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## Non-drug expenses boost CAR-T immunotherapy costs

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By Marilynn Larkin

NEW YORK (Reuters Health) - Taken together, non-drug and drug costs of the two approved chimeric antigen receptor T-cell (CAR-T) immunotherapies could result in annual expenditures of more than \$3 billion for the U.S. healthcare system, researchers say.

Dr. Immaculada Hernandez of the University of Pittsburgh School of Pharmacy and colleagues evaluated drug and non-drug costs of tisagenlecleucel (Kymriah) and axicabtagene ciloleucel (Yescarta) using various clinical scenarios.

Both are approved for treatment of adults with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Non-drug costs included those associated with leukapheresis, lymphodepletion therapy and adverse effects of CAR-T immunotherapy, such as stays in the intensive care unit for cytokine release syndrome (CRS), which occurred in 44% of patients who received tisagenlecleucel in clinical trials.

As reported online April 26 in JAMA Oncology, the total costs per patient treated with tisagenlecleucel ranged from \$478,777 for those without CRS to \$531,823 for those with severe (grade 3 or higher) CRS.

The mean expected cost was \$510,963, which decreased to \$432,131 under an outcomes-based pricing arrangement with the manufacturer.

The mean expected cost of axicabtagene ciloleucel per patient treated was \$402,647.

"With approximately 600 U.S. patients eligible for tisagenlecleucel every year, the \$432,131 estimate would translate into annual expenditures of \$259 million," the authors state. "With

7,500 U.S. patients annually eligible for axicabtagene ciloleucel, the total expenditures would be more than \$3 billion."

"Health care resources are not unlimited," Dr. Hernandez told Reuters Health. "Money needed to cover new highly expensive therapies with a high budget impact such as CAR-T needs to come from somewhere - either from a re-allocation of funds from other therapies and health services that will no longer be covered or from increased premiums."

"If we don't want premiums to keep increasing," she said by email, "it is necessary to evaluate new therapies thoroughly and assess the benefit they bring for their cost, and how that ratio compares to that of other health services."

"Only with that evidence, we can make the best informed decision on what health services should be and should not be covered," she added. "This is what cost-effectiveness does; however, cost-effectiveness is not free of limitations."

"A limitation of this methodology particularly relevant for this case is that, since cost-effectiveness estimates are calculated in an incremental manner, highly expensive therapies can misleadingly appear cost-effective when compared to other highly expensive therapeutic options," she continued.

"The 'not so different incrementally' argument has been used to justify that CAR-T is not that expensive when compared to allogenic stem cell transplantation, with costs estimated at \$600,000," she said. "However, emerging data suggests that, even among patients responding to CAR-T, 36% relapse in one year. It is possible some providers will consider this relapse rate unacceptable, and choose to consolidate response with allogenic transplant, leading to greater number of transplants than would have occurred otherwise."

"Far from replacing transplants, CAR-T could even increase the number of transplants that would have occurred otherwise," she said. "For this reason, the comparison with transplant costs is unacceptable for justifying the costs of CAR-T."

Interventional oncologist/radiologist Dr. Kien Vuu of the University of California's David Geffen School of Medicine and Olive View Medical Center in Los Angeles told Reuters Health by email, "Both drug and non-drug costs (for CAR-T) are usually too much for the average American. Like many 'high-ticket' medical procedures, including organ transplantation, these procedures are usually prohibitive without being in pooled system, such as with insurance."

"The issue here is not whether patients can afford non-drug costs as the average American can't afford either, but rather how can we shift our resources to more preventive lifestyle options which could alleviate the rising costs of healthcare," he concluded.

Dr. Locke Bryan of the Georgia Cancer Center at Augusta University said by email, "The non-drug costs are a barrier as treating institutions will need to determine fiscally responsible strategies to manage patients."

"Patients admitted for management of the expected post-treatment complications will require high-levels of care," he said by email. "These non-drug costs may have limited reimbursement for provided services, translating into losses for institutions and shift financial burden to patients."

"Overall," he concluded, "the high expense of CAR-T immunotherapy will place further strain on the US health system, but (it) certainly warrants pursuit . . . for otherwise fatal diseases."

SOURCE: <http://bit.ly/2HJFzpl>

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