

Two new studies examine rising cancer drug spending in the US

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As cancer drug spending grows, so do doubts over the evidence supporting the drugs' approvals and efficacy. Two new studies led by the Harvard Pilgrim Health Care Institute examine the use of and spending

on new cancer drugs, by evidence of clinical benefit. Both studies appear in the October 18 issue of *JAMA Internal Medicine*.

Therapies to treat cancers are expected to either extend lifespan or sustain quality of life. Many new cancer therapies come to market via the accelerated approval pathway, which allows the Food and Drug Administration (FDA) to approve drugs for marketing using surrogate endpoints that are "reasonably likely to predict" clinical benefit (overall survival or quality of life). Manufacturers are required to prove the expected clinical benefit after the approval and market entry of these drugs.

Despite growing concerns about the evidence supporting new cancer [drug](#) approvals, launch prices in the U.S. have substantially increased in recent years. Investigators from the Harvard Pilgrim Health Care Institute, in collaboration with colleagues in the UK, China, and Canada, conducted two studies examining the use of new cancer drugs and the amount of money spent on them in relation to their evidence of clinical benefit.

One study focuses on the use of and spending on oral targeted cancer drugs among U.S. residents with employer-sponsored health insurance between 2011 and 2018. Targeted cancer drugs interfere with mechanisms that are responsible for the growth, progression, and spread of cancers. The second study estimates Medicare spending on 10 accelerated approval cancer drug indications reevaluated by the FDA.

In the employer-sponsored [health insurance](#) study¹, study authors used deidentified claims data from insurers to examine the uptake and cost implications of 44 new oral targeted cancer drugs among a sample of 37,348 U.S. residents with private, employer-sponsored insurance. Investigators found that although most individuals received drugs for which evidence from randomized clinical trials existed, a growing share

of patients received drugs without documented overall survival benefit. The proportion of patients receiving drugs without documented overall survival benefit increased from 13% in 2011 to 59% in 2018, accounting for 52% of the \$3.5 billion estimated cumulative spending on 44 new oral targeted cancer drugs by the end of 2018.

"The goal of any medical intervention should be to help patients live better longer. Our findings suggest that cancer drugs without documented overall survival or quality of life benefits are adopted in the health system and account for substantial spending," says key collaborator on both studies Huseyin Naci, MHS, Ph.D., Associate Professor of Health Policy at the London School of Economics and Political Science (LSE).

In the Medicare study², the authors estimated Medicare spending on the 10 accelerated approval cancer indications with confirmed lack of overall survival benefit that were reevaluated by the FDA. Study results show that Medicare Part B and D cumulatively spent at least \$569 million between 2017-2019 on the 10 cancer indications following accelerated approval. Approximately \$224 million of this spending was for indications that were later either voluntarily withdrawn by the manufacturers or recommended by the FDA's Oncologic Drugs Advisory Committee for withdrawal.

"Unless the accelerated approval pathway is reformed, significant spending on drugs with no proven clinical benefit will likely continue," says Mahnum Shahzad, lead author of the Medicare-based study and research fellow at the Harvard Pilgrim Health Care Institute.

"Our findings suggest that the combination of drug regulatory, pricing, and reimbursement policies may contribute to likely wasteful health care spending in the U.S." said Anita Wagner, PharmD, MPH, DrPH, senior author of both studies and Associate Professor of Population Medicine

at the Harvard Pilgrim Health Care Institute and Harvard Medical School. "Policy approaches should consider the health system context in which approval regulations, pricing decisions, and coverage mandates for [cancer](#) drugs intersect."

More information: Real-world utilization of and spending on new oral targeted cancer drugs in the US, 2011-2018, *JAMA Internal Medicine*, 2021.

¹ Employer-sponsored private health insurance study: Real-world utilization of and spending on new oral targeted cancer drugs in the US, 2011-2018 is co-authored by investigators from: Harvard Pilgrim Health Care Institute, London School of Economics and Political Science, Queen's University, and Peking University.

² Medicare study: Medicare spending on cancer drug indications with confirmed lack of clinical benefit following FDA accelerated approval is co-authored by investigators from: Harvard Pilgrim Health Care Institute and the London School of Economics and Political Science.

Provided by Harvard Pilgrim Health Care Institute

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