



BRIEF REPORT



OPEN ACCESS



Medicare Part B and Part D drug eligibility for center for Medicare and Medicaid Services price negotiation under the Inflation Reduction Act: estimates using 2016–2019 data

Omar Qureshi ^a, Reshma Ramachandran ^{b,c} and Joseph S. Ross ^{b,c,d}

^aYale School of Medicine, New Haven, CT, USA; ^bSection of General Internal Medicine, Department of Internal Medicine, Yale School of Medicine, New Haven, CT, USA; ^cYale Collaboration for Regulatory Rigor, Integrity and Transparency (CRRIT), Yale School of Medicine, New Haven, CT, USA; ^dDepartment of Health Policy and Management, Yale School of Public Health; and Center for Outcomes Research and Evaluation, Yale-New Haven Health System, New Haven, CT, USA

ABSTRACT

Background: To reduce Medicare prescription drug expenditures, the 2022 Inflation Reduction Act (IRA) allows the Centers for Medicare & Medicaid Services (CMS) to directly negotiate with drug manufacturers on Medicare prices of high-expenditure drugs (\geq \$200m annual spending) which meet certain eligibility criteria. However, it is unclear what proportion of high-expenditure drugs covered by Medicare, and attributable annual drug spending, would typically be eligible for CMS negotiations in a given year.

Methods: We used historical Medicare drug spending data to determine how many high-expenditure drugs, and attributable drug spending, would have been eligible for CMS negotiations had the IRA been in effect from 2016–2019, while also determining which of the IRA's eligibility criteria is most restrictive.

Results: From 2016–2019, approximately one third (33.3% for Part B, 32.4% for Part D) of high-expenditure Medicare drugs would have been eligible for negotiation, with ineligible drugs accounting for 75.2% and 63.8% of spending on high-expenditure drugs in Medicare Part B and D, respectively. Most ineligible high-expenditure drugs were ineligible because they launched too recently. From 2016–2019, between 59 and 74 high-expenditure drugs were eligible per year, indicating that in some years there may not be enough eligible drugs for CMS to negotiate on the maximum number of drugs allowable by law.

Conclusions: The IRA's current eligibility criteria may restrict CMS from being able to negotiate drug prices on approximately two-thirds of the high-expenditure drugs covered by Medicare and may not allow CMS to negotiate on the maximum number of drugs allowable by law. Congress could consider relaxing eligibility requirements for price negotiation, such as those pertaining to launch date recency, to ensure there are a sufficient number of high-expenditure drugs

CONTACT Joseph S. Ross joseph.ross@yale.edu Section of General Internal Medicine, Yale University School of Medicine, P.O. Box 208093, New Haven, CT 06520-8093, USA

© 2024 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (<http://creativecommons.org/licenses/by-nc/4.0/>), which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited. The terms on which this article has been published allow the posting of the Accepted Manuscript in a repository by the author(s) or with their consent.

eligible for negotiation or make certain ineligible drugs contributing to significant annual Medicare spending eligible for negotiation on a case-by-case basis.

Abbreviations: IRA: Inflation Reduction Act; CMS: Centers for Medicare and Medicaid Services; FDA: Food and Drug Administration

KEYWORDS Inflation Reduction Act; Medicare Drug Price Negotiation Program; Centers for Medicare & Medicaid Services; Medicare Parts B and D; Medicare drug policy

Background

The Inflation Reduction Act (IRA) was enacted in 2022 with the goal of curbing U.S. inflation, including by reducing Medicare prescription drug spending (Assistant Secretary for Planning and Evaluation – Office of Health Policy, 2023; Cubanski, 2023; Niazi, 2022; Reitsma et al., 2023). Medicare Part B covers drugs which are typically administered in a healthcare setting by a healthcare provider or are administered as part of a physician service, while Medicare Part D covers prescription drugs obtained from an outpatient pharmacy for use outside of a healthcare setting, with drug coverage revised yearly (Assistant Secretary for Planning and Evaluation – Office of Health Policy, 2023; Seshamani, 2023). The IRA's Medicare Drug Price Negotiation Program authorises the Centers for Medicare & Medicaid Services (CMS), the federal agency which oversees Medicare, to negotiate drug prices with manufacturers of high-expenditure drugs (\geq \$200 m annual spending) covered by Medicare Part B or D starting in 2028 and 2026, respectively (Seshamani, 2023). Per the IRA, the maximum number of drugs by law the CMS can negotiate on is up to 10 Part D drugs in 2026, up to 25 Part D drugs in 2027, up to 45 Part B and D drugs in 2028, and up to 60 Part B and D drugs in 2029, with drugs selected for negotiation two years prior to the negotiated price going into effect (Cubanski, 2023; Reitsma et al., 2023; Seshamani, 2023). The IRA outlines eligibility requirements for high-expenditure Medicare Part B and D drugs for CMS negotiation, summarised in Table 1. High-expenditure drugs are considered ineligible for negotiation if they are multi-source, plasma-derived, orphan drugs marketed only for a single indication, or have too recent a launch date from negotiation (7 years prior for small molecule drugs and 11 years prior for biologics) (Cubanski, 2023; Seshamani, 2023).

Previous analyses have simulated potential IRA savings, predicted what drugs will be selected for negotiation, and suggested IRA modifications (Assistant Secretary for Planning and Evaluation – Office of Health Policy, 2023; Dickson & Hernandez, 2023; DiStefano et al., 2023; Reitsma et al., 2023; Rome et al., 2023). However, these studies all examined 2020 prescription drug use and spending, an anomalous year because of the COVID-19 pandemic (IQVIA, 2020; IQVIA Institute for Human Data Science, 2022), and

Table 1. Summary of IRA drug eligibility criteria excluding high-expenditure drugs with ≥\$200 million of Medicare drug spending annually from CMS negotiation, along with proposed rationale for each exclusion criteria.*

Per the IRA’s drug eligibility criteria, high-expenditure drugs are excluded from CMS negotiation if they are any of the following:	Proposed rationale for exclusion criteria
(1) Multi-source**	<ul style="list-style-type: none">• Avoids putting undue financial pressure on manufacturers of multi-source drugs that face pricing competition from other manufacturers• Focuses reduction of highly priced single-source drugs that do not face direct competition
(2) Plasma-derived	<ul style="list-style-type: none">• Avoids disincentivizing R&D of plasma-derived products
(3) Small molecule or biologic drugs launched in the U.S. within 7 or 11 years, respectively, or biologic drugs with anticipated biosimilar competition within the next 2 years	<ul style="list-style-type: none">• Affords manufacturers of novel small molecule and biologic drugs a leeway period to recoup R&D costs
(4) Orphan Drugs approved and marketed for only a single indication for which they also had an orphan drug indication (also known as Orphan Drug Exclusion)***	<ul style="list-style-type: none">• Avoids disincentivizing the R&D of novel drugs that provide therapeutic benefit to rare disease patients who lack effective treatments• Excludes only drugs with a single Orphan Drug indication, allowing CMS to negotiate on prices for drugs with multiple approved orphan drug indications

*Full list and description of IRA eligibility criteria can be found in References (Cubanski, 2023; Seshamani, 2023).

**Per the latest IRA guidance, a drug is considered multi-source if a generic or biosimilar drug with the same active ingredient/moiety is being actively sold in the U.S. for similar indications (Cubanski, 2023; Seshamani, 2023).

***Per the latest IRA guidance, drugs with multiple orphan drug designations or drugs with withdrawn orphan designations were not excluded from CMS negotiation under the Orphan Drug Exclusion, and were therefore considered eligible for CMS negotiation (Cubanski, 2023; Seshamani, 2023).

it remains unclear what proportion of high-expenditure drugs, and attributable Medicare spending, would typically be eligible for CMS negotiations in a given year. If eligible drugs comprise a minor proportion of high-expenditure Medicare drugs and spending, the IRA may not meaningfully reduce drug spending, or there may not be enough eligible drugs available for CMS to negotiate prices on the maximum number of drugs allowable by law (Cubanski, 2023; Seshamani, 2023).

In this study, we used historical Medicare drug spending data from 2016 to 2019 to determine how many high-expenditure drugs (≥\$200 m of annual spending), and attributable drug spending, would have been eligible for CMS negotiations had the IRA been in effect from 2016 to 2019, while also determining which of the IRA’s drug eligibility criteria is most restrictive.

Methods

We used Medicare Part B and D drug spending data to identify high-expenditure drugs with ≥\$200 m drug spending annually across Medicare

Parts B and D from 2016 to 2019, as these are the drugs which will be evaluated for potential eligibility for CMS negotiation under the IRA (US Centers for Medicare and Medicaid Services, 2023a, 2023b). Distinct dosage forms and formulations of drugs with the same active ingredient or moiety were considered a single product (e.g. Humira and Humira CF) (Seshamani, 2023).

For these high-expenditure drugs, we determined drug eligibility for CMS negotiation in each year according to the IRA's drug eligibility criteria, grouping ineligible drugs by criteria violated (Cubanski, 2023; Seshamani, 2023). IRA drug eligibility criteria are summarised in Table 1. Small molecule and biologic drugs were considered ineligible due to being multi-source if at least one generic or biosimilar drug with the same active ingredient or moiety was FDA-approved, actively marketed, and sold for patient use in the U.S. for similar indications during the year examined (Seshamani, 2023). Biologics were also considered multi-source if a biosimilar was historically launched within two years of the year examined, to replicate CMS's exclusion of biologics with a 'high likelihood' of biosimilar launch within two years (Seshamani, 2023). Plasma-derived drugs (e.g. immunoglobulins) were considered ineligible (Seshamani, 2023). Orphan drugs were considered ineligible under the IRA's Orphan Drug Exclusion if they were marketed for only a single indication for which they also had an orphan drug indication, per the U.S. Food and Drug Administration's (FDA's) orphan drug designation database, as of the year analyzed (Seshamani, 2023; US Food and Drug Administration, 2023). Drugs with multiple orphan drug designations or drugs with withdrawn orphan designations were considered eligible (Seshamani, 2023). Drugs were considered ineligible due to launch year if they were small molecule or biologic drugs launched within 7 or 11 years, respectively, of the year examined (Seshamani, 2023). We considered insulin products ineligible because, when we undertook our study, it was unclear whether leading insulins would be considered multi-source in the years following the IRA's launch, although this was expected (Rivzi, 2022). However, notably, insulins were included among the first set of drugs selected for CMS negotiation (U.S. Department of Health and Human Services, 2023). Drugs violating multiple criteria were categorised as ineligible due to multiple reasons.

Annual Medicare spending on eligible and ineligible high-expenditure drugs were calculated for each year from 2016 to 2019. Calculations were performed using Excel, version 16.67 (Microsoft).

Results

From 2016 to 2019, there were between 36 and 43 high-expenditure drugs in Medicare Part B each year (Table 2), representing 49 unique drugs and accounting for \$92.7b in total 2016–2019 spending. From 2016 to 2019,

33.3% of high-expenditure Part B drugs were eligible for negotiation while 66.7% were ineligible, representing 24.8% and 75.2% of Medicare Part B drug spending during this period, respectively. In each year, on average, 13 (32.5%) high-expenditure drugs were eligible for negotiation, while 27 (67.5%) were ineligible. From 2016 to 2019, the most common reason for ineligibility was launching too recently (37.1% of high-expenditure drugs). Overall, eligible drugs accounted for \$22.9b (24.7%) of total 2016–2019 Part B spending on high-expenditure drugs, while ineligible drugs accounted for \$69.7b (75.2%).

From 2016 to 2019, there were between 143 and 178 high-expenditure drugs in Medicare Part D each year (Table 3), representing 217 unique drugs and accounting for \$455.4b in total 2016–2019 spending. From 2016 to 2019, 32.4% of high-expenditure Part D drugs were eligible for negotiation while 67.6% were ineligible, representing 36.2% and 63.8% of Medicare Part D drug spending during this period, respectively. In each year, on average, 52 (32.4%) high-expenditure drugs were eligible for price negotiation, while 109 (67.6%) were ineligible. From 2016 to 2019, the most common reasons for ineligibility were due to being multi-source, including having anticipated biosimilar competition (25.9% of high-expenditure drugs), and launching too recently (25.5%). Overall, eligible drugs accounted for \$165.2b (36.2%) of total 2016–2019 Part D spending on high-expenditure drugs, while ineligible drugs accounted for \$290.4b (63.8%).

From 2016 to 2019, the total number of unique high-expenditure drugs eligible for negotiation across Medicare Parts B and D were 62 in 2016 (13 in Part B, 49 in Part D), 67 in 2017 (12 in Part B, 55 in Part D), 74 in 2018 (14 in Part B, 60 in Part D), and 59 in 2019 (14 in Part B, 45 in Part D).

Discussion

Per current IRA eligibility criteria, approximately one-third (33.3% for Part B, 32.4% for Part D) of high-expenditure drugs from 2016 to 2019 would have been eligible for CMS negotiation. Ineligible drugs comprised 66.7% and 67.6% of high-expenditure drugs and 75.2% and 63.8% of high-expenditure drug spending for Medicare Parts B and D, respectively. The IRA's eligibility criteria limits CMS's ability to negotiate on high-expenditure drugs which comprise most Medicare drug spending, which may hamper CMS efforts to meaningfully reduce Medicare drug spending.

Launching too recently was the most common reason for drug ineligibility from 2016 to 2019, with drugs ineligible due to launch date comprising 45.3% and 26.5% of Medicare Part B and D spending on high-expenditure drugs during the period, respectively. Being multi-source, or having anticipated biosimilar competition, was the second most common reason for drug ineligibility from 2016 to 2019, with drugs ineligible due to being multi-source

Table 2. Medicare Part B high-expenditure drugs with \geq \$200 million spending annually and attributable Medicare spending in year of selection stratified by eligibility for CMS negotiation under the IRA, 2016–2019.

	2016 (drugs selected would have prices negotiated on in 2018)			2017 (drugs selected would have prices negotiated on in 2019)			2018 (drugs selected would have prices negotiated on in 2020)			2019 (drugs selected would have prices negotiated on in 2021)		
Price negotiation eligibility	Drugs, No. (%)	2016 Medicare spend (%), \$b	2016 Median Medicare spend per drug in category (IQR), \$m	Drugs, No. (%)	2017 Medicare spend (%), \$b	2017 Median Medicare spend per drug in category (IQR), \$m	Drugs, No. (%)	2018 Medicare spend (%), \$b	2018 Median Medicare spend per drug in category (IQR), \$m	Drugs, No. (%)	2019 Medicare spend (%), \$b	2019 Median Medicare spend per drug in category (IQR), \$m
Overall	36 (100.0%)	18.9 (100.0%)	297.2 (243.6–647.0)	39 (100.0%)	21.4 (100.0%)	311.7 (254.0–700.1)	41 (100.0%)	24.0 (100.0%)	370.5 (248.7–722.3)	43 (100.0%)	28.4 (100.0%)	400.2 (298.5–797.3)
Eligible for CMS negotiation	13 (36.1%)	5.1 (27.0%)	295.0 (243.7–500.8)	12 (30.8%)	5.3 (24.8%)	313.0 (257.3–481.5)	14 (34.1%)	6.1 (25.4%)	357.4 (239.7–450.4)	14 (32.6%)	6.4 (22.5%)	383.3 (233.4–515.7)
Ineligible for CMS negotiation	23 (63.9%)	13.7 (72.5%)	299.4 (237.1–1044.1)	27 (69.2%)	16.1 (75.2%)	311.7 (253.0–782.4)	27 (65.9%)	17.9 (74.6%)	378.9 (252.1–821.8)	29 (67.4%)	22.0 (77.5%)	428.1 (314.9–914.3)
Ineligible due to launch year	12 (33.3%)	8.1 (42.9%)	329.5 (243.9–1074.9)	15 (38.5%)	9.3 (43.5%)	305.1 (229.8–1033.7)	16 (39.0%)	11.2 (46.7%)	283.4 (241.3–1184.9)	16 (37.2%)	13.4 (47.2%)	408.7 (314.1–1359.7)
Ineligible due to orphan drug status	0 (0.0%)	0.0 (0.0%)	N/A	0 (0.0%)	0.0 (0.0%)	N/A	0 (0.0%)	0.0 (0.0%)	N/A	1 (2.3%)	0.3 (1.1%)	276.3 (N/A)
Ineligible due to being multi-source*	5 (13.9%)	4.1 (21.7%)	702.9 (351.0–1355.2)	6 (15.4%)	4.9 (22.9%)	741.3 (388.0–1355.8)	6 (14.6%)	4.8 (20.0%)	810.5 (373.6–1205.0)	7 (16.3%)	6.2 (21.8%)	908.3 (432.3–1168.1)
Ineligible due to being plasma-derived	3 (8.3%)	0.7 (3.7%)	237.1 (229.5–282.7)	2 (5.1%)	0.6 (2.8%)	314.4 (N/A)	2 (4.9%)	0.7 (2.9%)	326.6 (N/A)	3 (7.0%)	1.1 (3.9%)	359.2 (330.1–385.6)
Ineligible due to multiple reasons	3 (8.3%)	0.8 (4.2%)	269.0 (210.8–299.4)	4 (10.3%)	1.2 (5.6%)	264.6 (220.2–404.5)	3 (7.3%)	1.3 (5.4%)	370.5 (248.2–645.4)	2 (4.7%)	1.0 (3.5%)	501.6 (N/A – N/A)

*Category includes biologic drugs with anticipated biosimilar launches within 2 years.

Table 3. Medicare Part D high-expenditure drugs with \geq \$200 million spending annually and attributable Medicare spending in year of selection stratified by eligibility for CMS negotiation under the IRA, 2016–2019.

Price negotiation eligibility	2016 (drugs selected would have prices negotiated on in 2018)			2017 (drugs selected would have prices negotiated on in 2019)			2018 (drugs selected would have prices negotiated on in 2020)			2019 (drugs selected would have prices negotiated on in 2021)		
	Drugs, No. (%)	2016 Medicare spend (%), \$b	2016 Median Medicare spend per drug in category (IQR), \$m	Drugs, No. (%)	2017 Medicare spend (%), \$b	2017 Median Medicare spend per drug in category (IQR), \$m	Drugs, No. (%)	2018 Medicare spend (%), \$b	2018 Median Medicare spend per drug in category (IQR), \$m	Drugs, No. (%)	2019 Medicare spend (%), \$b	2019 Median Medicare spend per drug in category (IQR), \$m
Overall	143 (100.0%)	98.3 (100.0%)	411.2 (277.5–762.5)	155 (100.0%)	105.7 (100.0%)	428.2 (271.2–698.7)	170 (100.0%)	119.3 (100.0%)	403.4 (274.3–695.4)	178 (100.0%)	132.1 (100.0%)	445.3 (276.6–791.2)
Eligible for CMS negotiation	49 (34.3%)	36.1 (36.7%)	379.2 (294.6–915.7)	55 (35.5%)	40.3 (38.1%)	415.0 (297.7–696.8)	60 (35.3%)	49.9 (41.8%)	488.8 (309.5–721.2)	45 (25.3%)	38.9 (29.4%)	524.7 (310.5–799.7)
Ineligible for CMS negotiation	94 (65.7%)	62.2 (63.3%)	411.1 (260.9–690.0)	100 (64.5%)	65.5 (62.0%)	405.7 (245.7–672.8)	110 (64.7%)	69.5 (58.3%)	350.9 (259.6–630.8)	133 (74.7%)	93.2 (70.6%)	364.3 (268.2–690.8)
Insulin drugs*	6 (4.2%)	11.6 (11.8%)	2044.8 (657.5–2725.6)	7 (4.5%)	12.8 (12.1%)	1878.1 (541.6–2697.7)	8 (4.7%)	13.8 (11.6%)	1527.2 (664.1–2751.6)	8 (4.5%)	14.6 (11.1%)	1731.5 (746.5–2813.7)
Ineligible due to launch year	34 (23.8%)	20.3 (20.7%)	461.5 (268.2–814.4)	34 (21.9%)	24.6 (23.3%)	558.7 (298.0–822.6)	41 (24.1%)	28.5 (23.9%)	470.7 (276.5–818.1)	56 (31.5%)	47.1 (35.7%)	487.8 (277.8–977.7)
Ineligible due to orphan drug status	4 (2.8%)	1.5 (1.5%)	306.2 (251.2–536.5)	4 (2.6%)	1.5 (1.4%)	298.8 (234.6–557.6)	5 (2.9%)	2.0 (1.7%)	346.5 (208.3–595.7)	3 (1.7%)	1.2 (0.9%)	318.6 (277.4–583.0)
Due to being multi-source**	38 (26.6%)	18.1 (18.4%)	345.7 (245.5–537.0)	40 (25.8%)	17.4 (16.5%)	379.1 (249.2–487.5)	44 (25.9%)	18.1 (15.2%)	303.9 (252.1–505.4)	45 (25.3%)	19.7 (14.9%)	309.0 (247.2–467.6)
Ineligible due to being plasma-derived	1 (0.7%)	0.3 (0.3%)	327.9 (N/A)	1 (0.6%)	0.3 (0.3%)	345.6 (N/A – N/A)	0 (0.0%)	0.0 (0.0%)	0.0 (0.0–0.0)	0 (0.0%)	0.0 (0.0%)	N/A (N/A – N/A)
Ineligible due to multiple reasons	11 (7.7%)	10.4 (10.6%)	756.9 (378.0–823.0)	14 (9.0%)	8.9 (8.4%)	447.8 (218.3–860.7)	12 (7.1%)	7.1 (6.0%)	428.3 (290.4–867.7)	21 (11.8%)	10.6 (8.0%)	508.1 (299.6–692.7)

*Insulin drugs covered by Medicare Part D were considered ineligible for negotiation.

**Category includes biologic drugs with anticipated biosimilar launches within 2 years.

comprising 21.6% and 16.1% of Medicare Part B and D spending on high-expenditure drugs during the period, respectively. Our evaluation of the most restrictive IRA drug eligibility criteria is in line with previous analyses in the literature, which cite launch date recency and being multi-source as the most common reasons for high-expenditure drug ineligibility under the IRA (Dickson & Hernandez, 2023; Niazi, 2022; Rome et al., 2023). Several drugs ineligible due to launch date recency are among the drugs that account for the most Medicare spending, such as Eylea (aflibercept) and Eliquis (apixaban). Congress may consider changing the IRA's eligibility criteria to address the frequency with which launch date recency excludes a drug from price negotiation, such as by aligning the exclusion criteria between small molecule drugs and biologic drugs to be 7 years for both, or make eligibility criteria exceptions for ineligible drugs with significant annual Medicare spending to make them eligible for negotiation on a case-by-case basis.

CMS will select 10 Part D drugs for negotiations in 2026, ramping up to 60 drugs across Parts B and D by 2029 (Cubanski, 2023; Seshamani, 2023). From 2016 to 2019, between 59 and 74 drugs across Medicare Parts B and D were eligible for negotiation in a given year. This implies that if CMS can negotiate on up to 60 drugs, there may be certain years, such as what we observed for 2019, where there may not be enough eligible drugs for CMS to negotiate on the maximum number of drugs allowable by law. Congress may have to make changes to the IRA's current eligibility criteria to ensure there are a sufficient number of eligible high-expenditure drugs as allowed by law.

Our analysis has several limitations. First, we examined each year independently. However, the IRA limits the number of negotiated drugs to 10 Part D drugs in 2026, another 15 Part D drugs in 2027, another 15 Part B and Part D drugs in 2028 and so on, suggesting that eligibility may be maximised quickly (Cubanski, 2023; Seshamani, 2023). Second, the time period analyzed does not match the IRA negotiation timeline, and our results may not be generalisable if the landscape of prescription drugs covered by Medicare Parts B and D change substantially going forward (Cubanski, 2023; Seshamani, 2023). Nevertheless, we expect our findings are likely to reflect historical norms and can inform expectations for the IRA's impact going forward as the changes to prescription drug use and spending resolve after the COVID-19 pandemic (IQVIA, 2020; IQVIA Institute for Human Data Science, 2022). Third, our retrospective analysis was able to use known biosimilar launch dates for high-expenditure biologic drugs, whereas CMS may have difficulty predicting biosimilar launches. Finally, we considered insulins ineligible for price negotiations in our analysis because the expectation was that high-expenditure insulins would be considered multi-source. However, surprising many, insulins were among the first Part D drugs selected for CMS negotiations under the IRA (U.S. Department of Health and Human Services, 2023). In the years 2016–2019, there were between 6 and 8 insulin drugs with \geq \$200 million Part D

spending, representing between 11.1% and 12.1% of Part D drug spending on high-expenditure drugs in a given year (Table 3). Had we considered insulins as eligible for CMS negotiation for Part D, the proportion of high-expenditure drugs eligible for negotiation, and attributable drug spending, would have increased commensurately in the years examined.

Conclusion

This study shows that current IRA drug eligibility criteria would restrict CMS from being able to negotiate drug prices on approximately two-thirds of the high-expenditure drugs covered by Medicare Parts B and D from 2016 to 2019, with the launch date eligibility criteria being the most restrictive. In the years examined, drugs ineligible for CMS negotiation accounted for approximately three-quarters of high-expenditure Medicare Part B spending and two-thirds of Part D spending. Additionally, our study suggests that in some years, as we observed in 2019, there may not be enough eligible drugs for CMS price negotiations to reach the maximum number of drugs allowed by the IRA. Congress could consider relaxing eligibility requirements for price negotiation, such as those pertaining to launch date recency, to ensure there are a sufficient number of high-expenditure drugs eligible for negotiation or make certain ineligible drugs contributing to significant annual Medicare spending eligible for negotiation on a case-by-case basis.

The IRA represents an innovative approach to reduce Medicare prescription drug spending. However, the IRA will be most effective if CMS is afforded enough flexibility to appropriately select high-expenditure drugs for negotiation. Current IRA eligibility criteria may not afford CMS this flexibility.

Acknowledgements

Not applicable.

Consent for publication

Not applicable.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

This research was supported by Yale University.

Ethics approval and consent to participate

Not applicable.

Notes on contributors

Mr. *Qureshi* is a medical student at Yale School of Medicine.

Dr. *Ramachandran* is a family medicine physician and assistant professor at Yale School of Medicine.

Dr. *Ross* is an internal medicine physician and professor at Yale Schools of Medicine and Public Health.

ORCID

Omar Qureshi  <http://orcid.org/0000-0002-2268-4648>

Reshma Ramachandran  <http://orcid.org/0000-0003-3845-3606>

Joseph S. Ross  <http://orcid.org/0000-0002-9218-3320>

Availability of data and materials

The datasets generated and/or analyzed during the current study are available in:

- (1) The Centers for Medicare and Medicaid Services' Medicare Part B by Drug dataset repository (link)
- (2) The Centers for Medicare and Medicaid Services' Medicare Part D by Drug dataset repository (link)

References

- Assistant Secretary for Planning and Evaluation – Office of Health Policy. (2023). — *Inflation Reduction Act research series— medicare enrollees' use and out-of-pocket expenditures for drugs selected for negotiation under the Medicare Drug Price Negotiation Program*. U.S. Department of Health and Human Services. Retrieved October 23, 2023, from <https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPE-IRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf>
- Cubanski, J. (2023). *FAQs about the Inflation Reduction Act's Medicare drug price negotiation program*. Kaiser Family Foundation. Retrieved October 23, 2023, from <https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/>
- Dickson, S., & Hernandez, I. (2023). Drugs likely subject to Medicare negotiation, 2026–2028. *Journal of Managed Care & Specialty Pharmacy*, 29(3), 229–235. Retrieved October 23, 2023, from <https://doi.org/10.18553/jmcp.2023.29.3.229>
- DiStefano, M. J., Levy, J. F., Odouard, I. C., & Anderson, G. F. (2023). Estimated savings from using added therapeutic benefit and therapeutic reference pricing in United States medicare drug price negotiations. *Value in Health*, 26(11), 1618–1624. <https://doi.org/10.1016/j.jval.2023.08.004>
- IQVIA. (2020). *Monitoring the impact of COVID-19 on the pharmaceutical market*. Retrieved October 31, 2023, from https://www.iqvia.com/-/media/iqvia/pdfs/nordics/covid-reports/nordic_covid-19_cross-country-report-may-2021.pdf

- IQVIA Institute for Human Data Science. (2022). *The use of medicines in the U.S. 2022: Usage and spending trends and outlook to 2026*. IQVIA. Retrieved October 31, 2023, from <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf>
- Niazi, S. K. (2022). The Inflation Reduction Act: A boon for the generic and biosimilar industry. *Journal of Clinical Pharmacy and Therapeutics*, 47(11), 1738–1751. <https://doi.org/10.1111/jcpt.13783>
- Reitsma, M. B., Dusetzina, S. B., Ballreich, J. M., Trujillo, A. J., & Mello, M. M. (2023). Examining opportunities to increase savings from medicare price negotiations. *JAMA Internal Medicine*, 183(6), 581. <https://doi.org/10.1001/jamainternmed.2023.0763>
- Rivzi, Z. (2022). Prices for leading insulins will likely not be negotiated under new drug pricing package. *Public Citizen*. Retrieved October 23, 2023, from <https://www.citizen.org/article/prices-for-leading-insulins-will-likely-not-be-negotiated-under-new-drug-pricing-package/>
- Rome, B. N., Nagar, S., Egilman, A. C., Wang, J., Feldman, W. B., & Kesselheim, A. S. (2023). Simulated Medicare drug price negotiation under the Inflation Reduction Act of 2022. *JAMA Health Forum*, 4(1), e225218. <https://doi.org/10.1001/jamahealthforum.2022.5218>
- Seshamani, M. (2023). *Medicare drug price negotiation program: Revised guidance, implementation of sections 1191–1198 of the social security Act for initial price applicability year 2026*. Department of Health & Human Services. Retrieved October 23, 2023, from <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>
- US Centers for Medicare and Medicaid Services. (2023a). *Medicare Part B spending by drug*. Retrieved October 23, 2023, from <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug>
- US Centers for Medicare and Medicaid Services. (2023b). *Medicare Part D spending by drug*. Retrieved October 23, 2023, from <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug>
- U.S. Department of Health and Human Services. (2023). *HHS selects the first drugs for Medicare drug price negotiation*. Retrieved October 31, 2023, from <https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html>
- US Food and Drug Administration. (2023). *Search orphan drug designations and approvals*. Retrieved October 23, 2023, from <https://www.accessdata.fda.gov/scripts/opdlisting/opdp/>