MILLIMAN REPORT

Insights into cost patterns and actionable factors in newly diagnosed Type 2 diabetes

Commissioned by Lark Health

December 2021

Melody Craff, PhD, MBA, MD, MS, MS, FAHM
Thomas Pu, MHI
Michael Hadfield
Austin Barrington, FSA, MAAA
Dale Skinner, MS

Milliman

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Executive Summary

Type 2 diabetes (T2D) affects approximately 32 million adults in the United States, including individuals who have not been formally diagnosed but who meet laboratory criteria for diabetes.[1] The CDC estimated that 82 million adults had prediabetes in 2018, and that 1.5 million patients are diagnosed with Type 2 diabetes each year.[1] Potentially modifiable risk factors for T2D include being overweight or obese, physical inactivity, poor glycemic control, and high blood pressure.[2]

The scope of this retrospective observational study aimed to estimate changes in total healthcare costs in newly diagnosed T2D patients, comparing the costs per person per year (PPPY) in the year before diagnosis to the costs in years 1 and 2 after diabetes diagnosis, and stratifying patients by the level of change in their glycemic control (glycosylated hemoglobin, HbA1c) and body mass index (BMI).

The study uses healthcare claims data to measure the actual total costs incurred by patients newly diagnosed with T2D in each major insurance type (Commercial, Medicaid, Medicare), and how these costs are influenced by clinically documented levels of glycemic control or BMI (rather than potentially subjective self-reported survey information). Median costs (50th percentile) and mean costs are reported. Mean healthcare costs exceed the median, because the top decile of patients with the highest spending incurs costs that are severalfold greater than the median. We consider median costs to be more representative of a typical patient than mean costs which are skewed by a few high-cost patients.

Total costs of care are reported for inpatient, emergency department (ED), outpatient clinic, medical professional, prescription drugs and ancillary services. We also report patterns of healthcare utilization, specifically inpatient admissions, ED visits, and primary care office visits. We measured the prevalence of diabetic complications and total cost of care for these complications, in addition to comorbidities and other healthcare costs.

We further examined healthcare cost, utilization, and T2D progression rates in the prediabetes population and for patients enrolled in the National Diabetes Prevention Program (DPP). Finally, we explored differences in healthcare cost and utilization for patients with diabetes living in primary care health professional shortage areas (HPSAs).

Take-Away Points: While all BMI groups incur higher healthcare costs after diagnosis of T2D, a higher BMI at diagnosis is associated with greater cost increases. Weight management appears to be associated with reduced cost increases after T2D diagnosis. Nearly 65% of newly diagnosed patients in this study did not receive more than one HbA1c test in the first year after diagnosis despite the importance of glycemic control. The average cost difference between severe and non-severe T2D was $2,660 and $2,630 PPPY (median cost) and $3,334 and $4,061 PPPY (mean cost) for commercially insured patients in the first and second year following T2D diagnosis, respectively. A potentially modifiable aspect of severe T2D is improvement of glycemic control, which may influence T2D complications and related admissions. Diabetes prevention programs, such as the DPP, may reduce the cumulative risk of progression to T2D in patients with prediabetes.

[1] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. U.S. Dept of Health and Human Services, 2020. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf Accessed October 2021.

[2] Knowler WC, Crandall JP, Chiasson JL, *et al*. Prevention Of Type 2 Diabetes. In: Diabetes in America. 3rd ed. Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases (US), August 2018. CHAPTER 38. PMID: 33651543. https://pubmed.ncbi.nlm.nih.gov/33651543/ Accessed August 2021.

This report was commissioned by Lark Health, which is a digital health company focused on chronic condition management. The findings in this report reflect the independent exploratory research of the authors; Milliman does not intend to endorse any product or organization. If this report is reproduced, we require that it be reproduced in its entirety, as pieces taken out of context can be misleading. The analyses in this report are based on real-world observational data from the Milliman MedInsight nationwide Emerging Experience research database. In preparation of our analysis, we relied upon the accuracy of data or information provided to us. We have not audited this information, although we have reviewed it for reasonableness. If the underlying data or information is inaccurate or incomplete, the results of our review may likewise be inaccurate or incomplete. Models used in the preparation of our analysis were applied consistently with their intended use. Where we relied on models developed by others, we have made a reasonable effort to understand the intended purpose, general operation, dependencies, and sensitivities of those models. One of the co-authors, Austin Barrington, and one of the advisors, Susan Pantely, are Members of the American Academy of Actuaries and meet its qualification standards to perform the analyses in this report.

Background

Type 2 diabetes (T2D) is a major global cause of mortality, disability, and economic burden. The Centers for Disease Control and Prevention (CDC) noted diabetes as the seventh leading cause of death in the United States in 2019. Diabetes was documented as the underlying cause of death in 26.7 deaths per 100,000 and was identified in 12.8% of ED visits.[3] The total cost of diagnosed diabetes in the United States is estimated at $327 billion, including $237 billion in direct medical costs and $90 billion in reduced productivity.[4] The mean annual healthcare expenditure for patients with diabetes in the U.S. was estimated to be $9,506 per patient in 2019.[5]

Longitudinal observational studies investigating the association of excess weight and diabetes-related complications have shown mixed findings: some reporting positive, inverse, or no associations.[6] For example, researchers at the University of Cambridge who conducted a follow-up analysis of patients enrolled in an Anglo–Danish–Dutch trial of intensive treatment for T2D found that a 5% or greater reduction in body weight in the year following diagnosis was associated with reduction in 10-year risk of developing cardiovascular disease (CVD).[7] In contrast, a clinical trial of intensive lifestyle intervention in T2D conducted at 16 study centers in the United States found that an 8.6% weight loss in the first year, sustained to 6.0% at 10 years, did not reduce the 10-year CVD risk.[8] Some researchers have distinguished patterns in association with microvascular complications (kidney disease, retinopathy, and neuropathy), compared to macrovascular complications (myocardial infarction and stroke).[9]

Early diagnosis of diabetes and early glycemic control from the time of diagnosis is associated with long-term reductions in all-cause mortality and myocardial infarction, as shown by a 2021 analysis of patients enrolled in the 20-year landmark U.K. Prospective Diabetes Study (UKPDS) trial of glycemic management therapies and its 10-year post-trial monitoring period when patients returned to routine care.[10] A prospective observational study of patients in UKPDS found strong association between HbA1c and the risk of diabetic complications.[11]

[3] National Center for Health Statistics. Diabetes. https://www.cdc.gov/nchs/fastats/diabetes.htm Accessed November 2021.

[4] American Diabetes Association. Economic costs of diabetes in the US in 2017. Diabetes Care. 2018 May;41(5):917–928. https://doi.org/10.2337/dci18-0007 Accessed November 2021.

[5] International Diabetes Federation. IDF Diabetes Atlas Ninth Edition 2019. https://diabetesatlas.org/idfawp/resource-files/2019/07/IDF_diabetes_atlas_ninth_edition_en.pdf Accessed November 2021.

[6] Fridman M, Lucas ME, Paprocki Y, Dang-Tan T, Iyer NN. Impact of Weight Change in Adults with Type 2 Diabetes Mellitus: A Literature Review and Critical Analysis. Clinicoecon Outcomes Res. 2020 Sep 29;12:555-566. https://doi.org/10.2147/CEOR.S266873 Accessed October 2021.

[7] Strelitz, J., Ahern, A.L., Long, G.H. et al. Moderate weight change following diabetes diagnosis and 10 year incidence of cardiovascular disease and mortality. Diabetologia. 2019 May; 62, 1391–1402. https://doi.org/10.1007/s00125-019-4886-1 Accessed October 2021.

[8] The Look AHEAD Research Group. Cardiovascular Effects of Intensive Lifestyle Intervention in Type 2 Diabetes. N Engl J Med 2013; 369:145-54. https://doi.org/10.1056/NEJMoa1212914 Accessed August 2021.

[9] Polemiti E, Baudry J, Kuxhaus O, Jäger S, Bergmann MM, Weikert C, Schulze MB. BMI and BMI change following incident type 2 diabetes and risk of microvascular and macrovascular complications: the EPIC-Potsdam study. Diabetologia. 2021 Apr;64(4):814-825. https://doi.org/10.1007/s00125-020-05362-7. Accessed October 2021.

[10] Lind M, Imberg H, Coleman RL, Nerman O, and Holman RR. Historical HbA1c Values May Explain the Type 2 Diabetes Legacy Effect: UKPDS 88. Diabetes Care 2021 Oct; 44(10): 2231-2237. https://doi.org/10.2337/dc20-2439 Accessed October 2021.

[11] Stratton I M, Adler A I, Neil H A W, Matthews D R, Manley S E, Cull C A et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ 2000; 321:405. https://doi.org/10.1136/bmj.321.7258.405 Accessed August 2021.

Actuarial analyses modeling the potential effect of hypothetical improvements in HbA1c, blood pressure, and lipids on diabetes-related complications provide helpful estimates of the opportunity to improve health outcomes and costs.[12] Previous economic evaluations of diabetes prevention programs, including lifestyle interventions, metformin medication, and screening of persons at high risk of developing diabetes were not definitive in determining cost savings and cost effectiveness, due to variation in their modeling assumptions, definitions and interventions.[13]

Our report of cost breakdowns and patterns of healthcare utilization in different insurance groups aims to add insights from recent emerging claims experience to this body of knowledge. We selected a study period before the coronavirus disease 2019 (COVID-19) Public Health Emergency began in April 2020, to avoid confounding factors such as increased risks of severe illness and mortality from COVID-19 in patients with diabetes.

Data Source and Methodology

This study used the Milliman MedInsight Emerging Experience research database of de-identified healthcare claims data nationwide for over 33 million unique individuals from 2017 to 2021. Approximately 75 healthcare organizations contribute monthly data to this research database, which is currently refreshed quarterly. The database provides a comprehensive view of all services received by patients provided by any healthcare professional in any location or setting billed to insurance, including approximately 1.7 million medical professionals and 340,000 healthcare facilities.

As a reference comparison to the U.S. population, the United States Census Bureau and the American Community Survey estimated there were 300 million individuals with healthcare insurance in the United States in 2019.[14] The National Plan & Provider Enumeration System (NPPES)[15] estimated that 4.4 million unique individual providers and 1.7 million unique facilities exist in the United States in 2019.

STUDY DESIGN

As shown in Figure 1a, the main study focused on a cohort of adult patients who were continuously enrolled in commercial, Medicare, or Medicaid health insurance plans throughout the year prior to their first T2D diagnosis and throughout the first and second year following that diagnosis, between January 2017 and March 2020. We used International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes reported on patients' healthcare claims to identify T2D and BMI. The first diagnosis date was defined as the earliest service date of the first medical claim incurred with an ICD-10 diagnosis code for T2D or the first pharmacy claim with a National Drug Code for a prescription drug intended to treat or manage T2D, if these codes were absent for the preceding 12 months. This dataset therefore includes patients with their first T2D diagnosis between January 2018 and March 2018. Due to this narrow first diagnosis window, no trending is applied to claims costs.

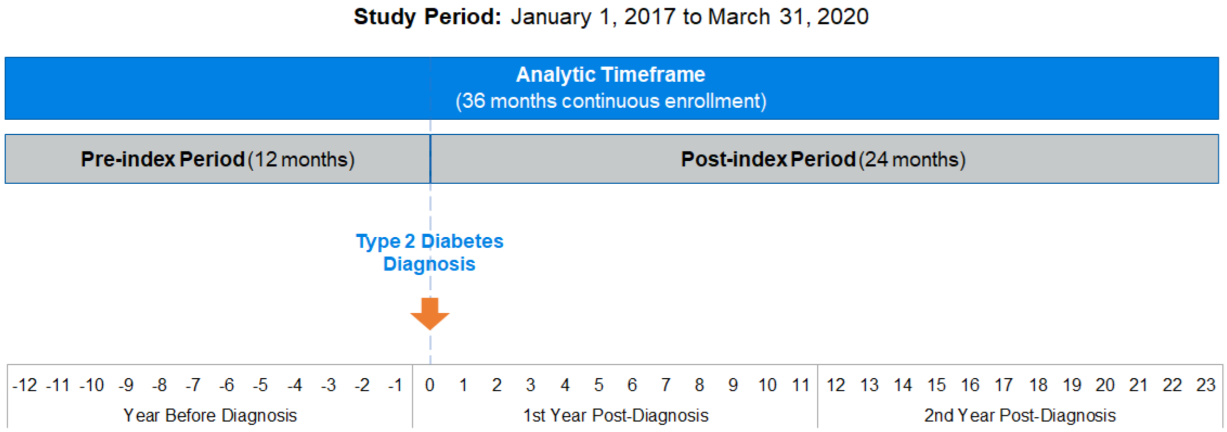
[12] Fitch K, Iwasaki K, Pyenson B. The Cost and Quality Gap in Diabetes Care: An Actuarial Analysis. Milliman client report. 2012. https://www.milliman.com/en/insight/the-cost-and-quality-gap-in-diabetes-care-an-actuarial-analysis Accessed May 2021.

[13] Roberts S, Barry E, Craig D, Airoldi M, Bevan G, Greenhalgh T. Preventing type 2 diabetes: systematic review of studies of cost-effectiveness of lifestyle programmes and metformin, with and without screening, for pre-diabetes. BMJ Open. 2017 Nov 15;7(11):e017184. https://doi.org/10.1136/bmjopen-2017-017184. Accessed November 2021.

[14] Keisler-Starkey K and Bunch LN. Health Insurance Coverage in the United States: 2019. U.S. Census Bureau Current Population Reports, P60-271, 2020. https://www.census.gov/library/publications/2020/demo/p60-271.html Accessed October 2021.

[15] National Plan & Provider Enumeration System (NPPES). https://nppes.cms.hhs.gov Accessed October 2021.

Figure 1a: Study design



We excluded underweight adults (BMI < 20.0 kg/m^2), patients without documentation of BMI, patients younger than 18 years of age and patients of unknown age. To remove patients with high-cost pre-existing conditions before T2D, we also excluded patients who had total annual healthcare expenditures above $15,000 in the year before their first diagnosis of T2D; $15,000 was chosen as a proxy cutoff because it approximates the 90th percentile of annual costs per patient in the aggregate dataset and removes outlier costs without excluding any specific clinical condition. A cohort tree and the characteristics of the final cohort are shown in Figures 1b and 1c.

1. **Milliman MedInsight Emerging Experience research database**
   N ≈ 33,000,000 unique persons, 2017 to 2021
   N ≈ 26,000,000 unique adults, 2017 to 2020
2. Adults newly diagnosed with Type 2 diabetes between January 2018 and March 2018
   N = 85,921 Commercial; 62,822 Medicaid; 100,995 Medicare
3. Patients continuously enrolled for 12 months prior to and 24 months following their first Type 2 diabetes diagnosis (inclusive of the diagnosis month)
   N = 30,353 Commercial; 10,200 Medicaid; 36,561 Medicare
4. Patients that have at least one BMI reading within the first year after diagnosis of Type 2 diabetes and a first (baseline) BMI above 20 kg/m^2
   N = 18,152 Commercial; 5,735 Medicaid; 22,977 Medicare
5. Patients that have annual healthcare expenditure not exceeding $15,000 before the first diagnosis of Type 2 diabetes
   N = 16,458 Commercial; 4,930 Medicaid; 19,857 Medicare
6. **Final Study Cohort**
   N = 41,245 patients

Figure 1c: Basic characteristics of the final study cohort

	COMMERCIAL	MEDICAID	MEDICARE
Patients (N)	16,458	4,930	19,857
Gender (% M, F)	M 48.9%, F 51.1%	M 38.0%, F 62.0%	M 47.5%, F 52.5%
Mean Age (years)	53.64	49.38	73.91
Median Age (years)	55	51	73

An additional analysis was conducted on the effect of diabetes prevention programs (DPP) in reducing the risk of T2D progression in patients with prediabetes. Prediabetes patients are defined as having abnormally elevated blood glucose levels but are not severe enough for a diagnosis of T2D.[16] Participation in a DPP is identified by CPT codes 0403T or 0488T on claims. The prediabetes population was defined using ICD-10 diagnosis codes in the R73 family. Consistent with the CDC's DPP-eligibility criteria, patients who had been previously diagnosed with T2D, those with a BMI under 25 kg/m^2, and patients who were pregnant were excluded, while patients previously diagnosed with gestational diabetes were included.[17]

This is a real-world observational study using an aggregate research database to report on patterns of healthcare cost and service utilization in patients with different characteristics. It is not an interventional study. No specific interventions were conducted or measured by the research team in any of the observational groups. However, we also did not influence, alter, or measure any resources that may have been sought by patients, such as educational information, coaching, weight loss programs, family support or healthcare services.

Main Findings

COST IMPACT OF NEWLY DIAGNOSED TYPE 2 DIABETES

In each insurance cohort, we identified patients who were newly diagnosed with T2D and were continuously enrolled in a health insurance plan from 1 year before diagnosis to 2 years after diagnosis. We measured the insurance allowed costs per patient per year (PPPY) in each year. Year 1 post-diagnosis includes the month of T2D diagnosis.

The distribution of costs is asymmetric and right skewed, similar to healthcare costs in the general population. The mean value exceeds the median, due to a relatively small number of patients (the top decile) incurring costs that were several times higher than the median.

As shown in figure 2, the median allowed cost in the Commercial population is approximately $4,500 higher PPPY after diabetes diagnosis compared to before diagnosis. In all insurance groups, we observed higher utilization and higher costs in the month of diagnosis (month = 0) and several months after diagnosis before reaching a cost plateau sustained through year 1 and 2. The spike around diagnosis may be related to evaluation of T2D and T2D-related complications, as well as other healthcare conditions identified through increased attention from clinical providers or increased patient engagement with healthcare services. Each patient is tracked longitudinally over time, so the same group of patients is tracked before and after T2D diagnosis.

To get a better understanding of costs, we separated the total cost of care into facility inpatient, facility outpatient (including clinics and ambulatory surgery centers), emergency department, medical professional, prescription drugs, and ancillary services for each insurance group, as shown in Figures 3a, 3b and 3c.

[16] Centers for Disease Control and Prevention (CDC). National Diabetes Prevention Program. About Prediabetes and Type 2 Diabetes. 2021. https://www.cdc.gov/diabetes/prevention/about-prediabetes.html Accessed November 2021.

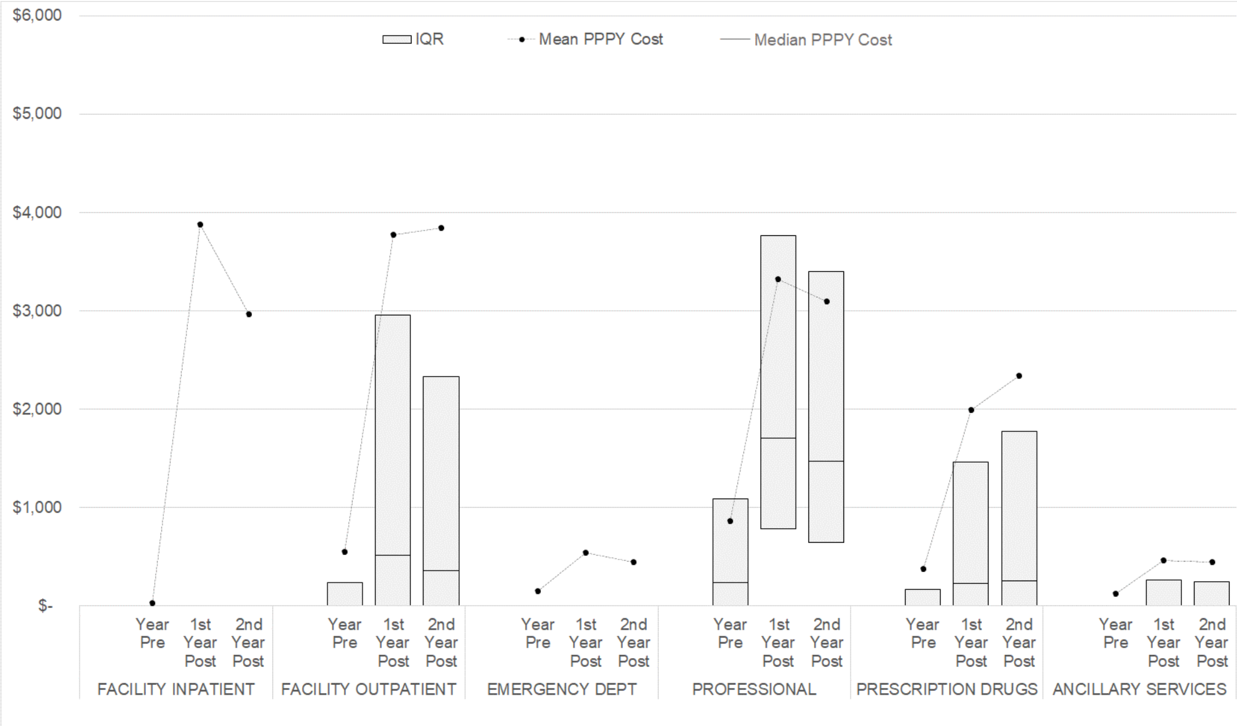
[17] Centers for Disease Control and Prevention (CDC). National Diabetes Prevention Program. Program Eligibility. 2021. https://www.cdc.gov/diabetes/prevention/program-eligibility.html Accessed November 2021.

Figure 2: Median and mean total cost of care (allowed PPPY) for newly diagnosed Type 2 diabetes patients

INSURANCE GROUP	NUMBER OF PATIENTS	COST METRIC	ANALYTIC YEAR		
			Year Before Diagnosis	1st Year After Diagnosis *[% comparison to year before diagnosis]*	2nd Year After Diagnosis *[% comparison to year before diagnosis]*
COMMERCIAL	**16,458**	**Median cost**	**$588**	**$5,098** *[867%]*	**$4,464** *[759%]*
		IQR [a]	$24 to $2,726	$1,827 to $13,751	$1,514 to $12,028
		Mean cost	**$2,079**	**$13,955** *[671%]*	**$13,124** *[631%]*
		Std. dev.[b]	$3,181	$37,518	$39,091
MEDICAID	**4,930**	**Median cost**	**$1,767**	**$3,815** *[216%]*	**$2,883** *[163%]*
		IQR	$537 to $4,766	$1,501 to $9,332	$998 to $8,124
		Mean cost	**$3,194**	**$8,782** *[275%]*	**$7,806** *[244%]*
		Std. dev.	$3,548	$19,167	$18,180
MEDICARE	**19,857**	**Median cost**	**$1,359**	**$5,909** *[435%]*	**$5,733** *[422%]*
		IQR	$118 to $4,253	$2,605 to $14,822	$2,425 to $14,390
		Mean cost	**$2,798**	**$14,532** *[519%]*	**$14,915** *[533%]*
		Std. dev.	$3,489	$27,035	$32,475

[a] Interquartile range (IQR) shows the 25th percentile to the 75th percentile. Median is the 50th percentile.
[b] Std. dev. = standard deviation

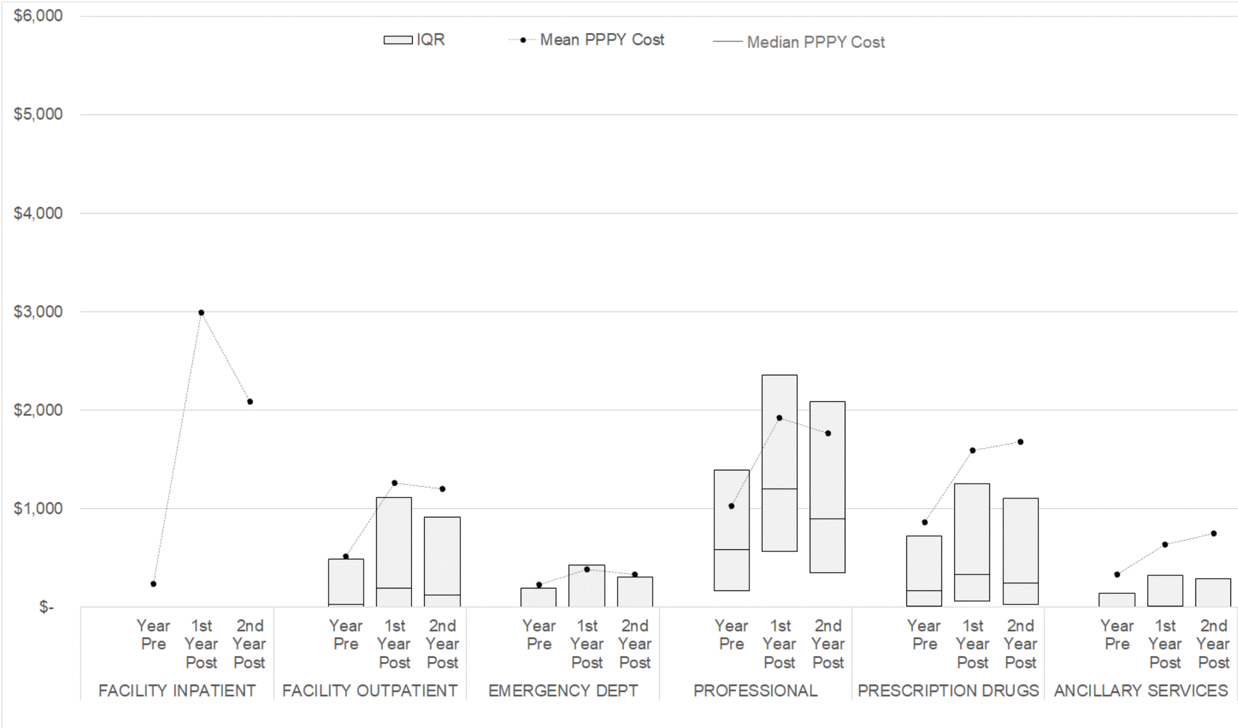
Figure 3a: Total cost of care (allowed PPPY) by service category before and after T2D diagnosis – Commercial



For commercially insured patients with T2D, median costs increased in year 1 following diabetes diagnosis, mainly driven by professional costs of physician and other clinician services, followed by outpatient clinics and prescription drugs. The majority of patients did not incur an inpatient admission or ED visit, resulting in zero median and first quartile costs for these two settings. However, the few patients that were admitted to the hospital or evaluated and treated in the ED drove up the mean cost in these settings. The taller IQR observed in the post-diagnosis years for most categories is also indicative of a larger variance of patient costs in those years compared to the pre-diagnosis year.

Median costs for prescription drugs increased after diagnosis, due in part to the need for new medications to treat T2D. Although the median pharmacy costs were steady in years 1 and 2 post-diagnosis, the mean drug costs continued to increase in year 2, potentially due to some patients needing to switch medications or diabetes disease progression requiring more than one medication. The mean pharmacy expenditures in the commercial group were higher than the Medicare and Medicaid groups.

Figure 3b: Total cost of care (allowed PPPY) by service category before and after T2D diagnosis – Medicaid



The Medicaid enrollees in our study dataset had the highest baseline PPPY costs of the three insurance groups but did not reach the same level of PPPY spending after diagnosis as the other groups. A lesser spend increase after T2D diagnosis might reflect a combination of lower reimbursement for Medicaid even in allowed dollars,[18] lower medication adherence,[19] or possibly barriers to access to prescription drugs and services that support disease management.[20]

Medicaid enrollees exhibited the highest spend on ED visits and ancillary services (which includes ambulance). The Medicaid group showed less utilization in outpatient clinics and clinical professional services than other insurance groups. Prescription drug spend was the lowest of all three insurance groups, which might reflect lower medication adherence among the Medicaid population. These patterns suggest that these patients may not have a sustained relationship with primary care and non-ED healthcare services.

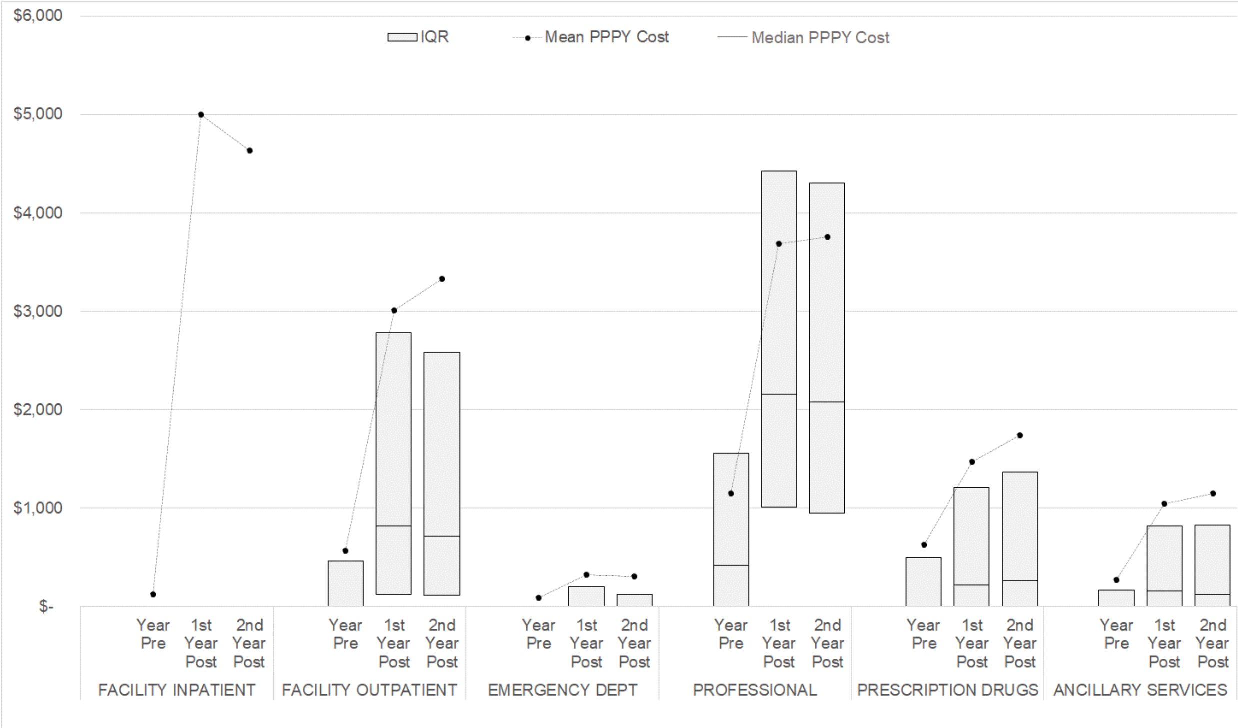
We note however that coaching, education, weight loss programs, medication adherence advice, glycemic monitoring, dietary advice, and nutrition counselling may also occur outside traditional healthcare settings, including disease management, wellness, and digital health companies.

[18] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. Trends in the Utilization of Emergency Department Services, 2009-2018. March 2021. https://aspe.hhs.gov/sites/default/files/private/pdf/265086/ED-report-to-Congress.pdf Accessed November 2021.

[19] Amin K, Farley JF, Maciejewski ML, Domino ME. Effect of Medicaid Policy Changes on Medication Adherence: Differences by Baseline Adherence. J Manag Care Spec Pharm. 2017 Mar;23(3):337-345. https://doi.org/10.18553/jmcp.2017.23.3.337. Accessed August 2021.

[20] Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services. Healthy People 2030. Access to Health Services. https://health.gov/healthypeople/objectives-and-data/social-determinants-health/literature-summaries/access-health-services Accessed December 2021.

Figure 3c: Total cost of care (allowed PPPY) by service category before and after T2D diagnosis – Medicare



Medicare beneficiaries with diabetes had the highest median costs for outpatient clinic visits and medical professional services, although lower mean outpatient costs than Commercial. This is expected due to increased complexity, severity, and comorbidities in this population, which includes beneficiaries aged 65 years and older and disabled individuals. The mean facility inpatient costs were also highest in this insurance group, which could result from more complex or more frequent admissions.

Some studies have reported that medication adherence is associated with a greater likelihood of achieving targets for glycemic management (HbA1c).[21]

[21] MacEwan JP, Sheehan JJ, Yin W, Vanderpuye-Orgle J, Sullivan J, Peneva D, Kalsekar I, Peters AL. The relationship between adherence and total spending among Medicare beneficiaries with type 2 diabetes. Am J Manag Care. 2017 Apr;23(4):248-252. https://pubmed.ncbi.nlm.nih.gov/28554205/ Accessed October 2021.

PREVALENCE OF COMPLICATIONS

As shown in Figure 4a, metabolic complications (including diabetic ketoacidosis, hyperosmolarity, lactic acidosis, and hypoglycemia) were the most prevalent category of diabetic complications in newly diagnosed Commercial and Medicaid T2D patients in the first two years after diabetes diagnosis. According to the National Institute of Diabetes and Digestive and Kidney Diseases, metabolic complications are acute, potentially life-threatening, and often result in hospitalization.[22] This category was the second most prevalent for Medicare patients, after other heart disease. The risk of developing coronary heart disease is increased by T2D and, among those with T2D, is elevated dramatically in older adults.[23] The economic burden of T2D complications of cardiovascular disease in T2D have been reviewed by other researchers.[24] Other heart disease (apart from heart failure and myocardial infarction) was the second most prevalent complication in Commercial and Medicaid patients.

Neuropathy, heart failure, kidney disease and ophthalmology (eye disease such as retinopathy) were the next most common complications in all insurance groups. The lower detection of these complications before T2D diagnosis may suggest that these conditions were underdiagnosed until individuals began to engage with healthcare services to manage their diabetes.

Figure 4a: Proportion of patients with healthcare claims for T2D complications before and after T2D diagnosis

	COMMERCIAL			*MEDICAID*			*MEDICARE*		
T2D COMPLICATION	**Year pre T2D**	**Year 1 post T2D**	**Year 2 post T2D**	**Year pre T2D**	**Year 1 post T2D**	**Year 2 post T2D**	**Year pre T2D**	**Year 1 post T2D**	**Year 2 post T2D**
Metabolic	1.7%	38.3%	32.9%	2.0%	32.2%	22.5%	1.0%	32.1%	27.9%
Other heart disease	4.6%	12.7%	12.6%	8.1%	13.5%	12.0%	21.2%	37.8%	39.0%
Neuropathy	0.3%	9.2%	9.6%	0.3%	8.5%	7.1%	0.2%	15.8%	15.9%
Heart failure	0.8%	3.5%	3.7%	3.7%	7.6%	6.4%	5.4%	14.5%	16.1%
Kidney disease	0.2%	6.8%	7.1%	0.2%	5.1%	4.5%	0.2%	14.7%	16.4%
Ophthalmology	0.5%	6.1%	6.4%	1.6%	5.5%	4.2%	0.5%	8.3%	8.8%
Peripheral angiography	0.1%	4.1%	4.4%	0.0%	5.1%	4.0%	0.1%	9.8%	10.5%
Myocardial infarction	0.6%	2.7%	2.5%	1.4%	3.7%	3.0%	2.7%	8.0%	8.0%
Stroke	0.3%	1.7%	1.5%	1.1%	2.8%	2.3%	2.0%	5.4%	5.5%
Dermatology	0.0%	1.3%	1.2%	0.0%	1.8%	1.3%	0.0%	1.7%	1.8%
Oral and periodontal	0.0%	0.0%	0.0%	0.0%	0.2%	0.0%	0.0%	0.0%	0.1%
Gangrene and amputations	0.0%	0.2%	0.2%	0.1%	0.5%	0.3%	0.0%	0.3%	0.3%

[22] Rewers A. Acute Metabolic Complications in Diabetes. In: Cowie CC, Casagrande SS, Menke A, et al., editors. Diabetes in America. 3rd edition. Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases (US); 2018 Aug. CHAPTER 17. Available from: https://www.ncbi.nlm.nih.gov/books/NBK567993/ Accessed November 2021.

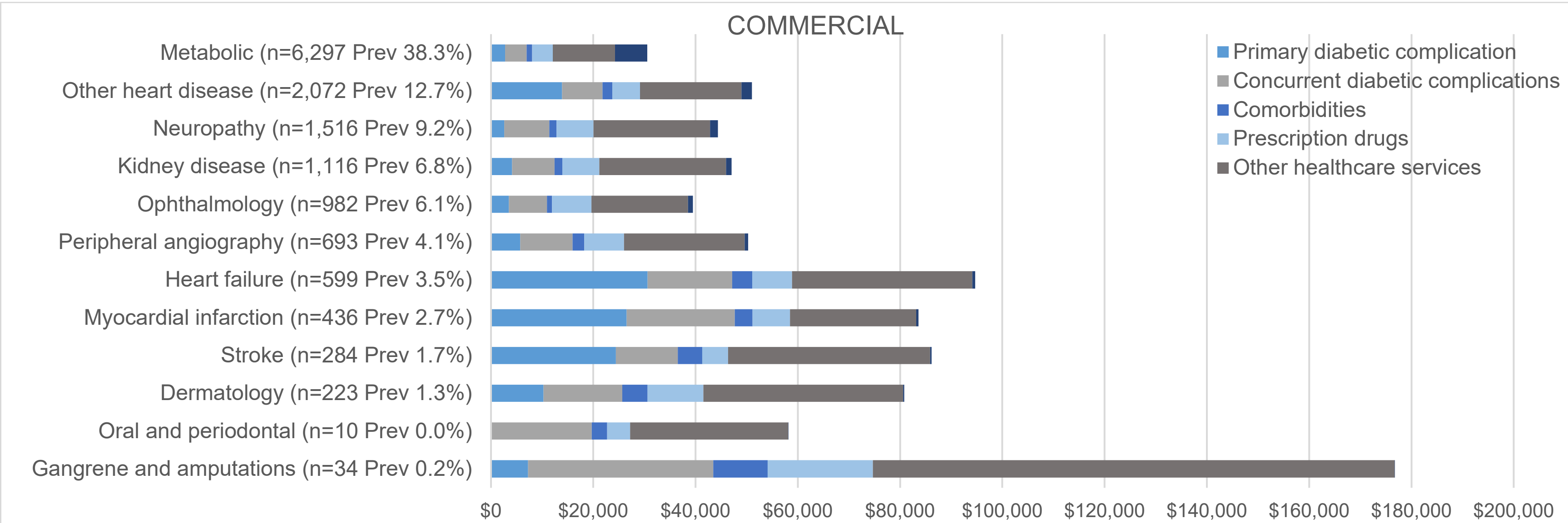
[23] Barrett-Connor E, Wingard D, Wong N, et al. Heart Disease and Diabetes. In: Cowie CC, Casagrande SS, Menke A, et al., editors. Diabetes in America. 3rd edition. Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases (US); 2018 Aug. CHAPTER 18. Page 18-4. Available from: https://www.ncbi.nlm.nih.gov/books/NBK568001/ Accessed December 2021.

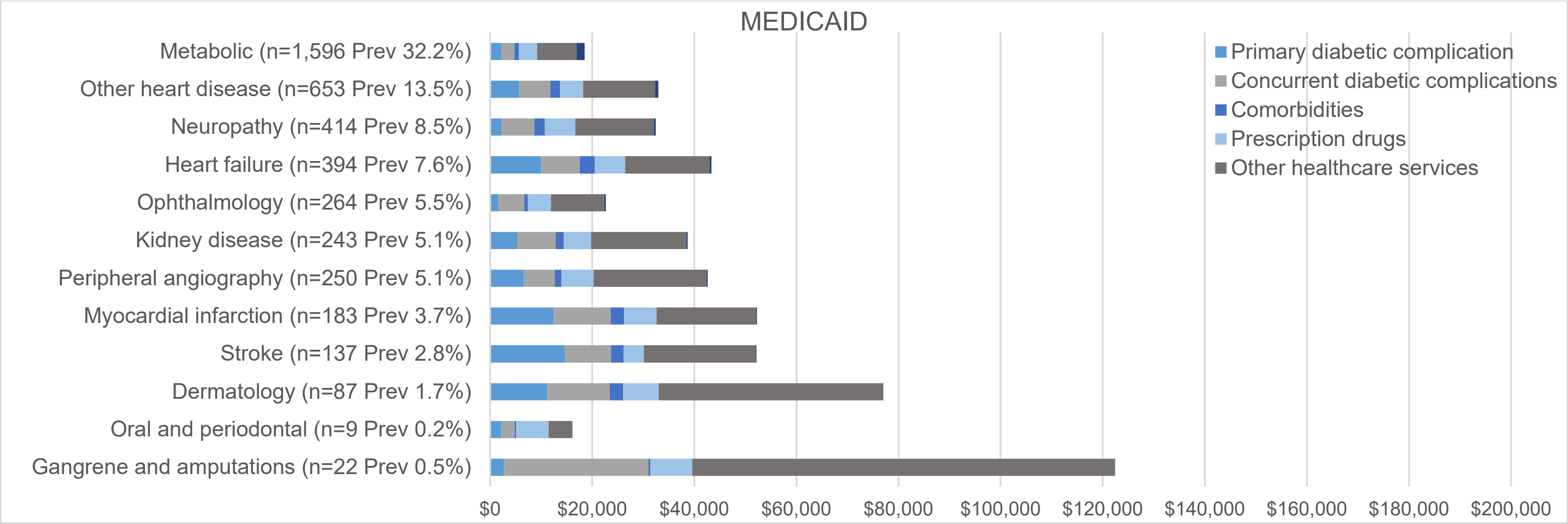
[24] Einarson TR, Acs A, Ludwig C, Panton UH. Economic Burden of Cardiovascular Disease in Type 2 Diabetes: A Systematic Review. Value Health. 2018 Jul;21(7):881-890. https://doi.org/10.1016/j.jval.2017.12.019. Accessed November 2021.

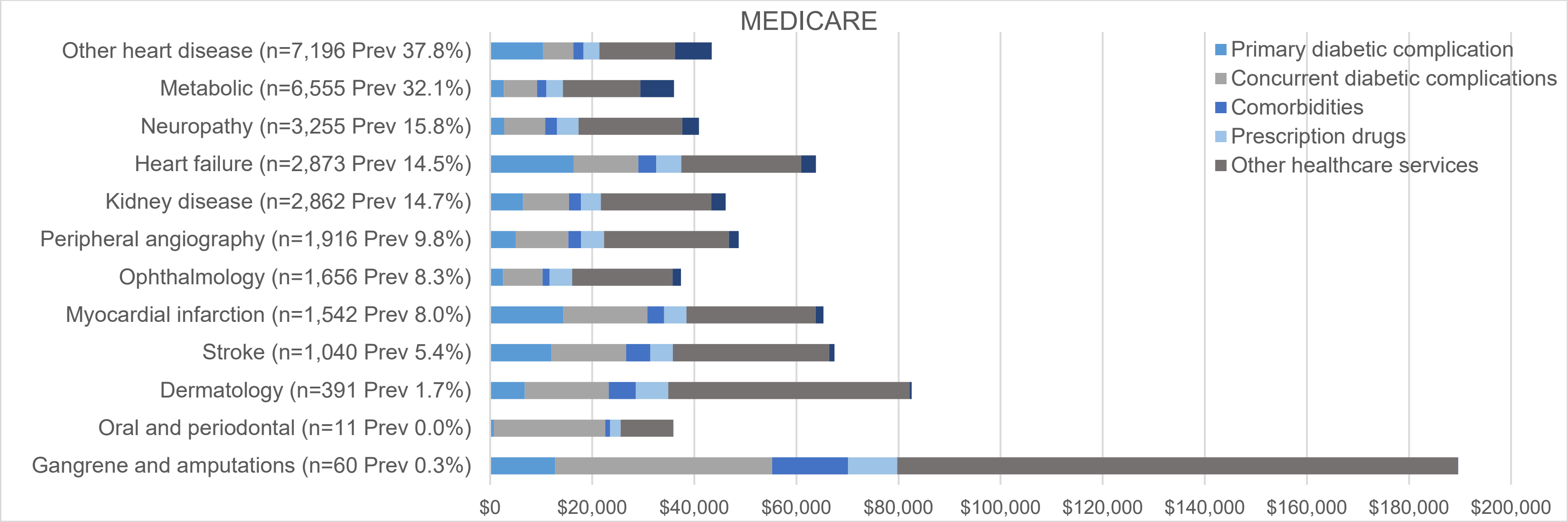
Figure 4b shows the mean total costs of care in the first year after T2D diagnosis, categorized by T2D complications. Total costs are broken down into costs associated with the primary diabetic complication (the primary diagnosis), concurrent diabetic complications (the other T2D complications in the table above), other selective comorbidities which have been reported in association with T2D but are not a T2D complication (specifically chronic obstructive pulmonary disease, pulmonary hypertension, sleep apnea and dementia), prescription drugs, and other healthcare services (unrelated to diabetic complications and specified comorbidities). The primary T2D complication refers to the condition named in the vertical axis beside the bar, while a concurrent T2D complication refers to any of the other complications in the vertical axis apart from the primary T2D complication.

Figure 4b: Mean total cost of care PPPY for patients with diabetic complications in the first year after T2D diagnosis

The number of patients N and prevalence rate (%) are shown in the axis category titles.




MEDICAID
Metabolic (n=1,596 Prev 32.2%)
Other heart disease (n=653 Prev 13.5%)
Neuropathy (n=414 Prev 8.5%)
Heart failure (n=394 Prev 7.6%)
Ophthalmology (n=264 Prev 5.5%)
Kidney disease (n=243 Prev 5.1%)
Peripheral angiography (n=250 Prev 5.1%)
Myocardial infarction (n=183 Prev 3.7%)
Stroke (n=137 Prev 2.8%)
Dermatology (n=87 Prev 1.7%)
Oral and periodontal (n=9 Prev 0.2%)
Gangrene and amputations (n=22 Prev 0.5%)
$0
$20,000
$40,000
$60,000
$80,000
$100,000
$120,000
$140,000
$160,000
$180,000
$200,000
Primary diabetic complication
Concurrent diabetic complications
Comorbidities
Prescription drugs
Other healthcare services


MEDICARE
Other heart disease (n=7,196 Prev 37.8%)
Metabolic (n=6,555 Prev 32.1%)
Neuropathy (n=3,255 Prev 15.8%)
Heart failure (n=2,873 Prev 14.5%)
Kidney disease (n=2,862 Prev 14.7%)
Peripheral angiography (n=1,916 Prev 9.8%)
Ophthalmology (n=1,656 Prev 8.3%)
Myocardial infarction (n=1,542 Prev 8.0%)
Stroke (n=1,040 Prev 5.4%)
Dermatology (n=391 Prev 1.7%)
Oral and periodontal (n=11 Prev 0.0%)
Gangrene and amputations (n=60 Prev 0.3%)
$0
$20,000
$40,000
$60,000
$80,000
$100,000
$120,000
$140,000
$160,000
$180,000
$200,000
Primary diabetic complication
Concurrent diabetic complications
Comorbidities
Prescription drugs
Other healthcare services

BODY MASS INDEX AND WEIGHT MANAGEMENT

As shown in Figure 5a and 5b, the median change in cost after T2D diagnosis tends to increase with increasing BMI tiers in all insurance groups. Each BMI point is equivalent to 1.0 kg/m^2; ICD-10 codes define BMI ranges, for example, Z68.31 is defined as BMI 31.0-31.9, adult. The CDC defines BMI ranges as overweight (25-29.9), class 1 obesity (30-34.9), class 2 obesity (35-39.9) or class 3 obesity (40 or higher).[25] The mean is higher than the median, because the top decile of patients incurs costs that are severalfold higher than the median: the data is described as asymmetrically distributed and right skewed. The wide variation in individual patient costs causes a large interquartile range. Age and gender distribution in each BMI tier are shown in Figure 5c.

These observational data suggest that higher baseline BMI at the time of diagnosis is associated with higher costs after diagnosis. Each 5-point BMI tier escalation is associated with an average growth of annual healthcare expenditures of approximately $421 in year 1 and $265 in year 2 after T2D diagnosis in the Commercial group. These estimates were calculated as the average cost difference between each BMI tier compared to the preceding tier.

Figure 5a: Median total cost of care (allowed PPPY) for newly diagnosed T2D patients, grouped by baseline BMI at time of diabetes diagnosis (as defined by ICD-10 codes) – table

BASELINE BMI (KG/M^2) AT TIME OF DIAGNOSIS		YEAR BEFORE DIAGNOSIS	1ST YEAR AFTER DIAGNOSIS			2ND YEAR AFTER DIAGNOSIS		
	Number of patients	Median allowed total cost of care	Median allowed total cost of care	Median change from baseline	Interquartile range of change from baseline	Median allowed total cost of care	Median change from baseline	Interquartile range of change from baseline
COMMERCIAL								
25 - 29.9	3,245	$414	$3,975	$2,618	$597 to $8,828	$3,743	$2,237	$381 to $8,099
30 - 34.9	4,458	$512	$4,703	$2,988	$724 to $9,966	$4,137	$2,553	$405 to $9,002
35 - 39.9	3,531	$650	$5,561	$3,688	$795 to $11,830	$4,803	$2,872	$407 to $10,101
40 - 44.9	2,310	$724	$6,093	$4,082	$944 to $13,973	$5,109	$3,144	$418 to $11,347
45 - 49.9	1,070	$800	$6,664	$4,559	$979 to $15,395	$5,453	$3,353	$387 to $12,825
>= 50	841	$966	$6,785	$4,721	$863 to $18,577	$5,519	$3,562	$414 to $12,487
MEDICAID								
25 - 29.9	1,002	$1,450	$3,175	$1,098	$-39 to $4,069	$2,580	$594	$-466 to $3,385
30 - 34.9	1,215	$1,589	$3,809	$1,264	$60 to $5,217	$2,774	$741	$-511 to $4,174
35 - 39.9	842	$2,117	$4,212	$1,316	$-31 to $5,235	$3,003	$603	$-965 to $4,016
40 - 44.9	617	$1,992	$4,063	$1,352	$106 to $5,522	$3,289	$817	$-598 to $4,863
45 - 49.9	354	$2,130	$4,276	$1,599	$-127 to $5,379	$3,385	$793	$-735 to $5,233
>= 50	367	$2,025	$4,917	$1,666	$117 to $7,135	$3,771	$1,037	$-500 to $5,796
MEDICARE								
25 - 29.9	5,499	$1,383	$5,465	$3,148	$789 to $10,658	$5,346	$2,890	$515 to $9,617
30 - 34.9	5,705	$1,313	$5,761	$3,333	$820 to $11,080	$5,597	$3,050	$569 to $11,291
35 - 39.9	3,217	$1,343	$5,806	$3,409	$917 to $11,143	$5,814	$3,281	$641 to $11,870
40 - 44.9	1,828	$1,165	$6,877	$4,078	$1,114 to $14,615	$6,359	$3,915	$747 to $13,970
45 - 49.9	716	$1,303	$7,576	$4,735	$1,244 to $15,540	$6,565	$4,242	$740 to $13,768
>= 50	478	$1,171	$7,150	$4,862	$1,059 to $15,427	$7,704	$4,895	$1,095 to $16,264

[25] Centers for Disease Control and Prevention (CDC). Defining Adult Overweight & Obesity. Page last reviewed: June 7, 2021. https://www.cdc.gov/obesity/adult/defining.html Accessed November 2021.

Figure 5b: Median total cost of care (allowed PPPY) for newly diagnosed T2D patients, grouped by baseline BMI at time of diabetes diagnosis (as defined by ICD-10 codes) – chart

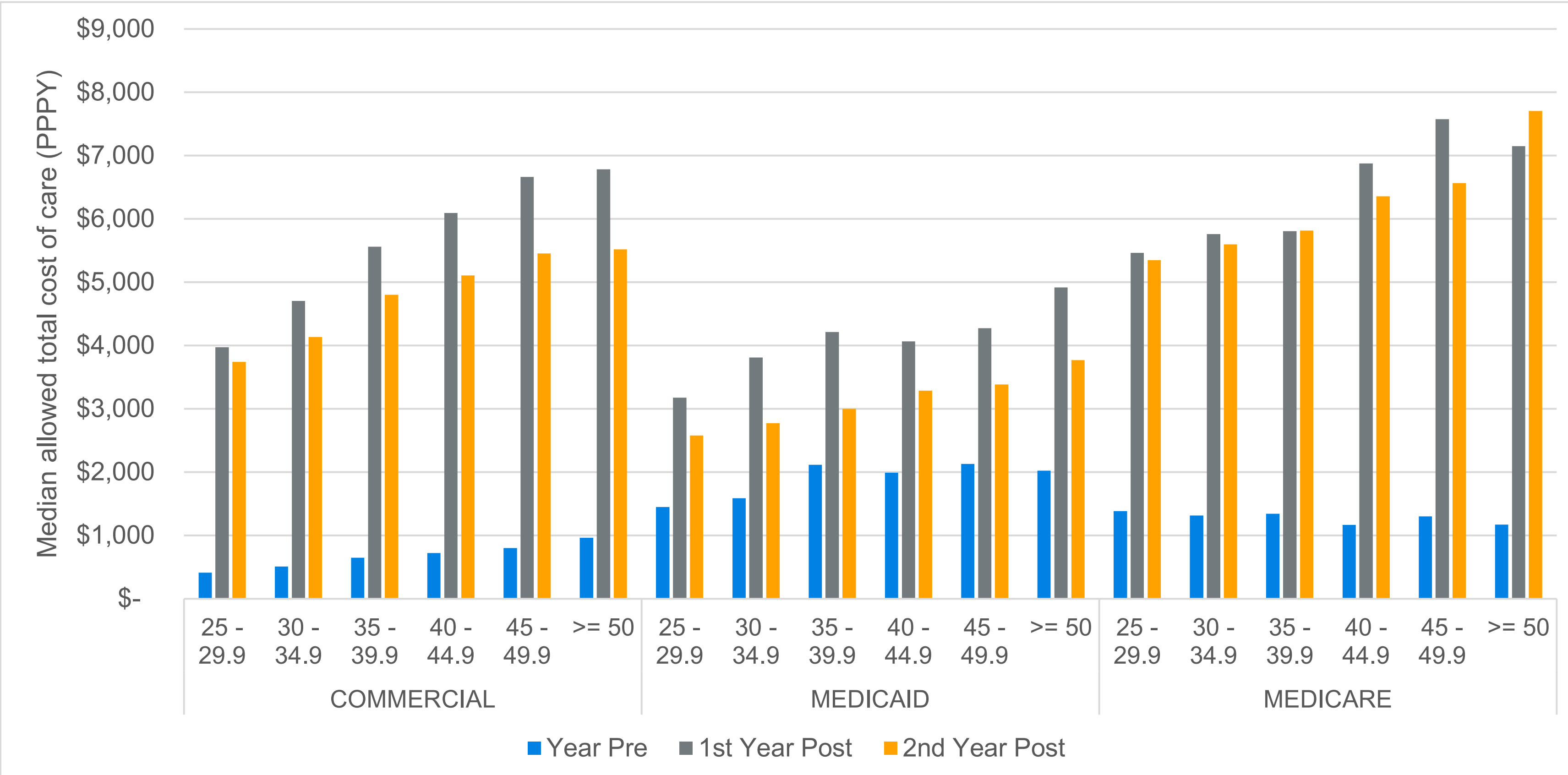


Figure 5c: Age and gender distribution for each BMI tier in newly diagnosed T2D patients

BASELINE BMI (KG/M²) AT TIME OF DIAGNOSIS	MEAN AGE	MEDIAN AGE	FEMALE	MALE
COMMERCIAL				
25 - 29.9	55.70	57	43%	57%
30 - 34.9	54.62	56	47%	53%
35 - 39.9	53.02	54	51%	49%
40 - 44.9	52.05	53	59%	41%
45 - 49.9	50.06	52	61%	39%
>= 50	48.88	49	67%	33%
MEDICAID				
25 - 29.9	52.49	54	56%	44%
30 - 34.9	50.11	51	62%	38%
35 - 39.9	47.00	47	65%	35%
40 - 44.9	45.35	47	67%	33%
45 - 49.9	43.06	43	70%	30%
>= 50	40.88	40	67%	33%
MEDICARE				
25 - 29.9	73.60	73	48%	52%
30 - 34.9	71.29	71	50%	50%
35 - 39.9	69.44	70	55%	45%
40 - 44.9	68.41	69	62%	38%
45 - 49.9	66.66	68	65%	35%
>= 50	62.80	66	69%	31%

To investigate the primary drivers of increased cost, we examined patterns of utilization for 3 different categories of healthcare services – inpatient admissions, emergency department (ED) visits and primary care (PCP) visits.

As shown in Figure 6, increasing BMI appears to be associated with an increasing proportion of patients incurring an inpatient admission for all insurance groups. The relationship between admits per 1,000 and the proportion of patients with an inpatient admission demonstrates that, on average, those admitted were admitted more than once in the first year after T2D diagnosis.

While the patterns in ED utilization exhibited greater fluctuations, increased ED utilization appears to be associated with higher BMI. Patients in every BMI tier and every insurance group increased their number of primary care visits in the year following T2D diagnosis; primary care utilization increased by approximately 40% in Commercial and Medicare insurance groups, but only 20% increase in Medicaid. This is shown in the Year 1 change column of Figure 6.

Figure 6: Inpatient, ED, and PCP utilization for newly diagnosed T2D patients, grouped by baseline BMI at time of diabetes diagnosis

INPATIENT ADMISSIONS	Proportion of patients with an inpatient admission in year 1 post-diagnosis			Inpatient admissions per 1000 in year 1 post-diagnosis			Year 1 change in the proportion of patients with an inpatient admission		
BASELINE BMI	**COMMERCIAL**	**MEDICAID**	**MEDICARE**	**COMMERCIAL**	**MEDICAID**	**MEDICARE**	**COMMERCIAL**	**MEDICAID**	**MEDICARE**
25 - 29.9	11%	15%	20%	144	211	357	10%	11%	16%
30 - 34.9	10%	17%	20%	138	226	319	10%	13%	17%
35 - 39.9	12%	19%	19%	152	278	333	11%	14%	17%
40 - 44.9	15%	20%	25%	200	266	437	15%	16%	22%
45 - 49.9	17%	17%	28%	220	226	513	16%	13%	24%
>= 50	18%	26%	28%	244	335	577	18%	21%	24%

ED VISITS	Proportion of patients with an ED visit in year 1 post-diagnosis			ED utilization per 1000 in year 1 post-diagnosis			Year 1 change in the proportion of patients with an ED visit		
BASELINE BMI	**COMMERCIAL**	**MEDICAID**	**MEDICARE**	**COMMERCIAL**	**MEDICAID**	**MEDICARE**	**COMMERCIAL**	**MEDICAID**	**MEDICARE**
25 - 29.9	19%	38%	28%	284	957	450	12%	11%	15%
30 - 34.9	21%	47%	26%	319	1105	439	12%	16%	13%
35 - 39.9	21%	48%	26%	334	1176	424	12%	12%	14%
40 - 44.9	25%	48%	29%	406	1263	470	15%	10%	16%
45 - 49.9	27%	51%	34%	422	1328	616	14%	11%	20%
>= 50	26%	53%	31%	422	1313	582	14%	13%	18%

PCP VISITS	Proportion of patients with an PCP visit in year 1 post-diagnosis			PCP utilization per 1000 in year 1 post-diagnosis			Year 1 change in the proportion of patients with a PCP visit		
BASELINE BMI	**COMMERCIAL**	**MEDICAID**	**MEDICARE**	**COMMERCIAL**	**MEDICAID**	**MEDICARE**	**COMMERCIAL**	**MEDICAID**	**MEDICARE**
25 - 29.9	85%	83%	92%	3,514	4,315	4,641	46%	21%	37%
30 - 34.9	87%	85%	93%	3,543	4,744	4,635	45%	23%	39%
35 - 39.9	88%	83%	92%	3,720	4,380	4,720	45%	17%	40%
40 - 44.9	89%	87%	91%	3,814	4,817	4,681	44%	16%	40%
45 - 49.9	90%	84%	90%	3,889	4,893	4,832	43%	17%	40%
>= 50	89%	87%	90%	4,017	5,120	5,075	40%	22%	41%

To explore whether weight management changes patterns in the total cost of care, we stratified newly diagnosed T2D patients according to change in BMI from the greatest BMI measure in post-diagnosis year 2 compared to the patient's baseline BMI at the time of their T2D diagnosis. Single point drops in BMI were only detectable for patients with a baseline BMI between 25 kg/m^2 and 40 kg/m^2; beyond 40 kg/m^2 the ICD-10 codes for BMI are no longer in single point increments.

Figure 7 shows median cost reductions between the first and second year after T2D diagnosis. Note that a negative cost reduction signifies increased cost. In the commercially insured group, patients who did not have a change in BMI had higher costs in year 2 than year 1, and reductions in median total cost in year 2 appeared to be associated with greater reductions in BMI. Patterns in Medicaid and Medicare had a similar general trend, but inconsistencies were observed, with some patients exhibiting cost increases.

In all insurance groups, a relatively low number of patients experienced 6-point, 7-point, 8-point, 9-point, or 10-point reductions in BMI, resulting in a small sample size and greater volatility of median cost results in those groups. It is important not to view BMI in isolation. BMI changes could result from improved diet and exercise but might also be associated with other illness.

Figure 7: Impact of weight management on median total cost reduction

Median cost reduction in total cost of care in the second year compared to the first year after T2D diagnosis*

	Increased BMI	No change	Decreased BMI									
			BMI point reduction									
			-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
COMMERCIAL	$75.84	-$34.43	$0.80	$84.70	$280.42	$235.07	$677.91	$4,131.89	$749.67	$369.32	$10,827.26	$2,838.78
MEDICAID	$164.75	$211.40	$336.38	$471.60	$65.43	$96.59	$378.21	$149.72	-$1,326.90	$2,356.56	-$795.96	$1,219.76
MEDICARE	$122.68	$103.73	-$37.35	$2.40	$46.42	$1,021.94	$912.24	-$852.71	$310.66	-$463.47	$534.69	-$488.69

Sample size of patients with a change in BMI in the second year after T2D diagnosis compared to baseline BMI at diagnosis

	Increased BMI	No change	Decreased BMI									
			BMI point reduction									
			-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
COMMERCIAL	1,943	1,282	694	282	143	61	35	17	9	6	11	6
MEDICAID	596	279	145	81	34	15	19	12	6	4	1	3
MEDICARE	2,691	1,777	1,026	510	216	139	63	43	22	17	6	8

***a negative dollar amount signifies that the cost in year 2 was higher than the cost in year 1 post-diagnosis**

HBA1C TESTING AND THE EFFECTS OF GLYCEMIC CONTROL

Effective October 2019, the Centers for Medicare & Medicaid Services (CMS) retired the procedure codes for the 7.0% - 9.0% HbA1c tier and created new tiers for 7.0% to 8.0% and 8.0% to 9.0% HbA1c levels. These new and more granular tiers are useful for measurement of improvements in HbA1c; however, they only appear in the last 6 months of our study period (ending March 31, 2020).

To navigate the CMS change in HbA1c coding and prevent a small analysis cohort, we took 2 different analytic approaches to exploring the impact of glycemic control on total costs:

a) The first approach categorized T2D according to disease severity, where "severe" is defined as having any of the following: uncontrolled HbA1c >7.0%, combined drugs or more than one anti-diabetic medication within a 6-month period, or the presence of diabetic complications in the first year after T2D diagnosis. This definition of severe status in T2D approximates the severity levels defined by the MedInsight Chronic Conditions Hierarchical Grouper, which is based on literature,[26] claims data research and clinical consensus.[27]

b) The second approach shortened the length of continuous enrollment required to a 2-year period from 12 months before to 12 months after T2D diagnosis, instead of the 3-year continuous enrollment. This loosening of the inclusion restriction expands the number of patients in the study cohort.

HBA1C ANALYTIC APPROACH 1 – DISEASE SEVERITY

Figure 8a shows the mean and median change in costs after T2D diagnosis in the severe group and non-severe group. The median increase in cost in the severe group is approximately $5,799 in year 1 after T2D diagnosis and $5,112 in year 2, compared to baseline for the commercial insurance group. The non-severe group has lower median cost than the severe group. In this newly diagnosed cohort, the median cost difference between severe and non-severe patients is estimated at $2,660 and $2,630 respectively in years 1 and 2 after T2D diagnosis in the commercial population. Although we consider median to be a more conservative estimate of the typical average patient, we also included the mean cost differences for ease of comparison to other studies. Mean differences in cost between severe and non-severe groups were $3,334 and $4,061 respectively in years 1 and 2 post-T2D-diagnosis in the commercial insurance group, however standard deviations were very large due to high-cost outliers. This is also evident in the wide interquartile ranges for each measure. For commercially insured patients with severe T2D, all patients exhibited increased cost compared to the baseline year before diagnosis, 25% of patients incurred costs up to two times higher than baseline, and another 25% incurred costs that were over ten times higher than the baseline.

For commercial and Medicaid populations, the median and mean cost gap between severe and non-severe were sustained in years 1 and 2 post-diagnosis. Results for commercial, Medicaid, and Medicare were consistent with previous analyses of other claims datasets (not shown).[28] There may be opportunity to lower costs by improving glycemic control, reducing T2D complications, and reducing healthcare utilization or admissions related to complications. Combined or multiple T2D drug therapy may not be impactable, if necessary to address metabolic dysfunction.

The United States Preventive Services Task Force recommended screening for prediabetes and T2D in asymptomatic adults aged 35 to 70 years who have overweight or obesity ('person-first' language based on public feedback) and that clinicians should offer or refer patients with prediabetes to effective preventive interventions.[29]

[26] Dall TM, Yang W, Halder P, et al. Type 2 diabetes detection and management among insured adults. Population Health Metrics. 2016; 14:43. https://doi.org/10.1186/s12963-016-0110-4 Accessed August 2021.

[27] MedInsight Chronic Conditions Hierarchical Groups, Diabetes Severity Status Rules, version 2020. Proprietary technical guide. Accessed August 2021.

[28] MedInsight Chronic Conditions Hierarchical Groups. Unpublished confidential document 2019. Accessed December 2020.

[29] US Preventive Services Task Force. Screening for Prediabetes and Type 2 Diabetes. US Preventive Services Task Force Recommendation Statement. JAMA. 2021;326(8):736-743. doi:10.1001/jama.2021.12531. Accessed December 2021.

Figure 8a: Allowed costs (PPPY) by disease severity at diagnosis for newly diagnosed T2D patients

INSURANCE GROUP	DISEASE SEVERITY	NUMBER OF PATIENTS	ANALYTIC YEAR	CHANGE IN TOTAL COST (ALLOWED PPPY) COMPARED TO YEAR BEFORE T2D DIAGNOSIS						DIFFERENCE BETWEEN SEVERE AND NON-SEVERE	
				Mean allowed total cost	Mean change from year before T2D diagnosis	Standard deviation	25th percentile	50th percentile (median)	75th percentile	MEAN	MEDIAN
COMMERCIAL	Non-severe	9,878	Year before T2D	$2,197							
			T2D Year 1	$13,516	$11,319	$32,470	$790	$3,140	$10,346		
			T2D Year 2	$12,424	$10,227	$41,622	$414	$2,481	$8,649		
	Severe	4,257	Year before T2D	$1,691							
			T2D Year 1	$16,344	$14,653	$49,733	$1,421	$5,799	$15,457	**$3,334**	**$2,660**
			T2D Year 2	$15,979	$14,288	$36,550	$957	$5,112	$14,266	**$4,061**	**$2,630**
MEDICAID	Non-severe	3,307	Year before T2D	$3,320							
			T2D Year 1	$8,100	$4,781	$18,263	($132)	$1,023	$4,180		
			T2D Year 2	$7,008	$3,688	$17,125	($833)	$477	$3,277		
	Severe	1,318	Year before T2D	$2,935							
			T2D Year 1	$9,823	$6,888	$19,237	$95	$1,712	$6,918	**$2,107**	**$689**
			T2D Year 2	$8,904	$5,969	$18,985	($295)	$974	$5,830	**$2,281**	**$498**
MEDICARE	Non-severe	11,044	Year before T2D	$2,794							
			T2D Year 1	$13,590	$10,796	$26,148	$795	$3,042	$10,362		
			T2D Year 2	$13,763	$10,969	$31,337	$504	$2,789	$9,794		
	Severe	4,798	Year before T2D	$2,526							
			T2D Year 1	$17,537	$15,011	$33,361	$1,234	$4,429	$14,753	**$4,215**	**$1,387**
			T2D Year 2	$16,734	$14,208	$33,219	$921	$4,052	$14,623	**$3,239**	**$1,263**

HBA1C ANALYTIC APPROACH 2 – SHORTENING OF CONTINUOUS ENROLLMENT

Another approach we explored to investigate the effects associated with improvements in HbA1c was a modification of the continuous enrollment restriction to only require 1 year of continuous enrollment following T2D (while still requiring 1 year of continuous enrollment prior to diagnosis). This loosening of the restriction results in more than twice the number of patients with documented HbA1c tests.

Two additional cohorts with shorter continuous enrollment periods (from 6 months before T2D diagnosis to 1 or 2 years after diagnosis) were used to test the sensitivity of this analysis and found that reducing the length of continuous enrollment increased the cohort size but did not alter the distribution of changes in HbA1c. The sensitivity analyses are included in the Appendix.

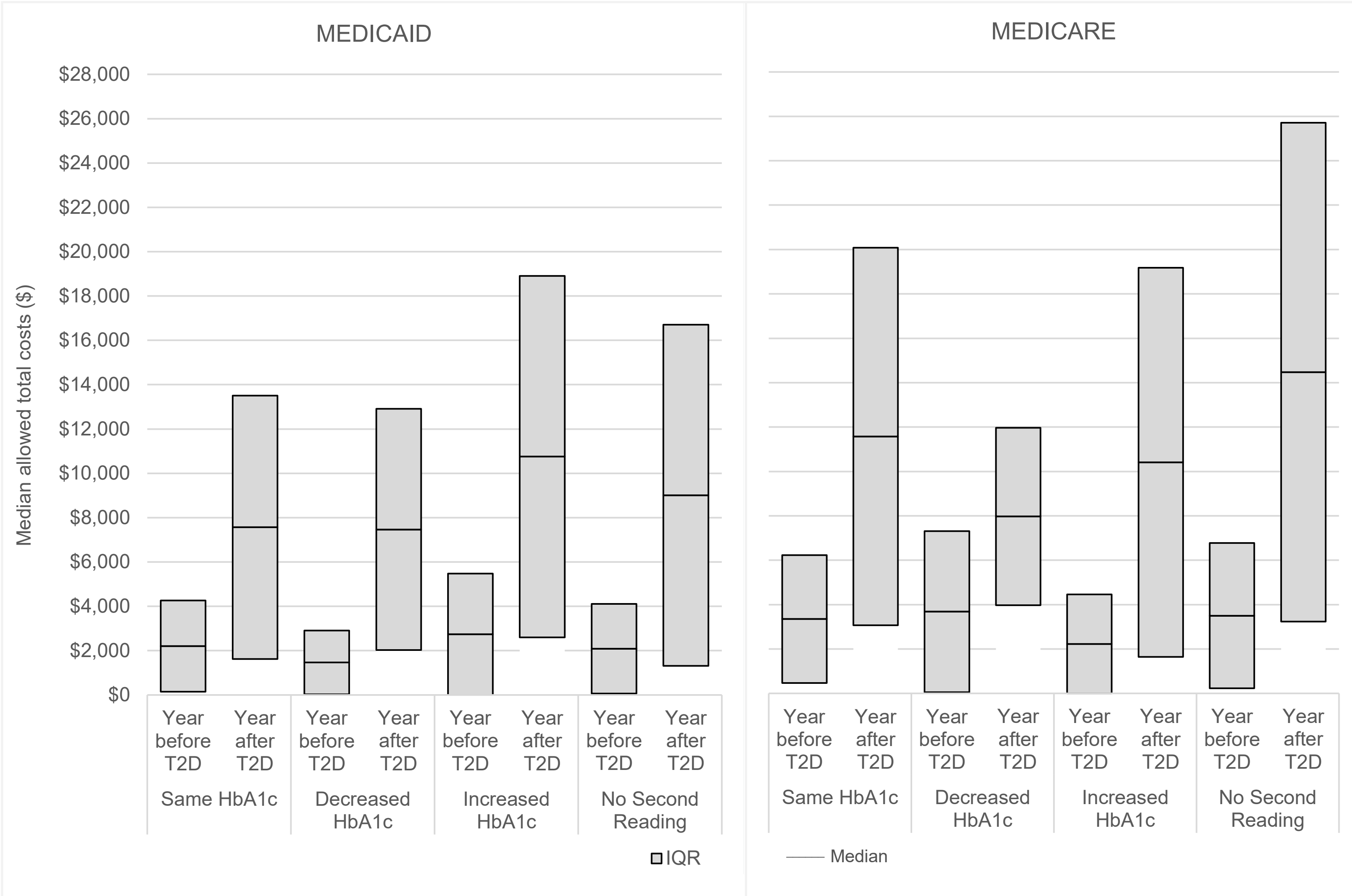
Figure 8b: Glycemic management in newly diagnosed T2D patients in the year after T2D diagnosis

LAST HBA1C READING COMPARED TO FIRST HBA1C READING	NUMBER OF PATIENTS	% OF PATIENTS	COMMERCIAL	MEDICAID	MEDICARE
Unchanged HbA1c	926	26.4%	96 (22.4%)	683 (27.6%)	147 (24.3%)
Decreased HbA1c	224	6.4%	30 (7.0%)	178 (7.2%)	16 (2.6%)
Increased HbA1c	97	2.8%	15 (3.5%)	74 (3.0%)	8 (1.3%)
No second HbA1c reading	2,263	64.5%	288 (67.1%)	1,541 (62.2%)	434 (72.7%)
Total patients	3,510	100.0%	429 (100.0%)	2,476 (100.0%)	605 (100.0%)

Figure 8c visualizes the change in median total allowed costs during the first year after T2D diagnosis and interquartile ranges for Medicaid and Medicare patients. It suggests that patients with decreased HbA1c (improving glycemic control) have lesser cost increases in the first year than those with increased HbA1c (worsening glycemic control). Patients without a second HbA1c reading appear to have higher median costs and IQR than those with unchanged HbA1c results. Few patients increased or decreased their HbA1c, and small sample sizes limit interpretation. Utilization volumes in the commercial groups were too low and volatile to detect a pattern.

The detailed cost and utilization results underlying Figure 8c are provided in the Appendix Figure 12. Although limited by small sample sizes in some groups, the results suggest that lower inpatient admissions and fewer outpatient visits are associated with decreased HbA1c in Medicaid and Medicare populations. Rates of emergency department visits and primary care visits were similar between all groups. Mean prescription drug costs appeared to be lower in the decreased HbA1c groups.

Figure 8c: Impact of glycemic control on the median total allowed costs in first year after T2D diagnosis



PREDIABETES AND DIABETES PREVENTION PROGRAMS

Prediabetes is a condition that precedes development of T2D and is characterized by sustained blood sugar levels that are higher than normal but not yet high enough to be diagnosed as diabetes.[30] We identified a separate cohort of patients with prediabetes and examined the impact of diabetes prevention programs (DPP) on the progression from prediabetes to T2D in the two years (month 0 to month 23) following prediabetes diagnosis.

We measured this progression rate for prediabetes patients with and without mental health conditions. Consistent with eligibility criteria for the CDC DPP for comparison purposes, patients who were pregnant during the study time period were excluded, and patients who had previously received a diagnosis of gestational diabetes were included.

As shown in Figure 9a, the cumulative risk of developing T2D increases with each month after recognition of prediabetes.

Figure 9a: Monthly cumulative percentage of prediabetes patients who progressed to T2D

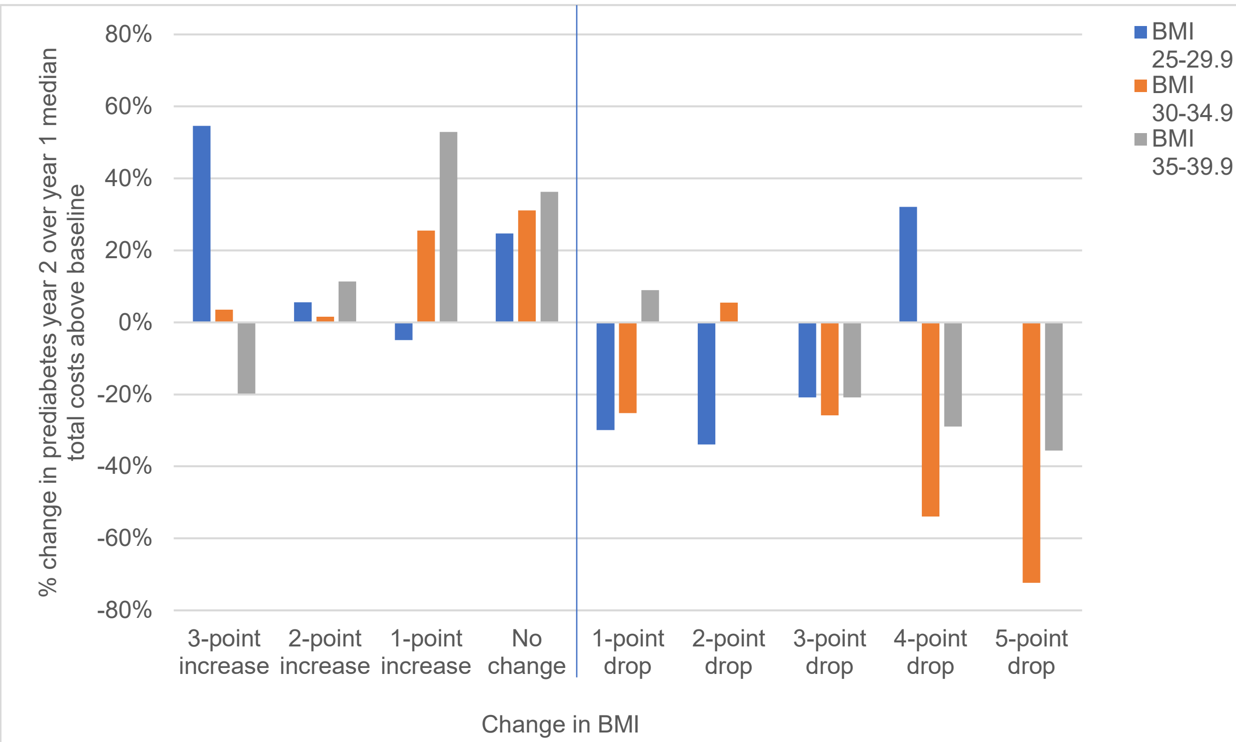
		INCLUDING PATIENTS WITH MENTAL HEALTH CONDITIONS			EXCLUDING PATIENTS WITH MENTAL HEALTH CONDITIONS		
		COMMERCIAL	MEDICAID	MEDICARE	COMMERCIAL	MEDICAID	MEDICARE
Number of Patients with Prediabetes		**23,488**	**6,447**	**22,076**	**12,263**	**2,169**	**9,869**
Mean Age		53.7	48.1	78.2	53.7	47.4	72.7
Median Age		55	51	72	55	51	72
% Male, % Female		48.8%, 51.2%	40.7%, 59.3%	44.9%, 55.1%	52.3%, 47.7%	45.2%, 54.8%	49.9%, 50.1%
Months since prediabetes diagnosis date		**Cumulative percentage of prediabetes patients who progressed to T2D diagnosis**					
Year 1	0	4%	4%	3%	4%	5%	4%
	1	6%	7%	5%	6%	7%	5%
	2	7%	8%	5%	6%	8%	6%
	3	8%	9%	6%	7%	9%	7%
	4	8%	9%	7%	8%	10%	8%
	5	9%	10%	7%	8%	10%	8%
	6	9%	11%	8%	9%	11%	9%
	7	10%	11%	9%	9%	11%	10%
	8	10%	12%	9%	10%	12%	10%
	9	11%	12%	10%	10%	12%	11%
	10	11%	13%	10%	10%	13%	11%
	11	11%	13%	10%	11%	13%	12%
Year 2	12	12%	14%	11%	11%	14%	12%
	13	13%	14%	12%	12%	14%	13%
	14	13%	15%	12%	12%	15%	13%
	15	14%	15%	13%	12%	15%	14%
	16	14%	16%	13%	13%	15%	14%
	17	14%	17%	14%	13%	16%	15%
	18	15%	17%	14%	14%	16%	15%
	19	15%	17%	15%	14%	17%	16%
	20	16%	18%	15%	14%	17%	16%
	21	16%	18%	15%	15%	17%	17%
	22	16%	19%	16%	15%	18%	17%
	23	17%	19%	16%	15%	18%	17%

[30] American Diabetes Association. 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes - 2021. Diabetes Care 2021;44(Suppl. 1):S15–S33. https://doi.org/10.2337/dc21-S002 Accessed October 2021.

We analyzed the impact of weight management on median total allowed cost PPPY for 8,237 patients with prediabetes with commercial insurance whose measured BMI was categorized as overweight, class 1 obesity, or class 2 obesity.

Figure 9b shows the year-over-year percentage change in prediabetes cohort median total allowed costs above baseline (year before prediabetes diagnosis) from year 1 to year 2, grouped by BMI change from baseline. Weight reduction appears to be associated with a downward trend in total costs in overweight and class 1 and 2 obesity groups. For patients whose weight stayed the same, higher BMI tiers exhibited escalated cost increases in year 2 over year 1. Results for BMI increases had greater variability of costs. Overweight patients achieving a 5-point drop was the smallest group skewed by outlier costs; this data point is included in the table and omitted from the chart.

Figure 9b: Observed impact of weight change on median growth of total allowed costs (PPPY) after prediabetes diagnosis



	% Change in prediabetes year 2 over year 1 median total costs above baseline			Number of patients		
Baseline BMI	**25-29.9**	**30-34.9**	**35-39.9**	**25-29.9**	**30-34.9**	**35-39.9**
Change in BMI from baseline to last reading in year 2 post-diagnosis						
3-point increase	55%	4%	-20%	96	115	90
2-point increase	6%	2%	11%	253	289	228
1-point increase	-5%	26%	53%	524	578	429
No change	25%	31%	36%	1364	1703	1090
1-point drop	-30%	-25%	9%	264	348	220
2-point drop	-34%	6%	0%	77	134	101
3-point drop	-21%	-26%	-21%	39	81	69
4-point drop	32%	-54%	-29%	14	31	45
5-point drop	448%	-72%	-36%	6	18	31

As a sensitivity test, we conducted a similar analysis of the impact of BMI reduction on commercially insured patients newly diagnosed with hypertension, shown in the Appendix, which also suggests that weight management in overweight or obese patients may lower costs.

National Diabetes Prevention Program participants

The National Diabetes Prevention Program (DPP) was initiated in 2010 as a public-private partnership to facilitate access to interventions to delay or prevent the onset of T2D in patients with prediabetes, including an evidence-based lifestyle change program recognized by the CDC.[31] The National DPP includes patients age >18 years, who have not been previously diagnosed with T2D or Type 1 diabetes, have a BMI of 25 or higher, are not pregnant, and have had either a blood test result (HbA1c, fasting glucose, or glucose tolerance) in the prediabetes range in the past year or previous gestational diabetes.[17] The majority of DPP participants in our cohort had Commercial insurance. Progression rates for prediabetes patients participating in a DPP, shown in Figure 9c, were 3 to 10-fold lower than without DPP.

Figure 9c: Monthly cumulative percentage of DPP participants who progressed to T2D

	INCLUDING PATIENTS WITH MENTAL HEALTH CONDITIONS		
	COMMERCIAL	**MEDICAID**	**MEDICARE**
NUMBER OF DPP PARTICIPANTS	**2,873**	**5**	**16**
Mean age	47.4	57.6	61.5
Median age	48	59	64
% Male, % Female	22.4%, 77.6%	25.0%, 75.0%	13.6%, 86.4%

	Months since prediabetes diagnosis	Cumulative percentage of prediabetes patients who progressed to T2D diagnosis		
Year 1	0	0.3%	Insufficient sample size	Insufficient sample size
	1	0.8%		
	2	1.0%		
	3	1.3%		
	4	1.7%		
	5	2.0%		
	6	2.4%		
	7	2.6%		
	8	2.9%		
	9	3.3%		
	10	3.5%		
	11	3.9%		
Year 2	12	4.2%		
	13	4.4%		
	14	4.6%		
	15	4.8%		
	16	5.0%		
	17	5.2%		
	18	5.3%		
	19	5.3%		
	20	5.4%		
	21	5.5%		
	22	5.5%		
	23	5.5%		

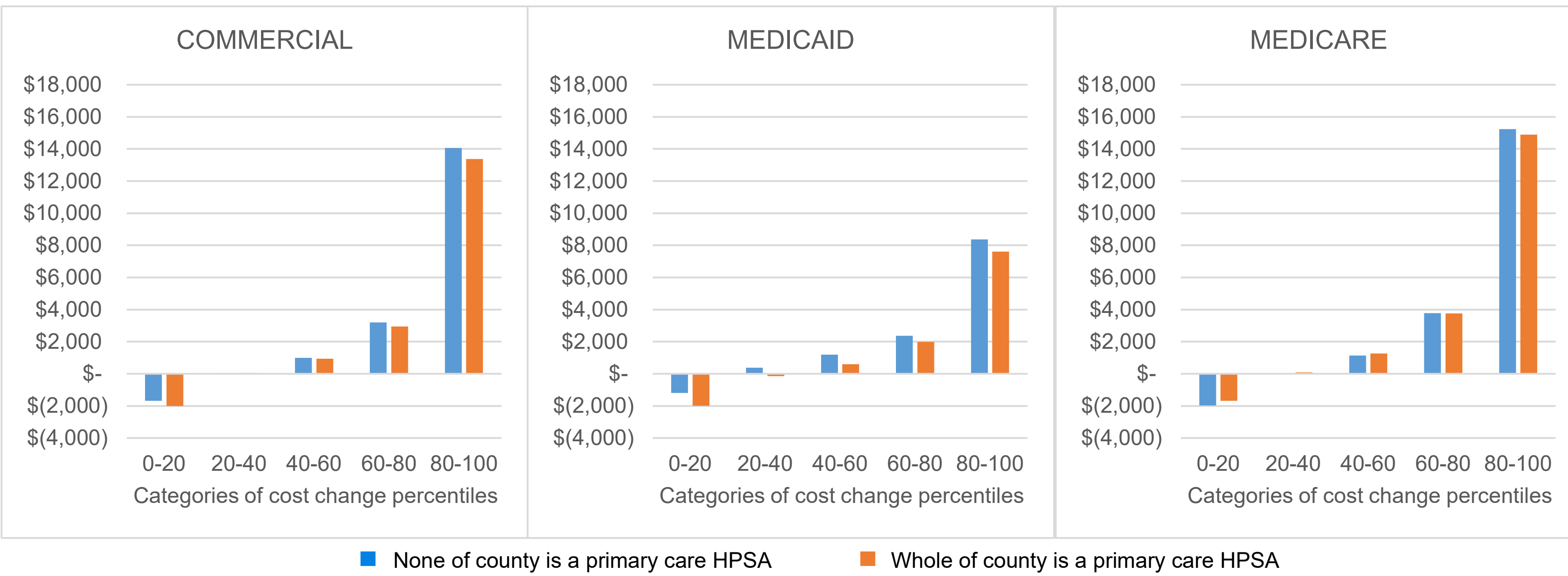
[31] Centers for Disease Control and Prevention (CDC). National Diabetes Prevention Program. About the National DPP. Page last reviewed August 19, 2021. https://www.cdc.gov/diabetes/prevention/about.htm. Accessed September 2021.

PREDIABETES IN HEALTH PROFESSIONAL SHORTAGE AREAS – QUANTILE REGRESSION

The Health Resources & Services Administration designates geographic areas as Health Professional Shortage Areas (HPSAs) if there is a lack of primary, dental, or behavioral healthcare professionals and provides information on population-to-provider ratios at the census tract level. We mapped this information to counties (defined by Federal Information Processing System (FIPS) codes for states and counties which uniquely identify geographic areas in our research dataset). For patients with prediabetes, we measured their change in annual healthcare expenditures after prediabetes diagnosis and explored whether this was associated with residing in primary care HPSAs that may limit access to care.

We used quantile regression to estimate the difference-in-differences of allowed mean total costs PPPY between patients living in counties wholly outside of a primary care HPSA labeled 'none of county' and counties wholly encompassed by a primary care HPSA labeled 'whole of county'. Difference-in-differences is a statistical technique used in econometrics and quantitative research. 'None of county' or 'Whole of county' was the binary variable for the quantile regression. The difference-in-differences was statistically significant in the lower three quintiles for Medicaid and Medicare, and in two of the quintiles for Commercial, visualized in Figure 10a and detailed in Figure 10b. A result for a quintile is statistically significant if the [slope of the regression line +/- 1.96 times the standard error of the slope] does not cross over zero (no cost difference).[32]

Figure 10a: Impact of primary care HPSAs on the mean change in total cost of care in the first year after prediabetes diagnosis, compared to the year before diagnosis – shown by quintiles (categories of percentiles)



[32] Petscher Y, Logan JAR. Quantile regression in the study of developmental sciences. Child Dev. 2014;85(3):861-881. https://doi.org/10.1111/cdev.12190 See Regression with One Dichotomous Predictor, p872. Accessed October 2021.

Figure 10b: Quantile regression analysis of the impact of primary care HPSAs on the mean change in total cost of care (allowed PPPY) in the first year after prediabetes diagnosis, compared to the year before diagnosis

	MEAN YEAR 1 CHANGE IN TOTAL COST COMPARED TO BASELINE				
PERCENTILE RANGE	**NONE OF COUNTY IS A HPSA**	**WHOLE OF COUNTY IS A HPSA**	**Slope of quantile regression line *(difference-in-differences)***	**Standard error of the slope**	**Statistically significant***
COMMERCIAL					
0 to 20th	-$1,687	-$2,011	-$324	$96	Yes
20th to 40th	$42	$53	$12	$19	No
40th to 60th	$998	$945	-$54	$30	No
60th to 80th	$3,193	$2,947	-$245	$78	Yes
80th to 100th	$14,061	$13,383	-$678	$634	No
MEDICAID					
0 to 20th	-$1,197	-$1,994	-$796	$389	Yes
20th to 40th	$376	-$146	-$522	$122	Yes
40th to 60th	$1,193	$596	-$596	$117	Yes
60th to 80th	$2,361	$1,983	-$378	$274	No
80th to 100th	$8,367	$7,607	-$760	$1,706	No
MEDICARE					
0 to 20th	-$1,963	-$1,684	$279	$90	Yes
20th to 40th	$11	$87	$77	$26	Yes
40th to 60th	$1,136	$1,270	$134	$41	Yes
60th to 80th	$3,781	$3,751	-$30	$112	No
80th to 100th	$15,232	$14,887	-$345	$661	No

* Statistically significant if [slope of the regression line +/- 1.96 times the standard error of the slope] does not cross over zero.

For patients insured by Medicaid, we interpret this to infer that residing in an area affected by primary care professional shortages significantly impacts patients' access to healthcare, particularly in the low to medium cost change quintiles, suggesting limited access to routine care and disease management services. At the highest cost change quintiles, there is no statistically significant difference between groups living in HPSAs and those that do not lack primary care professionals in their residential area. As hospital admissions likely drive the majority of costs in the higher cost quintiles, this is reasonable.

In the Commercial group, the difference-in-differences followed a similar trajectory but were not statistically significant in most quintiles, potentially reflecting the greater economic resources in this population and possibly greater flexibility to travel to other counties to obtain healthcare services.

In Medicare beneficiaries, costs were not lower in the primary care HPSAs, which might reflect better connection to other care resources in this group due to pre-existing concurrent comorbidities, such as heart disease, as illustrated in Figure 4a.

Discussion

IMPLICATIONS AND COMPARISON TO OTHER STUDIES

Diabetes is a chronic illness that increases the risk of many acute and chronic complications.[33]

The American Diabetes Association (ADA) published obesity management guidelines in their Standards of Medical Care in Diabetes 2021, which included recommendations for “diet, physical activity, and behavioral therapy designed to achieve and maintain ≥5% weight loss… for most patients with type 2 diabetes who have overweight or obesity and are ready to achieve weight loss”.[34] The ADA graded the level of evidence for these recommendations at B, which indicates there is evidence from well-conducted prospective cohort studies or registries, meta-analyses of such studies, or a well-conducted case-control study.[35] The ADA also noted the importance of frequent monitoring of clinical health metrics and counseling for obesity management in the treatment of T2D, particularly in the presence of other comorbidities (such as heart failure) and with consideration of an individual patient’s preferences and motivation.[34]

Economic studies of savings associated with weight loss in T2D have yielded variable results. Our findings suggest that higher BMI is associated with higher cost for newly diagnosed T2D patients in all insurance groups, and that each BMI point reduction appears to trend with reduced cost, particularly in the Commercial group. For comparison, the Thorpe et al. modeling study estimated a $752 annual cost savings in diabetes for each single point (1 kg/m^2) reduction in BMI.[36] Our observational estimate was smaller at $778 per 5-point BMI tier reduction in year 1 and $638 in year 2.

Other researchers have found a consistent relationship between glycemic control and modeled health outcomes, based on a meta-analysis of 76 studies.[37] Some have produced estimates of annualized medical costs for T2D-related complications and comorbidities in patients diagnosed at least 15 years earlier.[38] As mentioned in the background section of this report, 30-year follow-up investigations of the original UKPDS cohort found association of early interventions with impacts on long-term health outcomes.[10]

In our analysis of the first year following T2D diagnosis, better glycemic control appeared to improve health outcomes, as suggested by fewer ED visits and admissions for diabetes complications and lower costs PPPY in the non-severe group compared to the severe group, with a median cost difference of $2,660 PPPY and a mean cost difference of $3,334 PPPY. For patients who were successful in achieving improvements in glycemic control, total costs in the first year after T2D diagnosis were reduced in inpatient and ED settings, but were increased by higher pharmacy costs, outpatient visits and medical professional fees, however this second analytic approach to examine HbA1c changes was limited by sample size. Almost 65% of newly diagnosed T2D patients in our study cohort did not receive more than HbA1c test in the first year after T2D diagnosis, despite the importance of this measure to monitor chronic glycemic control and the efficacy of treatment and its strong predictive value for T2D complications.[39] Current

[33] Papatheodorou, K., Papanas, N., Banach, M., Papazoglou, D. & Edmonds, M. Complications of Diabetes 2016. J. Diabetes Res. 2016. https://doi.org/10.1155/2016/6989453 Accessed August 2021.

[34] American Diabetes Association. 8. Obesity Management for the Treatment of Type 2 Diabetes: Standards of Medical Care in Diabetes - 2021. Diabetes Care 2021;44(Suppl. 1):S100–S110. https://doi.org/10.2337/dc21-S008 Accessed October 2021.

[35] Diabetes Care 2021 Jan; 44(Supplement 1): S1-S2. https://doi.org/10.2337/dc21-Sint Accessed October 2021.

[36] Thorpe K, Toles A, Shah B, Schneider J, Bravata DM. Weight Loss-Associated Decreases in Medical Care Expenditures for Commercially Insured Patients With Chronic Conditions. J Occup Environ Med. 2021 Oct 1;63(10):847-851.https://doi.org/10.1097/JOM.0000000000002296 Accessed November 2021.

[37] Hua X, Lung TW, Palmer A, Si L, Herman WH, Clarke P. How Consistent is the Relationship between Improved Glucose Control and Modelled Health Outcomes for People with Type 2 Diabetes Mellitus? a Systematic Review. Pharmacoeconomics. 2017;35(3):319-329. https://doi.org/10.1007/s40273-016-0466-0 Accessed November 2021.

[38] Li R, Bilik D, Brown MB, Zhang P, Ettner SL, Ackermann RT, Crosson JC, Herman WH. Medical costs associated with type 2 diabetes complications and comorbidities. Am J Manag Care. 2013 May;19(5):421-30. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4337403/pdf/nihms-517053.pdf Accessed November 2021.

[39] American Diabetes Association Professional Practice Committee. 6. Glycemic Targets: Standards of Medical Care in Diabetes—2022. Diabetes Care 1 January 2022; 45 (Supplement 1): S83–S96. https://diabetesjournals.org/care/issue/45/Supplement_1. Accessed December 2021.

national guidelines[39,40] and international guidelines [41] recommend HbA1c testing at least every 6 months in T2D patients with stable glycemic control, or every 3 months or as needed for patients whose therapy has recently changed or who are not meeting glycemic goals.

A 5-year retrospective cohort study of 6,424 T2D patients at approximately 250 general practices reported a median HbA1c testing frequency of 1.6 tests per year and 50% guideline adherence rate, defined as the proportion of HbA1c tests performed within the testing intervals recommended by Australian guidelines that are similar to those above. The HbA1c levels in patients with high (>66%) adherence remained controlled or improved over time, whereas HbA1c values gradually increased or remained inadequately controlled in patients with low (<33%) and moderate (34-66%) adherence.[42] One challenge to traditional HbA1c laboratory testing is that results may not be available at the time of the provider-patient visit, which can delay communication and treatment modifications, and pre-visit HbA1c testing can be inconvenient for patients.[43] A study at Kaiser Permanente, which is an integrated health care system based in California, identified lab orders for 186,306 adult T2D patients who were continuously enrolled from July 1, 2008 to December 31, 2009 and found that one in seven patients did not complete HbA1c lab tests within 6 months of provider referral; this nonadherence rate rose to one in four patients age 19 to 34 years and one in five patients age 35 to 50 years.[44] No significant variation by race, socioeconomic status, patient-provider communication or trust in the clinical provider, and no association with depression, English language fluency or health literacy was found in that study.

HbA1c POCT may enhance adherence to testing guidelines, patient satisfaction, glycemic control and adherence to T2D therapy.[43, 45] Researchers at the Massachusetts General Hospital in Boston, Massachusetts studied electronic health records for adult patients with T2D for a six-month period from January to July 2019, comparing a control group of 377 sequentially scheduled patients at one practice without POCT to an intervention group of 530 sequentially scheduled patients at two practices with POCT, and found that HbA1c POCT reduced guideline nonadherence from 20% to 5.5% (3.7 times improvement).[46]

Our findings underscore the importance of intervening preventatively before the onset of T2D. The United States Preventive Services Task Force (USPSTF) commissioned a systematic review of evidence which concluded moderate net benefit for screening and preventive interventions in patients with screen-detected prediabetes, screen-detected T2D or recently diagnosed T2D. Examples of benefits were reducing the progression of prediabetes to T2D, reducing other cardiovascular disase risk factors such as blood pressure and lipid levels, or reducing all-cause mortality, diabetes-related mortality and the risk of myocardial infarction after 10 to 20 years of intervention.[47] The USPSTF recommended screening for prediabetes and Type 2 diabetes in asymptomatic adults aged 35 to 70 years who have overweight or obesity (person-first language), and that clinicians should offer or refer patients with

[40] Centers for Disease Control and Prevention. Living With Diabetes; All About Your A1C: Who Should Get an A1C Test, and When? Page last reviewed: August 10, 2021. https://www.cdc.gov/diabetes/managing/managing-blood-sugar/a1c.html. Accessed December 2021.

[41] National Institute for Health and Care Excellence. Type 2 diabetes in adults: management. NICE guideline [NG28]. Published: 02 December 2015. Last updated: 24 November 2021. https://www.nice.org.uk/guidance/ng28. Accessed December 2021.

[42] Imai C, Li L, Hardie RA, Georgiou A. Adherence to guideline-recommended HbA1c testing frequency and better outcomes in patients with type 2 diabetes: a 5-year retrospective cohort study in Australian general practice. BMJ Qual Saf. 2021;30(9):706-714. https://doi.org/10.1136/bmjqs-2020-012026. Accessed December 2021.

[43] Schnell O, Crocker JB, Weng J. Impact of HbA1c Testing at Point of Care on Diabetes Management. J Diabetes Sci Technol. 2017;11(3):611-617. https://doi.org/10.1177/1932296816678263. Accessed December 2021.

[44] Moffet HH, Parker MM, Sarkar U, et al. Adherence to laboratory test requests by patients with diabetes: the Diabetes Study of Northern California (DISTANCE). Am J Manag Care. 2011;17(5):339-344. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3189790/ Accessed December 2021.

[45] Lewandrowski EL, Lewandrowski K. Implementing point-of-care testing to improve outcomes. J Hosp Adm. 2013;2(2):125-132. : http://dx.doi.org/10.5430/jha.v2n2p125. Accessed December 2021.

[46] Crocker JB, Lynch SH, Guarino AJ, Lewandrowski K. The Impact of Point-of-Care Hemoglobin A1c Testing on Population Health-Based Onsite Testing Adherence: A Primary-Care Quality Improvement Study. J Diabetes Sci Technol. 2021;15(3):561-567. https://doi.org/10.1177/1932296820972751. Accessed December 2021.

[47] United States Preventive Services Task Force. Final Recommendation Statement. Prediabetes and Type 2 Diabetes: Screening. August 24, 2021. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes. Accessed December 2021.

prediabetes to effective preventive interventions. The interventions reviewed included behavioral counseling focused on diet or physical activity, or both, and pharmacotherapy for glycemic, blood pressure or lipid control.[29]

A study of patients with prediabetes enrolled in a digital DPP program found $669 annual reductions in inpatient spend per DPP participant, driven by fewer hospital admissions and decreased length of stay.[48] Other researchers have studied the impact of participation incentives in Medicaid beneficiaries enrolled in a community-based DPP delivered by the Minnesota Department of Human Services and the Minnesota Department of Health.[49] Given that T2D is a complex and multifactorial disease, it may not be possible to isolate disease management strategies perfectly, or to attribute subsequent outcomes solely to one approach.

Limitations and next steps

PURPOSE AND LIMITATIONS

This study is intended to be used to understand and estimate the patterns of cost and utilization for patients newly diagnosed with T2D, it may not be appropriate for other purposes.

This is not an interventional study. No interventions were conducted or measured in any of the observational groups. This report describes observed patterns and is not intended to evaluate an intervention. Randomized controlled trials may be more suited to assessing the impact of specific interventions to avoid over-estimation of effects due to regression to the mean.[50]

Healthcare claims data that are relied on for our conclusions are documented and collected primarily for administrative purposes and often lack clinical details such as lab values, clinician notes, and plans of care. Despite this limitation, claims data has the advantage of providing a comprehensive view of all healthcare services incurred and billed to insurance from any healthcare professional or facility. The claims research database we used comprises over 10 billion lines of healthcare claims data from approximately 75 healthcare organizations spread across all 50 states and can be considered a randomized sample. We examined the geographical, age, and gender distribution of the research database, which was found to be similar to the American Community Survey (ACS) results for each census region.

This study does not include uninsured individuals, and it does not include undiagnosed individuals who are estimated to represent 21.4% of all U.S. adults with diabetes.[1] It also does not include patients who died during the study period or patients who lack 3 years of continuous enrollment, such as adult children who rolled off their parent's coverage during the study period and individuals who turned 65 and qualified for Medicare during the study period.

Our three-year enrollment requirement reduced our cohort size by 65% in commercial and Medicare populations and by 84% in Medicaid. The requirement for documented BMI reduced the sample size by a further 40% in commercial, 37% in Medicare and 44% in Medicaid. Exclusion of patients in the top cost decile in the year before T2D diagnosis resulted in a cohort of patients that did not have pre-existing high-cost conditions before the onset of T2D. The intent was to exclude conditions such as cancer, HIV treatment, psychosis, dementia, multiple sclerosis, orthopedic and spine conditions. Although it is possible that might also exclude undiagnosed T2D patients if they experienced serious complications, our T2D incidence rate is comparable to national estimates from the CDC,[1] and our study was focused on understanding post-diagnosis impacts for patients who did not previously have T2D.

Only 35% of the remaining patients received more than one HbA1c test during the first year after T2D diagnosis. Multiple approaches were tested to analyze the impact of changes in glycemic control. Our first approach to

[48] Castro Sweet C, Bradner Jasik C, Diebold A, DuPuis A, Jendretzke B. Cost Savings and Reduced Health Care Utilization Associated with Participation in a Digital Diabetes Prevention Program in an Adult Workforce Population. JHEOR. 2020;7(2):139-147. https://doi.org/10.36469/jheor.2020.14529 Accessed November 2021.

[49] Gilmer T, O'Connor PJ, Schiff JS, Taylor G, Vazquez-Benitez G, Garrett JE, Vue-Her H, Rinn S, Anderson J, Desai J. Cost-Effectiveness of a Community-Based Diabetes Prevention Program with Participation Incentives for Medicaid Beneficiaries. Health Serv Res. 2018 Dec;53(6):4704-4724. https://doi.org.10.1111/1475-6773.12973. Accessed November 2021.

[50] Linden, A. Assessing regression to the mean effects in health care initiatives. BMC Med Res Methodol 13, 119 (2013). https://doi.org/10.1186/1471-2288-13-119

addressing this limitation by using a binary variable of ≥7.0% HbA1c or <7.0% HbA1c to categorize glycemic control when grouping patients into severe and non-severe. Our second approach was to detect any change in HbA1c tier that reflected a change in HbA1c levels, and to broaden the size of our HbA1c cohort by focusing on patients continuously enrolled for 1 year before and 1 year after T2D diagnosis. Subgroups by insurance type and levels of change were small, however, aggregate numbers of patients were comparable to those reported in HbA1c POCT publications by other researchers.[43]The CMS defined tiers for HbA1c levels limited the level of granularity of tracking changes in HbA1c and the CMS made changes to HbA1c administrative coding during the analytic period. Effective October 2019, CMS retired the procedure codes for the 7.0 - 9.0% HbA1c tier and created new tiers for 7.0 to 8.0 (exclusive) and 8.0 to 9.0 HbA1c levels. A 1.0% change in HbA1c could only be detected as a shift in HbA1c tier and could not be detected for patients in whom first and last HbA1c tests were both in the 7.0 - 9.0% range.

The ICD-10 codes for BMI define discrete ranges for BMI values, rather than a continuous variable.

Costs and utilization vary widely from person to person even among those diagnosed with T2D, which limits the ability to pinpoint likely costs for any individual. Results presented here only represent best estimates of future experience. Actual experience will vary from our estimates for many reasons, potentially including differences in population health status, reimbursement levels, delivery systems, random variation, or other factors. It is important that actual experience be monitored, and adjustments made, as appropriate.

POTENTIAL FUTURE RESEARCH

The observational findings from this nationwide research database can be weighted to the age, gender, and BMI distribution of an organization's specific population, and/or tailored to a particular geography. Future research into the potential impact of disease management interventions could utilize a matched case/control study or a probabilistic predictive model to assign cost estimates to potential outcomes.

Additional research is needed to learn about the impacts of screening and preventive interventions on different populations, particularly racial and ethnic groups that have a high prevalence of T2D. Further research might also be able to identify interventions and factors associated with reversion to normoglycemia.

Conclusion

Diabetes is a global problem, impacting well-being, productivity, and healthcare expenditures. Newly diagnosed patients with Type 2 diabetes experience a sharp increase in total cost, hospitalizations, emergency department visits, professional costs, and pharmacy spend, particularly in the first year following diagnosis. Early interventions may have long-term impacts on health outcomes.

Acknowledgements

We would like to thank Susan E. Pantely, FSA, MAAA and Andrew Naugle, MBA for their thoughtful review.

Appendix

DIAGNOSIS CODES

We used ICD-10 codes used to identify T2D and complications, including ICD-10 codes categorized by the Agency for Health Research and Quality (AHRQ) Clinical Classification System (CCS). ICD-10-CM is the International Classification of Diseases, Tenth Revision, Clinical Modification, maintained by the CDC National Center for Health Statistics (NCHS). We used ICD-10 Z-codes to identify BMI.

SUPPLEMENTARY CODES

We used CPT Category II codes, intended for performance measurement, to report HbA1c and blood pressure levels when documented.

We used the Health Resources and Services Administration Data Warehouse, maintained by the Department of Health and Human Services, to identify Health Professional Shortage Areas, by FIPS county code.

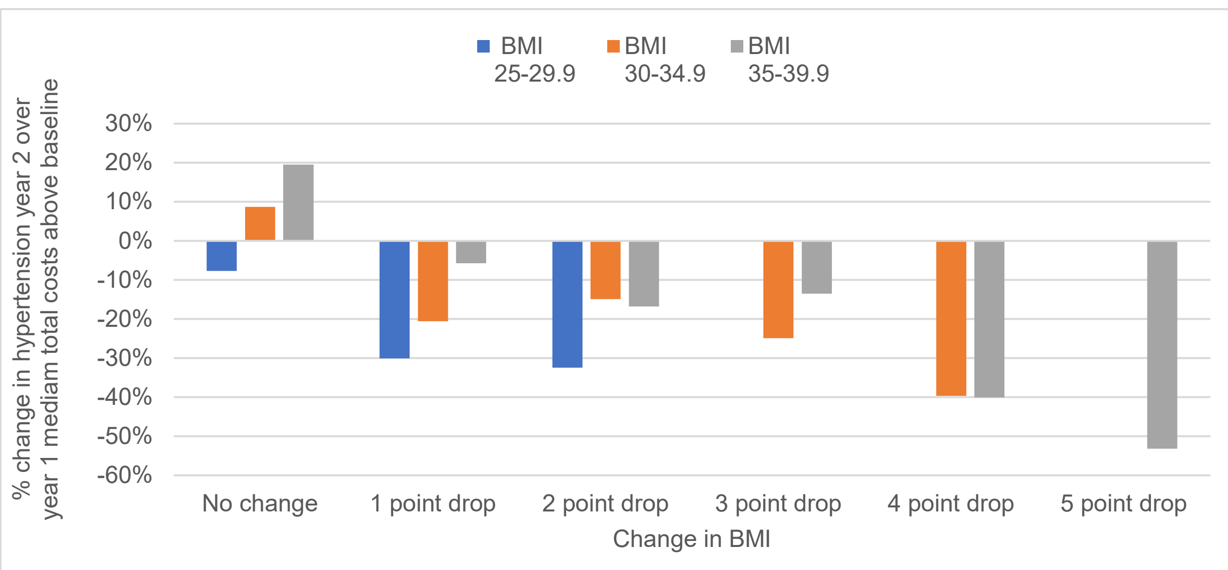
SENSITIVITY TESTS

Sensitivity test #1: Impact of weight reduction in patients newly diagnosed with hypertension

As a sensitivity test for the impact of weight reduction on total cost, we used the same data source to conduct a limited analysis of a larger cohort of 14,121 patients with commercial insurance, who were continuously enrolled 1 year before and 2 years after diagnosis of hypertension.

Figure 11 examines the year over year percentage change in hypertension cohort median total allowed costs above baseline (year before hypertension diagnosis) from year 1 to year 2, grouped by BMI change from baseline to last reading in year 2. The trend suggests that weight reduction in overweight or obese hypertension patients can reduce total costs PPPY. Groups with fewer patients than 0.5% of the total cohort (fewer than 70 patients) exhibited volatility due to outliers (not shown).

Figure 11: Sensitivity test of the impact of weight change on growth of median total allowed costs (PPPY) after hypertension diagnosis



	% Change in hypertension year 2 over year 1 median total costs above baseline			Number of patients		
Baseline BMI	**25-29.9**	**30-34.9**	**35-39.9**	**25-29.9**	**30-34.9**	**35-39.9**
Change in BMI from baseline to last reading in year 2 post-diagnosis						
No change	-8%	9%	19%	3,593	4,109	2,723
1-point drop	-30%	-21%	-6%	699	854	584
2-point drop	-32%	-15%	-17%	219	345	273
3-point drop		-25%	-14%		155	156
4-point drop		-40%	-40%		101	93
5-point drop			-53%			71

Sensitivity test #2: HbA1c additional cohorts

Two cohorts with shorter continuous enrollment periods were tested to explore how this improved the number of patients and HbA1c readings. These tests gave us confidence that we were able to detect a large volume of patients with HbA1c testing with the selected study cohorts, and that the continuous enrollment period defining the study cohorts was a key factor limiting the size of the sample.

i) The cohort limited to continuous enrollment for 6 months before and 1 year following T2D diagnosis with 5,538 patients had the same percentage distribution of HbA1c shifts as the cohort limited to continuous enrollment for 1 year before and 1 year following T2D diagnosis, and a similar percentage of patients who did not receive a second HbA1c test. This cohort was not used for analysis because the 6-month period before diagnosis would be subject to greater volatility if annualized.

ii) The cohort limited to continuous enrollment for 6 months before and 2 years following T2D diagnosis with 3,556 patients suffered from the same issue of volatility when annualizing costs for 6 months pre-diagnosis and contained fewer continuously enrolled patients than the cohort limited to continuous enrollment for 1 year before and 1 year following T2D diagnosis cohort.

ADDITIONAL TABLES:

Impact of glycemic control on mean and median total costs and utilization

As referenced in the main text, Figure 12 provides the detailed cost and utilization results from our analyses of the impact of glycemic control on total cost PPPY.

Figure 12: Change in mean [standard deviation] and median [interquartile range] of total costs and utilization PPPY in the first year after T2D diagnosis, grouped by HbA1c change

			MEAN [STDV]			MEDIAN [IQR]		
			COMMERCIAL	**MEDICAID**	**MEDICARE**	**COMMERCIAL**	**MEDICAID**	**MEDICARE**
Unchanged HbA1c	**Number of Patients**		**96**	**683**	**147**	**96**	**683**	**147**
	Facility Inpatient	Total allowed	$815 [$4,053]	$1,921 [$7,210]	$3,103 [$11,751]	$0 [$0 - $0]	$0 [$0 - $0]	$0 [$0 - $0]
		Utilization	0 [1]	1 [7]	2 [13]	0 [0 - 0]	0 [0 - 0]	0 [0 - 0]
	Facility Outpatient	Total allowed	$776 [$2,370]	$2,554 [$42,536]	$1,657 [$4,985]	$0 [$0 - $474]	$93 [$0 - $845]	$64 [$0 - $1,333]
		Utilization	1 [4]	5 [20]	3 [9]	0 [0 - 1]	1 [0 - 6]	0 [0 - 3]
	Emergency Department	Total allowed	$299 [$1,557]	$212 [$734]	$224 [$756]	$0 [$0 - $0]	$0 [$0 - $257]	$0 [$0 - $259]
		Utilization	0 [1]	1 [2]	0 [1]	0 [0 - 0]	0 [0 - 1]	0 [0 - 1]
	Professional	Total allowed	$1,599 [$2,961]	$1,171 [$2,353]	$1,796 [$2,976]	$623 [$213 - $1,812]	$646 [$149 - $1,422]	$1,038 [$183 - $2,391]
		Utilization	28 [27]	30 [62]	29 [37]	25 [14 - 46]	20 [6 - 38]	23 [8 - 39]
	PCP Office Visit	Total allowed	$362 [$352]	$196 [$306]	$464 [$491]	$294 [$106 - $500]	$120 [$0 - $296]	$379 [$152 - $742]
		Utilization	4 [4]	3 [4]	4 [4]	4 [2 - 6]	2 [0 - 5]	3 [1 - 6]
	Prescription Drug	Total allowed	$1,019 [$3,224]	$1,095 [$3,200]	$1,898 [$4,388]	$188 [$68 - $577]	$153 [$11 - $775]	$507 [$60 - $2,784]
		Utilization	28 [28]	33 [38]	26 [33]	23 [9 - 41]	23 [8 - 49]	19 [7 - 36]
	Ancillary	Total allowed	$41 [$188]	$798 [$3,142]	$981 [$3,046]	$0 [$0 - $0]	$0 [$0 - $282]	$75 [$0 - $800]
		Utilization	12 [14]	12 [39]	10 [16]	9 [1 - 21]	2 [0 - 11]	5 [0 - 16]
Decreased HbA1c	**Number of Patients**		**30**	**178**	**16**	**30**	**178**	**16**
	Facility Inpatient	Total allowed	$13,137 [$42,719]	$2,193 [$9,641]	$665 [$1,819]	$0 [$0 - $0]	$0 [$0 - $0]	$0 [$0 - $0]
		Utilization	2 [8]	1 [5]	1 [2]	0 [0 - 0]	0 [0 - 0]	0 [0 - 0]
	Facility Outpatient	Total allowed	$2,441 [$11,435]	$773 [$2,596]	$745 [$1,327]	$0 [$0 - $0]	$214 [$0 - $868]	$146 [$0 - $979]
		Utilization	0 [1]	1 [2]	0 [1]	0 [0 - 0]	0 [0 - 1]	0 [0 - 1]
	Emergency Department	Total allowed	$233 [$2,487]	$191 [$532]	$89 [$349]	$0 [$0 - $0]	$0 [$0 - $267]	$0 [$0 - $215]
		Utilization	0 [1]	1 [2]	0 [1]	0 [0 - 0]	0 [0 - 1]	0 [0 - 1]
	Professional	Total allowed	$2,362 [$4,014]	$1,220 [$2,762]	$1,011 [$1,041]	$958 [$456 - $1,623]	$675 [$230 - $1,479]	$542 [$281 - $1,487]
		Utilization	42 [43]	31 [37]	22 [12]	23 [16 - 42]	23 [11 - 42]	20 [16 - 28]
	PCP Office Visit	Total allowed	$410 [$338]	$253 [$276]	$398 [$275]	$390 [$95 - $638]	$185 [$62 - $389]	$413 [$234 - $546]
		Utilization	5 [4]	4 [4]	4 [2]	5 [2 - 8]	3 [1 - 6]	4 [3 - 6]
	Prescription Drug	Total allowed	$880 [$1,351]	$1,753 [$3,245]	$2,416 [$3,930]	$489 [$115 - $951]	$468 [$95 - $1,965]	$514 [$143 - $3,167]
		Utilization	40 [32]	49 [47]	22 [26]	35 [15 - 50]	38 [19 - 65]	14 [7 - 34]
	Ancillary	Total allowed	$218 [$655]	$540 [$1,691]	$474 [$1,114]	$0 [$0 - $22]	$41 [$0 - $483]	$0 [$0 - $329]
		Utilization	11 [15]	9 [28]	9 [11]	5 [1 - 19]	4 [0 - 13]	3 [0 - 17]
Increased HbA1c	**Number of Patients**		**15**	**74**	**8**	**15**	**74**	**8**
	Facility Inpatient	Total allowed	$756 [$2,927]	$5,218 [$21,213]	$2,920 [$9,258]	$0 [$0 - $0]	$0 [$0 - $0]	$0 [$0 - $2,430]
		Utilization	0 [0]	6 [41]	5 [11]	0 [0 - 0]	0 [0 - 0]	0 [0 - 4]
	Facility Outpatient	Total allowed	$42 [$326]	$1,195 [$2,493]	$930 [$1,794]	$0 [$0 - $0]	$361 [$0 - $1,580]	$226 [$0 - $1,104]
		Utilization	0 [1]	7 [11]	3 [4]	0 [0 - 0]	2 [0 - 11]	1 [0 - 4]
	Emergency Department	Total allowed	($272) [$1,050]	$353 [$946]	$533 [$864]	$0 [$0 - $0]	$0 [$0 - $499]	$0 [$0 - $916]
		Utilization	0 [0]	1 [2]	1 [1]	0 [0 - 0]	0 [0 - 1]	0 [0 - 1]
	Professional	Total allowed	$700 [$1,226]	$1,775 [$3,645]	$1,290 [$1,050]	$412 [$201 - $609]	$695 [$241 - $2,016]	$1,092 [$615 - $1,733]
		Utilization	29 [27]	39 [59]	28 [12]	25 [13 - 38]	22 [11 - 46]	28 [19 - 33]
	PCP Office Visit	Total allowed	$307 [$400]	$292 [$328]	$718 [$598]	$226 [$36 - $499]	$181 [$50 - $435]	$552 [$188 - $1,171]
		Utilization	3 [4]	4 [5]	7 [5]	3 [1 - 5]	3 [1 - 6]	5 [4 - 9]
	Prescription Drug	Total allowed	$53 [$1,067]	$2,276 [$5,255]	$3,326 [$6,600]	$73 [$25 - $161]	$363 [$23 - $2,188]	$825 [$194 - $2,045]
		Utilization	14 [15]	39 [38]	27 [25]	11 [6 - 17]	33 [10 - 57]	18 [13 - 32]
	Ancillary	Total allowed	$5 [$152]	$991 [$2,868]	$915 [$1,937]	$0 [$0 - $0]	$145 [$0 - $840]	$200 [$0 - $595]
		Utilization	17 [13]	18 [44]	10 [10]	20 [6 - 25]	5 [0 - 17]	7 [2 - 18]

			MEAN [STDV]			MEDIAN [IQR]		
			COMMERCIAL	MEDICAID	MEDICARE	COMMERCIAL	MEDICAID	MEDICARE
No second HbA1c reading	**Number of Patients**		**288**	**1541**	**434**	**288**	**1,541**	**434**
	Facility Inpatient	Total allowed	$7,496 [$52,592]	$4,428 [$24,320]	$5,223 [$18,597]	$0 [$0 - $0]	$0 [$0 - $0]	$0 [$0 - $0]
		Utilization	1 [7]	3 [30]	3 [11]	0 [0 - 0]	0 [0 - 0]	0 [0 - 0]
	Facility Outpatient	Total allowed	$1,066 [$3,357]	$1,050 [$7,210]	$1,727 [$5,641]	$0 [$0 - $220]	$30 [$0 - $784]	$173 [$0 - $1,848]
		Utilization	2 [6]	3 [9]	5 [23]	0 [0 - 1]	1 [0 - 4]	1 [0 - 5]
	Emergency Department	Total allowed	$205 [$670]	$234 [$1,161]	$392 [$1,231]	$0 [$0 - $0]	$0 [$0 - $247]	$0 [$0 - $552]
		Utilization	0 [1]	1 [2]	1 [1]	0 [0 - 0]	0 [0 - 1]	0 [0 - 1]
	Professional	Total allowed	$1,437 [$2,784]	$1,346 [$3,843]	$2,385 [$5,049]	$484 [$136 - $1,437]	$476 [$85 - $1,443]	$1,182 [$276 - $2,761]
		Utilization	26 [29]	29 [64]	33 [45]	21 [10 - 34]	17 [4 - 34]	24 [10 - 43]
	PCP Office Visit	Total allowed	$277 [$270]	$213 [$292]	$457 [$519]	$232 [$90 - $410]	$144 [$15 - $328]	$405 [$114 - $728]
		Utilization	3 [3]	3 [4]	4 [5]	3 [1 - 5]	2 [0 - 5]	3 [1 - 6]
	Prescription Drug	Total allowed	$644 [$2,650]	$997 [$4,175]	$3,033 [$9,505]	$146 [$27 - $359]	$81 [$2 - $526]	$523 [$65 - $2,809]
		Utilization	23 [22]	28 [36]	31 [36]	18 [5 - 35]	18 [4 - 42]	20 [5 - 46]
	Ancillary	Total allowed	$226 [$1,491]	$1,194 [$3,879]	$772 [$2,449]	$0 [$0 - $0]	$0 [$0 - $424]	$40 [$0 - $778]
		Utilization	8 [9]	20 [62]	10 [15]	7 [1 - 11]	4 [0 - 13]	6 [0 - 14]

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milliman.com

CONTACT

Melody Craff
melody.craff@milliman.com

Austin Barrington
austin.barrington@milliman.com

Thomas Pu
thomas.pu@milliman.com

Dale Skinner
dale.skinner@milliman.com