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ACCC
Association of Community Cancer Centers



June 15, 2018

*BY ELECTRONIC DELIVERY*

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**Re: National Coverage Analysis (NCA) Tracking Sheet for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N)**

Dear Ms. Syrek Jensen:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) opening of an NCA for CAR T therapies for cancers.[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 20,000 cancer care professionals from approximately 2,000 hospitals and private practices nationwide. It is estimated that 65 percent of cancer patients nationwide are treated by a member of ACCC.

On May 16, 2018, CMS accepted a request to open an NCA with respect to CAR T therapies, of which two, Kymriah® (tisangenlecleucel) and Yescarta® (axicabtagene ciloleucel), currently are approved by the Food and Drug Administration (FDA).

[1] CMS, National Coverage Analysis (NCA) Tracking Sheet for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N), https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=291 (last visited June 7, 2018).

These two drugs were each approved under a Biologics License Application,[2] and each is subject to a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of these therapies outweigh their risks.[3]

ACCC is excited about the promise these revolutionary CAR T therapies hold to save lives and transform cancer care, and we appreciate CMS's efforts to ensure that they are appropriately covered by Medicare. ACCC urges CMS to cover CAR T therapies for their FDA-approved indications in all settings of care permitted under their labeling and REMS, to allow Medicare Administrative Contractors (MACs) discretion to cover other uses of these therapies that are supported by the compendia or literature, to ensure that coverage is not interrupted during the NCA process, to complete this process in as short a time as possible, and to minimize any unintended consequences of this process, such as stifling innovation of CAR T therapies currently in the pipeline. These issues are addressed in more detail below.

1. **CMS should adopt a national coverage policy ensuring full Medicare coverage of CAR T therapies for their FDA approved indications in all settings of care permitted by their labeling and REMS**

CAR T therapies, such as Yescarta and Kymriah, should be covered for their FDA-approved indications. By including "any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication" in Medicare's statutory definition of drugs,[4] Congress clearly intended for such therapies to be covered by Medicare. Congress also defined a "medically accepted indication" to include any FDA-approved indication.[5] There can be no question that under this statutory definition, Kymriah and Yescarta, as well as any other CAR T therapies currently in the pipeline, should be covered for their FDA-approved indications. For these reasons, completing an NCA for these CAR T therapies should be swift and straightforward. ACCC therefore urges CMS to adopt a national coverage policy to cover CAR T therapies for their FDA approved indications promptly and without qualification.

We also urge CMS to cover these therapies in all settings of care permitted by their FDA-approved labeling and REMS. The REMS for Yescarta and Kymriah limit the settings of care in which these therapies can be offered to sites that are specially certified, have immediate access to tocilizumab, and implement required training for staff involved in the prescribing, dispensing, or administering of the therapies.[6] These requirements help to ensure that these therapies are provided safely, in accordance with the clinical data, and CMS should not impose further requirements on physicians or hospitals that furnish these therapies. Not only would any additional requirements be unnecessary for the therapies available

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[2] Letter from Wilson W. Bryan, M.D., Director, Officer of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research, FDA, to Dr. Manisha Patel, PharmD, Novartis Pharmaceuticals Corporation (Aug. 30, 2017), *available at* https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM574106.pdf and Letter from Tejashri Purohit-Sheth, M.D., Director, Division of Clinical Evaluation and Pharmacology/Toxicology, Center for Biologics Evaluation and Research, FDA, to Jonelle Chapman, Director Regulatory Affairs, Novartis Pharmaceuticals Corporation (May 1, 2018), *available at* https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM606523.pdf; and Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics and Evaluation and Research, CMS and Wilson W. Bryan, Director, Office of Tissues and Advanced Therapeutics, Center for Biologics Evaluation and Research, CMS, to Rizwana F. Sproule, Ph.D., Vice President, Regulatory Affairs, Kite Pharma, Inc. (Oct. 18, 2017), *available at* https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM581259.pdf.

[3] *Id.*

[4] Social Security Act (SSA) § 1861(t)(2)(A).

[5] *Id.* § 1861(t)(2)(B).

[6] What is the Yescarta REMS Program? https://www.yescartarems.com/; Risk Evaluation and Mitigation Strategy (REMS), http://www.kymriah-rems.com/.

today, but they also might be inappropriate for CAR T therapies approved in the future. Trials currently are ongoing in the community setting, and the results of these studies could support access to care under different conditions than are currently required by the REMS. In addition, we are hopeful that continued innovation will improve management of cytokine release syndrome and other adverse events, allowing CAR T therapy to be administered safely in outpatient settings. We urge CMS to not establish additional limitations on settings of care, beyond those required by the FDA, that could inappropriately limit access to CAR T therapies.

**2. CMS should allow Medicare Administrative Contractors (MACs) to cover FDA-approved CAR T therapies for indications listed in national compendia or supported by certain literature**

CMS should permit MACs to determine whether other uses of CAR T therapies outside of their FDA-approved indications will be covered. The Medicare statute also defines a "medically accepted indication" with respect to an anticancer chemotherapeutic regimen as one where a drug has been approved by the FDA and either the use is supported by a list of statutorily approved compendia or a MAC determines, based on medical evidence and guidance from CMS, the use is medically accepted.[7] ACCC urges CMS to allow MACs to cover off-label uses of CAR T therapies that meet these criteria, including through coverage decisions made on a case-by-case basis for existing CAR T therapies and any others that are approved in the future. Such a practice would be consistent with longstanding Medicare policy and would allow coverage of these therapies to evolve along with the evidence regarding their uses.

**3. CMS should clarify that FDA approved indications for CAR T therapies are covered by Medicare during the NCA process and complete that process as soon as possible to maintain uninterrupted patient access to these therapies**

Past experience suggests that stakeholders can become confused during the NCA process about whether a particular therapy is actually covered. CMS should be proactive about staving off this confusion and immediately issue guidance that coverage of CAR T therapies for FDA-approved indications should continue uninterrupted, consistent with the statute. Without such guidance, ACCC is concerned that MACs, providers, and patients might believe that these therapies are not covered while the NCA process is underway, inadvertently limiting patient access to these essential and potentially life altering therapies.

In addition, ACCC urges CMS to complete the NCA process as quickly as possible. Though CMS has set the deadline for this process as February 16, 2019, consistent with the statutory requirement for completion of NCAs that are referred to the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) within nine months,[8] CMS is permitted to complete this process sooner. ACCC urges CMS to complete this process as soon as possible to ensure patient access to these therapies.

**4. Concern over the outcome of the NCA process may be stifling innovation of CAR T therapies in the pipeline**

There are currently a number of CAR T therapies at various stages in the pipeline that could potentially be affected by whatever policy decision CMS adopts. CAR T therapies are a revolutionary

[7] *Id.*
[8] *Id.* § 1862(l)(2)(B).

treatment for patients with cancer that have the potential to dramatically improve survival rates and improve patient outcomes. They are also particularly costly therapies to develop, however, and manufacturers need to be confident that Medicare will cover these therapies once approved to make investment in this research sustainable. CMS should make sure that it does not take any steps to stifle innovation of needed CAR T treatments, such as finalizing a coverage decision that would limit coverage of CAR T therapies.

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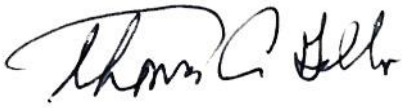
ACCC appreciates this opportunity to comment on the CAR T therapies NCA. If you have any questions regarding these comments, please do not hesitate to contact Leah Ralph, ACCC Director of Health Policy at lralph@accc-cancer.org or (301) 984-9496 ext. 223.

Respectfully,



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