February 23, 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; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit Programs

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit our comments on the Contract Year 2023 Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit Programs [CMS-4192-P] proposed rule.

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. The clinical teams in our society 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.

The members of ASTCT have been focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases, for more than 25 years.

ASTCT supports the use of network reviews as part of the Medicare Advantage bid process

Under current rules, MA plans must attest that they have adequate provider networks that provide enrollees with sufficient access to covered services and CMS asserts that it will not deny an application based on the evaluation of the MA plan’s network. MA plans are expected to use CMS MA Network Adequacy Criteria Guidance (2017), to plan their adherence to CMS’ expectations concerning networks. In the guidance, CMS lists both provider and facility specialties that MA plans are expected to include in their networks to help ensure access to Part A and Part B covered services.

CMS is proposing to move beyond attestation by requiring new or expanding MA applicants to demonstrate compliance with the network adequacy standards. We support CMS’ proposal to reinstate network reviews as part of the application process.
ASTCT requests that network adequacy standards include stem cell/bone marrow transplant facilities

Appendix E of the current network adequacy guidance includes facility types that furnish all types of specialty services, including solid organ transplants, but fails to include a requirement for facilities that include stem cell and/or bone marrow transplants. This means that MA plans can set up networks that do not include any facilities that furnish stem cell/bone marrow transplants to beneficiaries and MA plans lacking these important facilities would likely receive approval by CMS. The ASTCT hopes that this is an unintended oversight since the history of Part A and Part B coverage of stem cell/bone marrow transplants is over twenty years old. 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\(^1\). 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. The ASTCT asks CMS to notify existing MA plans that they must update their networks to include stem cell/bone marrow transplants in their networks.

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\(^2\)). 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.

The ASTCT wishes to express its appreciation for the opportunity to provide these comments on the proposed Medicare Advantage Contract Year 2023 Technical Changes [CMS-4192-P]. The ASTCT welcomes the opportunity to discuss these recommendations in more detail or to answer any questions you may have. Please contact Alycia Maloney, ASTCT Director of Government Relations, at amaloney@astct.org for any follow up issues.

Sincerely,

\(^1\) Medicare Coverage Database; National Coverage Determination 110.23: Stem Cell Transplantation

\(^2\) Medicare Coverage Database: National Coverage Determination 110.24: Chimeric Antigen Receptor (CAR) T-cell Therapy
Stella M Davies, MBBS, PhD, MRCP
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