time necessary to recoup the cost of the transplant procedure. Since the likelihood that MA plans will benefit financially by encouraging transplantation of Age/Disability-eligible or ESRD-disabled Medicare beneficiaries is uncertain, it is extremely important that access to kidney transplantation be monitored closely by CMS.

It is worrisome that the available data indicates that the number of Medicare patients enrolled in MA plans who receive transplants is substantially lower than the number of transplants predicted by the CMS Hierarchical Condition Risk Adjustment Model. A 2016 study conducted by Avalere found that the CMS model over-predicts the number of MA transplant patients by 15%, and that the difference is statistically significant. Our concerns are reinforced by USRDS' observation in its most recent report that the percentage of transplant recipients covered by MA in 2019 was relatively low (8.2%), even though, by 2019, MA plans covered nearly 25% of Medicare beneficiaries with ESRD.²

A number of other factors exacerbate our concerns. Transplantation is universally subject to prior authorization by health plans, including MA plans. As noted in the MA RFI, concerns have been raised by MA plans' use of prior authorization (PA) to limit access to Part A and Part B benefits available to Medicare beneficiaries who obtain covered services under traditional Medicare. A recent analysis of MA plans' PA practices that conducted by the Office of the Inspector General³ indicates that, among the PA requests that MA plans denied, 13% met Medicare coverage rules. Moreover, transplant centers are not subject to time and distance network adequacy requirements, and access to transplant programs is limited in many areas of the country.

For these reasons, we urge CMS to closely monitor ESRD-eligible MA plan enrollees transplant rates and to ensure that MA plan enrollees are provided the same access to transplantation as those beneficiaries who obtain coverage under Medicare FFS.

Living Donor Transplantation

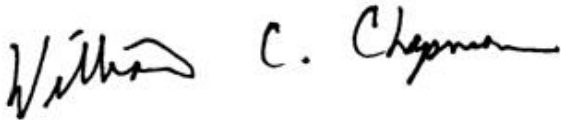
We are particularly concerned about MA enrollees' access to living donor transplantation. Unfortunately, due to prior authorization requirements, it is our experience that MA Plans do not provide the same access to living donor transplants as Medicare FFS, and when coverage is provided, payment is often limited by, for example, limiting eligibility to living donors who are related to the recipient or limited the number of potential living donors who may be evaluated. We encourage CMS to audit MA plans' coverage and payment policies for living donor transplantation to ensure that MA coverage and payment policies do not limit MA enrollees' access to living donor transplantation.

Payment to MA Plans for Non-Renal Organ Acquisition Costs (OAC)

Under current policy, while Medicare pays transplant programs for renal OAC based on a reasonable cost methodology regardless of whether or not a Medicare beneficiary is enrolled in MA, the same is not true of extra-renal OAC. Rather, while Medicare FFS pays for extra-renal organs on the basis of reasonable costs, payment for extra-renal organs under MA is based on amounts negotiated between the MA plan and the transplant center. Negotiated amounts, which may include extra-renal OAC as part of a "global" payment that also includes other transplant program items and services, are often inadequate to cover actual extra-renal OAC. CMS is currently considering changing the way its share of renal and extra-renal OAC under Medicare FFS, to ensure that Medicare FFS does not pay for the OAC of non-Medicare patients. A basic assumption underlying this

potential change is that non-Medicare FFS payers pay for their fair share of both renal and extra-renal OAC. Because the negotiated amounts paid by MA plans and other health plans for extra-renal organs generally do not cover the OAC for these organs, the policy change under consideration by CMS for FFS Medicare has the potential to jeopardize the financial viability of extra-renal transplant programs. To ensure that MA plans pay their fair share of OAC for MA enrollees who need extra-renal organ transplants, we urge CMS to modify the MA payment methodology so that Medicare pays for the reasonable costs of extra-renal organs provided to MA enrollees, as it does for extra renal organs provided to Medicare FFS beneficiaries.

Sincerely yours,

A handwritten signature in black ink that reads "William C. Chapman". The signature is written in a cursive style with a large, stylized "W" and "C".

William Chapman, MD, FACS
President
American Society of Transplant Surgeons

¹ Under prior law, only those who were already enrolled in a MA plan at the time they developed ESRD were eligible for enrollment in a MA plan. And while Special Needs Plans (SNPs) could enroll Medicare beneficiaries with ESRD, the number of SNP plans that did so was relatively limited.

² <https://adr.usrds.org/2021/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd>.

³ *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care* Christi A. Grimm Inspector General April 2022, OEI-09-18-00260. <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>.