



American Society for  
Transplantation and Cellular Therapy

August 8, 2019

Tamara Syrek Jensen, JD  
Director, Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Re: National Coverage Decision for Chimeric Antigen Receptor (CAR) T-cell Therapy for  
Cancers (CAG-00451N)

Dear Ms. Syrek-Jensen,

The American Society for Transplantation and Cellular Therapy (ASTCT) is very pleased with the recent coverage announcement from The Centers for Medicare and Medicaid Services (CMS) in the Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N). The Society appreciates the opportunity to work closely with the Agency on this National Coverage Determination (NCD). ASTCT is a professional membership association of more than 2,200 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 participating in trials that led to current FDA approvals for CAR T-cell therapy.

In comments to CMS dated March 15, 2019, the Society expressed its concerns about the CAR T-cell coverage policy as proposed and provided suggestions to improve the policy. Specifically, ASTCT emphasized that the implementation of an NCD that covered these therapies through coverage with evidence development (CED) would create significant barriers to providing current and future CAR T-cell therapies to beneficiaries in need of these breakthrough treatments. The Society is delighted that the Agency eliminated the CED requirement for coverage and instead encourages centers to submit data to registries such as the Center for International Blood and Marrow Transplant Research (CIBMTR). ASTCT is also pleased that CMS has expanded coverage for FDA-approved products to include labeled indications or others supported in one or more CMS-approved compendia. This change is critical to ensuring patients have access to the latest approved CARs without the need to regularly reconsider this coverage policy.

Although data reporting to a registry is not mandatory, we appreciate that CMS encourages healthcare facilities to report data on CAR T-cell recipients to a registry such as the CIBMTR. The National Cancer Institute (NCI) has supported the CIBMTR in establishing the Cellular Immunotherapy Data Resource (CIDR) to capture high-quality long-term follow-up data on patients receiving CAR T-cell therapies, including data that will be utilized by the Food and



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Drug Administration (FDA) for post-approval safety studies. Continued support of the CIDR and the CIBMTR by the NCI will be critical so that high-quality data on safety and efficacy of these therapies for Medicare beneficiaries are available to the Agency.

While the Society is extremely encouraged by these coverage improvements for CAR T-cell therapies, we remain deeply concerned about patient's access to this therapy given Medicare's inpatient reimbursement rates and policies. These policies are expected to continue creating barriers to access for patients; CAR-T certified centers should not be forced to incur significant financial losses to deliver covered CARs to Medicare beneficiaries nor should they be forced to set high charges in an attempt to appropriately reverse engineer Medicare's new technology add-on payment to receive the maximum add-on payment. While we appreciate that CMS did increase the NTAP from 50 percent to 65 percent, it left the "lesser of" formula in place which means structural payment system problems remain intact which is exactly what needs to change. We recognize that it takes time to make large changes to long-standing policies and payment systems but with these novel therapies upon us and more on the way we welcome the opportunity to work with the Agency to fix the inadequacies that remain in the payment system.

In summary, we are very appreciative that CMS considered ASTCT's recommendations in establishing the NCD for CAR T-cell therapy and applaud this decision. ASTCT thanks the Agency for its commitment and looks forward to working together further to ensure access to these highly-innovative lifesaving therapies for patients.

Sincerely,

A handwritten signature in black ink, appearing to read "Navneet Majhail".

Navneet Majhail, MD, MS  
Director, Blood and Marrow Transplant Program, Cleveland Clinic  
President, American Society for Transplantation and Cellular Therapy

cc: Seema Verma, CMS Administrator