Sociodemographic and spending characteristics of Medicare beneficiaries taking prescription drugs subject to price negotiations

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Plain language summary

Medicare is a government program that helps older adults and people with disabilities pay for prescription medications. Medicare is negotiating the prices they pay for 10 expensive medications and implementing new measures to reduce costs. We explored who will be impacted. People with higher incomes who are older and sicker could experience lower costs from negotiation. Other measures will affect costs for people with low incomes and people taking insulin or a cancer drug.

Implications for managed care pharmacy

Beneficiaries using negotiated drugs have higher-than-average out-of-pocket costs, but the drug pricing provisions of the Inflation Reduction Act will not have a uniform impact. The $2,000 out-of-pocket cap will primarily benefit White and higher-income beneficiaries. Low-income beneficiaries and insulin users will benefit from low-income subsidy expansion and the monthly $35 insulin cap. Programs are needed to provide savings to the remaining beneficiaries without low-income subsidies, who are older and have substantial costs and more comorbidities.

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ABSTRACT

BACKGROUND: The 2022 Inflation Reduction Act authorizes Medicare to negotiate the prices of 10 drugs in 2026 and additional drugs thereafter. Understanding the sociodemographic and spending characteristics of beneficiaries taking these specific drugs could be important describing the impact of the legislation.

OBJECTIVE: To describe sociodemographic and spending characteristics of Medicare beneficiaries who use the 10 prescription drugs ("negotiated drugs") that will face Medicare drug price negotiations in 2026.

METHODS: A 20% sample of Medicare Part D beneficiaries from 2020 (n=10,224,642) was used. Sociodemographic and spending characteristics were descriptively reported for beneficiaries taking the negotiated drugs, including subgroups by low-income subsidy (LIS) status and by drug, and for Part D beneficiaries not taking negotiated drugs.

RESULTS: Part D beneficiaries taking a negotiated drug compared with Part D beneficiaries not taking a negotiated drug overall had similar sociodemographic characteristics, more comorbidities (3.9 vs 2.2) and higher mean [median] Medicare ($33,882 [$18,251] vs $12,366 [$3,429]) and out-of-pocket (OOP) spending ($813 [$307] vs $441 [$160]). There was variation in characteristics by LIS status. The mean age was highest among non-LIS beneficiaries taking a negotiated drug compared with LIS beneficiaries taking a negotiated drug and beneficiaries not taking a negotiated drug (76.2 vs 69.9 vs 71.4). Among beneficiaries using negotiated drugs, a higher percentage of LIS beneficiaries compared with non-LIS was female (59.7% vs 48.0%), was Black (20.9% vs 6.6%), and resided in lower-income areas (39.1% vs 20.3%). Mean [median] annual Part D OOP spending for negotiated drugs was $115 [$59] for beneficiaries with LIS and

$1,475 [$1,204] for beneficiaries without LIS. There were also differences depending on which negotiated drug was used. Drugs for cancer and blood clots had the highest proportions of White users, whereas type 2 diabetes and heart failure drugs had the highest proportions of Black users and beneficiaries residing in lower-income areas. Annual Part D OOP costs were lowest for sitagliptin (LIS: $104 [$60], non-LIS: $1,391 [$1,153]) and highest for ibrutinib (LIS: $649 [$649], non-LIS: $6,449 [$6,867]). Among non-LIS beneficiaries, 24% (22% to 76%) had more than $2,000 in OOP costs.

CONCLUSIONS: Inflation Reduction Act OOP spending caps and LIS expansion will lower prescription drug costs for beneficiaries with OOP costs exceeding $2,000 who are mostly White and live in higher-income areas, insulin users who are disproportionately Black with multiple chronic conditions, and beneficiaries with low incomes. However, these provisions will not impact the 76% of non-LIS beneficiaries using negotiated drugs who have OOP costs that are still substantial but below $2,000. Negotiations could reduce OOP costs through reduced coinsurance payments for this group, which is older and has more chronic conditions compared with beneficiaries not taking negotiated drugs. Part D plan design, spending, and utilization changes should be monitored after negotiation to determine if further solutions are needed to lower OOP costs for this group.

A key provision in the Inflation Reduction Act (IRA) of 2022 authorizes Medicare to negotiate the prices for physician-administered and pharmacy-dispensed drugs covered by Medicare Parts B and D. Pharmaceutical manufacturers are obligated to participate in the negotiation process to retain Medicare coverage, or face a substantial tax on prior year revenues.[1] The Act focuses the negotiations on single-source drugs with high total Medicare spending that have been on the market for at least 9 years (small molecules) or 13 years (biologics).[1,2] Implementation is staggered, with the first 10 Part D drugs selected for negotiation in 2023 and the reductions taking effect in 2026. An additional 15 to 20 drugs will be discounted each year in 2027, 2028, and 2029.[3] The IRA outlines minimum discount rates varying from 25% to 40% depending on number of years the drug has been on the market, with the negotiation considering factors including degree of therapeutic value, research and development costs, and prior federal funding.[2]

In addition to the negotiations, the IRA also caps annual Part D out-of-pocket (OOP) spending at $2,000, caps monthly OOP spending on insulin at $35, removes 5% coinsurance in the catastrophic coverage phase, and expands low-income subsidies (LISs). LIS, also known as "Extra Help," provides Part D premium and cost-sharing subsidies to beneficiaries with incomes up to 150% of the federal poverty level (nearly 30% of Part D beneficiaries). The IRA expansion will grant the full LIS, which requires nominal copayments instead of coinsurance, to beneficiaries previously only eligible for a partial subsidy.[4] In contrast, the standard Part D benefit for non-LIS beneficiaries will maintain its current mix of copayments or coinsurance in the initial coverage phase but will eliminate the coverage gap phase that currently includes 25% coinsurance.[5,6] The impacts of the negotiation program will be realized within the context of these new and existing elements of Part D benefit design.

There is significant policy and clinical interest in understanding how drug pricing provisions of the IRA will impact Medicare beneficiaries and whether the impact will differ depending on sociodemographic and spending characteristics.[2,7-9] The primary purpose of the legislation is to lower the cost of prescription drugs to the Medicare program and beneficiaries, but there has been limited peer-reviewed literature describing the Medicare beneficiaries most likely to be directly impacted. There has been empirical work published on the characteristics of beneficiaries taking the drugs selected for negotiation[10] and expected changes in OOP costs because of provisions including the $2,000 Medicare Part D OOP cap and expansion of LIS, but none of these are peer-reviewed.[11-13] This study expands on existing research regarding the impact of the IRA by examining the sociodemographic and spending characteristics of beneficiaries who use the first 10 drugs selected for negotiation and discussing which subgroups of patients may experience direct impacts on OOP costs because of the negotiations vs because of other IRA provisions, depending on drug use and benefit design.

We calculated Part D spending and OOP spending for each Part D drug selected for the first round of negotiation. We describe the sociodemographic and Part D spending characteristics of Part D beneficiaries who use negotiated drugs compared with the rest of the Medicare Part D beneficiary population, among LIS and non-LIS beneficiaries, and among users of each negotiated drug. Such information is necessary to better anticipate how the negotiations and other IRA provisions will impact OOP costs for different categories of Medicare beneficiaries.

Methods

DATA

We identified the 10 drugs selected for the first round of negotiation from the Centers for Medicare and Medicaid Services website (Supplementary Table 1, available in online article).[14] We used the Medicare Part D Spending Dashboard to identify individual drug spending in 2020.[15] We then used the 20% restricted nationally representative sample of 2020 Medicare fee-for-service claims database to identify prescription drug claims associated with the negotiated drugs.

TABLE 1 Medicare Use and Spending on Prescription Drugs Facing Price Negotiations (2020)

Drug name (Brand)	Total Part D claims (millions)[a]	Total Part D spending (billions)[a,b]	Part D mean (median) spending per claim[b]	Part D mean (median) total spending per beneficiary per drug[b]	Unique beneficiaries[a]
Apixaban (Eliquis)	15,048,580	$10,078,119,040	$670 (489)	$4,135 (4,622)	2,518,740
Rivaroxaban (Xarelto)	6,575,295	$4,771,942,720	$726 (494)	$4,498 (5,089)	1,125,465
Sitagliptin phosphate (Januvia)	4,716,425	$3,922,768,640	$832 (500)	$4,462 (4,997)	825,230
Insulin aspart (Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill)	3,695,410	$3,035,492,480	$821 (579)	$4,684 (3,522)	729,920
Ibrutinib (Imbruvica)	231,090	$2,948,750,400	$12,760 (13,031)	$126,205 (145,952)	24,850
Empagliflozin (Jardiance)	2,717,050	$2,415,311,680	$889 (549)	$4,465 (4,811)	497,340
Etanercept (Enbrel)	342,175	$2,219,628,000	$6,487 (5,749)	$53,876 (58,412)	42,310
Sacubitril and valsartan (Entresto)	1,524,510	$1,223,642,000	$803 (573)	$4,712 (5,089)	222,355
Ustekinumab (Stelara)	55,165	$1,126,836,880	$20,427 (23,079)	$114,602 (95,226)	11,995
Dapagliflozin (Farxiga)	863,265	$743,649,200	$861 (536)	$4,339 (4,739)	151,860
All 10 drugs	35,768,965	$32,486,141,040	$908 (500)	$6,459 (5,059)	6,150,065
Nonnegotiated drugs	1,488,526,080	$169,453,742,080	$114 (13)	$3,538 (620)	47,340,190

[a]*Number of claims, total spending, and number of unique beneficiaries are inflated by a multiple of 5 since data were 20% restricted sample.*
[b]*Part D spending includes Medicare spending, patient OOP spending, and third-party spending.*

This database also included Medicare Part C (Medicare Advantage) beneficiary information for those beneficiaries with a Medicare Part D plan, although spending data besides Part D and OOP spending were not available for these beneficiaries. Beneficiary sociodemographic characteristics came from the master summary file,[16] spending came from the cost and use segment,[17] and number of comorbidities came from the chronic conditions segment.[18] The median household income and rural/urban characterization by zip code was obtained using Census Bureau data.[19]

COHORT CONSTRUCTION

We constructed our cohort using the 20% nationally representative sample of the Medicare Beneficiary Summary File from 2020 to identify traditional Medicare and Medicare Advantage beneficiaries who had Part D coverage in 2020 (n = 10,224,624).

SOCIODEMOGRAPHIC AND SPENDING VARIABLES

We calculated the number of claims and spending per negotiated drug, across all negotiated drugs, and across all nonnegotiated drugs. For the purposes of these drug-level calculations, beneficiaries using negotiated drugs could contribute to nonnegotiated drug spending. In our analysis of beneficiary characteristics, Medicare Part D beneficiaries taking negotiated drugs and Medicare Part D beneficiaries taking nonnegotiated drugs were mutually exclusive groups. We conducted descriptive analyses of the sociodemographic and spending characteristics of beneficiaries who used the 10 negotiated drugs in 2020 (overall, by LIS status, and by drug) and of the beneficiaries who did not use negotiated drugs. Aggregate measures (total claims and total Part D spending) were inflated by a multiple of 5 given that the dataset represents 20% of beneficiaries.

Cost variables were defined as follows: in Table 1, total Part D spending represents Medicare program, OOP, and third-party spending on the drugs; in Tables 2 and 3, Medicare spending per beneficiary on Part D claims, hospital claims, outpatient claims, and in total on any type of claim represent Medicare program spending only; in Tables 2, 3, and 4, annual Part D OOP spending per beneficiary represents OOP spending on any Part D drug. Hospital, outpatient, and total spending in Tables 2 and 3 did not include data from Medicare Advantage beneficiaries. Income data by zip code from the Census Bureau were matched with Medicare beneficiaries in that zip code to describe the distribution of median household income among beneficiaries using negotiated drugs compared with all other Part D beneficiaries.

TABLE 2 Sociodemographic and Spending Characteristics of Part D Beneficiaries Taking the First 10 Drugs Facing Price Negotiations Compared With All Other Part D Beneficiaries (2020)

	Beneficiaries taking drugs being negotiated			All Part D beneficiaries not taking drugs that will be negotiated	*P* value (beneficiaries taking negotiated drugs compared with beneficiaries taking nonnegotiated drugs)
	All	LIS	Non-LIS		
Mean age (SD)	73.9 (10.5)	69.9 (12.7)	76.2 (8.3)	71.4 (11.2)	<0.01
Sex, %					
Female	52.2	59.7	48.0	57.7	<0.01
Male	47.8	40.3	52.0	42.3	<0.01
Race, %					
White	78.2	61.1	87.7	78.2	NS
Black	11.8	20.9	6.6	10.8	<0.01
Other[a]	10.0	18.0	5.6	11.0	<0.01
Zip code median household income, %					
<$25,000	1.2	1.2	1.1	1.5	<0.01
$25,000 - <$50,000	26.5	37.9	20.2	24.0	<0.01
$50,000 - <$75,000	41.5	40.7	41.9	41.1	<0.01
$75,000 - <$100,000	18.8	13.3	21.8	20.0	<0.01
≥$100,000	12.0	6.9	14.9	13.4	<0.01
Type of locality, %					
Urban	80.2	78.7	81.0	81.1	<0.01
Suburban	16.1	17.6	15.3	15.3	<0.01
Rural	3.7	3.7	3.6	3.7	<0.01
Mean number of comorbidities per beneficiary (SD)	3.9 (4)	4.4 (4.3)	3.6 (3.9)	2.2 (2.9)	<0.01
Medicare Advantage, %	50.3	51.6	49.6	52.2	<0.01
Mean (median) annual Medicare spending per beneficiary[b]					
Medicare Part D	$11,376 ($6,552)	$14,417 ($8,439)	$9,715 ($6,074)	$3,204 ($555)	<0.01
Hospital	$10,099 ($0)	$13,548 ($0)	$8,258 ($0)	$3,327 ($0)	<0.01
Outpatient	$12,043 ($5,349)	$13,909 ($6,372)	$11,048 ($4,912)	$5,948 ($1,932)	<0.01
Total[c]	$33,882 ($18,251)	$42,091 ($24,515)	$29,501 ($15,581)	$12,366 ($3,429)	<0.01
Mean (median) Part D annual out-of-pocket costs[d]	$813 (307)	$115 (59)	$1,475 (1,204)	$441 (160)	<0.01

[a]*Other includes Hispanic, Asian, North American Native, Other, and Unknown racial categories.*

[b]*Medicare program spending only. Hospital, outpatient, and total costs exclude beneficiaries with Medicare Advantage, for whom that spending data are not available. Medians are shown instead of SDs because of right-tailed distribution.*

[c]*These totals exclude skilled nursing facility and durable medical equipment spending.*

[d]*Represents total annual Part D out-of-pocket spending on any drug claims for beneficiaries using a negotiated or nonnegotiated drug.*

LIS = low-income subsidy; NS = not significant.

STATISTICAL ANALYSIS

Prior to statistical testing, distributions of characteristics were analyzed to determine whether to use a parametric t-test or a nonparametric Wilcoxon rank sum test. Given the distributions, parametric t-tests were used to compare demographic characteristics and Wilcoxon rank sum tests were used to compare spending characteristics. Chi-square tests were used to compare differences in proportions (eg, differences in sex). We compared Medicare beneficiaries using drugs to be negotiated with Medicare beneficiaries

TABLE 3 Sociodemographic and Spending Characteristics of Part D Beneficiaries Taking Each Drug Facing Price Negotiations (2020)

	Apixaban (Eliquis)	Rivaroxaban (Xarelto)	Sitagliptin (Januvia)	Insulin aspart (Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill)	Ibrutinib (Imbruvica)	Empagliflozin (Jardiance)	Etanercept (Enbrel)	Sacubitril and valsartan (Entresto)	Ustekinumab (Stelara)	Dapagliflozin (Farxiga)
Mean age (SD)	76.8 (9.7)	75.0 (9.9)	72.6 (10.0)	69.0 (11.7)	75.7 (8.3)	68.9 (9.0)	67.2 (10.9)	72.3 (10.5)	61.5 (14.2)	68.6 (9.6)
Sex, %										
Female	53.0	50.6	54.6	54.8	41.1	45.8	71.4	35.8	59.0	47.6
Male	47.0	49.4	45.4	45.2	58.9	54.2	28.6	64.2	41.0	52.4
Race, %										
White	84.0	83.7	67.0	69.3	84.6	70.7	75.4	73.3	79.5	70.6
Black	9.4	8.8	15.6	18.3	9.2	12.6	10.9	17.9	9.9	13.0
Other[a]	6.6	7.5	17.4	12.4	6.2	16.7	13.7	8.8	10.6	16.3
Zip code median household income, %										
<$25,000	0.9	1.2	1.9	1.1	0.8	1.3	1.8	1.0	1.4	1.6
$25,000 - <$50,000	24.5	23.5	30.1	32.6	20.6	28.3	26.4	30.9	23.9	30.1
$50,000 - <$75,000	41.6	41.5	40.1	43.0	40.9	41.1	39.9	40.3	41.9	40.9
$75,000 - <$100,000	19.8	20.2	17.4	15.3	21.4	18.1	19.3	17.5	20.4	17.3
≥$100,000	13.2	13.6	10.6	7.9	16.3	11.2	12.6	10.4	12.3	10.1
Type of locality, %										
Urban	80.2	80.4	81.9	77.4	81.1	81.0	80.2	80.6	80.3	78.6
Suburban	16.1	15.9	14.9	18.4	14.9	15.7	16.0	16.2	16.6	17.6
Rural	3.7	3.7	3.2	4.2	4.0	3.3	3.8	3.2	3.1	3.7
Mean number of comorbidities per beneficiary (SD)	4.3 (4.3)	3.9 (4.0)	3.4 (3.8)	4.9 (4.4)	3.4 (3.7)	3.1 (3.5)	2.6 (3.2)	4.4 (4.4)	2.6 (3.1)	3.7 (3.6)
Medicare Advantage, %	48.9	48.2	56.4	46.0	44.9	57.0	55.9	51.9	48.9	47.0
Mean (median) annual spending per beneficiary[b]										
Medicare Part D	$9,461 ($6,106)	$9,847 ($6,203)	$11,364 ($7,598)	$15,467 ($10,105)	$117,692 ($127,878)	$13,898 ($9,739)	$59,796 ($63,107)	$11,729 ($8,025)	$99,255 ($80,839)	$14,637 ($10,735)
Hospital	$12,616 ($0)	$9,180 ($0)	$6,847 ($0)	$13,939 ($0)	$9,927 ($0)	$4,777 ($0)	$3,602 ($0)	$14,010 ($0)	$6,292 ($0)	$5,184 ($0)
Outpatient	$13,464 ($6,373)	$11,656 ($5,474)	$8,714 ($3,533)	$16,312 ($7,636)	$17,937 ($7,963)	$7,664 ($3,347)	$7,021 ($3,257)	$14,137 ($6,743)	$13,754 ($5,666)	$7,744 ($3,239)
Total[c]	$35,850 ($19,138)	$30,897 ($16,699)	$27,517 ($15,327)	$46,014 ($28,530)	$147,273 ($160,919)	$26,932 ($17,421)	$71,092 ($70,307)	$40,313 ($24,007)	$123,514 ($104,395)	$28,383 ($18,305)
Mean (median) Part D annual out-of-pocket costs[d]	$900 (553)	$872 (492)	$652 (168)	$634 (111)	$4,824 (3,794)	$820 (220)	$833 (55)	$934 (439)	$873 (32)	$748 (176)

[a]*Other includes Hispanic, Asian, North American Native, Other, and Unknown racial categories.*

[b]*Medicare program spending only. Hospital, outpatient, and total costs exclude beneficiaries with Medicare Advantage, for whom that spending data are not available. Medians are shown instead of SDs because of right-tailed distribution.*

[c]*These totals exclude skilled nursing facility and durable medical equipment spending.*

[d]*Represents total annual Part D out-of-pocket spending on any drug claims for beneficiaries using each negotiated drug.*

TABLE 4 Medicare Beneficiary Out-of-Pocket Costs for Each of the Drugs Facing Price Negotiations (2020)

Drug name (Brand)	Mean patient out-of-pocket spending among beneficiaries with low-income subsidies, mean (median)		Mean patient out-of-pocket spending among beneficiaries without low-income subsidies, mean (median)		Beneficiaries who reached $2,000 in annual Part D out-of-pocket costs, %
	Per claim	Per year (total Part D)[a]	Per claim	Per year (total Part D)[a]	Non-LIS
Apixaban (Eliquis)	$5 (0)	$119 (40)	$107 (57)	$1,433 (1,187)	22
Rivaroxaban (Xarelto)	$5 (0)	$114 (49)	$116 (68)	$1,426 (1,190)	22
Sitagliptin phosphate (Januvia)	$4 (2)	$112 (69)	$104 (60)	$1,391 (1,153)	25
Insulin aspart (Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill)[b]	$4 (0)	$107 (46)	$111 (72)	$1,859 (1,672)	42
Ibrutinib (Imbruvica)	$22 (0)	$242 (9)	$649 (649)	$6,449 (6,867)	76
Empagliflozin (Jardiance)	$5 (4)	$126 (86)	$109 (63)	$1,619 (1,386)	36
Etanercept (Enbrel)	$3 (0)	$60 (29)	$241 (60)	$2,224 (1,039)	35
Sacubitril and valsartan (Entresto)	$6 (4)	$142 (90)	$109 (60)	$1,616 (1,423)	34
Ustekinumab (Stelara)	$4 (0)	$42 (17)	$552 (88)	$2,868 (1,160)	38
Dapagliflozin (Farxiga)	$4 (4)	$124 (88)	$110 (70)	$1,631 (1,390)	35
All 10 drugs	$4 (0)	$115 (59)	$114 (60)	$1,475 (1,204)	22
Nonnegotiated drugs	$1 (0)	$59 (28)	$16 (5)	$658 (360)	25

[a]*Represents total annual Part D out-of-pocket spending on any drug claims for beneficiaries using each negotiated drug.*

[b]*Affected by $35 insulin cap.*

LIS = low-income subsidy.

not using negotiated drugs. Statistical analysis was performed using Stata 17 (StataCorp). This study was exempted from institutional review board review as it did not constitute human participant research.

Results

MEDICARE USE AND SPENDING FOR NEGOTIATED DRUGS

The total number of Medicare Part D claims in 2020 for negotiated drugs ranged from 55,165 (ustekinumab) to 15,048,580 (apixaban), with total claims volume across all 10 negotiated drugs of 35 768 965. Medicare 2020 spending for negotiated drugs was $32,486,141,040; spending on most negotiated drugs was between $743,649,200 and $4,771,942,720, with apixaban as a notable outlier ($10,078,119,040). The mean [median] cost per claim across all negotiated drugs was $908 [$500], and by drug ranged from $670 [$489] (apixaban) to $20,427 [$23,079] (ustekinumab). Part D mean [median] spending per beneficiary was $6,459 [$5,059] and ranged from $4,135 [$4,622] (insulin aspart) to $126,205 [$145,952] (ibrutinib). There were 6,150,065 unique beneficiaries using negotiated drugs in 2020. In comparison, there were 47,340,190 unique beneficiaries using nonnegotiated drugs with 1,488,526,080 claims, total spending was $169,453,742,080, mean [median] cost per claim was $114 [$13], and mean [median] Part D spending per beneficiary was $3,538 [$620] (Table 1).

BENEFICIARY SOCIODEMOGRAPHIC CHARACTERISTICS

Beneficiaries taking negotiated drugs overall had similar sociodemographic characteristics to beneficiaries not taking negotiated drugs (statistically significant results reflect the large sample size), but there were differences by LIS status. Non-LIS beneficiaries taking negotiated drugs were older than LIS beneficiaries taking negotiated drugs and beneficiaries taking nonnegotiated drugs (76.2 vs 69.9 vs 71.4 years). Although the percentage of beneficiaries in each racial- and zip code–income category was similar overall between beneficiaries using negotiated drugs compared with beneficiaries using nonnegotiated drugs, the LIS subgroup compared with the non-LIS subgroup using negotiated drugs skewed more female (59.7% vs 48.0%), Black (20.9% vs 6.6%), and lower income (39.1% vs 21.3% resided

in zip codes with median household income <$50 000). Beneficiaries taking the negotiated drugs had more comorbidities: 4.4 among LIS recipients and 3.6 among non-LIS recipients (3.9 overall), compared with 2.2 among Part D beneficiaries not taking negotiated drugs (Table 2).

There were differences in sociodemographic characteristics among beneficiaries using negotiated drugs. Beneficiaries using apixaban had the highest mean age (76.8), whereas users of ustekinumab had the lowest mean age (61.5). The proportion of female patients was approximately 50% for most drugs except ibrutinib (41.1%), sacubitril and valsartan (35.8%), etanercept (71.4%), and ustekinumab (59.0%). Ibrutinib, apixaban, and rivaroxaban were the only drugs for which more than 80% of beneficiaries were White. A higher percentage of Black beneficiaries used insulin (18.3%), other diabetes drugs (empagliflozin, dapagliflozin, and sitagliptin; 12.6%-15.6%), and a heart failure drug (sacubitril and valsartan; 17.9%) compared with the other negotiated drugs (8.8%-10.9%). The same drugs with a higher percentage of Black beneficiaries had a higher percentage of beneficiaries residing in zip codes with median household income under $50,000 (29.6%-33.7%) compared with other negotiated drugs (21.2%-28.2%). Beneficiaries who used insulin aspart had the highest mean number of comorbidities (4.9). Users of autoimmune drugs, etanercept and ustekinumab, had the lowest number of comorbidities (2.6), whereas beneficiaries using other negotiated drugs had between 3.1 (empagliflozin) and 4.4 (sacubitril and valsartan) (Table 3).

BENEFICIARY SPENDING CHARACTERISTICS

Beneficiaries taking a negotiated drug had higher mean [median] total Medicare program costs compared with those who did not take a negotiated drug ($33,882 [$18,251] vs $12,366 [$3,429]). Medicare program Part D costs were also higher for beneficiaries taking negotiated drugs ($11,376 [$6,552] vs $3,204 [$555]). Among beneficiaries taking negotiated drugs, mean total Medicare program costs ($42,091 [$24,515] vs $29,501 [$15,581]) and Part D costs $14,417 [$8,439] vs $9,715 [$6,074]) were higher for beneficiaries with LIS compared with beneficiaries without LIS. Hospital and outpatient costs followed a similar pattern. Beneficiaries taking negotiated drugs had higher mean annual Part D OOP spending ($813 [$307]) than Part D beneficiaries not taking a negotiated drug ($441 [$160]), driven by non-LIS beneficiaries ($1,475 [$1,204]). Beneficiaries taking a negotiated drug with LIS had the lowest annual Part D OOP costs ($115 [$59]) (Table 2).

Among beneficiaries taking negotiated drugs, mean [median] annual Medicare Part D program spending per beneficiary ranged from $9,461 [$6,106] (apixaban) to $117,692 [$127,878] (ibrutinib). Beneficiaries using ibrutinib and ustekinumab ($99,255 [$80,839]) had the highest Part D costs. Beneficiaries using autoimmune (etanercept and ustekinumab) and cancer (ibrutinib) drugs had substantially higher Part D costs compared with hospital and outpatient costs, whereas beneficiaries using other drugs had total Medicare costs more evenly split between Part D, hospital, and outpatient services. Mean annual Part D OOP costs ranged from $634 [$111] (insulin aspart) to $4,824 [$3,794] (ibrutinib) (Table 3).

BENEFICIARY OOP COSTS FOR EACH OF THE NEGOTIATED DRUGS

Having a LIS reduced Part D OOP spending. Non-LIS beneficiaries using negotiated drugs overall paid more than 10 times more in annual Part D costs than LIS beneficiaries using negotiated drugs. Mean [median] per claim OOP costs were less than $25 for beneficiaries with LIS and between $104 [$60] (sitagliptin) and $649 [$649] (ibrutinib) for beneficiaries without LIS. Mean [median] annual Part D OOP spending for beneficiaries with LIS ranged from $42 [$17] (ustekinumab) to $242 [$9] (ibrutinib), compared with $1,391 [$1,153] (sitagliptin) to $6,449 [$6,867] (ibrutinib) among beneficiaries without LIS. Mean annual Part D OOP costs for beneficiaries using the other negotiated drugs were less than $1,000. Overall, 24% of beneficiaries using a negotiated drug without LIS exceeded $2,000 in annual OOP costs. Ibrutinib and insulin aspart had the highest percentage of non-LIS beneficiaries exceeding $2,000 in total annual Part D OOP costs (76% and 42%). The percentage exceeding $2,000 in OOP costs among the other drugs ranged from 22% (apixaban and rivaroxaban) to ustekinumab (38%) (Table 4).

Discussion

Compared with Medicare beneficiaries not using negotiated drugs, beneficiaries using the 10 negotiated drugs have more comorbidities, higher overall Medicare spending, and greater total Part D OOP costs compared with other Part D beneficiaries; these findings reinforce the rationale to focus the negotiations on drugs with the highest spending. Among beneficiaries using negotiated drugs, there was variation in sociodemographic and spending characteristics depending on which drug they used and LIS status. OOP spending was substantially lower among LIS beneficiaries, and there was variation in total Part D and OOP spending between the negotiated drugs. These findings suggest that the benefits of drug price negotiations for beneficiaries will depend on which drugs they use, LIS status, and Part D benefit design, which has implications for which sociodemographic groups will be most impacted.

Our findings demonstrate that beneficiaries with LIS, of whom a higher proportion live in lower-income zip codes, identify as Black, and have a higher number of comorbidities, had mean annual Part D costs of $115, indicating they are most likely to benefit from expansion of LIS introduced by the IRA and not from negotiations or new OOP caps. Beneficiaries with LIS are less likely to benefit directly from negotiations because they do not face coinsurance.[5] Savings from the negotiation program will likely be used in part by Medicare to offset the cost of the subsidies.[6]

The $2,000 cap is expected to lower patient OOP costs, which are currently uncapped, for an estimated 866,000 Medicare Part D beneficiaries.[20] According to our analysis, 24% (22% to 76%) of beneficiaries without LIS using 1 of the 10 negotiated drugs exceeded $2,000 in OOP costs in 2020. Of the beneficiaries using negotiated drugs, the new cap will benefit the highest proportion of non-LIS beneficiaries using ibrutinib (76%). Although a high proportion of insulin aspart users without LIS (42%) also exceeded $2,000 in OOP costs, these beneficiaries will experience the greatest cost reductions from the monthly $35 insulin cap. A higher proportion of ibrutinib users are White, live in higher-income areas, and have annual Medicare costs exceeding $100,000 compared with insulin aspart users who more commonly identified as Black, lived in lower-income areas, had the highest number of comorbidities (4.9), and had annual Medicare costs under $50,000; this suggests that the $2,000 cap is likely to benefit more affluent beneficiaries who use particularly high-cost drugs, whereas the $35 insulin cap will benefit lower-income beneficiaries from racial and ethnic minorities with multiple chronic conditions.

In addition to OOP cost reductions from LIS expansion, the $2,000 annual cap, and the monthly $35 insulin cap, negotiation could lead to lower OOP costs for non-LIS beneficiaries using negotiated drugs either directly by lowering coinsurance payments or indirectly by lowering premiums. Our findings suggest that non-LIS beneficiaries whose OOP costs do not exceed $2,000 (76% of beneficiaries taking negotiated drugs) will not be impacted by the caps but could benefit directly from negotiations through reduced coinsurance payments. Beneficiaries with OOP costs of more than $2,000 will benefit first from the $2,000 cap but could also experience further reductions in coinsurance payments because of the negotiations. Non-LIS beneficiaries typically pay a mix of copayments and coinsurance in the initial coverage phase, which will continue even after all Part D benefit redesign provisions take effect by 2025.[6] Negotiated drugs are brand-name and high-cost drugs, and some are biologics, meaning they are more likely to appear on Part D plan specialty tiers[21] that require coinsurance. Therefore, it is likely that at least some non-LIS beneficiaries face coinsurance for negotiated drugs and will experience OOP cost reductions because of the negotiations.

Because LIS beneficiaries will benefit from LIS expansion and insulin aspart and ibrutinib users will be most impacted by the $35 insulin cap and $2000 cap, respectively, the group most likely to benefit directly from negotiations consists of non-LIS beneficiaries using negotiated drugs whose OOP costs did not exceed $2,000. This includes the majority of non-LIS beneficiaries using the negotiated drugs treating blood clots (apixaban and rivaroxaban), type 2 diabetes (sitagliptin, empagliflozin, dapagliflozin), heart failure (sacubitril and valsartan), and autoimmune conditions (etanercept and ustekinumab). Non-LIS beneficiaries using negotiated drugs are older, have more comorbidities, and spend more than $1,000 in Part D OOP costs compared with beneficiaries using nonnegotiated drugs. These findings suggest that there is a group of older beneficiaries managing multiple conditions who will not be impacted by other IRA provisions but still have substantial OOP costs, and therefore should be monitored to determine if negotiations are sufficient to lower their OOP costs or if other solutions are needed.

The true impact of the negotiations will depend on utilization controls and any further changes to cost-sharing structure implemented by Part D plans in response to the negotiations; lowering the cost-sharing amount could result in greater use.[22] Although the IRA represents an important step in lowering prescription drug spending for Medicare and its beneficiaries, the interactions between these policy changes are complex and there could be unintended consequences, including inequitable impacts on different groups of beneficiaries, Part D plan design changes that limit cost savings to beneficiaries or the Medicare program, and decreasing incentives for pharmaceutical manufacturer innovation.[22,23]

Our analysis indicates that beneficiaries using the negotiated drugs may not all be impacted the same way but are likely to experience lower OOP costs from at least 1 of the IRA provisions; the $2,000 cap will primarily benefit White and affluent beneficiaries taking particularly high-cost drugs, the $35 insulin cap will primarily benefit Black and lower-income beneficiaries with multiple chronic conditions, and beneficiaries with LIS, who are younger and more commonly female, Black, and lower income, will benefit from expansion of the LIS program regardless of which negotiated drugs they take. The remaining non-LIS beneficiaries, who are older, and have more chronic conditions and substantial OOP costs compared with beneficiaries not taking negotiated drugs, will not benefit from these provisions but could benefit from the negotiations through reduced coinsurance payments.

LIMITATIONS

Our report has several limitations. First, there is uncertainty about how the provisions of the IRA will influence patient use of negotiated drugs. For example, if patient OOP costs decrease because of the IRA, use of these drugs could increase in the future. This limits the ability to predict with certainty which beneficiaries will be impacted by the negotiations. Second, it is uncertain how Part D plans will respond to the negotiations and other provisions of the IRA. They may choose to change benefit design, coinsurance rates, copayment amounts, or which drugs appear on coinsurance tiers. It is also uncertain how they will use the savings from negotiations—directly to lower coinsurance payments, indirectly to lower premiums, or both. Because many beneficiaries make Part D choices based on premiums, lowering premiums could be an attractive scenario for Part D plans.[24] Third, this analysis does not account for manufacturer changes to production, development timelines, and pricing. Fourth, this analysis is based on the group of beneficiaries using the drugs selected for negotiation in 2020, which may not be reflective of the sociodemographic and spending characteristics of beneficiaries using the negotiated drugs in 2026, when the first negotiated prices take effect. Fifth, the comparisons among beneficiaries taking negotiated drugs are descriptive in nature and do not control for confounding factors.

Conclusions

Medicare drug price negotiations could be the only IRA provision directly impacting OOP costs for beneficiaries using negotiated drugs without LIS who have OOP costs under $2000. Compared with Part D beneficiaries not taking negotiated drugs, this group is older, managing more chronic conditions, and has substantial OOP costs, but they will not be impacted by Part D benefit redesign IRA provisions and should be monitored to determine the effect of negotiations. Among the remaining beneficiaries using negotiated drugs, expansion of the LIS program will disproportionately impact beneficiaries who are younger, are female, are Black, and already qualify for partial LIS; the $2,000 OOP cap will lower OOP costs for most ibrutinib users who are mostly White older male patients living in higher-income areas; and the $35 insulin cap will impact a higher proportion of Black and lower-income beneficiaries with multiple chronic conditions. There are still uncertainties about how the various provisions will interact and influence the behaviors of Part D plans and beneficiaries.

DISCLOSURES

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