MultipleMyelomaHub

Relapsed/refractory patients, General MM

Medicare announces coverage of chimeric antigen receptor (CAR) T-cell therapy in the United States (US)

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Chimeric antigen receptor (CAR) T-cell therapy is a highly personalized treatment approved by the United States (US) Food & Drug Administration (FDA) for the treatment of certain types of relapsed/refractory (R/R) non-Hodgkin lymphoma (NHL) and pediatric R/R acute lymphoblastic leukemia (ALL). CAR T products are also being developed, or are in clinical trials, in other indications such as additional hematological malignancies and solid tumors.[1-4] The two FDA approved CAR T therapies are tisagenlecleucel, which is licensed for R/R diffuse large B-cell lymphoma (DLBCL) and R/R pediatric ALL, and axicabtagene ciloleucel, approved in R/R DLBCL, primary mediastinal B-cell lymphoma, high-grade B-cell lymphoma and DLBCL that results from follicular lymphoma.[1-4] These CAR T products were also approved by the European Medicines Agency (EMA) in August 2018.[5,6]

CAR T therapy involves removing a patient's T-cells via apheresis, genetically modifying them to express a CAR, and then reinfusing the cells into the patient. Due to the personalized aspect of the therapy, there are significant associated costs. The current list price for axicabtagene ciloleucel is $373,000, and tisagenlecleucel is $475,000.[5] This is true for the treatment-associated costs such as product manufacturing and delivery, but there are also additional costs associated with any inpatient admissions as well as the patient-associated costs such as travel to, and from, the hospital.

It has now been announced by the Centers for Medicare and Medicaid Services (CMS), that Medicare will pay for CAR T therapies. This will cover associated costs, as well as that of the therapy itself including: administration of the drug, apheresis to collect the cells, the manufacturing of the cells, and the reinfusion into the patient. Additionally, Medicare will cover outpatient or inpatient care. The treatment must take place at certified healthcare facilities which are enrolled in the Risk Evaluation and Mitigation Strategies (REMS) program which is FDA-mandated. Furthermore, Medicare will support the use of CAR T in an FDA approved indication or for other uses when the product is FDA-approved and the use is supported in ≥ one CMS-approved compendia.[7,8] The American Society for Hematology (ASH) have supported this decision in a comment *The Washington Post*.[9]

Whilst CAR T is not currently approved for the treatment of multiple myeloma (MM), there are many ongoing trials of CAR T products for R/R MM. Click the links to read more about the latest clinical data from CAR T trials in MM and when to use CAR T in MM.

References

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