Comparative Effectiveness and Costs of Insulin Pump Therapy for Diabetes

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iabetes affects 29 million Americans, imposing a substantial health and economic burdens on the US population.¹ Intensive blood glucose management improves health outcomes for most patients,² but achieving this goal requires them to monitor blood glucose more often, use more medications, including insulin; and to follow up regularly with healthcare providers. These activities increase healthcare expenditures and are perceived by many patients to reduce their quality of life (QOL).³ This has stimulated efforts to develop less demanding forms of insulin delivery to reduce patient burden, while attemping to limit adverse effects, such as hypoglycemia and weight gain.

Over the past 2 decades, there has been an increase in the use of continuous subcutaneous insulin infusion (CSII) therapy, or "insulin pumps," for the treatment of diabetes. 4-6 An insulin pump is a small programmable device that uses a computer algorithm to administer insulin both continuously and by patient-initiated bolus infusion through a small catheter that is left under the skin. The American Diabetes Association and American Association of Clinical Endocrinologists recommend intensive blood glucose management using either multiple daily insulin injections (MDII) or CSII, but advise CSII primarily for well-educated and motivated patients who are unable to achieve optimal glycemic control with MDII. 6-8

Prior research has suggested some potential advantages of CSII over MDII therapy, such as reduced pain, less stigma, lower frequency and severity of hypoglycemia, and overcoming some barriers to adherence. 9,10 However, a recent meta-analysis of trials directly comparing MDII with CSII found that CSII did not reduce hypoglycemia or weight gain and had inconsistent effects on QOL and blood glucose control, with the results of only 1 trial showing greater improvement in glycated hemoglobin (A1C) among adults with type 1 diabetes (T1D) who had comparatively higher A1C levels at baseline. Recent reports have called for clearer evidence-based guidelines for CSII indications and more transparent reporting of safety data by pump manufacturers. 8

Insulin infusion pumps have been reported to cost about \$4500, with additional costs for supplies exceeding \$1500 per

ABSTRACT

OBJECTIVES: Continuous subcutaneous insulin infusion (CSII), or "insulin pump" therapy, is an alternative to multiple daily insulin injections (MDII) for management of diabetes. This study evaluates patterns of healthcare utilization, costs, and blood glucose control for patients with diabetes who initiate CSII.

STUDY DESIGN: Pre-post with propensity-matched comparison design involving commercially insured US adults (aged 18 to 64 years) with insulin-requiring diabetes who transitioned from MDII to CSII between July 1, 2009, and June 30, 2012 ("CSII initiators"; n = 2539), or who continued using MDI (n = 2539).

METHODS: Medical claims and laboratory results files obtained from a large US-wide health payer were used to construct direct medical expenditures, hospital use, healthcare encounters for hypoglycemia, and mean concentration of glycated hemoglobin (A1C). We fit difference-in-differences regression models to compare healthcare expenditures for 3 years following the switch to CSII. Stratified analyses were performed for prespecified patient subgroups.

RESULTS: Over 3 years, mean per-person total healthcare expenditures were \$1714 (95% confidence interval [CI], \$1184-\$2244) higher per quarter for CSII initiators compared with matched MDII patients (total mean 3-year difference of \$20,565). Compared with matched controls, mean A1C concentrations became lower for CSII initiators by 0.46% in year 2 (P = .0003) and by 0.32% in year 3 (P = .047). CSII initiators also had a higher rate of hypoglycemia encounters in year 1 (P = .002).

CONCLUSIONS: For adults with insulin-requiring diabetes, transitioning from MDII to CSII was associated with modest improvements in A1C but more hypoglycemia encounters and increased healthcare expenditures, without significant improvement in other potentially offsetting areas of healthcare consumption.

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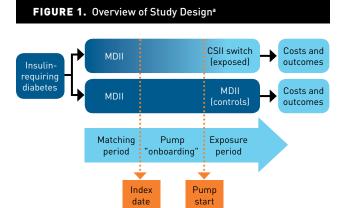
TAKEAWAY POINTS

- ➤ Mean total healthcare expenditures were estimated to be \$1714 higher per person per quarter for patients who initiate continuous subcutaneous insulin infusion (CSII) compared with matched multiple daily insulin injection (MDI) patients, equating to a total 3-year mean difference of about \$20,565 per person.
- Subgroup analyses showed modest differences in glycated hemoglobin favoring CSII recipients in years 2 and 3, but also statistically significant differences in healthcare visits for hypoglycemia as CSII was being initiated.
- It may remain challenging for health payers or providers to develop policies regarding access or coverage for CSII when, in aggregate, CSII appears to add immediate costs with short-term benefits that are uncertain and/or are difficult to measure.

improvements in health that translate into higher QOL and/or lower utilization of health-care services. A related important question is whether those outcomes might vary among different subgroups of patients. To address these gaps, we designed this study to evaluate patterns of healthcare utilization and costs for adults who primarily have T1D and transition to CSII in practice, comparing them with otherwise similar patients who continued MDII therapy.

person per year. 10 Because health insurance typically pays for 80% to 90% of CSII costs, access to insurance and coverage policies naturally play a strong role in whether patients choose to initiate this approach. Health payers generally offer insurance coverage for CSII to patients who meet specific clinical criteria and demonstrate good self-management practices and participation with healthcare visits. Medicare provides coverage for CSII in patients who have evidence of either: a) prior use of CSII with adherence to glucose self-testing prior to Medicare enrollment, or b) persistent hyperglycemia, recurring hypoglycemia, or other forms of poor blood glucose control despite completion of a comprehensive diabetes education program and adherence to glucose self-monitoring and MDII for at least 6 months. 12 Patients must then complete regular follow-up visits with a supervising physician at least every 3 months to continue receiving health payer coverage for CSII.

Although prior research has demonstrated the high acquisition costs for insulin infusion pumps and supplies, it is not yet known if those higher upfront costs can be recovered through



CSII indicates continuous subcutaneous insulin infusion; MDII, multiple daily insulin injections.

METHODS

Overall Design and Study Setting

We used a pre-post with propensity-matched comparison group quasi-experimental study design with difference-in-differences estimation to evaluate patterns of healthcare costs, utilization, and blood glucose control associated with the intiation of CSII by adults with insulin-requiring diabetes who received health insurance coverage from a single, large, nationwide commercial health insurer. The study design is depicted in **Figure 1** and described further below.

Study Sample and Exposures

The evaluation sample included patients with insulin-requiring diabetes who were aged 18 to 64 years. Insulin-requiring diabetes was defined as at least 1 encounter with an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code 250.XX and at least 1 dispensing event for MDII, but no previous use of an oral hypoglycemic class medication. This exclusion made it more likely, but not certain, that individuals included in the study had T1D. CSII initiators were defined by a new dispensing event for an infusion pump (Healthcare Common Procedure Coding System billing code E0784 or A9274) any time between July 1, 2009, and June 30, 2012. Additional CSII-related utilization and supplies were identified using specific procedural and encounter codes (see eAppendix Table 1 for details [eAppendix available at ajmc.com]). The date of the first occurrence of one of these codes within 270 days before the pump device dispensing date was defined as the index date for our pre-post analysis (Figure 1). This date occurred a median of 145 days before the pump dispensing date, and the time between these 2 dates was referred to as the "pump onboarding" period. In follow-up analyses, CSII initiators were considered to have stopped CSII if they had 120 days of enrollment without any claims for CSII-related supplies or services and had at least 2 basal insulin refills during that same period.

To identify a comparison group with similar baseline characteristics, we used a nearest-neighbor propensity-matching

^aThe pump "onboarding" period comprised a median of 145 days during which additional "pump-related" services could be utilized before the pump device dispensing date.

approach.13,14 The patient-level propensity model used logistic regression to predict the odds of CSII initiation and included baseline variables relating to the outcomes of interest, for which prior research results have demonstrated associations with diabetes treatment choice or intensity. Propensity model predictive variables included patient sex, age category, Charlson Comorbidity Index score, presence/absence of a prior obesity-related ICD-9-CM code, most recent A1C test result ≥ or <8% (or "value missing" if not available), and each of the following utilization criteria within 180 days before the CSII index date: total encounters for a hypoglycemia diagnosis, total encounters with an endocrinologist, and the presence or absence of at least 1 billing code suggestive of poorly controlled diabetes (eAppendix Table 1). To enable direct comparisons between groups, matched control clients were assigned the same index date as the CSII initiator to whom they were paired. To construct baseline variables for the match, individuals in both groups were required to have continuous health plan enrollment for at least 3 months before and 3 months after the index date.

Measures and Outcomes

Study outcomes included direct medical costs, categorized as inpatient, outpatient, pharmacy, and total healthcare costs; emergency department (ED) visits; encounters for hypoglycemic events; and, when available, A1C values. Total healthcare costs, including both health plan and patient cost share components, were assessed equally across all patient groups by applying a standardized price for each claim. To minimize the effect of extreme outliers on mean cost estimates, we replaced costs above the 95th percentile with the 95th percentile value.¹⁵

Data Sources

Data sources included national member enrollment files, medical inpatient and ambulatory claims, and pharmacy claims made available by a large US-based commercial health insurer. Although the completion of all laboratory tests (including A1C tests) could be determined for all patients in both groups (ie, based on laboratory claims), a subset of national commercial laboratory vendors also included the laboratory result with each claim submitted to the payer. A1C test results were available for about 40% of submitted A1C laboratory claims for both CSII- and MDII-treated patients. Because the availability of an A1C result was determined by where the test was perfored rather than by a patient's individual characteristics or form of diabetes treatment, this subsample of individuals with A1C test results enabled a unique opportunity for the analysis of glycemic control within an unbiased subset of patients nationally. The Northwestern University Institutional Review Board reviewed the parent study and determined that this work involved the use of coded, nonidentifiable data and was not classifiable as human subjects research.

Statistical Analysis

Univariate and bivariate descriptive statistics for baseline characteristics were calculated for both CSII initiators and the matched MDII comparison group. Student t tests were used to compare continuous variables; χ^2 tests were used to compare categorical variables. Means of continuous outcomes were plotted for each 90-day period before and after the index date to observe comparability of time trends between groups.

To minimize the potential for bias introduced by the nonrandomized study design, we used a pre-post with propensity-matched comparison group design. We estimated mean between-group differences in quarterly outcomes over different time horizons (year 1, year 2, year 3) using enrollee-level difference-in-differences random effects regression models that included a dummy variable for group (CSII initiator versus MDII), calendar year indicators (ie, calendar year of the index date), exposure year (ie, year 1, 2, or 3 relative to the index date), and group-by-exposure-year interaction terms. Means and 95% confidence intervals (CIs) were estimated using a generalized method of moments approach. For estimating continuous outcomes, we used linear models because they provide estimates in natural units of the outcome variable and have been shown to produce reliable and unbiased estimates of mean cost differences and CIs when sample sizes are large. 16 For count outcomes (eg, hypoglycemic encounters or ED visits), estimations used negative binomial distributional assumptions. Analyses were conducted on the overall sample as well as across prespecified patient subgroups, including different pump-qualifying diagnoses—hypoglycemia encounters or evidence of poor glycemic control within 180 days of the index date—and whether or not the CSII initiator also used real-time continuous glucose monitoring (rt-CGM) (see eAppendix Table 1).

Because our analysis assumed a health payer perspective, each patient who was no longer enrolled with the health plan was censored from future measurement periods, rather than imputing missing data or assuming them to have zero costs. To avoid potential bias from differential dropout rates across the 2 groups, we censored both the CSII initiator and matched control patient at any point when either one was no longer enrolled in the health plan. This reduced sample sizes but ensured comparability throughout the evaluation period.

RESULTS

The baseline characteristics of 2539 CSII initiators and 2539 matched controls are presented in **Table 1**. There were no statistically significant differences in any major characteristics between the 2 comparison groups, with good balance on sex, age, comorbidity index score, frequencies of encounters for hypoglycemia or hyperglycemia, and visits to endocrinologists. About half of patients in both groups were women and almost two-thirds were

CLINICAL

TABLE 1. Baseline Characteristics of CSII Initiators and Propensity-Matched Controls

Characteristic	Matched MDII Controls (n = 2539)	CSII Initiators (n = 2539)	P ª
Female, n (%)	1238 (48.8)	1305 (51.4)	.06
Age range category, years: n (%)			
18-27	373 (14.7)	391 (15.4)	.78
28-37	458 (18.0)	468 (18.4)	
38-49	740 (29.2)	744 (29.3)	
50-64	968 (38.1)	936 (36.9)	
Charlson Comorbidity Index score, n [%]			
0-1	1038 (42.9)	1067 (42.0)	.51
2	305 (12.0)	320 (12.6)	
3	553 (21.8)	502 (19.8)	
4	241 (9.5)	241 (9.5)	
≥5	402 (15.8)	409 (16.1)	
Encounters for hypoglycemia in past 3 months, n [%]			.10
0	2485 (97.9)	2467 (97.2)	
≥1	72 (2.1)	54 (2.8)	
Encounter for uncontrolled hyperglycemia, n (%)	970 (38.2)	998 (39.3)	.42
Any encounter with obesity diagnosis, n [%]	305 (12.0)	300 (11.8)	.83
Endocrinologist visits in the past 6 months, n (%)			.66
0	684 (26.9)	720 (28.4)	
1-2	492 (19.4)	492 (19.4)	
3-5	556 (21.9)	552 (21.7)	
≥5	807 (31.8)	775 (30.5)	
Last A1C in 12 months before index date, n (%)			.15
No test performed	609 (24.0)	564 (22.2)	
Test performed but no result available	1148 (45.2)	1176 (46.3)	
Test performed and result available	782 (30.8)	799 (31.5)	
Result <8%	281 (11.1)	324 (12.8)	
Result ≥8%	501 (19.7)	475 (18.7)	

A1C indicates glycated hemoglobin concentration; CSII, continuous subcutaneous insulin infusion; MDII, multiple daily insulin injections.

40 years or older. Only 2.1% of controls and 2.8% of CSII initiators had a hypoglycemia billing code in the 90 days prior to the index date. More than one-fourth of CSII initiators did not have an encounter with an endocrinologist in the 6 months before the index date, suggesting management by another type of provider. For the subgroup of patients who used laboratory vendors that provided test results to the payer (about 31% of patients in each treatment group at baseline), about 60% had baseline A1C concentrations greater than or equal to 8%.

Among CSII initiators, 25% were no longer enrolled after 24 months. For those who remained enrolled, 8.5% had resumed regular refills of basal insulin and had no further evidence of

pump-related supplies by the end of year 1; 13.9% had assumed this pattern by the end of year 2. There were no statistically significant differences in mean age, sex, or comorbidity scores between patients who remained with their health plan and those who did not remain enrolled. Among those who remained enrolled, the probability of stopping CSII use was higher among patients younger than 50 years compared with those aged 50 to 64 years (15.3% vs 11.6%; P = .03).

Overall Utilization and Cost Patterns

Figure 2 (panels A-D) displays the mean perperson-per-quarter healthcare expenditures of CSII initiators and matched MDII users before and after index dates. Cost trends between groups were comparable before the index date, but there was a small uptick in total expenditures for the pump users during the first 6 months after the index date (ie, during the pump "onboarding" period). This increase was associated with claims for pump-related services, such as education and laboratory testing required for pump authorization, followed by a subsequent large spike in total medical expenditures during the first quarter (Q) after receiving the pump (Q3 for most clients), which related to the pump device (mean cost = \$4786) plus supplies, additional educational encounters, and follow-up visits. Modest differences in ambulatory medical and pharmacy expenditures also persisted after Q3, reflecting ongoing expenditures for pump supplies and follow-up encounters.

Predicted differences in mean healthcare expenditures per person per quarter are displayed in **Table 2**. Mean per-person total

healthcare expenditures during year 1 were estimated to be \$2247 higher per quarter for CSII initiators than for matched MDII patients, amounting to a total difference of about \$9000 over the first year. Over the entire 3-year evaluation period, the adjusted mean per-person total healthcare expenditures were estimated to be \$1714 (95% CI, \$1184-\$2244) higher per quarter for CSII initiators compared with matched MDII patients, amounting to a total mean difference of about \$20,565 over 3 years. There were no statistically significant differences during any follow-up year in potentially offsetting utilization, such as ED visit rates, inpatient utilization, or ambulatory expenditures that were not directly related to CSII therapy (data not shown).

aStudent t tests for means of continuous variables; χ^2 tests for categorical variables

Lower numbers reflect fewer comorbid conditions and better health.

Matched MDI

CSII

Glycemic Control and Hypoglycemia Encounters

For the subgroup analysis of 31% of clients with available A1C results, trends in mean A1C concentrations prior to the index date were well balanced, but then increased slightly for CSII initiators during the pump onboarding period (Q1-Q3) (data not shown) before dropping precipitously near the time of pump initiation. The mean A1C was estimated to be 0.46% lower for CSII initiators than MDII controls in year 2 (P = .0003) and 0.32% lower in year 3 (P = .047). However, CSII initiators also had a higher rate of hypoglycemia encounters throughout year 1 after their index date (P = .002).

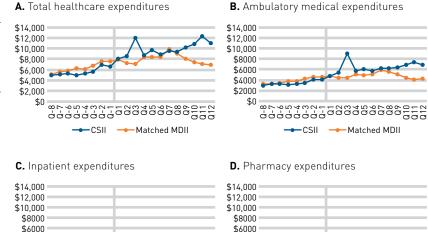
Comparative Effectiveness Among Prespecified Patient Subgroups

Figure 3 displays quarterly trends in total healthcare expenditures for the prespecified subgroups of CSII initiators: presence/absence of encounters for hypoglycemia (panels A and B), presence/absence of encounters for uncontrolled or labile blood glucose (panels C and D), and concomitant use/nonuse of rt-CGM in the first 2 years of CSII initiation (panels E and F). These comparisons show that CSII initiators with either uncontrolled blood glucose or hypoglycemia encounters tended to have higher mean quarterly healthcare expenditures both before and after the index date than did CSII initiators without those qualifying conditions. In addition, the expenditure trends following CSII initiation did not seem to differ significantly between those qualifying conditions. Third, concomitant use of rt-CGM (39.6% of CSII users) appeared to have no measurable impact on CSII expenditure trends.

FIGURE 2. Quarterly Trends in Healthcare Expenditures^a

Matched MDII

CSII



CSII indicates continuous subcutaneous insulin infusion; MDII, multiple daily insulin injections.

*In all plots, Q1, 2, 3, etc, represent the first, second, third, etc, quarter after the index date, and Q-1, Q-2, Q-3, etc, represent quarters before the index date.

\$4000

\$2000

TABLE 2. Comparison of Mean per-Patient Quarterly Healthcare Expenditures, by Year

Expenditure	Adjusted Between-Group Difference in Mean per-Person-per-Quarter Healthcare Expenditures³ Mean (95% CI) in US\$				
Category	Year 1	Year 2	Year 3	Sum Years 1-3	
Ambulatory	1872	808	1626	1445	
	(1531-2213)	(377-1239)	(908-2345)	(1117-1773)	
Inpatient	-866	-2530	9609	-618	
	(-5377 to 3645)	(-7941 to 2881)	(625-18,592)	(-4664 to 3429)	
Pharmacy	202	136	148	173	
	(155-249)	(68-205)	(12-284)	(120-226)	
Total	2247	775	2449	1714	
	(1677-2821)	(79-1471)	(1351-3548)	(1184-2244)	

CI indicates confidence interval.

\$4000

\$2000

*Estimated from difference-in-differences models. Positive numbers indicate that mean per-person expenditures are higher for the continuous subcutaneous insulin infusion (CSII) initiators than for the multiple daily insulin injections patients; negative numbers indicate expenditures are lower for the CSII initiators.

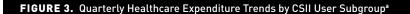
DISCUSSION

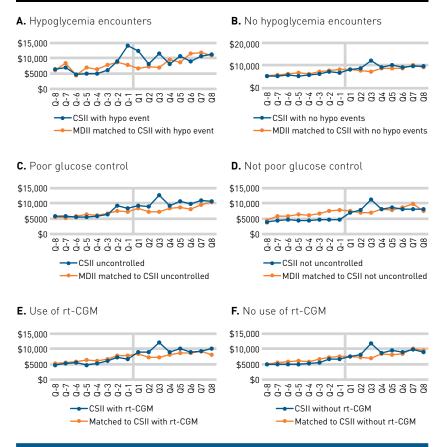
This natural experiment provides new information that adults with insulin-requiring diabetes who transition from MDII to CSII have mean total healthcare expenditures over a 3-year period that are about \$1700 higher each quarter, equating to about \$20,500 more per person over 3 years compared with otherwise similar patients who continue to use MDII. Although we did observe a favorable mean difference in A1C of 0.46% in year 2 and 0.32% in year 3, we also observed statistically significant differences in hypoglycemic encounters, which may indicate an adverse effect of

intensification in some patients or a need for additional education or training. Although we explored if there might be different expenditure trends for prespecified patient subgroups, we observed no differences between patients with or without recent encounters for hypoglycemia, with or without evidence of poor glucose control, or those who used rt-CGM concomitantly with CSII.

Cost differences were driven primarily by 3 types of pump-related expenditures: 1) the infusion pump, 2) pump insulin and other supplies, and 3) the incremental use of health services required for

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CSII, continuous subcutaneous insulin infusion; hypo, hypoglycemia; MDII, multiple daily insulin injections; rt-CGM, real-time continuous glucose monitor.

In all plots, Q1, 2, 3, etc, represent the first, second, third, etc, quarter after the index date, and Q-1, Q-2, Q-3, etc, represent quarters before the index date.

ongoing pump coverage. Those costs began over a median of 145 days prior to initiation of the pump and continued after CSII initiation throughout the entire 3-year analytic time horizon. Because patient-level costs and utilization were matched before the index date, incremental ambulatory expenditures were unlikely to be caused by differences in diabetes severity between the 2 comparison groups. Conversely, these expenditures may have resulted from coverage requirements that CSII patients meet certain indications (eg, hypoglycemia, poor glucose control) or complete certain services (diabetes self-management training quarterly physician visits) in order to retain pump coverage. To the extent that patients pay cost sharing amounts for those services, these incremental costs are likely to impact not only the payer but also patients and healthcare providers.¹⁷

Limitations

First, we only had access to administrative data sources, which do not capture some meaningful outcomes, such as reduced pain and distress, improved QOL, or mild to moderate hypoglycemic events.

If these unmeasured outcomes improve significantly for select patients who are offered CSII, it may alter conclusions about the balance of value and costs. Second, adherence to pump therapy could not be verified. We censored individuals from the analysis when they appeared to have stopped refilling pump supplies and insulin while resuming regular refills of basal insulin, but we had no way of verifying whether CSII users continued to use the pump as prescribed. Third, we were only able to analyze direct medical costs. Patients may also incur nonmedical costs (eg, transportation to doctor visits) or indirect costs (eg, missed workdays) after receiving different therapies or services. Last, although longer than most randomized controlled trials, the analysis period in our study of 3 years is still relatively short. In those for whom CSII improves glycemic control, it may require a longer period of time for this beneficial outcome to translate into lower overall healthcare utilization and costs.

CONCLUSIONS

Considering the ongoing movement toward value-based payment and delivery systems, there will be increasing incentives to offer management approaches that have higher upfront costs only when there is a strong likelihood of benefit to the patient. One important implica-

tion of our findings is that it may remain challenging for health payers or providers to develop policies regarding access or coverage for CSII when, in aggregate, CSII appears to add very high immediate costs with uncertain and/or difficult-to-measure short-term benefits. Unfortunately, our analysis did not uncover a clear patient subgroup for which the comparative effectiveness or costs of transitioning to CSII were more favorable in the short term. Payers already require a relatively strict set of criteria to be documented before approving CSII. These steps are intended to ensure CSII is appropriate and that the patient is fully informed and motivated. However, these efforts also have an unintended effect of increasing healthcare utilization and costs even before an insulin pump is dispensed, with some patients never actually initiating CSII and others reverting to MDII within only a few months. For CSII to be viewed as high value, additional research will be needed to inform more efficient strategies that identify patients who are most likely to benefit, as well as to provide the right balance of clinical education and support to prepare those patients for CSII and maximize its potential benefit.

Insulin Pumps for Adults With Diabetes

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Full text and PDF at www.ajmc.com

eAppendix Table 1. Definition of Patient Characteristics or Exposures Using Administrative Data Sources

Patient Characteristic or	Definition
Exposure	
Insulin-requiring diabetes	≥1 encounter with a 250.XX <i>ICD-9-CM</i> code; AND 0
mellitus	dispensing events for an oral hypoglycemic-class medication;
	AND dispensing events for insulin within 90 days of the
	index date
Dispensing of Insulin Pump	≥1 encounter with HCPCS billing code E0784 or A9274
CSII-related utilization &	Any encounter including codes 86337; 86341; 84681; G0108;
supplies	G0109; 98960; 98961; 98962; A4221; A4222; A4231;
	A4232; A9274; G0454; J1817; K0552; S9140; S9141; S9150;
	S9160; S9165; V65.46; OR V53.91;
Encounters for hypoglycemia	Any occurrence of ICD-9-CM code: 250.3x; 251.0; OR 251.2
Poorly controlled or labile	≥1 encounter with any of the following ICD-9-CM codes:
blood glucose control	250.02; 250.03; 250.12; 250.13; 250.22; 250.23; 250.32;
	250.33; 250.42; 250.43; 250.52; 250.53; 250.62; 250.63;
	250.72; 250.73; 250.82; 250.83; 250.92; OR 250.93
Use of rt-CGM	Any occurrence in the follow-up period of codes 95250;
	95251; A9276; A9277; OR A9278

ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; HCPCS, Healthcare Common Procedure Coding System; CSII, continuous subcutaneous insulin infusion; MDI, multiple daily insulin injections; rt-CGM, real-time continuous glucose monitor