American Society for
Transplantation and Cellular Therapy

August 31, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: Medicare Program; Request for Information on Medicare (CMS–4203–NC)

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit comments in regard to the *Medicare Program; Request for Information on Medicare Advantage (RFI)*.

The ASTCT is a professional membership association of more than 3,000 physicians, scientists, and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current FDA approvals for chimeric antigen receptor T-cell (CAR-T) therapy.

For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases. ASTCT members very much rely on team care for the complex cancers and other disorders requiring hematopoietic stem cell transplants (HSCTs) and newer cell therapies like CAR-T. Therefore we are pleased to comment on the agency's request for information on shared/split E/M services in facilities and coverage and payment for dental care.

If CMS has any questions regarding these comments, please contact Alycia Maloney, the ASTCT's Director of Government Relations, at amaloney@astct.org.

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ASTCT President, 2022-2023

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The ASTCT wishes to provide the following comments specific to three objectives identified in the RFI (A, B and D).

RFI Objective A. Advance Health Equity

What steps should CMS take to better ensure that all MA enrollees receive the care they need, including but not limited to the following:

- *Enrollees from racial and ethnic minority groups.*
- *Enrollees who identify as lesbian, gay, bisexual, or another sexual orientation.*
- *Enrollees who identify as transgender, nonbinary, or another gender identity.*
- *Enrollees with disabilities, frailty, other serious health conditions, or who are nearing end of life.*
- *Enrollees with diverse cultural or religious beliefs and practices.*
- *Enrollees of disadvantaged socioeconomic status.*
- *Enrollees with limited English proficiency or other communication needs.*
- *Enrollees who live in rural or other underserved communities.*[1]

Rural and Underserved Communities: Hematopoietic stem cell transplants, hematopoietic stem cell gene therapies, Chimeric Antigen Receptor T-cell (CAR-T) therapy, and other cellular immunotherapies are all highly complex medical procedures requiring very specialized facilities and care teams. Accordingly, these episodes of care are most likely to happen in academic medical centers or specialized cancer centers; these facilities are limited in their number and are almost exclusively in major metropolitan areas. Patients in need of HSCT, CAR-T or similar therapies often need to seek care far from home, potentially for extended periods of time in order to complete the necessary clinical evaluations, the procedure itself and sufficiently recover under medical supervision. **We ask that the agency consider mandating travel and lodging benefits for certain types of specialized care that are not widely available, such as transplantation and cellular therapy**. The ASTCT recommends up to 180 days of travel and lodging support in conjunction with a prior authorization for cellular therapy in order to allow a beneficiary to travel for an evaluation and care planning, return and stay close to their treatment center throughout the immediate post-treatment monitoring period (transplant centers often require patients to stay nearby for 100 days) and return trips for follow-up care and monitoring. This support is commonly available in commercial (non-governmental) payer benefits and would ensure that beneficiaries are not excluded from potentially life-saving care because of their geographic location.

[1] CMS defines ''underserved communities'' as ''populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.'' CMS derives this definition from that of the same term in Executive Order 13895 (United States, Executive Office of the President [Joseph Biden]). ''Executive Order 13985 of January 20, 2021, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' 86 FR 7009 (January 25, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf.

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<u>RFI Objective B. Expand Access: Coverage and Care</u>

What factors do MA plans consider when determining whether to make changes to their networks? How could current network adequacy requirements be updated to further support enrollee access to primary care, behavioral health services, and a wide range of specialty services?

The current network adequacy guidance provided by CMS to MA plans includes facility types that furnish many types of specialty services, including solid organ transplants, but fails to include a requirement for facilities that provide stem cell and/or bone marrow transplants. This means that MA plans can set up networks that do not include any facilities able to provide stem cell/bone marrow transplants to beneficiaries and these network swould likely receive approval by CMS. The ASTCT hopes that this is an unintended oversight since Part A and Part B coverage of stem cell/bone marrow transplants have been in place for over twenty years. **The ASTCT asks CMS to include stem cell/bone marrow transplants in the list of facility specialty types that MA plans are required to include in their networks.**

Medicare has a long history of requiring coverage for both autologous and allogeneic stem cell/bone marrow transplants through National Coverage Determination 110.23[2]. Without ensuring access to facilities that can provide the services described in NCD 110.23, MA plans will be unable to fulfill their requirement of providing at least the same level of services to MA beneficiaries as those accessible to Fee-for-Service beneficiaries.

Finally, we note that many of the hospitals and providers offering stem cell/bone marrow transplant services are also at the forefront of providing other cellular therapies for cancer and blood system disorders, including Chimeric Antigen Receptor T-cell therapy (NCD 110.24[3]). These therapies are also critically important to offer to Medicare beneficiaries enrolled in MA plans. Therefore, we reiterate our ask that CMS add stem cell/bone marrow transplants in this listing of facility specialty types that MA plans must include in their networks.

<u>RFI Objective D. Support Affordability and Sustainability</u>

As MA enrollment approaches half of the Medicare beneficiary population, how does that impact MA and Medicare writ large and where should CMS direct its focus?

Parity of additional inpatient day requirement: CMS requires all Medicare supplement plans to offer an additional 365 days of inpatient care if/when a beneficiary exceeds their annual benefit and lifetime reserve days. MA plans do not have the same requirement, which can cause severe financial distress to beneficiaries that need additional care after exhausting their reserve days. This type of benefit is not something that the average beneficiary would know to seek out information on and utilize to influence his/her coverage choices in advance. As the MA population grows and as these beneficiaries seek and receive stem cell transplant, cellular therapies and other care that

[2] Medicare Coverage Database; *National Coverage Determination 110.23: Stem Cell Transplantation*

[3] Medicare Coverage Database: *National Coverage Determination 110.24: Chimeric Antigen Receptor (CAR) T-cell Therapy*

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currently requires lengthy inpatient stays, this disparity between benefits will become increasingly problematic.

Use of Medicare Advantage shadow claims for IPPS rate-setting: ASTCT recently submitted the following comments to CMS in response to the FY 2023 Inpatient Prospective Payment System Proposed Rule. We repeat them here as they are relevant to the agency's questions about how the growth in Medicare Advantage beneficiaries impacts the overall program.

The ASTCT recommends that CMS study how the use of Medicare Advantage shadow claims could be used to bolster case volumes for the treatment of rare diseases and conditions.

In 2021, more than 40 percent of Medicare beneficiaries were enrolled in MA plans; this is a dramatically different landscape than only 10 years ago, when the MA enrollment rate was just above 10 percent.[4] The Congressional Budget Office (CBO) projects that this trend will continue, with the share of all beneficiaries enrolled in MA plans rising to approximately 51 percent by 2030.[5]

MA enrollment also varies significantly across the United States, with substantially higher enrollment in MA on both coasts, the populous Southern states (e.g., Texas, Tennessee, Georgia and Florida) and the upper Midwest.[5] This variation means that the FFS claims that Medicare utilizes are not only decreasing in total number (now representing only 50-60 percent of enrollees) but also are becoming increasingly less representative of the national population's geographic distribution.

Finally, the states where MA enrollment is the highest are also those states with the highest number of academic and specialized medical centers, where many patients with rare diseases seek specialized care. These factors create a situation where claims from a limited number of centers in certain geographic areas of the country will drive an increasing share of the rate-setting data, even though they may not be representative of the majority of the patients and/or care being provided.

In addition to the decreased FFS claims volume creating rate-setting concerns within the FFS segment itself, we note that MA plans frequently utilize FFS MS-DRG base payments for their payment benchmarks. For the reasons stated above, the use of a set of claims that is no longer nationally representative to establish payment to hospitals treating MA beneficiaries is neither logical nor appropriate.

Conclusion

Once again, the ASTCT thanks CMS for the opportunity to comment. Please contact Alycia Maloney, ASTCT Director of Government Relations, at amaloney@astct.org, for any further questions or discussion on these issues.

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[4] Freed M, et al., *Medicare Advantage in 2021: Enrollment Update and Key Trends*, June 21, 2021. Online: www.kff.org/medicare/issue-brief/medicare-advantage-in-2021-enrollment-update-and-key-trends/

[5] Congressional Budget Office (CBO), *Medicare - CBO's March 2020 Baseline as of March 6, 2020*, Washington (DC): CBO, March 19, 2020. Online: https://www.cbo.gov/system/files/2020-03/51302-2020-03-medicare.pdf

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