



COLLEGE of AMERICAN PATHOLOGISTS

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RE: Proposed Decision Memo for 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 to the Centers for Medicare & Medicaid Services (CMS) on its proposed national coverage policy 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 CMS' efforts to nationally cover 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 CAR T-cell therapies, we urge CMS to consider the following recommendations.

Flexibility to allow for new technologies. The quality of care provided to Medicare beneficiaries depends on access to treatments appropriate to their needs, including new technologies. The Coverage with Evidence Development (CED) process has historically taken years to result in a coverage or non-coverage decision. The CAP is concerned that a national coverage policy that depends on CED 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. As a result, Medicare beneficiaries may suffer from delays in coverage of CAR-T therapies. For this reason, we urge CMS to ensure that its national coverage policy be sufficiently flexible to allow 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 establish a process for routinely extending coverage for newer therapies as new technologies advance with the accumulation of scientific evidence through ongoing clinical trials by manufacturers and others.



Recognize the individual services provided by physicians and other health care

professionals. Treatment protocols involve several separate and distinct treatment processes required of highly trained physicians and other health care professionals that are separate and distinct from the CAR-T cell manufacturing process. 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 a national coverage policy 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. 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.

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 is inappropriate as it conflicts with other CMS-instructed standard provider billing guidance and practices. The CAP 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 this technology. Physician services and facility reimbursement can be properly described and captured through the 2019 AMA CPT Codes noted below. Efforts by CMS to develop coverage policies should take these activities into account to align with the services necessary to make these important therapies available to Medicare and Medicaid beneficiaries.

2019 AMA CPT Codes:

CPT Long Descriptor

- 0537T Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
- 0538T Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
- 0538T Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
- 0540T Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

Do not preclude Medicare Administrative Contractors (MACs) from determining coverage for new technologies at the local level as they become available. Given that CAR-T cell therapy is a rapidly expanding innovative therapy and ongoing clinical trials are likely to identify new biomarker targets for both hematological and solid malignancies which may not all be reviewed by the FDA, we urge CMS to develop a process to update coverage as new evidence emerges so that Medicare



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beneficiaries may have timely and appropriate access to care. We urge CMS to allow MACs to have the flexibility to cover new technologies not yet reviewed by the FDA, by applying a rigorous review process per national guidelines.

Thank you for your willingness to consider our comments on the Proposed Decision Memo. The CAP welcomes the opportunity to provide additional information to the CMS to support coverage for CAR-T services.