

Growing Financial Burden From High-Cost Targeted Oral Anticancer Medicines Among Medicare Beneficiaries With Cancer

Meng Li, ScM, PhD¹; Kaiping Liao, PhD¹; I-Wen Pan, PhD¹; and Ya-Chen Tina Shih, PhD¹

QUESTION ASKED: What are the recent trends in the uptake of targeted oral anticancer medicines (TOAMs) among cancer patients with Medicare Part D, the share of TOAM users who reached catastrophic coverage, and the annual spending on TOAMs in the catastrophic phase?

SUMMARY ANSWER: From 2011 to 2016, the uptake of TOAMs among patients with cancer on any systemic therapy increased from 3.6% to 8.9%. The percentage of TOAM users without the low-income subsidy (LIS) who reached catastrophic coverage increased from 54.6% to 60.3%. Among those who reached the catastrophic phase, mean total gross spending on TOAMs in the catastrophic phase increased from \$16,074 in US dollars (USD) to \$64,233 (USD) and mean patient out-of-pocket spending from \$596 (USD) to \$2,549 (USD).

WHAT WE DID: We analyzed the 5% SEER-Medicare linked database. We included patients age 65 years and older who had one primary cancer diagnosis between 2011 and 2016. We included person-years where patients were enrolled in a Part D plan for the entire year, did not receive the LIS at any time of the year, and received anticancer systemic therapies. We estimated the trends in the share of patients who used TOAMs, the percentage of TOAM users reaching catastrophic coverage, and the total and patient out-of-pocket spending on TOAMs in the catastrophic phase in a year. We focused on high-cost TOAMs and excluded early-generation oral targeted therapies (ie, tamoxifen citrate, anastrozole, letrozole, and exemestane). Total spending on TOAMs in the catastrophic coverage phase was calculated by summing the gross drug costs associated with TOAM claims in a year. The gross drug costs on SEER-Medicare Part D claims include drug costs paid by Medicare, sponsoring drug plans, beneficiaries, and other parties.

WHAT WE FOUND: From 2011 to 2016, there were 45,614 person-years with full-year enrollment in a Part

D plan and used anticancer systemic therapy. The top three cancers in terms of person-years among the non-LIS group were prostate (29.2%), leukemia (17.4%), and lung (14.3%). The uptake of TOAMs among patients with cancer on any systemic therapy increased from 3.6% to 8.9%. The percentage of TOAM users without the LIS who reached catastrophic coverage increased from 54.6% to 60.3%. Among those who reached the catastrophic phase, mean total gross spending on TOAMs in the catastrophic phase increased from \$16,074 (USD) to \$64,233 (USD), mean patient out-of-pocket spending from \$596 (USD) to \$2,549 (USD), and the mean 30-day out-of-pocket spending from \$154 (USD) to \$328 (USD). The majority of patients reached catastrophic coverage phase in the same month they started taking TOAM (59.7%) or in the month following treatment initiation (16.2%).

BIAS, CONFOUNDING FACTORS, DRAWBACKS: This is a descriptive analysis. When calculating spending, we only included claims that were completely in the catastrophic coverage phase. This led to an underestimation of the spending in the catastrophic phase as some (3.3%) claims straddled between the catastrophic phase and earlier phases. Additionally, the gross drug cost used to calculate the total spending on TOAMs in the catastrophic phase included discounts at the point of sale but not rebates negotiated between the pharmacy benefit managers on behalf of Part D plans and the drug manufacturers, thus overestimating the net cost.

REAL-LIFE IMPLICATIONS: Patients with cancer on TOAMs in Medicare Part D have a high and growing likelihood of reaching catastrophic coverage phase, and the spending in catastrophic phase has been increasing in recent years. These findings highlight the need for reining in drug prices and capping patient out-of-pocket spending.

ASSOCIATED CONTENT

Appendix

Author affiliations and disclosures are available with the complete article online.

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abstract

PURPOSE The rapidly rising costs of targeted oral anticancer medicines (TOAMs) raise concerns over their affordability. Our goal was to examine recent trends in the uptake of TOAMs among cancer patients with Medicare Part D, the share of TOAM users who reached catastrophic coverage, and the annual spending on TOAMs in the catastrophic phase.

METHODS Using the 5% SEER-Medicare, we included patients age 65 years and older who had one primary cancer diagnosis between 2011 and 2016. We included person-years where patients were enrolled in a Part D plan for the entire year, did not receive the low-income subsidy at any time of the year, and received anticancer systemic therapies. We estimated the trends in the share of patients who used TOAMs, the percentage of TOAM users reaching catastrophic coverage, and the total and patient out-of-pocket spending on TOAMs in the catastrophic phase in a year.

RESULTS From 2011 to 2016, the uptake of TOAMs among our study population increased from 3.6% to 8.9%. The percentage of non-low-income subsidy TOAM users who reached catastrophic coverage increased from 54.6% to 60.3%. Among those who reached the catastrophic phase, mean total gross spending on TOAMs in the catastrophic phase increased from \$16,074 (USD) to \$64,233 (USD) and mean patient out-of-pocket spending from \$596 (USD) to \$2,549 (USD). The mean 30-day total spending increased from \$4,011 (USD) to \$8,857 (USD), and the mean 30-day out-of-pocket spending from \$154 (USD) to \$328 (USD).

CONCLUSION The high and growing burden from TOAMs highlighted the need for reining in drug prices and capping out-of-pocket spending.

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INTRODUCTION

Targeted oral anticancer medicines (TOAMs) are playing an increasingly important role in the treatment of cancer. They can not only improve survival, but also offer the convenience of treatment at home.^{1,2} For example, imatinib, a TOAM for treating chronic myeloid leukemia, improved the 5-year overall survival from 30% to 89% in a group of patients historically treated with cytotoxic drugs, stem-cell transplantation, and interferon therapy.³ TOAMs have also been a focus of the new drug research and development in cancer. Between 2010 and 2017, 53 out of the 105 new cancer drugs approved are delivered in an oral formulation.⁴ Nearly half of the molecules in the late-phase oncology pipeline in 2018 were oral targeted small molecules or hormonals.⁵

Although TOAMs confer major clinical and other benefits to many patients with cancer, the rapidly rising costs of these therapies have raised concerns over their affordability. In one of our previous studies, we analyzed Medicare Part D beneficiaries with cancer and found that the per patient per month (PPPM) cost of TOAMs increased by nearly 12% annually between 2007 and 2012 and reached \$7,719 (USD) in 2012, in contrast to the general prescription drug price inflation at about 3% annually during the same period.⁶ A study of the privately insured found that PPPM prices of TOAMs increased 5% each year, after inflation adjustment, between 2007 and 2013.⁷ Another study of the privately insured nonelderly patients with cancer found that the PPPM cost of TOAMs was rising faster than that for targeted intravenous (IV) anticancer

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therapies.⁸ Moreover, the literature has documented both increases in launch price and continuous price escalation after launch for TOAMs.⁶⁻⁹

The high and rising cost of TOAMs may pose a particularly large financial burden on Medicare Part D beneficiaries with cancer because of a lack of out-of-pocket spending cap in the benefit design. The standard Part D plan has four phases and beneficiaries spend through the phases: (1) the deductible phase where the beneficiary pays 100% of the cost of a prescription drug, (2) the initial coverage phase where the beneficiary pays approximately 25%, (3) the donut hole or coverage gap phase where the beneficiary used to pay 100% of the cost before the closure of the coverage gap began in 2011 and the cost sharing was gradually lowered to 25% in 2020, and (4) the catastrophic coverage phase where the beneficiary pays 5% of the total cost of the drug for the remainder of the year.^{10,11} In 2016, for example, once beneficiaries reached \$4,850 (USD) in out-of-pocket spending, including any manufacturer discounts, they enter the catastrophic coverage phase. Moreover, drug claims can straddle between phases, meaning that total spending on a claim can occur in multiple coverage phases. For Part D beneficiaries without any form of subsidies, such benefit design put them at risk of high financial liability. Furthermore, unlike privately insured or uninsured patients, Medicare beneficiaries are not eligible for copay cards from manufacturers that can limit their out-of-pocket cost.

Historically, most Part D beneficiaries who reached the catastrophic coverage phase were already receiving either partial or full low-income subsidies (LIS) and were thus protected from high prescription drug spending.¹² For example, in 2016, copayment in the catastrophic coverage phase was \$0 (USD) for three out of the four LIS categories and \$2.95 (USD) for generics and \$7.40 (USD) for brand-name drugs for the category of < 150% Federal Poverty Line with resources between \$8,789-\$13,640 (USD) (\$13,930-\$27,250 [USD] if married).¹³ In recent years, approximately one quarter of Part D enrollees receive the LIS annually.¹⁴ However, the number of non-LIS beneficiaries with out-of-pocket spending above the catastrophic threshold nearly quadrupled over the past decade, from 407,200 in 2007 to 1.5 million in 2019.¹⁵ Furthermore, total spending in the catastrophic coverage phase among non-LIS beneficiaries also rose quickly: one study estimated that average non-inflation-adjusted annual Part D spending for patients who took high-cost specialty drugs from the top eight specialty drug classes in terms of spending (including oral cancer therapies) increased from \$18,335 (USD) in 2008 to \$33,301 (USD) in 2012, and the proportion of Part D expenditures incurred while in the catastrophic coverage phase increased from 70% to 80%.¹⁶

With the high costs of TOAMs, out-of-pocket costs at 5% of the purchase price in the catastrophic coverage phase may

still represent a considerable financial burden for patients with cancer who take them. Rising prices and the growing utilization of TOAMs further exacerbate these concerns. The objective of this study was to examine recent trends in the uptake of TOAMs, the share of TOAM users who had catastrophic spending, and total and patient out-of-pocket spending on TOAMs in the catastrophic coverage phase.

METHODS

Data Sources, Study Population, and Cancer Therapies

We used the SEER-Medicare 5% Cancer File (2011-2016) for this analysis. The data set includes individuals who resided in a SEER area, were reported to a SEER registry for having had a cancer diagnosis, and were in the Medicare 5% sample. Using this file allowed us to identify all cancers in a representative sample of Medicare beneficiaries.¹⁷

We included patients with cancer age 65 years and older from the 5% Cancer File who had one primary cancer diagnosis between 2011 and 2016. We included person-years where patients were enrolled in a Part D plan for the entire year, and received any anticancer systemic therapies but did not receive the LIS (either full or partial) at any time of the year because out-of-pocket spending on prescription drugs throughout the benefit phases was substantially lower for beneficiaries with the LIS.

We used the therapeutic drug classification by First Databank¹⁸ to identify all anticancer systemic therapies. We determined the list of TOAMs from the National Cancer Institute's Targeted Cancer Therapy Fact Sheet.¹⁹ The FDA's National Drug Code (NDC) Directory²⁰ was used to retrieve NDC information for oral anticancer drugs, and CMS's Healthcare Common Procedure Coding System Quarterly Update²¹ was used to identify IV anticancer drugs. Oral anticancer medications, including TOAMs, were identified in Part D claims using NDCs, generic names, and brand names. IV anticancer drugs were identified from Part B claims using Healthcare Common Procedure Coding System codes.

We focused on high-cost TOAMs and excluded early-generation oral targeted therapies (tamoxifen citrate, anastrozole, letrozole, and exemestane), because their costs are substantially lower than newer TOAMs. The 30-day average total spending for tamoxifen, anastrozole, letrozole, and exemestane in our data set was approximately \$18 (USD), \$20 (USD), \$174 (USD), and \$266 (USD), respectively, whereas the 30-day spending for other TOAMs in our data was all above \$1,000 (USD).

Statistical Analysis

We examined trends in (1) the share of cancer patients treated with anticancer systemic therapies who used TOAMs in a year, (2) the percentage of TOAM users reaching catastrophic phase in a year, (3) the total and patient out-of-pocket spending on TOAMs in the

catastrophic phase in a year, and (4) the 30-day total and out-of-pocket spending on TOAMs in a year. We further examined the time between initiating TOAM and reaching catastrophic threshold in a year.

A beneficiary was considered to have reached the catastrophic phase in a given year if the beneficiary had at least one Part D claim that was above the out-of-pocket threshold for this coverage phase or if the threshold was met on an event in that year (a straddled claim). In Part D of SEER-Medicare, claims are labeled as above the catastrophic threshold or straddled between the catastrophic phase and another phase.

Total spending on TOAMs in the catastrophic coverage phase was calculated by summing the gross drug costs associated with TOAM claims in a year. The gross drug costs on SEER-Medicare Part D claims include drug costs paid by Medicare, sponsoring drug plans, beneficiaries, and other parties. Patient out-of-pocket spending on TOAMs in the catastrophic coverage phase was calculated by summing the patient pay amount on the claims, which reflects the amount paid by beneficiaries that is not reimbursed by a third party. We calculated 30-day spending in the catastrophic phase by dividing total spending on TOAMs by total days of supply of TOAMs and then multiplying the ratio by 30. The 30-day spending reflected the average unit price of TOAMs. In the spending calculations, we only included claims above the catastrophic threshold and excluded the straddled claims, as the Part D claims lacked information to derive the share of spending in the catastrophic phase from straddled claims. All costs were calculated as nominal (ie, not inflation-adjusted) costs to facilitate comparison of TOAM pricing trends with the Prescription Drug Component of Consumer Price Index, an index for inflation of prescription drug prices.²²

RESULTS

Among patients aged 65 years and older and diagnosed between 2011 and 2016 with one primary cancer from the SEER-Medicare 5% Cancer File, there were 45,614 person-years with full-year enrollment in a Part D plan and used anticancer systemic therapy (Appendix Fig A1, online only). Among them, 34,213 did not qualify for LIS at any time during the year, 10,921 qualified for full-year LIS, and 480 had LIS for part of but not the full year. In the non-LIS population, 2,192 person-years used TOAMs, and the number of TOAM users increased from 154 in 2011 to 552 in 2016 (Table 1). The uptake of TOAMs among non-LIS cancer patients who received anticancer systemic therapies increased from 3.6% in 2011 to 8.9% in 2016, whereas the uptake among the LIS group grew from 5.8% to 11.6% between 2011 and 2016 (Appendix Fig A2, online only).

The average age for the group of non-LIS patients with cancer taking TOAMs between 2011 and 2016 was 75.2 (standard deviation: 6.8) years. Male accounted for 58.9% of the person-years, whereas female accounted for 41.1%.

Approximately 83.8% of the person-years were White, 6.8% were Black, and 7.6% were of other races (Table 1).

The top three cancers in terms of person-years among the non-LIS group were prostate (29.2%), leukemia (17.4%), and lung (14.3%; Table 1). These three cancers remained the top three through 2015, with breast cancer replacing lung cancer in 2016.

The average percentage of non-LIS TOAM users who reached catastrophic spending was 59.3% between 2011 and 2016, increasing from 54.6% in 2011 to 60.3% in 2016 (Fig 1). By cancer type, non-LIS TOAM users with myeloma had the highest percentage (80%) of patients reaching the catastrophic phase in our study period of 2011 to 2016, followed by thyroid cancer (73.3%), pancreatic cancer (72.7%), kidney cancer (66.7%), colorectal cancer (65.4%), leukemia (63.8%), breast cancer (59.7%), prostate cancer (59.6%), lymphoma (58.7%), and lung cancer (20.6%; Appendix Fig A3, online only). The majority of patients reached catastrophic coverage phase in the same month they started taking TOAM (59.7%) or in the month following treatment initiation (16.2%; Appendix Table A1, online only) in a given year. A small percentage (3.2%) of patients reached catastrophic phase before they started TOAMs in a given year. Furthermore, the later a patient initiated TOAM, the shorter the duration between the month of TOAM initiation and that of reaching the catastrophic phase (Appendix Table A1, online only).

Both mean total spending and mean patient out-of-pocket spending in the catastrophic phase increased around 4-fold in 6 years. Specifically, among non-LIS TOAM users who reached the catastrophic phase in any calendar year, mean total nominal gross spending on TOAMs in the catastrophic phase increased from \$16,074 (USD) (median: \$9,717 [USD]) in 2011 to \$64,233 (USD) (median: \$63,795 [USD]) in 2016 (Fig 2, Appendix Table A2, online only). Mean patient out-of-pocket spending on TOAMs in the catastrophic phase increased from \$596 (median: \$231 [USD]) in 2011 to \$2,549 (USD) (median: \$2,444 [USD]) in 2016.

The increase in spending on TOAMs in the catastrophic phase was explained by the growth in 30-day spending on TOAMs (average unit price) in combination of the growth in days of supply of TOAMs (quantity). The mean 30-day total nominal spending on TOAMs in the catastrophic phase increased from \$4,011 (USD) (median: \$4,698 [USD]) in 2011 to \$8,857 (USD) (median: \$9 [USD], 227) in 2016, and the mean 30-day out-of-pocket spending increased from \$154 (USD) (median: \$187 [USD]) to \$328 (USD) (median: \$427 [USD]), a more than 2-fold increase in 6 years for both measures (Fig 2). Had the average unit price of TOAMs increased at the same pace as the rate of inflation of prescription drug prices, the 30-day total spending would have increased from \$4,011 (USD) in 2011 to \$4,771 (USD) in 2016, and the 30-day out-of-pocket spending would have increased from \$154 (USD) to

TABLE 1. Characteristics of Unsubsidized Part D Beneficiaries With One Primary Cancer Diagnosis Who Used Targeted Oral Anticancer Medicines in Person-Years, 2011-2016

Characteristics	Year						
	2011-2016	2011	2012	2013	2014	2015	2016
No. of person-years (%)	2,192 (100)	154 (7.0)	196 (8.9)	328 (15.0)	425 (19.4)	537 (24.5)	552 (25.2)
Age, years	75.2 (6.8)	75.5 (6.9)	75.0 (6.9)	75.5 (7.4)	75.2 (6.7)	75.1 (6.7)	75.3 (6.6)
Sex							
Male	1,291 (58.9)	68 (44.2)	103 (52.6)	203 (61.9)	271 (63.8)	320 (59.6)	326 (59.1)
Female	901 (41.1)	86 (55.8)	93 (47.6)	125 (38.1)	154 (36.2)	217 (40.4)	226 (40.9)
Race/ethnicity							
White	1,836 (83.8)	120 (77.9)	161 (82.1)	276 (84.2)	360 (84.7)	457 (85.1)	462 (83.7)
Black	148 (6.8)	15 (9.7)	13 (6.6)	22 (6.7)	24 (5.7)	33 (6.2)	41 (7.4)
Other	167 (7.6)	17 (11.0)	20 (10.2)	26 (7.9)	34 (8.0)	36 (6.7)	34 (6.2)
Top three cancer							
1	Prostate	Lung	Lung	Prostate	Prostate	Prostate	Prostate
No. of person-years (%)	641 (29.2)	44 (28.6)	45 (23.0)	108 (32.9)	138 (32.5)	172 (32.0)	178 (32.3)
2	Leukemia	Leukemia	Leukemia	Lung	Leukemia	Leukemia	Leukemia
No. of person-years (%)	381 (17.4)	35 (22.7)	36 (18.4)	52 (15.9)	66 (15.5)	94 (17.5)	101 (18.3)
3	Lung	Prostate	Prostate	Leukemia	Lung	Lung	Breast
No. of person-years (%)	314 (14.3)	14 (9.1)	31 (15.8)	49 (14.9)	62 (14.6)	63 (11.7)	79 (14.3)

\$183 (USD). Between 2011 and 2016, the average days of supply of TOAMs in the catastrophic phase also showed a two-fold increase, from 97 to 201 days (Appendix Fig A4, online only).

DISCUSSION

In this analysis of the SEER-Medicare 5% Cancer File from 2011 to 2016, we found that the uptake of TOAMs among

non-LIS elderly patients with cancer treated with anticancer systemic therapies more than doubled during this 6-year period, from < 4% to nearly 9%. Among the non-LIS TOAM users, between 50% and 60% reached catastrophic coverage phase, with the trend moving upward over time. Total mean gross spending and patient out-of-pocket spending on TOAMs in the catastrophic coverage phase increased approximately four-fold in 6 years, reaching \$64,233 (USD)

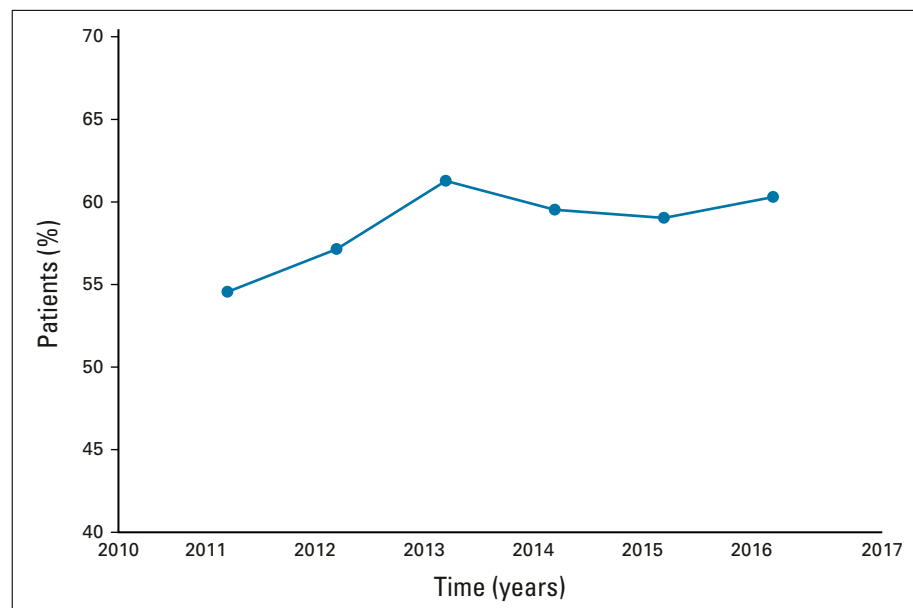


FIG 1. Share of unsubsidized patients treated with targeted oral anticancer medicines who reached catastrophic coverage phase.

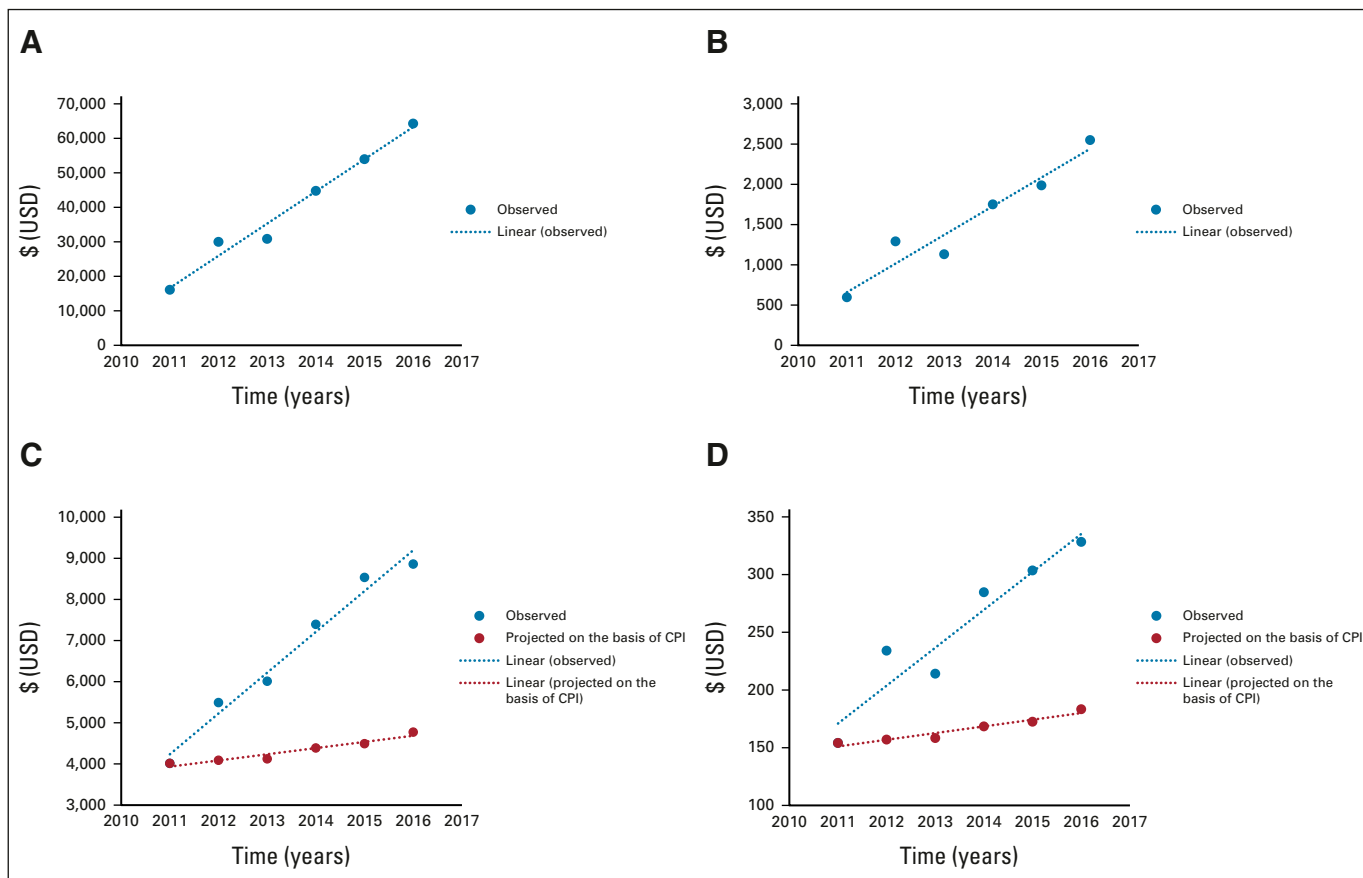


FIG 2. (A) Total gross spending, (B) patient out-of-pocket spending, (C) 30-day total gross spending, and (D) patient out-of-pocket spending on targeted oral anticancer medicines in the catastrophic coverage phase by unsubsidized patients. CPI, Consumer Price Index.

and \$2,549 (USD), respectively, in 2016. The increase in spending in the catastrophic coverage phase was driven by the combined effect of doubling the average unit price of TOAMs as well as days of supply during the study period.

The high and continuously rising prices of TOAMs impose substantial financial risk to patients with cancer treated with TOAMs. Trish et al²³ estimated that between 2007 and 2015, about 2% to 3.5% of all non-LIS Part D beneficiaries reached catastrophic coverage in each year and the likelihood of reaching catastrophic coverage among non-LIS TOAM users was more than 10-fold higher than among all non-LIS Part D beneficiaries. Estimates from Kaiser Family Foundation showed that the proportion of non-LIS Part D enrollees with out-of-pocket spending above the catastrophic threshold more than doubled, from 2.1% in 2010 to 4.4% in 2019.¹⁵ Previous research has shown that Part D beneficiaries taking TOAMs quickly spent through the benefit phases and entered catastrophic coverage.²⁴ Our study also demonstrated that the majority of TOAM users entered catastrophic phase in the same or the following month of initiating TOAMs.

The growth rate in TOAM prices documented by our study is similar to our previous estimates.⁶ In this analysis, we

included data from more recent years and focused on patients on TOAMs who reached catastrophic spending and their spending in that phase. During our 6-year study period, the 30-day total gross spending on TOAMs, a proxy for the average unit price, increased more than 100%, in contrast to about 19% for prescription drug price inflation during those years. The price increase for TOAMs far outpacing the price increase for other prescription drugs highlighted the need to rein in prices for these medicines. Although value-based pricing, including outcomes guarantee contracts, does not necessarily mean lower drug prices, it would result in better alignment between price and benefits of TOAMs.

The gradual closure of the coverage gap phase under the ACA, which reduced coinsurance in this coverage phase from 100% to 50% in 2012 and eventually to 25% in 2020, was intended to provide financial protection to Part D enrollees. Prior research has raised concerns that even with the closing of the coverage gap, a 5% coinsurance for high cost drugs, such as TOAMs, could still render Part D enrollees financially vulnerable.⁶ Indeed, the large and increasing share of non-LIS TOAM users reaching catastrophic coverage phase and the high and growing spending on TOAMs in this coverage phase reported in our

study underscore the need for implementing policies to lower patient out-of-pocket spending, such as an annual maximum of out-of-pocket spending. High patient cost sharing has been shown to be associated with lower rates of drug initiation, worse adherence, and more frequent discontinuation of therapy.²⁵ Although the traditional fee-for-service Medicare does not cap out-of-pocket spending for hospital and physician services under Parts A and B, beneficiaries can limit their out-of-pocket liability by enrolling in either a Medicare Advantage plan, where annual out-of-pocket spending on hospital and physician services is capped, or a Medicare supplemental policy (such as Medigap), which covers a substantial portion of the copay and coinsurance in traditional Medicare fee-for-service plans. The ACA introduced an annual out-of-pocket maximum for essential health benefits, which includes prescription drugs, for all nongrandfathered commercial plans.²⁶ Moreover, several proposals have been put forth on capping Part D out-of-pocket spending during the past 5 years.^{12,27}

Capping beneficiary cost sharing would increase Part D plans' spending, assuming no change to the drug prices or the federal reinsurance program, and plans would likely raise premiums in turn. One study estimated that implementing a cap on patient out-of-pocket spending at the catastrophic threshold would result in a premium increase of \$0.4-\$1.31 (USD) per member per month in 2015, a roughly 1%-4% premium increase in that year.²³ The premium increase would be small when spreading across a large population, but the financial protection for the small

fraction of non-LIS patients who use high-cost drugs such as TOAMs would be considerable. Such an out-of-pocket spending cap would also confer financial risk protection to healthy beneficiaries against uncertain risk of potentially very high out-of-pocket spending.

Our study has several limitations. First, when calculating spending on all drugs and on TOAMs, we only included claims that were completely in the catastrophic coverage phase. This led to an underestimation of the spending in the catastrophic phase as some (3.3%) claims straddled between the catastrophic phase and earlier phases. Second, the gross drug cost used to calculate the total spending on TOAMs in the catastrophic phase included discounts at the point of sale but not rebates negotiated between the pharmacy benefit managers on behalf of Part D plans and the drug manufacturers, thus overestimating the net cost. Third, although beneficiaries are not allowed to use coupons or other patient assistance programs to offset their out-of-pocket payment with the Medicare program, some of those payments may be erroneously captured. One analysis found that 6%-7% of seniors reported using coupons in Medicare.²⁸

In conclusion, patients with cancer on TOAMs in Medicare Part D have a high and growing likelihood of reaching catastrophic coverage phase, and the spending in catastrophic phase has been increasing in recent years. These findings highlight the need for reining in drug prices and capping patient out-of-pocket spending.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Conception and design: Meng Li, Ya-Chen Tina Shih

Financial support: Meng Li, Ya-Chen Tina Shih

Provision of study materials or patients: Ya-Chen Tina Shih

Collection and assembly of data: Kaiping Liao

Data analysis and interpretation: All authors

Manuscript writing: All authors

Final approval of manuscript: All authors

Accountable for all aspects of the work: All authors

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Growing Financial Burden From High-Cost Targeted Oral Anticancer Medicines Among Medicare Beneficiaries With Cancer

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APPENDIX

TABLE A1. Timing of Reaching Catastrophic Phase in Relation to Initiating Targeted Oral Anticancer Medicines

Timing of Initiating TOAMs	Quarter of Initiating TOAM				
	All	1	2	3	4
Before initiating TOAMs	3.2	0.7	7.6	6.8	8.2
Same month as initiating TOAMs	59.7	56.1	59.2	60.5	81.5
1 month after initiating TOAMs	16.2	17.7	14.0	16.4	9.6
2-4 months after initiating TOAMs	10.7	11.7	10.2	14.1	0.7
5-7 months after initiating TOAMs	7.5	9.4	8.9	2.3	NA
8-11 months after initiating TOAMs	2.9	4.4	NA	NA	NA

Abbreviation: TOAM, targeted oral anticancer medicines.

TABLE A2. Medians for Total Gross Spending, Total Out-of-Pocket Spending, 30-Day Gross Spending, and 30-Day Out-of-Pocket Spending (not adjusted for inflation)

Year	Total Gross Spending	Total Out-of-Pocket Spending	30-Day Gross Spending	30-Day Out-of-Pocket Spending
2011	9,717	231	4,698	187
2012	26,175	1,116	5,810	273
2013	27,272	624	6,655	262
2014	40,384	1,129	7,731	358
2015	49,566	1,298	8,890	389
2016	63,795	2,444	9,227	427

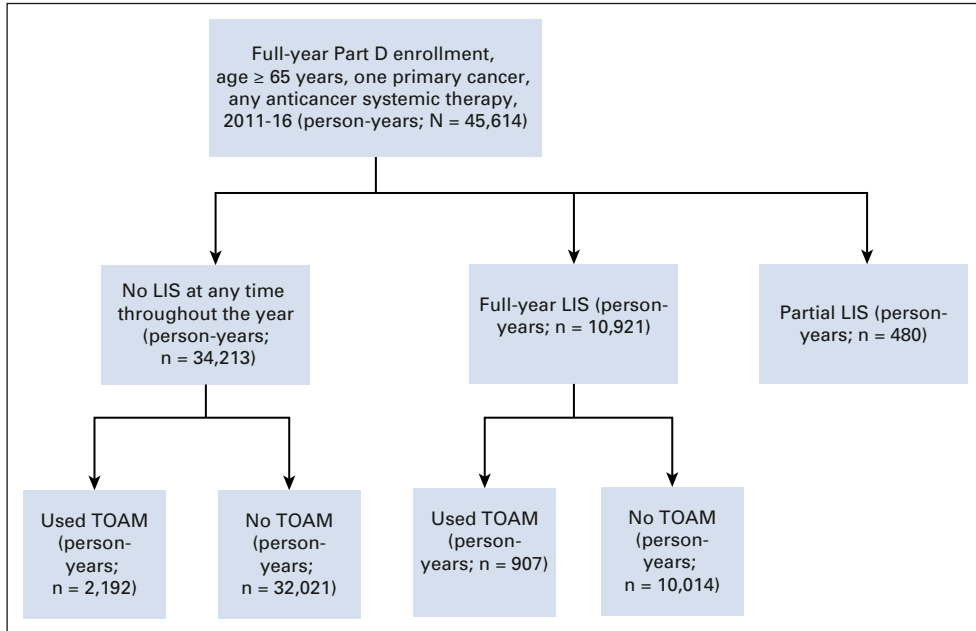


FIG A1. Study population flow chart. LIS, low-income subsidy; TOAM, targeted oral anticancer medicine.

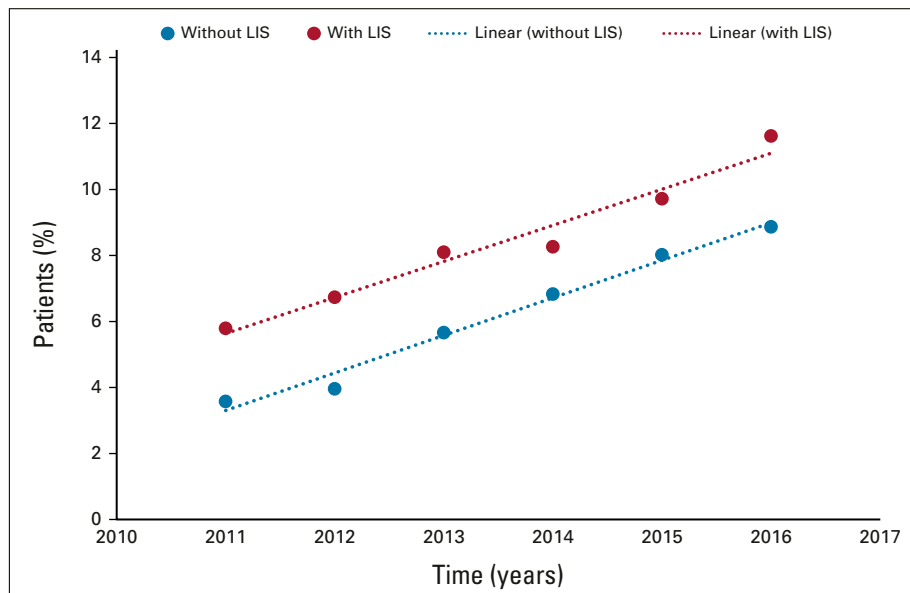


FIG A2. Uptake of oral targeted anticancer medicines among Medicare Part D beneficiaries treated with any anticancer therapies, by LIS status. LIS, low-income subsidy.

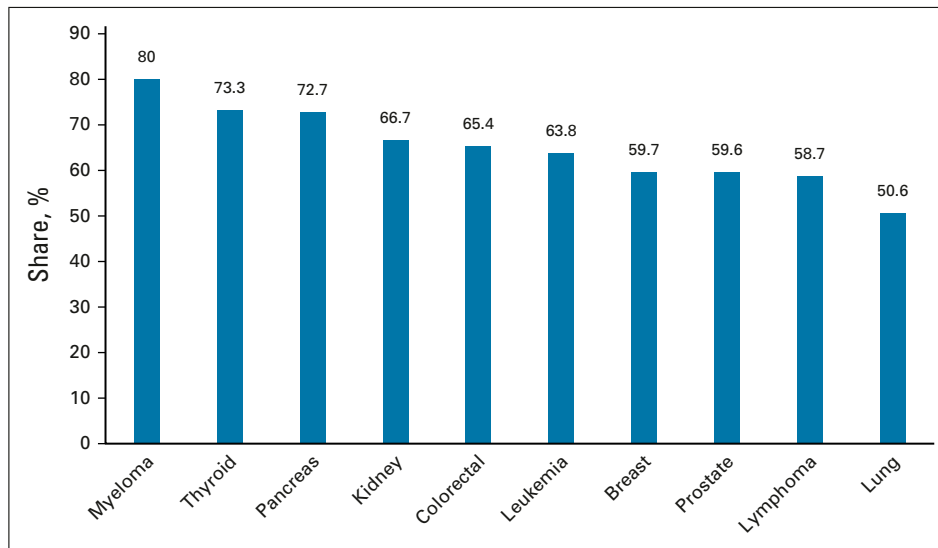


FIG A3. Share of patient-years reaching catastrophic coverage phase by cancer site among unsubsidized patients treated with oral targeted anticancer medicines.

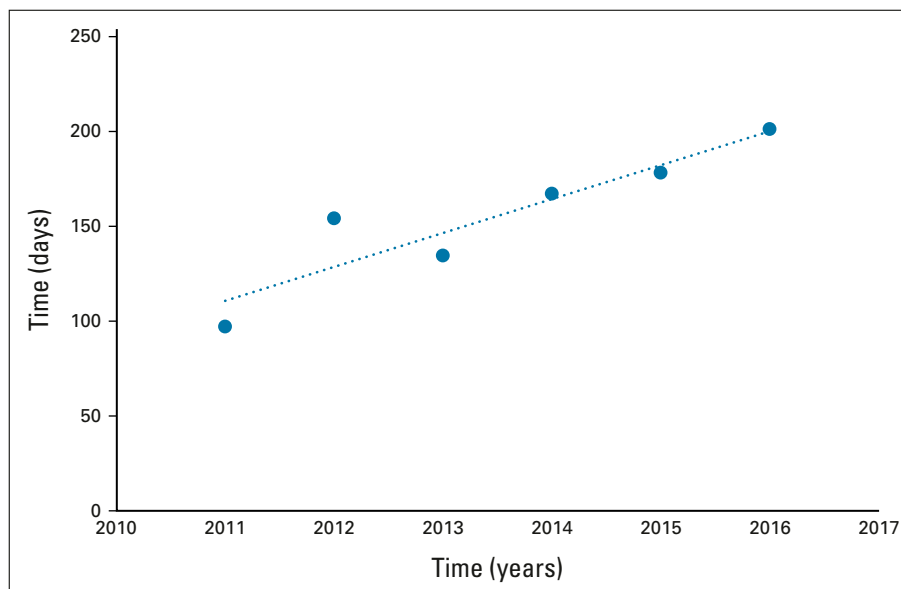


FIG A4. Average days of supply of targeted oral anticancer medicines in the catastrophic coverage phase.