



ASBMT™

American Society for Blood
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CC:
Carol Blackford
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RE: CMS issuance of code Q2041

Ms. Hake:

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.

Hematopoietic cell transplantation (HCT), also known as stem cell transplantation (SCT), is a medical sub-specialty comprised of physicians with Board Certifications in Internal Medicine, Medical Oncology, Pediatrics, Hematology and/or Immunology. Due to their unique clinical expertise and training, ASBMT member clinicians and cellular therapy programs will be the primary individuals and teams initially providing CAR-T to patients in need of treatment. The ASBMT anticipates that CAR-T is the first of many engineered cellular therapies to be approved in the coming decade and is tracking coding and reimbursement issues associated with these therapies accordingly. As part of that initiative, the ASBMT has assembled a Cellular Therapy Coding & Reimbursement Task Force that includes financial and clinical representatives from institutions currently providing CAR-T. We note that this Task Force is available to CMS staff for dialogue on any coding issues or changes being considered.

Concerns regarding Q code for Axicabtagene Ciloleucel (Yescarta)

The CMS [HCPCS Quarterly Update](#) page indicates that a Q code has been issued for the Axicabtagene Ciloleucel (Yescarta) product ([Other Codes Effective April 1, 2018](#)), with plans for implementation as of April 1, 2018.

HCPCS/MOD Code	Action	Short Descriptor	Long Descriptor	Effective Date	Pricing
Q2041	Add	Axicabtagene ciloleucel car+	Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion	4/1/2018	51

During a recent meeting of the Task Force, we discussed the issuance of Q2041 and the descriptor language associated with the code. The following concerns were raised by members of the Task Force.

The code descriptor includes leukapheresis. The facilities providing FDA-approved CAR-T products to patients enter into business agreements with the manufacturers of these products with specific stipulations regarding how services associated with the process should be handled financially. The distinct services within the CAR-T process include: collection of the autologous product used for manufacturing (apheresis/leukapheresis), preparation and handling of the product for shipment, receipt of the product and preparation of the product for infusion to the patient. Novartis's arrangements with treatment centers providing its product, Kymriah, include reimbursement to the center directly from the manufacturer for the assess fair market value of apheresis and other pre-shipment costs. The Kite/Gilead product, Yescarta, does not have the same contracting provision for direct reimbursement from manufacturer to the center for these services. For Yescarta, providers are expected to bill payers directly and separately for those services as they incur. The inclusion of leukapheresis within the description of the Q-code for Yescarta creates issues within the financial systems of these facilities because of the discrepancy between the manufacturer agreement provisions and CMS' Q code instructions. Please note that Task Force members have also expressed concern about the Novartis service agreement structure, but the Q code for Kymriah (Q2040) does accurately reflect the current provider-manufacturer agreement.

Providers on our task force strongly would prefer that the leukapheresis service remain separately billable outside of the provision of CAR-T for the following reasons:

- 1) The inclusion of three different sets of services that happen at three different time points is problematic for provider financial systems. Providing leukapheresis, performing processing to ship to the manufacturer, receiving the cells back from the manufacturer 14-30 days later and preparing them for infusion happen at different time points and across different parts of the organization. It is a substantial amount of administrative and financial system re-work to create a format that would allow for proper cost tracking and reimbursement allocation.
- 2) In the case where a patient receives leukapheresis but does not receive the infused CAR-T product, providers are concerned about how they would bill Medicare for Q2041, as Kite/Gilead would not be paying the provider for the leukapheresis. If CMS proceeds with releasing Q2041 as written, we respectfully ask that CMS release clear guidance about what providers are to do if they collect cells for the purpose of CAR-T, but do not move forward with infusion due to patient status or manufacturer failure.
- 3) Patients receiving apheresis for CAR-T manufacture are also receiving active treatment for their disease and likely will have other services on the same day of apheresis. Separating out the apheresis procedure from other services provided on the same date of service is not part of the normal operational process hospitals have in place for registered patients; for certain electronic health record systems, separation of a service provided on the same day as the provision of other services is not structurally possible within the billing system. The handling of a single code separate from the other services provided in a care episode will require manual intervention and be prone to error.
- 4) Adopting a code framework where the leukapheresis is packaged with the drug sets a precedent that may be problematic for future CAR-T products or the evolutions of current product systems, as the leukapheresis may happen in a location separate from the treatment center.
- 5) The ASBMT understands that Kite has applied for a permanent J code for the Yescarta product and that their application excludes leukapheresis from the code descriptor. Assuming CMS finalizes both the April release of Q2041 as written and also assigns the requested J-code beginning in January 2019, hospital providers would have to significantly modify their handling of the costs associated with CAR-T administration twice within the next year – once to ‘bundle’ leukapheresis with the product if the Q code goes into effect on April 1 as written and a second time to resume an unbundled structure when the J code goes into effect as requested by Kite. Maintaining a consistent billing pattern until and through the time of the J code implementation would be preferable which is why we request CMS revise its descriptor of Q2041.

The code descriptor includes “dose preparation” procedures. Task Force members expressed a lack of clarity for what particular processes are included within this description. On behalf of its members, the ASBMT requests clarity from CMS on which services it deems to be dose preparation procedures. The same concerns about separately billable services expressed in the prior paragraphs remain as handling, thawing and individual lab tests on the cells should be individually billed. Task Force members would prefer that only the processes directly performed by the manufacturer at their facilities would be included in the product’s HCPCS code.

Summary

We understand the desire of the Agency to maintain continuity between codes for similar products, particularly with new technology. We assume CMS will have concerns with variation in coding and share those sentiments with the Agency. However, the different business and contractual models employed by the current manufacturers make it difficult for providers to implement Q2041 as described. We would welcome the chance to dialogue further with CMS regarding this issue, as the many other products are expected to be available and FDA-approved within the next 3-5 years.

ASBMT Resources for CMS

The ASBMT appreciates the thoughtfulness CMS is putting into CAR-T issues and our ongoing opportunities to dialogue with staff on the issue. ASBMT peer-elected leaders, member clinicians and policy staff are available as a resource for issues associated with HCT, CAR-T and other cellular therapies. Please do not hesitate to reach out whenever we may be of assistance.



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ASBMT President, 2017-2018

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