Impact of state and federal insulin out-of-pocket cost caps on the type 1 diabetes population

An analysis of the size of the T1D population benefiting from insulin out-of-pocket cost caps and those still vulnerable to high-cost exposure

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We estimate that 45% of people with type 1 diabetes in the United States are covered by either a state or federal insulin out-of-pocket cost cap. Despite the existence of these caps nationally, many people with type 1 diabetes may still be vulnerable to high out-of-pocket insulin costs.

Type 1 diabetes (T1D) is a chronic disease that affects two million people in the United States.[1] The disease works by attacking the body's insulin producing cells.[2] Insulin is a hormone critical to the body's functioning because it is a key component of the mechanism which helps the body convert food into energy.[1] Individuals living with this condition depend on prescription insulin—without it, glucose builds up in the bloodstream, resulting in serious health complications.[3]

Breakthrough T1D commissioned Milliman to analyze insulin product utilization and costs using administrative claims and enrollment data from four major sources of health insurance coverage in 2022: Medicare fee-for-service (FFS), Medicare Advantage (MA), Medicaid, and commercial insurance. Approximately 90% of people identified with T1D in our analysis had evidence of insulin fills through their medical or pharmacy benefits each year. The remaining 10% of people with T1D likely secured insulin from non-claims based sources, such as direct purchase or participation in clinical trials. In our analysis, Medicare FFS enrollees had an average out-of-pocket (OOP) cost per fill of $51 for rapid-acting insulin and $46 for long-acting insulin; commercial enrollees had an average OOP cost per fill of $56 for rapid-acting insulin and $53 for long-acting insulin products.

People with T1D must use prescription insulin for the rest of their lives once diagnosed. As such, insulin affordability is especially important for individuals with T1D because financially strained users exposed to high OOP insulin costs may engage in cost-saving behaviors with potentially dire health consequences. Based on a 2021 national survey, more than one million insulin users admitted to rationing their insulin supply by skipping doses or taking less insulin than required to reduce their overall short-term cost burden.[4] Those who are unable to take their prescribed dosage of insulin may be at higher risk for life-threatening complications, such as ketoacidosis, hyperglycemia, and even death.[5,6,7]

Addressing insulin affordability

In recent years, the federal government, multiple state governments, and other key stakeholders have taken steps to reduce the cost burden of insulin and other prescription medications.[4,8,9]

THE INFLATION REDUCTION ACT

The Inflation Reduction Act (IRA) was signed into law in 2022 with a core aim of lowering the cost of prescription drugs for the Medicare population.[10] Prior to the introduction of the IRA, many Medicare beneficiaries, especially those with chronic conditions such as diabetes, were faced with extremely high OOP expenses for prescription drugs. A study of prescription drug affordability published by the U.S. Department of Health and Human Services (HHS) found that in 2019, 2.3 million (4.4%) Medicare beneficiaries aged 65 and older reported not filling their prescriptions due to high OOP costs.[11] The study also found that 3.5 million Medicare beneficiaries reported participating in other risky behaviors, such as skipping doses or taking less medication than prescribed to save on OOP costs.[11] To address this problem, one of the IRA's provisions capped overall OOP spending on prescription drugs for Medicare Part D beneficiaries at $2,000 per year starting in 2025.[10]

FIGURE 1: T1D POPULATION BY INSURANCE COVERAGE AND BY STATE AND FEDERAL INSULIN CAP ELIGIBILITY

Population group	Total U.S. population	Total population with T1D	Population group with T1D as a percentage of U.S. population	Population group as percentage of total population with T1D	Population with T1D covered by either federal or state OOP caps	Percentage of total population with T1D covered by federal or state caps
Total population	**334,914,900**	**2,064,000**	**0.62%**	**100%**	**936,200**	**45%**
By sources of health coverage						
Employer-sponsored insurance (ESI)	181,283,100	861,700	0.48%	42%	142,500	17%
Medicare	36,014,600	452,100	1.26%	22%	452,100	100%
Medicaid	53,320,000	303,500	0.57%	15%	135,200	45%
Dual-eligible beneficiaries*	10,875,900	159,900	1.47%	8%	159,900	100%
TRICARE program	4,119,700	18,400	0.45%	1%	0	0%
Veterans Affairs (VA)	813,700	4,900	0.60%	0%	0	0%
Indian Health Service (IHS)	257,600	600	0.23%	0%	0	0%
Direct purchase	21,193,000	109,600	0.52%	5%	46,400	42%
Uninsured	27,037,300	153,400	0.57%	7%	0	0%
By state insulin cap status						
Reside in a state with a state cap	149,801,500	917,600	0.61%	44%	582,800	64%
Reside in a state with no state cap	185,113,400	1,146,500	0.62%	56%	353,400	31%

**Dual-eligible beneficiaries are covered by both Medicare and Medicaid.*

In addition to overall caps on OOP drug costs, legislators included provisions designed specifically to support Medicare beneficiaries with diabetes because OOP costs for insulin were becoming increasingly unaffordable for millions of Americans. A report by the Insulin Access and Affordability Working Group, which was assembled by the American Diabetes Association, shows the average cost of insulin for Medicare Part D enrollees doubled between 2006 and 2013.[12] A separate report published by the HHS Office of the Assistant Secretary for Planning and Evaluation found that in 2019, the average OOP cost of insulin for Medicare beneficiaries was $63 for a 30-day supply.[13]

Beginning in 2023, the IRA established a $35 monthly cost-sharing limit per 30-day supply of insulin for Medicare beneficiaries.[10] The $35 cap applies to all insulin products regardless of dosage form (i.e., vial, pen, or inhaler) or insulin product type, including rapid-, short-, intermediate-, and long-acting varieties of insulin. Although all insulin products are covered by the federal cap, Medicare Part D plans are allowed to choose the specific products they offer.[10]

STATE INSULIN CAPS

As of January 1, 2025, 26 states and the District of Columbia implemented insulin caps for their state-run health insurance plans, which are largely state Medicaid plans and state employee health plans. Individuals covered by self-funded Employee Retirement Income Security Act (ERISA) and federal employee health plans are not covered by state insulin caps. Like the federal cap on insulin, caps within each state apply to all covered insulin products.[8] In addition, some states, such as Connecticut and Minnesota, have separate caps for specific diabetes devices and supplies.[8] State insulin caps allow people who may not be covered under the federal Medicare insulin OOP cap but have coverage through a state-regulated health plan to access insulin products with lower cost-sharing; however, state OOP caps vary widely in scale, with some states implementing caps as high as $100 while others are as low as $25.

Almost half of people with T1D in the United States are subject to an insulin OOP cap

We estimated the population with T1D in the United States subject to state and federal OOP cost caps on insulin to understand the share of people with T1D who may still be exposed to high insulin costs. We found that out of the over two million people in the United States with T1D, 900,000 (or 45%) are covered by either a state or federal cap as of January 1, 2025 (Figure 1).

INSULIN CAP IMPACTS BY INSURANCE TYPE

Thirty percent of the population with T1D are Medicare beneficiaries or dual-eligible beneficiaries. As such, these individuals are covered by the federal government's $35 OOP cap. The remaining 70% of individuals with T1D are only eligible for insulin caps within their respective states and may rely on assistance programs or plan benefits to lower their OOP costs if they are not enrolled in eligible plans. We estimate that 42% of people with T1D receive insurance coverage through employer-sponsored insurance (ESI) plans. Only 17% of those ESI enrollees with T1D are subject to a state cap. An additional 5% of people with T1D receive healthcare coverage via directly purchased plans, and 42% of enrollees in direct purchase plans are eligible for state caps.

We estimate that 15% of individuals with T1D are covered by Medicaid via non-dual coverage. Of this population, 45% live in states that have implemented insulin caps. Although most non-dual eligible people with T1D (55%) enrolled in Medicaid are not subject to an insulin cap, people in this group are likely to experience little to no OOP costs for insulin when purchasing covered products within their respective states.[14,15]

TRICARE, Veterans Affairs (VA) health benefits, and the Indian Health Service (IHS) collectively cover 1% of the total population with T1D. These groups are covered by neither federal nor state insulin caps; however, their plans offer ways to reduce or eliminate the cost of covered prescriptions, such as covering costs when insulin is purchased through specific pharmacies or channels or offering a range of OOP costs based on supply and formulary.[16,17,18]

CURRENT STATE INSULIN CAPS AND THEIR IMPACT

Fifty-six percent of the population with T1D live in states that do not have state insulin caps, and only 31% (300,000) of people with T1D in these states are impacted by federal caps. A potential driver of these results is that some of the highest population states had not implemented a cap on insulin as of January 1, 2025, the end of our analysis time frame. For example, Florida and California had not implemented caps but account for 10% and 7% of the total population with T1D, respectively. California's $35 insulin OOP cap goes into effect on January 1, 2026, for large group plans, which we expect will lower the number of people with T1D not covered by an insulin cap.[8]

As noted earlier, state caps can vary widely in scale. As of January 1, 2025, ten states had caps that were greater than the federal cap amount ($35 per month), ranging from $40 to $100, almost triple the monthly federal cap. The six states with $100 caps were Alabama, Colorado, Delaware, Illinois, New York, and Vermont. Seventeen states had set caps at or below the federal cap amount, ranging from $25 to $35. New York and Illinois have since reduced their caps to $35 or less. Going into 2026, 29 states and the District of Columbia will have instituted caps on insulin copayments in some form.[19]

Fifty-five percent of people with T1D are still exposed to high OOP costs for insulin

Despite the presence of caps in most insurance markets, there are some populations that remain vulnerable to high OOP insulin costs. According to our analysis, 7% of Americans with T1D are uninsured. Individuals without insurance must purchase insulin OOP at full cost or rely on assistance programs and coupons to lower the cost of their medication.[20] Use of potentially dangerous cost-saving practices are common within this population. According to the 2021 national survey discussed above, 29% of uninsured insulin users reported rationing their insulin in 2021, which the author notes can result in death.[4]

A sizable portion of the insured U.S. population is considered underinsured, meaning they were insured all year but still cannot access affordable care. According to the results of the Commonwealth Fund's Biennial health insurance survey, 23% of Americans report being underinsured.[21] The lack of affordable care can result in risky practices that are similar to what has been reported among other groups burdened by healthcare costs. For example, 57% of underinsured working-age adults report delaying necessary care, such as skipping medication doses and not filling prescriptions due to cost, which often worsens their conditions.[21]

One of the most concerning observations noted in the Commonwealth Fund's survey is that among the underinsured population, 66% of people are covered by ESI plans.[21] Based on our analysis, we expect that the T1D population with ESI coverage is among the least impacted by state and federal insulin OOP caps (17%) because the caps have not been implemented in all states and do not apply to all ESI plan types (e.g., ERISA plans, some high-deductible health plans, and federal employee health benefits plans). As a result, individuals with ESI coverage may experience higher OOP costs for insulin and greater fluctuations in insulin costs throughout the year as they work toward satisfying their deductible and coinsurance obligations.

ALTERNATIVE INSULIN AFFORDABILITY SOLUTIONS

Beyond OOP caps, some states have established urgent need programs for insulin as a safety net for those still burdened by the cost of insulin. Maine, Colorado, Minnesota, and Ohio help qualified individuals access insulin when they cannot afford it.[22] Colorado, for example, provides an emergency 30-day supply of insulin, capped at $35, once every 12 months to those in need; meanwhile, Ohio's program offers a 7-day supply every 12 months to those who qualify.[22] These programs do not provide long-term solutions for individuals vulnerable to high insulin costs, but they may provide temporary relief from insulin rationing and other unsafe measures.

The emergence of new insulin biosimilar products may present another solution to the issue of insulin affordability. The market's cheapest long-lasting insulin biosimilar product to-date launched on January 1, 2026.[23] This product is available to all people with diabetes regardless of insurance type and will be sold at a maximum price of $55 per box of five pens.[23] In California, the insulin will be sold under the CalRx brand, which, in conjunction with the state's recently implemented $35 OOP cap for insulin products, may provide additional protections for the T1D community in the near future.[23]

A Congressional Research Service report on insulin coverage suggests additional legislation on insulin manufacturer pricing may be another pathway to provide all people with diabetes with lower cost options for insulin.[24] In theory, capping

manufacturer list prices for insulin would result in lower OOP costs for consumers once pharmacy benefit managers negotiate prices and update their formularies.[24]

POTENTIAL IMPLICATIONS FOR HEALTH PLANS

Price caps on insulin have the potential to lower OOP spend and increase adherence for individuals who depend on the drug; however, there is limited research on the impact of insulin caps on overall healthcare costs for all enrollees.[5,10] One potential consequence of caps on insulin is that insurers may shift the cost of covering the drug onto all plan members or onto plan sponsors through higher premiums. This may especially be true if negotiated insulin prices remain high because plans will absorb more of the cost burden and will need to find ways to offset the expense without increasing OOP spend for consumers.[25,26]

New policy dynamics may impact people's exposure to insulin costs

The impact of insulin caps may rapidly evolve with new policy dynamics, such as anticipated funding cuts and policy changes in the Medicaid and Affordable Care Act (ACA) markets through Public Law 119-21, also known as the One Big Beautiful Bill Act. These changes may meaningfully impact the portion of people with T1D experiencing capped OOP costs for insulin.[27,28] In particular, changes to eligibility requirements for Medicaid may disqualify enrollees from Medicaid coverage and shift them into individual marketplace plans with higher OOP insulin costs or into the uninsured population. In these cases, direct-to-consumer access to lower cost insulins may be necessary for people to maintain their prescriptions and may result in higher OOP costs for people impacted by changing coverage.

Conclusion

Our analysis shows that more than half of the U.S. population with T1D is not covered by an OOP cap on insulin costs, despite the recent implementation of a federal OOP cost cap on insulin for Medicare beneficiaries and numerous state-level caps. As a result, many people with T1D are still vulnerable to high OOP costs for insulin. This is a challenge as individuals facing issues related to insulin affordability may resort to cost-saving measures, which can lead to life-threatening complications.

Groups seeking to institute policy or business solutions to this challenge may wish to explore insulin cost and utilization dynamics among the ESI population, given the large percentage of people in this population with T1D who are not currently subject to a cap or who may be underinsured. Another area of focus could be direct-to-consumer insulin access and costs, given that 7% of the population with T1D are uninsured and will be unaffected by any policy actions aimed solely at reducing insulin costs for people through their insurance.

Methodology and data sources

INSULIN COST AND UTILIZATION ANALYSIS

Milliman's analyses of insulin product utilization are based on enrollment and medical and pharmacy claims data for commercial, Medicare, and Medicaid populations with T1D. The commercial findings were obtained from Milliman's Consolidated Health Cost Guidelines™ (HCG) Sources Database (CHSD) from 2021-2023 (analysis year 2023). Medicare findings were based on the Centers for Medicare and Medicaid Services (CMS) 100% Research Identifiable Files (RIF) from 2020-2024 (analysis years 2022 and 2024). Medicaid findings were based on Transformed Medicaid Statistical Information System (T-MSIS) data from 2020-2022 (analysis year 2022). Enrollees were required to have continuous enrollment in medical and pharmacy coverage for the entire 12 months of the respective analysis year to be included in the study.

After identifying eligible enrollees in each insurance type, we identified the total diabetes population. Enrollees with diabetes needed to have a combination of claims representing direct interactions with healthcare providers that included ICD-10 diagnosis codes for diabetes or prescription fills for hypoglycemic, antihyperglycemic, insulin, or insulin devices during the analysis year or preceding two-year lookback period. We classified all people with diabetes as having either T1D or type 2 diabetes (T2D) based on the count of claims with ICD-10 diagnosis codes for each type of diabetes and whether they were dispensed drug, drug combinations, or biologic drugs that are specific to either T1D or T2D. Once we identified people with T1D in each insurance type, we looked for evidence of insulin usage in each analysis year based on the presence of NDC or HCPCS codes for insulin on pharmacy or medical claims, respectively. We did not include disposable insulin pumps in our insulin product usage results.

INSULIN OUT-OF-POCKET ANALYSIS

Milliman leveraged state-level insulin cap information collected and shared with Milliman by Breakthrough T1D along with 2023 American Community Survey (ACS) data and prior published Milliman research projecting the size and demographic characteristics of the U.S. population with T1D as the basis for this analysis.[29]

ACS data was used to identify the total U.S. population by state, insurance coverage type, and demographic factors such as age (0-19, 20-64, and 65+), race (Black only, Hispanic, Other, and White only), and gender/sex. Insurance coverage was determined by ranking individual's primary sources of coverage using the following hierarchy: ESI, Medicare, Medicaid, dual-eligible beneficiaries, TRICARE, VA, IHS, direct purchase, and uninsured.

Prior Milliman research leveraged in this analysis used nationally representative administrative claims data from 2018-2020 to project the U.S. population with T1D and their insurance coverage distribution. We used calendar year 2023 projection data from this model, which contained T1D population estimates by region, age, gender, and coverage type, as our starting point to determine the T1D population size and prevalence within each state in our analysis.[29]

We developed a crosswalk to map states, coverage types, race, and age groups from the ACS data to their respective groupings in the prior research work. Each state was mapped to a region, and we applied region-specific distributions of the T1D population across each coverage type, age, and gender combination. To account for variability in T1D prevalence by race, race-specific prevalence relativity factors were developed based on a recent publication on T1D prevalence.[30] Since the prior projection model did not include detail for insulin users with primary insurance coverage through TRICARE, IHS, direct purchase, or dual-eligible coverage, additional actuarial adjustments were made to calibrate the data to the level of detail required for the current analysis.

Once population estimates were established, we used Breakthrough T1D's data on insulin caps to determine the percentage of the T1D population subject to federal and state caps. For ESI, we assumed that only fully insured private sector and fully insured public sector (non-federal employee health benefits) enrollees would be subject to state insulin caps because not all sectors within ESI are bound to state insurance rules and regulations. We used Department of Labor (DOL) data on the ESI population by state and Office of Personnel Management (OPM) data on federal civilian employees by state to determine the percentage of the ESI population impacted by state insulin caps.[31,32] We identified the ESI population impacted by state caps as the total number of individuals enrolled in private sector fully insured ESI plans or public sector (non-federal) fully insured ESI plans.

Adjustment factors were also applied for specific states depending on their insulin cap legislation or for other small population rightsizing. For example, insulin caps in New Jersey and Connecticut do not apply to people enrolled in high-deductible health plans.

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Caveats and Limitations

This report was commissioned by Breakthrough T1D.

The model this paper is based on relied on data as provided by Breakthrough T1D, ACS, CMS, and other government agencies. We reviewed the data for reasonableness and consistency but did not perform a detailed audit of this data. Actual experience will vary from model estimates. If the underlying data or methodology is inaccurate or incomplete, the results provided in this illustration may likewise be inaccurate or incomplete.

Milliman has developed certain models to estimate the values included in this analysis. The intent of the models is to help understand the T1D population impacted by government insulin caps. We have reviewed the models, including their inputs, calculations, and outputs for consistency, reasonableness, and appropriateness to the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP).

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Carrie Scott is employed by Milliman, Inc., and a member of the American Academy of Actuaries; she is qualified to render the actuarial opinions contained herein.

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