FDA Eases Access to CAR-T Therapies

Removal of Risk Evaluation and Mitigation Strategies will make the immunotherapy available to more people and may reduce

geographic, income and racial disparities.

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The Food and Drug Administration (FDA) has loosened restrictions on CAR-T therapies for blood cancers, a move that is expected to make the revolutionary immunotherapy available to more people in more settings, especially those who do not live near major cancer centers.

The new policy lifts Risk Evaluation and Mitigation Strategies (REMS) for the following approved BCMA-directed and CD19-directed autologous CAR-T therapies:

- Abecma (idecabtagene vicleucel)
- Breyanzi (lisocabtagene maraleucel)
- Carvykti (ciltacabtagene autoleucel)
- Kymriah (tisagenlecleucel)
- Tecartus (brexucabtagene autoleucel)
- Yescarta (axicabtagene ciloleucel)

The newest CAR-T therapy, Aucatzyl (obecabtagene autoleucel), was approved in November without a REMS requirement. Experts expect that future approvals likely will not include REMS.

“REMS is a useful safety system, but reevaluation over time helps inform whether a REMS is still needed to ensure that the benefits of a product outweigh its risks,” FDA chief medical and scientific officer Vinay Prasad, MD, MPH, said in a statement. “Eliminating the REMS that is no longer needed also expedites the delivery of potentially curative treatments to patients and reduces burden on providers.”

Chimeric antigen receptor T-cell therapy—better known as CAR-T—modifies an individual’s own T cells to enable them to better fight cancer. The treatment involves removing a sample of a patient’s white blood cells and using gene therapy to reprogram T cells with synthetic receptors that recognize a particular type of cancer. The engineered cells are then multiplied in a laboratory and infused back into the body.

The first CAR-T therapy, Kymriah, was approved in 2017 to treat children and young adults with relapsed or refractory acute lymphoblastic leukemia. (Cancer Health featured the advent of this new type of treatment in its first issue in 2018.) Since then, several other CAR-Ts have been approved for leukemia, lymphoma and multiple myeloma.

Unleashing genetically modified T cells not only kills cancer cells but also can lead to an excessive immune response that harms healthy tissue, with symptoms ranging from fever and flu-like symptoms to organ failure and death. Prescribing information for approved CAR-T therapies includes warnings about cytokine release syndrome (CRS) and neurological toxicity. CRS can be treated with immunosuppressive drugs, such as tocilizumab (Actemra), and corticosteroids.

To mitigate this risk, the FDA initially required hospitals administering CAR-T therapies to be specially certified, with staff trained to recognize and manage these adverse effects and tocilizumab on hand for immediate administration.

But over the past decade, as the treatment has become more widely used, clinicians have learned to spot these side effects earlier and manage them better, making REMS unnecessary. The FDA also made changes to the prescribing information for Abecma and Breyanzi, advising that patients must stay near a healthcare facility for two instead of four weeks and shortening the length of time patients must wait before driving from eight to two weeks.

As a result, CAR-T therapies are expected to become more readily available at community cancer centers, including those in rural areas, which should help reduce geographic, income and racial disparities.

The change is a “patient-friendly move that will significantly reduce the burden on patients seeking transformative treatments for deadly blood cancers,” Stephen Majors, of the Alliance for Regenerative Medicine, told BioSpace.

Information about CAR-T risks can be conveyed adequately via product labeling and medication guides, according to the FDA’s June 27 statement. These therapies will continue to be subject to safety monitoring through adverse event reporting requirements. The elimination of the REMS does not change FDA requirements for manufacturers to conduct post-marketing safety studies to assess the risk of secondary malignancies and long-term safety with 15 years of follow-up.

“Physicians and institutions now have greater experience identifying and managing toxicities with the currently approved CAR-T products,” said Richard Pazdur, MD, director of the FDA Oncology Center of Excellence. “This approach will potentially facilitate patient access to these treatments while continuing to prioritize safety.”

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