CMS Proposes Coverage with Evidence Development for CAR T-Cell Therapies

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On Friday, February 15, 2019, CMS released a proposed decision memo to cover FDA-approved Chimeric Antigen Receptor (CAR) T-cell therapy, which uses a patient's immune system T-cells to fight certain types of blood cancers, pursuant to a Coverage with Evidence Development (CED). Two CAR T-cell products are currently approved by the FDA for treatment of certain patients with relapsed or refractory acute myeloid leukemia and large B-cell lymphoma. In addition, multiple clinical trials involving CAR T-cell therapies are currently underway across the country, including FDA-required post-approval studies. There is no national Medicare policy currently regarding coverage for this therapy, and local Medicare Administrative Contractors currently determine whether to pay for it.

This announcement by CMS appears to be a generally positive development for stakeholders seeking more clarity regarding parameters for coverage of the therapy. If adopted, the CED does ensure coverage on a national basis for the near future for certain types of CAR T-cell therapy under certain conditions, and during that time stakeholders can continue to gather additional data to support an argument for broader coverage as appropriate, as well as to support an argument for an appropriate reimbursement methodology.

The goal of the CED is to provide nationwide consistency in Medicare coverage determinations, improve patient access, and generate further evidence regarding the therapy. Under the proposed decision memo, a number of requirements would apply for coverage, including, without limitation, the following: (1) the patient must either be enrolled in a prospective, national, audited registry or enrolled in a CMS-approved clinical study; (2) the hospital must have a cellular therapy program that meets certain conditions, along with a designated care area and written guidelines; (3) the treatment must be an FDA-approved biological; (4) specific data regarding the clinical characteristics of patients and outcomes must be provided in response to the CED questions; (5) the patient must be monitored for at least two years after treatment; and (6) the studies must adhere to certain standards of scientific integrity and relevance to the Medicare population. CMS would then use the evidence generated to further evaluate coverage for the therapy.

This proposed decision memo has been in process for some time, with CMS initially commencing a National Coverage Analysis (NCA) in May of 2018, including an initial comment period, which ran through June 15, 2018. In the proposal, CMS describes the review that it has engaged in to date to determine whether there is

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sufficient evidence to conclude that the therapy will improve health outcomes, including the review of results of multiple clinical trials published in peer-reviewed journals, FDA materials, professional society recommendations, and other expert opinions. CMS concluded that "this is a rapidly evolving field and that initial evidence appears promising but inconclusive at this time to definitively determine whether CAR T-cell therapy improves health outcomes in the Medicare population."

For the avoidance of doubt, CMS states, in proposed language to be added to the National Coverage Determination (NCD) Manual, that the proposed CED would not alter Medicare coverage for items or services that are covered or non-covered pursuant to the existing national coverage policy for Routine Costs in a Clinical Trial, NCD section 310.1 (the Medicare Clinical Trial Policy or CTP). Under the CTP, the clinical trial item or service is an excluded cost, but routine costs — including items and services typically provided absent a clinical trial (referred to as "standard of care"), clinically appropriate monitoring and prevention of complications, and reasonable and necessary items and services in the event of complications from participation in the clinical trial – are covered. In this case, routine costs would continue to be covered, as well as other items and services provided as a result of coverage under the CED.

Of note, an NCD addresses coverage parameters, but the reimbursement methodology for the therapy is a separate process altogether. Receiving appropriate reimbursement for CAR T-cell therapy, which is extremely expensive (i.e., $373,000 or more for the drug product alone) continues to be a significant issue because Medicare does not generally provide for pass-through payment of high-cost inpatient drugs. Academic medical centers and other health systems that offer the therapy rely on new technology add-on payments and outlier payments to offset (often only partially) the substantial costs associated with CAR T-cell therapy. The reimbursement problems associated with inpatient CAR T-cell therapy are expected to intensify in the coming years because the new technology add-on payments will expire after FY 2020 and the high cost of CAR T-cell drug products is expected to distort the weighting of inpatient diagnosis related groups (DRGs), which are set in a budget-neutral manner, as well as the outlier payment threshold, which must be set to produce outlier payments of only 5 to 6 percent of DRG payments. These Medicare reimbursement concerns may also fuel efforts to transition CAR T-cell therapy from the inpatient to outpatient setting, where Medicare reimbursement for drugs is largely based on the average sales price plus six percent, to the extent evidence from the CED process indicates such a transition is feasible from a clinical care perspective.

CMS is seeking comments on the proposal through March 17, 2019, and anticipates completing the NCA process in May 2019.

Hooper, Lundy & Bookman's Academic Medical Center/Teaching Hospital Working Group provides assistance to academic medical centers and teaching hospitals in all aspects of medical education compliance. For assistance relating to this issue, please contact Katrina Pagonis in San Francisco at 415.875.8500, Bob Roth or David Vernon in Washington, D.C. at 202.580.7713, Amy Joseph in Boston at 617.532.2702, or your regular Hooper, Lundy & Bookman contact.

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