April 29, 2019

The American Society for Transplantation and Cellular Therapy (ASTCT) is a professional membership association of more than 2,200 physicians, scientists and other healthcare professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication and clinical standards. ASTCT is dedicated to improving the application and success of hematopoietic cell transplants and other cellular therapies, such as CAR-T.

To that end, ASTCT would like to request the modification of the two current CAR-T HCPCS product codes: Q2041 and Q2042. We believe that the inclusion of the leukapheresis and dose preparation procedures inside the product code presents numerous coding and charging complications for providers. Additionally, combining medical procedures with the product itself inside of code creates issues with the HIPAA standard transaction set rules that govern the use of codes on hospital claims.

Last year, for the 2018 HCPCS Committee Meeting, ASTCT (formerly ASBMT) submitted a comment that respectfully but firmly disagreed with the preliminary coding recommendations offered by CMS for codes Q2040 and Q2041 (Q2040 having since been replaced by Q2042). We expressed our concerns in detail through a letter submitted to CMS in February of 2018, and at an in-person meeting with CMS in May 2018. At the time, we were also aware that many providers have reached out to CMS independently to share similar concerns. In fact, at last year's May meeting there was unanimous support for the coding change request. Since that time, we have spent considerable time working with providers, discussing their experience with using the Q-codes, and how the issues involved with these codes have impacted their organizations.

The feedback and information we have received has only strengthened our belief that hospital services such as cell collection and cell processing should be removed from the product Q- codes. We again ask CMS to consider the following points and to modify the existing CAR-T product Q-codes so that they exclude clinical services provided to patients by hospitals and reported in hospital cost reports. We would also like to take the opportunity to emphasize that our concerns about the Q code are related to coding, billing, and data accuracy in regard to CAR-T and not to reimbursement as that is a separate determination that we understand the Hospital Outpatient Payment Policy group will make. Rather, we observe continued operational issues with these codes which have been made more challenging since the release of new revenue codes for the hospital services effective April 1, 2019 and the AMA Category III CPT codes effective January 1, 2019. These concerns have been echoed by many others, and most recently by the National Uniform Billing Committee (NUBC) at its April 9th, 2019 meeting. It is for these reasons we again feel it critical that CMS revise the existing CAR-T Q-codes.

ASTCT continues to disagree with the Agency's perspective that inclusion of hospital rendered clinical services, such as cell collection and cell processing, are a manufacturing element of the drug and are required due to the FDA definition of a biological. We agree that the cells collected by the hospital are a necessary step in the overall therapy. The work and the expense associated with the physician-ordered and hospital performed cell collection and cell processing is borne solely by the hospital and recorded in the hospital's cost report and should be able to be reported to CMS on claims following standard code and claim transactions governed by Administrative Simplification. Embedding these services into a drug code is inappropriate in our opinion and runs counter to all other CMS-instructed standard provider billing guidance and practices about how hospitals are to report services rendered to patients at the time and in the care setting they are provided.

The American Medical Association's release of Category III CAR-T CPT codes along with the NUBC's unanimous approval of new CAR-T related revenue codes for the reporting of hospital services should be

recognized by CMS separately from the reporting of the drug product code when infused. It is the ASTCT's expectation that Category III CPT codes will eventually transition to being Category I CPT codes, but only if providers are able to report these codes and CMS and the AMA are able to see the occurrence of these in the population.

Codes released by the AMA, and the NUBC, are governed by transaction set rules, as such CMS and all other payers should accept the coded data submitted by providers in a uniform manner while addressing coverage and payment issues outside of standard claim and code reporting. In addition, hospitals are governed by unique cost reporting rules requiring gross charges for the same services to be posted to all patients' accounts at the same amount, and this requirement among other important guardrails dictate how they document and report hospital services provided to patients on the date of service. The cell collection for CAR-T, when it occurs in the hospital department, is a procedure performed on a patient within the four walls of the hospital, and the hospital alone bears the cost of this service which it is required to report as charges on all patient accounts and to report on claims via claim and code transactions and finally, through the cost report. With respect to CAR-T, CMS has to date, instructed providers to perform so many things in enormously complex and atypical manner that providers must incur tremendous administrative burden to deviate from their usual process for reporting the services rendered to their patients simply to conform to CMS' Q code reporting instructions.

The concerns of the provider community responsible for serving patients and providing access to these therapies have significantly increased since the last HCPCS meeting, rather than having decreased due to the continued and exacerbated complexities that ensue as a result of CMS' current coding and billing guidance. The current Q code structure reflects a concept of the therapy that does not match the provider or patient experience. As such, we implore the agency to allow coding and claims reporting to occur in a straightforward manner while addressing payment and coverage issues internally upon adjudication of standard claims.

We welcome the opportunity to discuss these issues further with CMS.
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