Medicare Will Partially Cover CAR-T Therapy

The program will pay 65% of the cost of providing the custom-made immunotherapy.

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Medicare, the federal health insurance program for people age 65 and older and some people with disabilities, will now cover chimeric antigen receptor T-cell therapy, better known as CAR-T, the Centers for Medicare and Medicaid Services (CMS) announced this week. However, the program will not pick up the full cost of providing the one-time treatment, which approaches half a million dollars for the medication alone.

CAR-T therapy was first approved in 2017, but its adoption has been slow, in part because of uncertainties about how to pay for the costly custom therapy. To date, these therapies have been available at some cancer centers—especially major comprehensive cancer centers and those affiliated with academic institutions—but not others.

In a long-awaited decision, CMS said that Medicare will cover CAR-T therapies for indications approved by the Food and Drug Administration (FDA) when provided in qualified healthcare facilities—including oncology clinics as well as hospitals—that follow special safety guidelines. The program will also cover certain recommended medically accepted off-label uses of the treatment.

“As the first type of FDA-approved gene therapy, CAR T-cell therapies are an important scientific advancement in this promising new area of medicine and provide treatment options for some patients who had nowhere else to turn,” CMS administrator Seema Verma said in a press release. “Today’s coverage decision provides consistent and predictable patient access nationwide. CMS will work closely with our sister agencies to monitor outcomes for Medicare patients receiving this innovative therapy going forward.”

CAR-T therapy reprograms immune cells to recognize and attack cancer. A sample of a patient’s T cells are collected and sent to a manufacturing facility, where they are genetically modified to create a customized “living drug” designed to target specific types of cancer cells. The personalized therapy is then infused back into the same individual after they receive strong chemotherapy to kill off some of their existing immune cells to make room for the new ones.

There are currently two FDA-approved CAR-T therapies. Novartis’s Kymriah (tisagenlecleucel) is approved for children and young adults with B-cell acute lymphoblastic leukemia (ALL) and for

adults with large B-cell lymphoma. Gilead/Kite's Yescarta (axicabtagene ciloleucel) is also approved for adults with large B-cell lymphoma.

CAR-T therapies have also shown promise for the treatment of chronic lymphocytic leukemia and multiple myeloma. To date, CAR-T therapy has not shown as much success against solid tumors, but variations on this approach are being studied for triple-negative breast cancer, lung cancer and other malignancies. Researchers are also working on off-the-shelf versions of CAR-T therapy that don't require modifying an individual patient's cells, making it less costly and available more quickly.

Kymriah and Yescarta are priced at $475,000 and $373,000, respectively, for the one-time treatment, though Novartis matches Kite/Gilead's price for Kymriah's adult lymphoma indication.

CMS said that Medicare will cover 65% of the cost of providing the treatment, and hospitals may request additional reimbursement on a case-by-case basis. However, the agency has not yet determined the full payment rate—including expenses related to administering the treatment and managing side effects—and it could be years before this is settled, Verma told STAT.

CMS will monitor response to CAR T-cell therapies among Medicare recipients, as outcomes data for this population is relatively limited and the treatment represents a significant change from current practices, the agency said. CMS will draw on information obtained from post-approval safety studies required by the FDA.

The National Cancer Institute (NCI) supports the Cellular Immunotherapy Data Resource, developed by the Center for International Blood and Marrow Transplantation Research, which collects data on stem cell transplants and other cell therapies . To date, the registry has information about the course of treatment, response outcomes and adverse events for 1,400 people treated with CAR-T therapies.

"We remain committed to supporting the efficient development of safe and effective CAR T-cell therapies," said acting FDA commissioner Ned Sharpless, MD. "We will also continue to carefully assess the benefits and risks when considering whether to approve new CAR T-cell products. We will continue working with our partners at CMS and [NCI] to help advance the development and availability of these therapies to patients in need."

Click here to read the CMS CAR-T coverage decision memo.

Click here to read the CMS booklet Medicare Coverage of Cancer Treatment Services.

Click here for a feature about CAR-T therapy in the Winter 2018 issue of Cancer Health.

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