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High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients With Newly Diagnosed Chronic Myeloid Leukemia

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KEY FINDINGS: Medicare Part D beneficiaries with higher out-of-pocket costs are more likely to delay starting or not start a recommended specialty drug when newly diagnosed with leukemia. Policy changes are needed to ensure optimal access to specialty medications under Medicare Part D.

THE QUESTION

Does high cost sharing in Medicare Part D drug plans affect whether and how quickly patients initiate a recommended and life-extending drug treatment? LDI Senior Fellows Jalpa Doshi, Pengxiang Li and colleagues assess whether Medicare patients newly diagnosed with chronic myeloid leukemia (CML) and subject to significant coinsurance, take longer to initiate tyrosine kinase inhibitors (TKI) treatment than low-income (subsidized) Medicare patients subject to a nominal copayment. Oral TKIs allow most patients with CML to enjoy a near-normal life expectancy, and no lower-cost option exists.

The complexity of the Medicare Part D benefits structure makes this research particularly relevant. In 2011-2015, non-subsidized Medicare beneficiaries who needed a specialty drug faced coinsurance of 25%-33% in the 'initial coverage' phase and 45%-50% in the 'coverage gap', also known as the 'donut hole'. After patients reach a 'catastrophic coverage limit' (\$4,550-\$4,700 from 2011-2015), they pay 5% coinsurance for the rest of that calendar year.

THE FINDINGS

The first 30-day prescription fill of TKI had a mean price of \$6,800; non-subsidized patients were required to pay approximately \$2,600 out-of-pocket for the initial fill, while low-income subsidy (LIS) patients paid \$5 or less. The high out-of-pocket costs of the first fill pushed non-subsidized patients out of the initial coverage phase and into the coverage gap phase.

Non-subsidized beneficiaries were less likely than LIS beneficiaries to initiate TKI treatment within 6 months of their diagnosis with CML – 45% versus 67% respectively. Non-subsidized beneficiaries who did initiate TKI treatment took more than twice as long as LIS beneficiaries to do so – 50.9 days versus 23.7 days respectively.

The patient's subsidy status remained highly associated with TKI initiation even when the authors controlled for sociodemographic, clinical and plan characteristics. These findings suggest that high cost sharing may impede access to life saving specialty drug treatment. It should be noted, however, that this was a cross-sectional analysis. The study documents associations and cannot establish a causal relationship between out-of-pockets costs and treatment initiation.

THE IMPLICATIONS

This study demonstrates how high out-of-pocket costs may limit or delay initiation of high-value treatments under Medicare Part D. It shows that the one-size-fits-all cost sharing in Medicare Part D plans, where cost sharing is directly a function of the medication cost, may serve as a barrier to patient initiation of specialty medications.

This is the first study to utilize a full set of national Medicare Part A, B, and D fee-for-service claims linked with Part D plan and formulary information to explore the relationship between high cost sharing and access to specialty cancer drugs. Most prior evidence is out-of-date and focused on privately insured populations with lower levels of cost sharing.

The mean out-of-pocket payment for the first TKI prescription fill far exceeded the average monthly Social Security benefit (less than \$1,350), which is the main source of income for many Medicare beneficiaries. Although the Affordable Care Act is meant to close the Part D coverage gap by 2020, patients will still be responsible for high rates of coinsurance, effectively extending the cost sharing currently in place for specialty drugs during the initial coverage phase.

The authors suggest several policy fixes to protect patients against inordinately high out-of-pocket costs. These include: reducing beneficiary cost-sharing responsibility for drugs that have higher demonstrated efficacy and value; establishing an out-of-pocket spending maximum similar to many private insurance plans; and allowing beneficiaries to distribute total out-of-pocket costs more evenly throughout the year.

THE STUDY

The authors used the 2011-2013 Medicare Chronic Condition Data Warehouse files, which contain data on all fee-for-service Medicare beneficiaries in the U.S. They identified 1,053 newly diagnosed CML patients using a series of claims-based selection criteria. The main outcome was the time to TKI initiation, or the number of days elapsed between the first date of CML diagnosis and the date that the first TKI prescription was filled. The authors compared initiation of TKI treatment among non-subsidy Medicare beneficiaries against a comparison group of newly-diagnosed LIS patients. Extensive sensitivity analyses related to sample selection criteria, measuring time to TKI initiation, and analytic techniques confirmed the robustness of the findings.

Doshi JA, Li P, Huo H, Pettit AR, Kumar R, Weiss BM, Huntington SF. [High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients With Newly Diagnosed Chronic Myeloid Leukemia.](#)

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