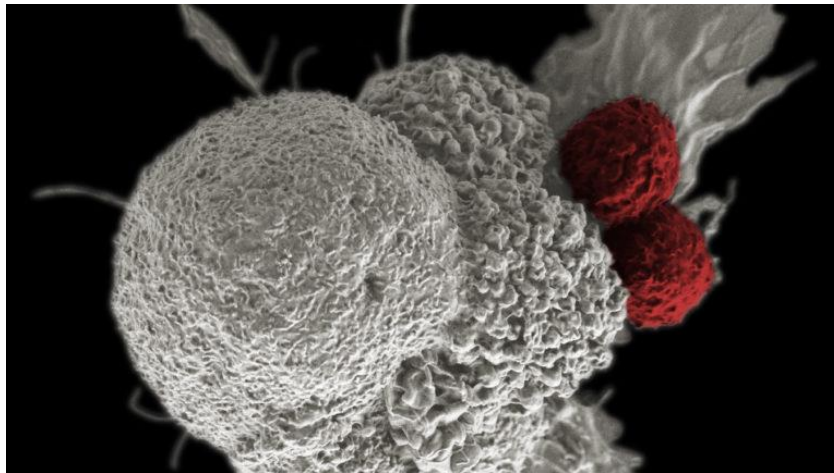


## Another Advocacy Win for Patients: Medicare Finalizes Coverage for Some CAR T-Cell Therapies



Source: NIH and Referenced in [STAT News Article](#)

On August 7, the Centers for Medicare & Medicaid Services (CMS) finalized the decision to cover FDA-approved Chimeric Antigen Receptor T-cell, or “CAR T-cell” therapy, which is a form of cancer treatment that uses a patient’s own genetically-modified immune cells to fight disease. FDA-approved CAR T-cell therapies are approved to treat some people with specific types of cancer – certain types of non-Hodgkin lymphoma and B-cell precursor acute lymphoblastic leukemia.

CMS approved the NCD (National Coverage Decision) without some of the requirements that had some providers concerned. With the decision, it establishes coverage that increases reimbursement, approves usage in certain FDA-approved healthcare facilities other than hospitals, reduces some reporting requirements that may have discouraged adoption, and supports ongoing monitoring and collaboration in the future between CMS, the FDA, and the NCI.

“This decision is great news,” commented Dellann Elliott Mydland, President and CEO of the EndBrainCancer Initiative. “We applaud the CMS for moving this forward and providing expanded coverage for these promising treatments. The EBICI is excited about the research for CAR T-Cell Therapy to treat brain cancer and we hope that research will progress to the point where these treatments will become approved and funded for brain cancer patients in the future.”

Highlights from the CMS decision include:

- Provides consistent and predictable patient access nationwide.
- Increases reimbursement from 50% to 65%
- CMS will work closely with its sister agencies (FDA & NCI) to monitor outcomes for Medicare patients receiving this innovative therapy going forward.
- Will cover CAR T-cell therapies when they are provided in healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) for FDA-approved indications (according to the FDA-approved label).
- Medicare will cover FDA-approved CAR T-cell therapies for off-label uses that are recommended by CMS-approved compendia, thus approving a rollback of previous regulations so that treatments can be done in a clinical setting other than a hospital, potentially expanding access and lowering the costs.
- FDA required the manufacturers of CAR T-cell therapies to conduct post-marketing observational studies involving patients treated with the therapies. CMS will leverage information obtained from the FDA's required post-approval safety studies for CAR T-cell therapies to the fullest extent possible.

In the decision released Wednesday, CMS acknowledged that it had received a wide range of comments about the topic of patient reported outcomes and said it encouraged patient participation in ongoing research that may include PROs in the future. But incorporating them as part of the NCD was not included.

#### **Articles and Sources for Information**

- CMS Decision Memo ([LINK](#))
- CMS Press Release ([LINK](#))
- American Journal of Managed Care (AJMC) Article ([LINK](#))
- ASCO (American Society of Clinical Oncology) Post ([LINK](#))
- Physicians Weekly Article ([LINK](#))
- STAT News Article ([LINK](#))