



Commentary

Ensuring Patient Access to CAR T Therapy *AACI Responds to CMS Medicare Coverage Proposal*

By Richard Bondi and Clint Divine



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Commentary Overview

- Appropriate reimbursement models will be vital to guaranteeing equitable access to chimeric antigen receptor T-cell (CAR T) therapies and their associated supportive care and hospitalization.
- With about half of AACI cancer centers approved to provide CAR T therapies, the growing demand for such treatment is posing administrative challenges for AACI members.
- In response to the Centers for Medicare & Medicaid Services' coverage proposal for CAR T therapy, AACI has made recommendations in a number of areas to ensure patient access to these life-saving treatments.

There is currently no national Medicare policy for chimeric antigen receptor T-cell (CAR T) therapies—which can cost hundreds of thousands of dollars, well beyond the means of most patients—leaving coverage decisions to regional Medicare administrative contractors. In February, the Centers for Medicare & Medicaid Services (CMS) released its proposed National Coverage Analysis for CAR T therapy.

As noted in a **previous AACI Commentary**¹, appropriate reimbursement models will be vital to guaranteeing equitable access to CAR T therapies and their associated supportive care and hospitalization – especially important to patients insured by Medicare and Medicaid. U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb voiced concerns that the current reimbursement system could stifle development of novel treatments, noting that the FDA may soon allow CAR T products to be administered in outpatient settings to reduce costs.

The first CAR T therapy, which reinfuses patients with boosted versions of their own immune cells, was approved by the U.S. Food and Drug Administration in 2017. That approval, for

Novartis' Kymriah®, was soon followed by YESCARTA®, from Gilead Sciences, Inc. It is believed that FDA will approve several new CAR T therapies within the next five years.

CAR T therapies are encouraging, yet the reimbursement barriers associated with CAR T are apparent. The cost for patient infusion ranges from \$350,000 to \$500,000. This may not include additional costs associated with the preparation and administration of the therapies. This also does not consider instances where patients must be hospitalized or monitored closely to ensure the side effects a patient incurs are not life-threatening.

With nearly half of AACI cancer centers approved to provide CAR T therapies by early 2018, the growing demand for such treatment is posing administrative challenges for AACI member centers. To establish best practices, AACI launched a **CAR T Initiative** in fall 2018. Prior to the initiative's formalization, AACI submitted public comments to CMS regarding its proposed national coverage analysis. In March, the initiative's administrative barriers working group approved final comments on CMS' coverage proposal, adapted from comments from the American Society for Transplantation and Cellular Therapy (ASTCT), an organization that AACI has collaborated with through the working group.

It is vital that access to CAR T therapy for Medicare patients is not hindered, but rather expanded. Beyond presenting a burden to patients, many of the components of CMS' national coverage determination (NCD), as proposed, may cause undue stress for AACI member centers that provide these life-saving therapies because of the rapid advancements being made to develop new CAR T therapies. It is AACI's view that it is too early to implement the NCD. However, should CMS proceed with implementing an NCD, AACI asks CMS to consider the following recommendations.

Patient Coverage

AACI previously requested clarification that YESCARTA® and Kymriah® are covered by Medicare for their medically-accepted uses. CMS proposes to cover "autologous treatment with T-cells expressing at least one chimeric antigen receptor..." in patients with "relapsed or refractory cancer." As these considerations are already part of the FDA approval process, AACI asks that CMS revise this language to indicate coverage for FDA-approved products and to include indications covered on the FDA-approved label. This will ensure coverage for effective treatments that have already been approved, as well as guaranteeing coverage for new FDA-approved CAR T treatments.

Coverage with Evidence Development (CED) and Registry Requirements

In consultation with its members and partner organizations, AACI recommends eliminating the CED requirement in favor of a data collection condition that would reduce the burden on cancer centers. Section (3)(a)(iii) of the proposal lists a number of clinical data elements that furnishing hospitals must track, "at baseline, at treatment, and at follow-up three months, six months, 12 months, and 24 months after the treatment is administered," as part of the coverage requirements. AACI is concerned that many of its member cancer centers do not have the resources to meet this requirement. As a result, hospitals may opt out of the CED – an especially troublesome scenario for patients living in rural areas who already have difficulty accessing these therapies.

In addition to the CED requirement, CMS states that furnishing hospitals must participate in "a prospective, national, audited registry" reviewed and approved by CMS. AACI supports designation of the Center for International Blood & Marrow Transplant Research (CIBMTR) as an approved registry. Many AACI members are familiar with CIBMTR reporting, and AACI believes using this registry will reduce the burden on many providers. AACI also requests that CMS approve a registry on or before the decision implementation date to allow for consistent coverage for Medicare patients.

Patient Reported Outcomes (PROs)

CMS has also proposed that furnishing hospitals track PROs in the outpatient setting. While PRO measurement is important, its implementation in clinical trials requires significant expenditure of financial and human resources. Like the CED requirement, many AACI member centers may not be able to launch and support PRO studies, further increasing the possibility that some centers may opt out of providing CAR T therapy for Medicare patients. More

importantly, asking Medicare patients being treated with CAR T, most of whom are extremely sick, to report outcomes may cause them more stress. Therefore, AACI requests that PROs not be included as a condition of coverage at this time. If the PRO requirement is included in the final decision, AACI requests that CMS provide further clarification on the definition of an “outpatient setting,” as this language will impact who will be covered for CAR T treatment and where.

Practitioner and Provider Criteria

In listing practitioner and provider criteria, CMS proposes coverage of CAR T therapy in a hospital that meets requirements “consistent with a nationally accredited Cellular Therapy Program.” The agency notes that standards it would expect to find in a Cellular Therapy Program are included in the Foundation for the Accreditation of Cellular Therapy (FACT) Common Standards for Cellular Therapies (2015) and Standards for Immune Effector Cell Administration (2016), which describe quality management guidelines to incorporate performance data, as well as policies and procedures that address risk management of operations.

AACI supports the use of FACT as a required accreditation program if CMS requires accreditation for centers. Many AACI cancer centers are FACT-accredited, and AACI believes the program promotes patient safety and ensures exemplary clinical and administrative practice.

Conclusion

As CAR T therapies expand and develop further, it is important that CMS ensures all patients can access such treatments if recommended by their physician. Consequently, AACI urges CMS to maintain its commitment to allowing cancer centers to practice medicine and allow treatment decisions to remain with the patient and their physician.

¹ *McGuirk, J. A Revolution in Cancer Care: AACI's New Initiative Will Establish Best Practices in CAR T Therapy. AACI Commentary. December 2018.*

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