The impact of a statewide insulin copay cap policy for insured patients with diabetes in Utah

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Plain language summary

Many people with diabetes have trouble paying for insulin in the United States. There is a policy in Utah that starting January 1, 2021, capping insulin copays at $30 per month. This study looked at changes in how much patients pay for insulin and found that patients paid less for insulin after implementation of the policy.

Implications for managed care pharmacy

This study exploring an insulin copay cap policy in Utah found that patient insulin out-of-pocket costs decreased and insulin costs for the health plan increased. Longer study periods are needed to see if improvements in health outcomes offset the increased insulin costs to the health plan. This study shed light on the potential outcomes of copay cap policies for insulin.

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ABSTRACT

BACKGROUND: Insulin affordability is a huge concern for patients with diabetes in the United States. On March 30, 2020, Utah signed House Bill 207 into law, aimed at capping copayments for insulin at $30 for a 30-day supply. The bill was enacted on January 1, 2021.

OBJECTIVE: To assess patient basal insulin adherence, out-of-pocket costs, health plan costs, total costs on insulin, and hemoglobin A1c (A1c) in prepolicy vs postpolicy periods.

METHODS: This study is a retrospective analysis using data from a regional health plan in Utah from October 1, 2019, to September 30, 2021. Inclusion criteria were fully enrolled members of all ages, under commercial insurance, with at least 1 fill for any type of insulin in both the preperiod and the postperiod. Adherence was measured by proportion of days covered (PDC). Paired t-tests and Wilcoxon sign rank tests were conducted to compare the health and economic outcomes.

RESULTS: Out of 24,150 commercially insured individuals, a total of 244 patients were included. Across all 244 patients, there was a significant decline in monthly median out-of-pocket costs of insulin by 58.5% ($P<0.001$), whereas the monthly median health plan costs of insulin increased by 22.0% ($P<0.001$). The total monthly costs of insulin (the sum of out-of-pocket and health plan costs) were unchanged ($P=0.115$). Only 74 patients with enough basal insulin fills in both periods were included in the analysis for PDC changes. PDC change was not statistically significant ($P=0.43$). Among the 74 patients with PDC calculations, 29 patients had A1c recorded in both periods. The change in A1c was not statistically significant ($P=0.23$).

CONCLUSIONS: An insulin copayment max of $30 in Utah demonstrated lower patient out-of-pocket costs, subsidized by the health plan. PDC did not change, and HbA1c did not improve. An assessment of a longer period and on a larger population is needed.

Diabetes is the seventh leading cause of death in the United States.[1] Despite pharmacological and behavioral interventions to control glucose, the prevalence of diagnosed diabetes in US adults continued to grow over the last 2 decades. In the state of Utah specifically, the prevalence of diagnosed diabetes increased by 35%, from 6.0% to 8.1%, between 2004 and 2019.[2] Diabetes also causes microvascular complications (eg, diabetic retinopathy) and macrovascular complications (eg, coronary heart disease).[3] Insulin is vital for patients with type 1 diabetes mellitus, and is ultimately required by more than half of patients with type 2 diabetes mellitus for desired glycemic control.[4] The list price of insulin, however, has increased dramatically over the years and posed a significant challenge to affordability.[5] According to a Kaiser Family Foundation poll, 53% of the public agreed that capping out-of-pocket costs for insulin at $35 a month should be a top priority for Congress to take action.[6] A study using nationally representative data showed that 1 in 7 patients receiving insulin in the United States reached catastrophic spending, defined as spending more than 40% of their postsubsistence income on insulin alone.[7] In a survey conducted in a urban diabetes center, 1 in 4 patients reported using a lower dose of insulin than prescribed because of cost.[8]

In Utah specifically, more than half of the residents (53%) surveyed experienced health care affordability burdens in 2019.[9] Cost influenced the ability to fill a prescription, with 24% of residents reporting not being able to fill a prescription.[9] In addition, 19% reported cutting pills in half or skipping doses of medicine to ration their medication. Costs were the most cited reason for not obtaining medical care, greater than other barriers such as transportation, difficulties obtaining an appointment, or lack of childcare.[9]

On March 30, 2020, Utah passed House Bill (HB) 207.[10] This bill was aimed at decreasing the cost of insulin by capping copayments on insulin at $30 for a 30-day supply for patients with commercial insurance, regardless of whether the enrollee had met the deductible. The bill went into effect on January 1, 2021. Utah is one of the many states that passed legislation aiming at reducing insulin out-of-pocket costs. At the time of writing, there are more than 20 states and the District of Columbia that have enacted similar legislations of placing an out-of-pocket copay cap, ranging from $20 to $100 per month on insulin since 2020.[11] In August 2022, the Congress passed the Inflation Reduction Act and the President signed the act into law but limited the $35 cap to Medicare beneficiaries only.[12]

This study is a retrospective, secondary data analysis using pharmacy claims data from a regional health plan in Utah from October 2019 to September 2021. This exploratory study seeks to answer these questions: (1) Did capped copayments on insulin at $30 for a 30-day supply impact monthly patient out-of-pocket costs, health plan costs, and monthly total costs (sum of patient out-of-pocket costs and health plan costs) on insulin? (2) Did health outcomes (basal insulin adherence and hemoglobin A1c [A1c]) differ in prepolicy vs postpolicy periods? This study adds to a growing body of literature on assessing the impact of insulin copay cap policy.[13,14]

Methods

This retrospective observational study used adjudicated pharmacy claims data linked with electronic medical records data provided by a regional commercial health plan in Utah. The study period was from September 2019 to October 2021. The prepolicy period was defined as September 2019 to December 2020, and the postpolicy period lasted from January 2021 to October 2021 (Supplementary Figure 1, available in online article). For each insulin prescription, the database reports insulin type, days supply, patient out-of-pocket payments, and health plan payments. The linked electronic medical records report patient demographic information and diagnosis code. Inclusion criteria were continuous enrollment of patients of all ages, under commercial insurance, with at least 1 insulin fill (any insulin) in both the prepolicy and the postpolicy period (Supplementary Figure 2). Outcomes included monthly patient out-of-pocket costs, health plan costs, and monthly total costs (the sum of patient out-of-pocket costs and health plan costs) on insulin, proportion of days covered (PDC) (to measure insulin adherence), and A1c levels in the prepolicy and postpolicy periods. Costs were expressed in US dollars per patient per month (PPPM). A1c data came from the first reading in the prepolicy period and the last reading in the postpolicy period to ensure the gap between the two readings was larger than 90 days.

In both the prepolicy and the postpolicy period, the first insulin fill date was used as the first insulin fill date, and each patient was followed for 6 months after the first fill date in each time period. Following the recommendation by Loucks and colleagues, within each 6-month period, patients with a least 3 fills or two 90-day fills were included.[15] PDC was calculated as a fraction, in which the nominator was the number of days with insulin on hand, and the denominator was the number of days in a specified time interval (6 months).

Paired t-test was used to assess statistically significant difference in PDC and A1c. Costs were calculated as median costs with interquartile range (IQR). Wilcoxon signed rank test was used to assess statistically significant difference in costs in the prepolicy vs the postpolicy period. Two-sided

TABLE 1 Patient Demographic Information

Characteristics	N = 244
Age, years, mean (SD)	45.9 (15.9)
Sex, n (%)	
Female	105 (43.0)
Male	139 (57.0)
Race, n (%)	
White	174 (71.3)
Black	3 (1.2)
Asian	5 (2.0)
American Indian and Alaska Native	5 (2.0)
Choose not to disclose	1 (0.4)
Other	13 (5.3)
Missing/unknown	43 (17.6)
Ethnicity, n (%)	
Hispanic	19 (7.8)
Non-Hispanic	180 (73.8)
Missing	45 (18.4)

P values less than 0.05 were considered statistically significant. Analyses were conducted using STATA 17 (STATACorp, College Park, TX). This study conformed to the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines regarding conduct and reporting of the observational studies. The University of Utah Institution Review Board approved the study protocol on June 15, 2021 (IRB_00140608).

Results

Out of 24,150 commercially insured individuals, a total of 244 patients met the inclusion criteria. The patient demographic information is presented in Table 1. Less than half of the patients (43.0%) were female. The mean age was 45.9 years. Most of the patients were White (71.3%) and non-Hispanic (73.8%). Across all 244 patients, there was a statistically significant decline in their median out-of-pocket PPPM costs of insulin by 58.5%, from $65 in the prepolicy period to $27 in the postpolicy period ($P < 0.001$). The median PPPM costs of insulin paid by the health plan increased significantly by 22.0%, from $346 in the prepolicy period to $444 in the postpolicy period ($P < 0.001$). There was no statistically significant change in total PPPM costs, defined as the sum of the patient out-of-pocket PPPM costs and health plan PPPM costs, in the prepolicy period vs the postpolicy period ($P = 0.115$).

Regarding health outcomes results, because of the lack of data in other types of insulin, this study only focused on adherence to basal insulin, and 74 patients with enough basal insulin fills both in the prepolicy and in the postpolicy period were included for PDC analysis. The difference in PDC in the postperiod (63.2%) as compared with the PDC in the preperiod (61.6%) was not statistically significant ($P = 0.43$). Among the 74 patients with PDC calculations, 29 patients had their A1c values recorded in both the prepolicy and the postpolicy period. The mean A1c in the postpolicy period was 8.6% and was higher than the A1c in the prepolicy period (8.2%). The difference was not statistically significant ($P = 0.23$). A summary of the cost and health outcomes is shown in Table 2.

TABLE 2 Results on Costs of Insulin and Health Outcomes

	Prepolicy median (IQR), range, USD, N = 244	Postpolicy median (IQR), range, USD, N = 244	*P* value[a]
Results on costs of insulin			
Patient out-of-pocket PPPM cost	$65.01 ($144.36), $0-$1,127.37	$27.01 ($32.14), $0-$606.05	$P < 0.001$
Health plan PPPM cost	$346.19 ($434.33), $0-$2,805.49	$444.42 ($442.58), $0-$2,675.13	$P < 0.001$
Total PPPM cost	$464.06 ($432.31), $30.86-$2,805.49	$481.93 ($471.83), $48.74-$2,696.80	$P = 0.115$
Results on health outcomes			
	Prepolicy mean (SD), n = 74	Postpolicy mean (SD), n = 74	*P* value[b]
PDC	61.6% (0.2)	63.2% (0.1)	$P = 0.43$
	Prepolicy mean (SD), n = 29	Postpolicy mean (SD), n = 29	*P* value[b]
A1c	8.2% (1.3)	8.6% (1.7)	$P = 0.23$

[a]*Comparison of the median using Wilcoxon signed rank test.*

[b]*Comparison of the mean using paired t-test.*

A1c = hemoglobin A1c; PPPM = per patient per month; USD = US dollar.

Discussion

In this exploratory study, an insulin copayment cap of $30 in the state of Utah demonstrated lower patient out-of-pocket insulin costs, subsidized by the health plan. The total insulin costs to the health system did not change significantly, indicating the copay cap acted as a cost-shifting mechanism to the health plan, which is consistent with previous literature on value-based insurance design.[16,17] Also, the insulin copay cap did not solve the drug pricing problem, in which the list and net prices are too high, despite increasing rebates and discounts negotiated between intermediaries in the complex US drug supply chain.[5] This study also sheds light on the expected outcomes from the recent $35 copay cap on insulin, as well as the $2,000 out-of-pocket spending cap on prescription drugs in the Medicare beneficiaries mandated by the Inflation Reduction Act. A cost-effectiveness analysis on the $35 copay cap on insulin on the Medicare population also stated that the copay cap without accompanying regulations on insulin pricing may not be a cost-effective policy, as the incremental cost-effectiveness ratio of this policy was estimated between $810,000/QALY (quality-adjusted life-years) and $250,000/QALY, which was higher than the $100,000/QALY willingness-to-pay threshold from a societal perspective.[13] In March 2023, 3 major insulin manufacturers announced insulin list price reductions.[18] Future research could explore whether these list price reductions would result in an impact on economic and health outcomes. Additionally, more complete health care utilization data in larger populations are needed in future research and potentially longer term to identify whether there are improvements in insulin adherence and A1c, and if so, whether they lead to declines in health services use (such as fewer emergency visits, specialists visits, and hospitalizations). The savings in health services use could offset the insulin cost increase for health plans and result in cost savings, which could be reflected through no premium increase.

This study also showed that PDC did not change and that diabetes outcomes did not improve. Results from this study differed from previous literature on value-based insurance design that reducing coinsurance or copays for high-value medications in chronic conditions (eg, diabetes, hypertension) sees improvements in medication adherence ranging from 1.5% to 9.4%.[19] This is probably due to the disruptions to routine care during COVID-19 that overlapped with the study period. A nationally representative study showed that in 2020, frequency of foregone and delayed medical care due to the pandemic was 26.9% and 35.9%, respectively.[20] Readers should interpret changes in health outcomes in this study with caution, as chronic conditions such as diabetes require continuous patient-centered prevention and care and are sensitive to disruptions, such as COVID-19, in routine care.[21] Disruptions in routine health care services and access to medications and supplies for diabetes patients during COVID-19 have been documented in the US and worldwide, and disruptions can lead to worse diabetes outcomes during and after the disruptions.[21,22]

LIMITATIONS

There are several limitations in this study. First, the data drew on a predominantly fully insured non-Hispanic White sample. Previous research has shown that Black and Hispanic adults are more likely to develop diabetes, and more likely to have poor adherence and higher HbA1c than non-Hispanic White adults.[23-25] The uninsured population is more vulnerable to insulin-related economic burden than the insured.[26] Future analyses are needed to include more comprehensive race and ethnicity representation and the uninsured population. Second, data in this study only captured insulin fills and did not capture concomitant antidiabetic medications or diabetes supplies for glucose self-monitoring, such as test strips. Third, the study period is relatively short, and the sample size is small. An assessment for longer evaluation periods in a larger sample is needed. Fourth, the results did not address the impact of this policy on insulin initiation. Fifth, this study relied on pharmacy claims data, which did not capture insulin fills from manufacturer-sponsored free samples or copay assistance charities.[7] Sixth, it is unclear whether patients were aware of such policy taking place, so they might have filled more prescriptions if they were aware. Seventh, because of missingness in diagnosis codes, this study did not explore the differences between type 1 and type 2 diabetes. Finally, PDC is not a perfect way to measure insulin adherence because the units administered are unclear. A systematic review on all the existing insulin adherence measures, including PDC, concluded that there is no perfect measure of insulin adherence and called for new measures of insulin adherence.[27] Therefore, readers should interpret the results with caution.

Conclusions

As expected, an insulin copayment max of $30 in the state of Utah did demonstrate lower overall patient out-of-pocket costs, subsidized by the health plan. However, PDC did not change and diabetes outcomes did not improve, possibly due to the disruptions to routine care from COVID-19. An assessment of a longer period and on a larger, more diverse population, with data on both economic and health outcomes, may demonstrate greater impact.

DISCLOSURES

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REFERENCES

1. Centers for Disease Control and Prevention. Diabetes fast facts. December 17, 2021. Accessed August 2, 2022. https://www.cdc.gov/diabetes/basics/quick-facts.html

2. Chehal PK, Selvin E, DeVoe JE, Mangione CM, Ali MK. Diabetes and the fragmented state of US health care and policy. *Health Aff (Millwood)*. 2022;41(7):939-46. doi:10.1377/hlthaff.2022.00299

3. American Diabetes Association. Diabetes complications. Accessed November 1, 2023. https://diabetes.org/about-diabetes/complications

4. Matthews DR, Cull CA, Stratton IM, Holman RR, Turner RC; UK Prospective Diabetes Study (UKPDS) Group. UKPDS 26: Sulphonylurea failure in non-insulin-dependent diabetic patients over six years. *Diabet Med*. 1998;15(4):297-303. doi:10.1002/(SICI)1096-9136(199804)15:4<297:AID-DIA572>3.0.CO;2-W

5. Cefalu WT, Dawes DE, Gavlak G, et al; Insulin Access and Affordability Working Group. Insulin Access and Affordability Working Group: Conclusions and recommendations. *Diabetes Care*. 2018;41(6):1299-311. doi:10.2337/dci18-0019

6. Quasem M, Stokes M. KFF health tracking poll – March 2022: Economic concerns and health policy, the ACA, and views of long-term care facilities. Kaiser Family Foundation. March 31, 2022. Accessed August 9, 2022. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-march-2022/

7. Bakkila BF, Basu S, Lipska KJ. Catastrophic spending on insulin in the United States, 2017-18. *Health Aff (Millwood)*. 2022;41(7):1053-60. doi:10.1377/hlthaff.2021.01788

8. Herkert D, Vijayakumar P, Luo J, et al. Cost-related insulin underuse among patients with diabetes. *JAMA Intern Med*. 2019;179(1):112-4. doi:10.1001/jamainternmed.2018.5008

9. The Healthcare Value Hub. Utah residents struggle to afford high healthcare costs; support a range of government solutions across party lines. 2019. Accessed October 26, 2021. https://www.healthcarevaluehub.org/advocate-resources/publications/utah-residents-struggle-afford-high-healthcare-costs-support-range-government-solutions-across-party-lines

10. Thurston NK. H.B. 207 Insulin Access Amendments. 2020. Accessed August 2, 2022. https://le.utah.gov/~2020/bills/hbillenr/HB0207.pdf

11. Norris L. State and federal programs to cap insulin out-of-pocket costs. Verywell Health. July 27, 2022. Accessed August 3, 2022. https://www.verywellhealth.com/programs-to-cap-insulin-costs-5667166

12. Luhby T. Democrats lose effort to cap insulin at $35 for most Americans before passage of Senate reconciliation bill. CNN. August 7, 2022. Accessed August 9, 2022. https://www.cnn.com/2022/08/07/politics/insulin-cap-democrats-reconciliation-bill/index.html

13. Shao H, Guan D, Fonseca V, et al. Economic evaluation of the $35 insulin copay cap policy in Medicare and its implication for future interventions. *Diabetes Care*. 2022;45(11):e161-2. doi:10.2337/dc22-1230

14. Myerson R, Qato DM, Goldman DP, Romley JA. Insulin fills by Medicare enrollees and out-of-pocket caps under the Inflation Reduction Act. JAMA. 2023;330(7):660-2. doi:10.1001/jama.2023.12951

15. Loucks J, Zuckerman AD, Berni A, Saulles A, Thomas G, Alonzo A. Proportion of days covered as a measure of medication adherence. *Am J Health Syst Pharm*. 2022;79(6):492-6. doi:10.1093/ajhp/zxab392

16. Yeung K, Basu A, Hansen RN, Watkins JB, Sullivan SD. Impact of a value-based formulary on medication utilization, health services utilization, and expenditures. *Med Care*. 2017;55(2):191-8. doi:10.1097/MLR.0000000000000630

17. Maciejewski ML, Wansink D, Lindquist JH, Parker JC, Farley JF. Value-based insurance design program in North Carolina increased medication adherence but was not cost neutral. *Health Aff (Millwood)*. 2014;33(2):300-8. doi:10.1377/hlthaff.2013.0260

18. Eli Lilly. Lilly cuts insulin prices by 70% and caps patient insulin out-of-pocket costs at $35 per month | Eli Lilly and Co. Accessed September 12, 2023. https://investor.lilly.com/news-releases/news-release-details/lilly-cuts-insulin-prices-70-and-caps-patient-insulin-out-pocket

19. Sullivan SD, Yeung K, Vogeler C, et al. Design, implementation, and first-year outcomes of a value-based drug formulary. *J Manag Care Spec Pharm*. 2015;21(4):269-75. doi:10.18553/jmcp.2015.21.4.269

20. Giannouchos TV, Brooks JM, Andreyeva E, Ukert B. Frequency and factors associated with foregone and delayed medical care due to COVID-19 among nonelderly US adults from August to December 2020. *J Eval Clin Pract*. 2022;28(1):33-42. doi:10.1111/jep.13645

21. Hartmann-Boyce J, Morris E, Goyder C, et al. Diabetes and COVID-19: Risks, management, and learnings from other national disasters. *Diabetes Care*. 2020;43(8):1695-1703. doi:10.2337/dc20-1192

22. Valabhji J, Barron E, Gorton T, et al. Associations between reductions in routine care delivery and non-COVID-19-related mortality in people with diabetes in England during the COVID-19 pandemic: A population-based parallel cohort study. *Lancet Diabetes Endocrinol*. 2022;10(8):561-570. doi:10.1016/S2213-8587(22)00131-0

23. Brancati FL, Kao WHL, Folsom AR, Watson RL, Szklo M. Incident type 2 diabetes mellitus in African American and white adults: The Atherosclerosis Risk in Communities Study. JAMA. 2000;283(17):2253-9. doi:10.1001/jama.283.17.2253

24. Bancks MP, Kershaw K, Carson AP, Gordon-Larsen P, Schreiner PJ, Carnethon MR. Association of modifiable risk factors in young adulthood with racial disparity in incident type 2 diabetes during middle adulthood. JAMA. 2017;318(24):2457-65. doi:10.1001/jama.2017.19546

25. Li P, Zhang P, Guan D, et al. Changes in racial and ethnic disparities in glucose-lowering drug utilization and glycated haemoglobin A1c in US adults with diabetes: 2005-2018. *Diabetes Obes Metab*. 2023;25(2):516-25. doi:10.1111/dom.14894

26. Lin Y, Shao H, Fonseca V, Shi L. Exacerbation of financial burden of insulin and overall glucose-lowing medications among uninsured population with diabetes. *J Diabetes*. 2023;15(3):215-23. doi:10.1111/1753-0407.13360

27. Stolpe S, Kroes MA, Webb N, Wisniewski T. A systematic review of insulin adherence measures in patients with diabetes. *J Manag Care Spec Pharm*. 2016;22(11):1224-46. doi:10.18553/jmcp.2016.22.11.1224