Centers for Medicare & Medicaid Services; HCPCS Committee Meeting

May 16, 2018

The American Society for Blood and Marrow Transplantation (ASBMT) 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. The ASBMT is dedicated to improving the application and success of hematopoietic cell transplants and other cellular therapies, such as CAR-T.

The ASBMT respectfully but firmly disagrees with the preliminary coding recommendations offered by CMS for codes Q2040 and Q2041. We have expressed our concerns in detail through a letter submitted to CMS in February and at an in-person meeting with CMS in March 2018. We are also aware that many providers have reached out to CMS independently to share the same concerns. **We ask CMS to consider the following points and to modify the proposed coding recommendation to exclude provider clinical services from current and future Q or J codes for CAR-T products.**

The ASBMT considers the Agency's inclusion of clinical services, such as apheresis, with the payment for delivery of a drug to be inappropriate, as it runs counter to all other CMS-instructed standard provider billing guidance and practices. Providers are concerned about violating state transparency and price reporting laws and whether accepting payment from manufacturers for clinical services could conflict with the terms of hospitals' participation agreements with Medicare, which stipulate that hospitals agree to accept no more in payment than the Medicare allowable amounts for inpatient and outpatient services.

The inclusion of clinical services with payment for a drug is the *de facto* creation of a bundled care episode. If CMS' intention is to create a bundled payment, such as a C-APC, for the provision of CAR-T in the outpatient setting, a proposal should be made through the Outpatient Prospective Payment System rule-making process in order to allow for full stakeholder engagement and commentary.

Other than being the first autologous cell-based drug, Provenge (Q2043) is not related to CAR-T or other autologous cell therapies for hematologic malignancies. CAR-T represents an entirely new group of therapies with different processes, patient populations and treatment intentions. As an example of a core difference, the same providers provide apheresis and the infusion to the patient, versus a manufacturer-contracted model of apheresis providers different than the infusing provider for Provenge. CMS needs to review the CAR-T situation independently from prior autologous products.

The concerns of the provider community responsible for serving patients and providing access to these therapies should outweigh the preferences of manufacturers. The current Q-code structure reflects one company's business model and does not take the variation of other manufacturers' practice into account. If this Q-code structure is implemented uniformly with all upcoming autologous cell-derived products, providers will not have the ability to recover the costs associated with apheresis and other services if a manufacturer chooses not to reimburse providers. Patients do not receive CAR-T in isolation from the rest of the course of their treatment and providers should not have to take on unnecessary and undue steps to separate CAR-T clinical services from the rest of treatment course.

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