Heart Failure Drugs Can Be Unaffordable on Medicare, Study Finds

— Older adults are subject to cost-sharing and other medication coverage restrictions

by Michal Ruprecht, Editorial Intern, MedPage Today
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Nearly all Medicare prescription drug plans restricted coverage of established heart failure medications to some degree, most commonly by requiring cost-sharing, according to recent data.

Tier level 3 or higher cost-sharing was required for angiotensin receptor-neprilysin inhibitor (ARNI) therapy and at least one SGLT2 inhibitor in approximately 99% of the 4,065 Medicare Advantage and standalone Part D plans active in the second quarter of 2020 that covered these medications.

The sole ARNI on the market, sacubitril/valsartan (Entresto), was subject to prior authorization as well, as stipulated by 24.3% of drug plans. Meanwhile, step therapy was required for SGLT2 inhibitors and the mineralocorticoid receptor antagonist (MRA) eplerenone (Inspra) in 5.4% and 0.8% of plans, respectively, reported Kamil Faridi, MD, MSc, of Yale School of Medicine, and colleagues in the *Journal of the American College of Cardiology*.

Quadruple therapy for heart failure consists of ARNI, SGLT2 inhibitors, MRAs, and beta-blockers. Faridi's group estimated that out-of-pocket costs for a 30-day standard course of quadruple therapy reached a median $94 -- mostly driven by the cost of ARNI ($47) and SGLT2 inhibitors ($45) -- a total far exceeding the $3 cost of a wholly generic drug regimen.

"Quadruple therapy may be unaffordable for many Medicare patients with HFrEF [heart failure with reduced ejection fraction] unless medication prices and cost-sharing are reduced," the authors wrote.

"For patients to take these medications and experience their therapeutic benefits, they must be able to access them through their health insurance and afford the combined OOP [out-of-pocket] costs," they said. "This is an especially important issue for older patients enrolled in Medicare, who often have fixed incomes and significant expenses related to treatment of other comorbid conditions."

In a corresponding editorial, other cardiologists complained that cost-sharing limits access to care for many patients.

"These policies likely disadvantage relatively poorer patients," wrote Jason Wasfy, MD, MPhil, and Anna O'Kelly, MD, MPhil, both of Massachusetts General

Hospital in Boston. "A reasonable approach to considering appropriate drug prices and coverage policies is to start by making distinctions among efficacy, effectiveness, and cost-effectiveness."

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"As a general framework, cost-effectiveness analysis allows a rational basis for establishing a common ground between drug manufacturers and insurance plans," Wasfy and O'Kelly noted. "Without common ground, patients and clinicians are caught in the middle. This friction can disincentivize even cost-effective therapies and worsen disparities."

Faridi and colleagues estimated that for 50% of beneficiaries, out-of-pocket costs of quadruple therapy ate up at least 7% of their pretax income. The figure jumped to 13% when looking at those who were in the lowest quartile of income.

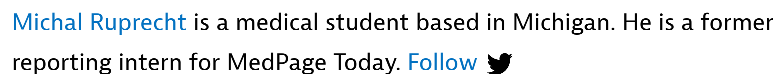
"Patients who do pay OOP costs for quadruple therapy may be at risk of financial toxicity, characterized by the myriad of adverse impacts of health care expenditures on patients and their families, including lower medication adherence, worse mental and physical health, delaying or foregoing medical care, and food insecurity," the authors wrote.

"Because of these findings, clinicians should assess whether OOP costs are affordable or may be leading to nonadherence among patients who are prescribed ARNI and [SGLT2 inhibitors]," they urged.

"More consensus on value-based pricing could improve access to critical therapies for patients who need them," Wasfy and O'Kelly suggested.

Study authors estimated that the majority of beneficiaries would have paid their $435 deductible by January, and the OOP costs would have been cleared once the coverage gap was reached around May. Once drug costs totaled $9,719, the beneficiaries would have moved from the coverage gap onto the catastrophic coverage phase in September.

A limitation of the study was that the authors estimated the costs of the drugs used by the participants without taking insurance plan premiums into account, nor the cost of other medications.



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Disclosures

The study was funded by a grant from the NIH.

Faridi reported no conflicts of interest.

Wasfy disclosed support by the American Heart Association and the NIH, consulting fees from Pfizer, honoraria from the Institute for Clinical and Economic Review, and serving as chair of the New England Comparative Effectiveness Public Affairs Advisory Council. O'Kelly reported no conflicts of interest.

Study co-authors disclosed relationships with the NIH, Agency for Healthcare Research and Quality, Laura and John Arnold Foundation, National Evaluation System for Health Technology Coordinating Center, Greenwall Foundation, Arnold Ventures, and Johnson and Johnson.

Primary Source

Journal of the American College of Cardiology

Source Reference: *Faridi KF, et al "Medicare coverage and out-of-pocket costs of quadruple drug therapy for heart failure" J Am Coll Cardiol 2022; DOI: 10.1016/j.jacc.2022.04.031.*

Secondary Source

Journal of the American College of Cardiology

Source Reference: *Wasfy JH, O'Kelly AC "Value-based prices could establish common ground on heart failure drug pricing and coverage" J Am Coll Cardiol 2022; DOI: 10.1016/j.jacc.2022.04.032.*

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