COLLEGE of AMERICAN PATHOLOGISTS

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RE: Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers CAG-00451N

Dear Ms. Syrek Jensen and Drs. Szarama and Paserchia:

The College of American Pathologists (CAP) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) National Coverage Analysis (NCA) for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The CAP appreciates the efforts of CMS to recognize cell transfer immunotherapy in the treatment of select cancer patients with certain malignancies. While the CAP supports coverage for the current on-label use of the Food and Drug Administration (FDA) approved tisagenlecleucel (Kymriah®) and axicabtagene ciloleucel (Yescarta®) CAR T-cell therapies, **we are concerned that any attempt at a national coverage policy to standardize these services at this time may fail to recognize the individual care services provided by physicians and other health care professionals, and we therefore urge CMS to consider the following.**

The proposed NCA states that "treatment protocols vary but may be summarized in five steps." These steps implicitly acknowledge several separate and distinct treatment processes required of highly trained physicians and other health care professionals that are separate and distinct from the manufacturing process. For example, pathologists play a critical role as integral members of the cancer patient management team during this therapy. In addition to contributions in diagnosing original diseases and monitoring disease persistence and recurrence, pathologists are also directly involved in the provision of CAR-T Cell therapy clinical services—notably, the harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T Cells. Additional related services such as the preparation for transportation of the harvested T lymphocytes, the receipt and preparation of genetically modified CAR-T Cell products, and the administration of autologous CAR-T Cells to patient recipients, must also be included in the coverage of CAR-T Cell therapy services. All of these services are separate and distinct from the manufacturing facility's genetic modification of T lymphocytes for CAR-T Cell development.

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We believe that the inclusion of “leukapheresis” or “harvesting of blood-derived T lymphocytes” which is a clinical service, with the payment for delivery of a CAR-T Cell drug to be inappropriate as it appears to conflict with other CMS-instructed standard provider billing guidance and practices. Physician services and facility reimbursement can be properly described and captured through development of AMA CPT Codes and/or HCPCS Level II “G” codes and subsequent valuation. The CAP has joined with other CAR-T Cell therapy providers and stakeholders in pursuing appropriate codes for reporting purposes to recognize the various service elements associated with that technology. The CAP would welcome the opportunity to provide additional information to the CMS to support the code development and valuation processes. Efforts by CMS to develop coverage policies should take these activities into account in order to be aligned with the services necessary to make these important therapies available to Medicare and Medicaid beneficiaries.

To ensure adequate support for these very intensive treatments when indicated, the CAP seeks to ensure that all provider services are recognized so that their resource requirements may be met. Therefore, we ask that if any national coverage policy is implemented, it should recognize the critical patient-centered care services provided by physicians and other health care professionals, during both the pre-and post-manufacturing phases of CAR-T cell therapy.

The quality of care provided to Medicare beneficiaries depends on access to treatments appropriate to their needs, including new technologies. For this reason, **the CAP opposes a national coverage policy that requires Coverage with Evidence Development (CED).** The CED process has historically taken years to result in a coverage or non-coverage decision, which is too slow to provide reasonable access to new technologies, and only offers treatment to a limited population of patients who have access to trials and registries.

We further recommend that CMS not preclude Medicare Administrative Contractors (MACs) from determining coverage for new technologies at the local level as they become available. MACs should have the flexibility to reasonably choose to cover new technologies not yet reviewed by the FDA, by applying a rigorous review process per national guidelines.

As new technologies advance with the accumulation of scientific evidence through ongoing clinical trials by manufacturers and others, any national coverage policy should be flexible to allow for new technologies as they are developed. We also recognize the large cost of a CAR-T therapy regimen and potentially severe side effects and we encourage CMS to establish an evidence-based but rapidly responsive process for routinely extending coverage for newer therapies as they become available, while at the same time providing patients with access to the best treatments. Our recommendation is that CMS institutionalize the expertise brought to such determinations by professional organizations such as the National Comprehensive Cancer Network (NCCN), rather than engaging in redundant efforts.

Thank you for your willingness to consider our comments on the proposed decision memo. The CAP welcomes the opportunity to provide CMS with additional clinical or other information to assist CMS with its coverage policy decision.

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