



## Assessing the Effect of Formulary Restrictions in Type 2 Diabetes Mellitus

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### Background

- Utilization management tools (e.g., prior authorization, quantity limits and step therapy) are used to restrict access to medications.
- Fee-for-service Part D plans are increasingly employing utilization management tools:
  - Average share of covered drugs subject to utilization management rose from **18% in 2007 to 32% in 2011**
  - Coverage of available chemical entities **decreased from 89% in 2007 to 84% in 2011**
- Previous research shows that **medication utilization is decreased when a prior authorization or step edit is required**, with an unclear impact on medical spending.
- Dipeptidyl peptidase-4 inhibitors (DPP4) are a commonly used class of antihyperglycemic drugs as an addition to metformin therapy, as an alternative to sulfonylureas.
- Current evidence is insufficient to judge the impact of complex formulary designs with multiple restrictions in this drug class.

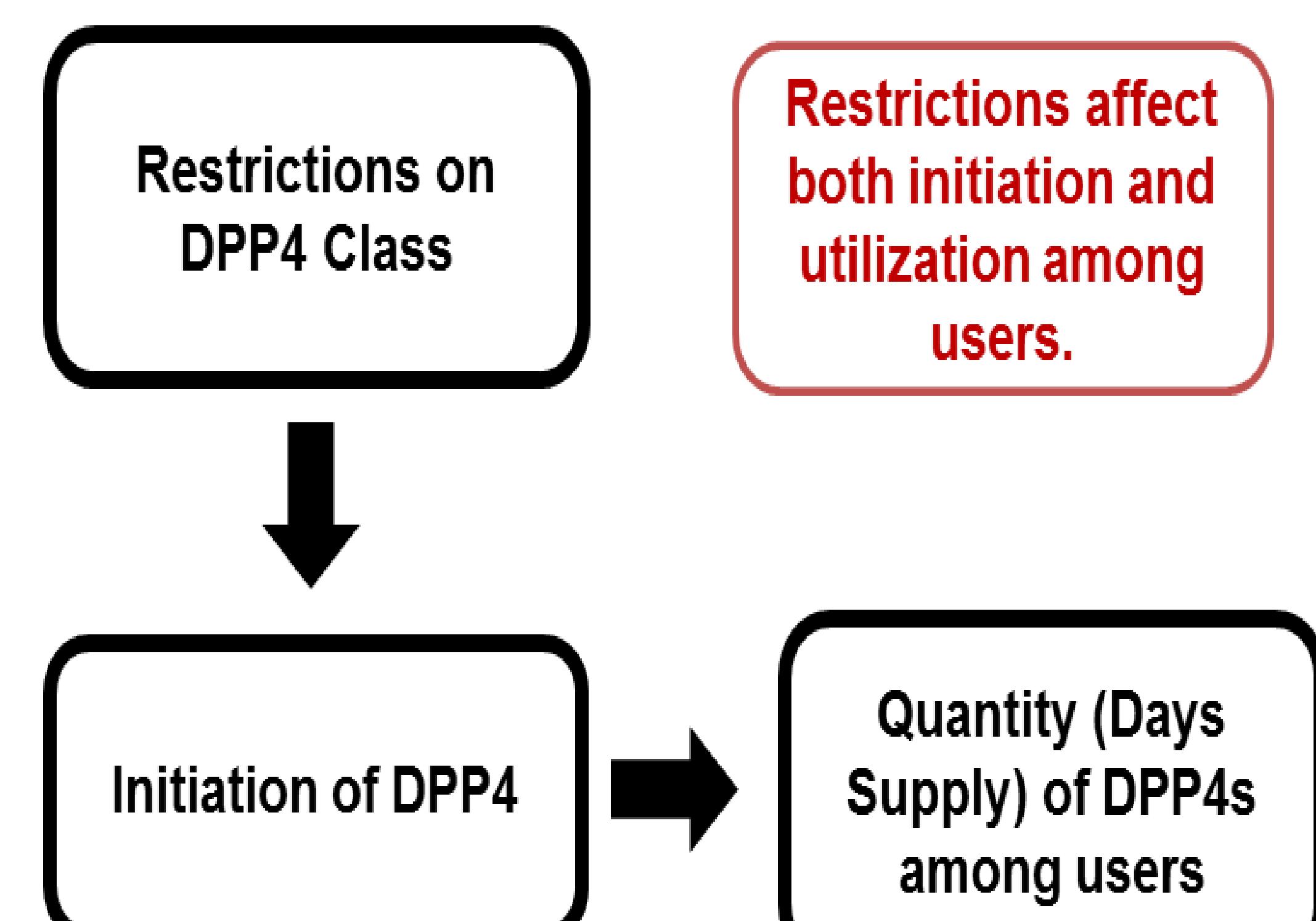
### Objective and Conceptual Framework

**Objective:** To examine the effect of formulary restrictions on the use of non-insulin antihyperglycemic drugs, with a focus on the DPP4 drug class.

**Hypothesis:** Formulary restrictions on the DPP4 drug class would result in:

- Decreased initiation of DPP4s as a second-line agent in current metformin users.
- Decreased utilization of DPP4 drugs among these DPP4 initiators.

Figure 1. Conceptual Framework.



### References

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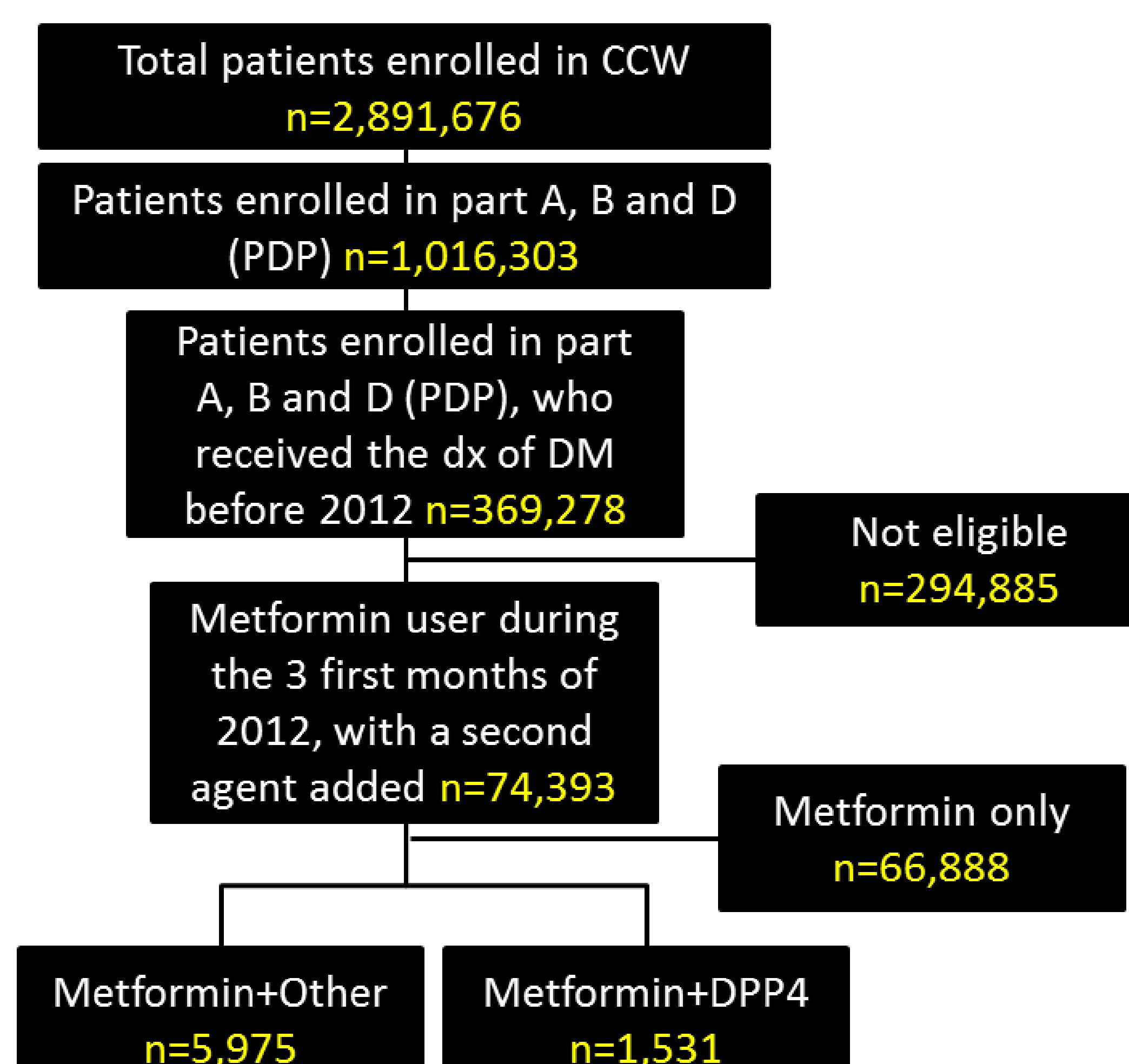
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### Methods

- Data:** 2012 Chronic Condition Data Warehouse 5% File (CCW) Medicare beneficiaries with a type 2 diabetes mellitus (T2DM) diagnosis prior to January 1, 2012 and whose only antihyperglycemic agent was metformin from January 1 – March 31, 2012.
- Part D prescription claims:** to identify antihyperglycemic drug exposure from April 1 – December 31, 2012: **metformin alone, metformin plus DPP4 (MET+DPP4) or metformin plus another non-insulin antihyperglycemic drug (MET+OTHER)**.
- Three possible formulary restrictions for DPP4s among the 337 formularies: **prior authorization, step therapy or formulary exclusion. (0: no drugs restricted, 1: 1 or more drugs restricted)**
- Logistic regression was used to measure the **association of restrictions in individual classes with initiation of a DPP4**. Multivariable linear regression was used to measure the **association of re-**

### Results

Figure 2. Cohort identification



- Of 74,393 eligible beneficiaries, **~90% took metformin alone, 2% took MET+DPP4 and 8% used MET+OTHER** (Figure 1).

Results of the logistic regression (Table 2) showed that **exclusion of DPP4s on formularies significantly decreased the odds of initiating DPP4s**.

- Among those who initiated DPP4s, **exclusion of one or more drugs on formularies was associated with a 19 day reduction in days supplied (p = 0.006)**. Step therapy on one or more DPP4s was associated with a 4 day reduction in days supplied, but this was not significant (Table 4).

Table 2. Odds ratio estimates of the use of DPP4 (n=1,531). Reference Group = other antihyperglycemic agent (n=5,975).

Effect	OR	95% CI
Exclusion DPP4	0.71	0.56 0.91
Step therapy DPP4	1.49	1.24 1.79
Exclusion Sulfonylurea	0.64	0.48 0.85
Step therapy Sulfonylurea	1.66	0.21 12.89
Prior authorization Sulfonylurea	0.93	0.71 1.21
Exclusion GLP1	1.02	0.80 1.30
Step therapy GLP1	0.88	0.74 1.05
Prior authorization GLP1	0.87	0.74 1.02

Adjusted for: Age, female, race, A1C test, admission to any facility, cancer, DM management class, ambulatory visit, eye exam, flu shot, glucose test, hypoglycemia, LDL test, long term complications, neurological symptoms, physician office visit, SNF admission, short term complications, and uncontrolled DM.

Table 1. Demographic Characteristics

	Metformin n=5,975	Metformin plus others n=1,531	p-value
Age (years)	10.5	10.6	0.17
Female	55.4%	60.2%	<0.001
Race			
White	74.1%	73.0%	
Black	14.3%	13.5%	
Hispanic	5.2%	6.7%	0.39
Other	6.5%	6.9%	
A1C test	8.9%	10.9%	0.02
Admission to any facility	2.0%	2.5%	0.15
Cancer	1.5%	1.9%	0.26
DM management class	0.3%	0.3%	0.39
Ambulatory visit	35.1%	41.1%	<0.001
Eye exam	3.2%	4.0%	0.11
Flu shot	1.8%	1.9%	0.89
Glucose test	1.2%	2.0%	0.01
Hypoglycemia	0.0%	0.0%	1.00
LDL test	6.3%	7.3%	0.18
Long term complications	3.5%	3.2%	0.64
Neurological symptoms	1.8%	2.0%	0.67
Physician office visit	24.2%	28.9%	<0.001
SNF admission	0.3%	0.7%	0.04
Short term complications	0.2%	0.3%	0.50
Uncontrolled DM	7.2%	9.1%	0.01

§ Fisher's exact test, for all the rest the default test was  $\chi^2$

Table 3. DPP4 days supplied, by restriction type in DPP4 users (n=1,531).

Variable	Observations	Mean	SD
Prior Authorization	Yes	3	157.0
	No	1528	124.1
Exclusion DPP4	Yes	1350	121.9
	No	181	141.3
Step therapy DPP4	Yes	375	121.7
	No	1156	125.0

SD Standard Deviation

Table 4. Multivariable regression results for DPP4 days supplied, by restriction type in DPP4 users (n=1,531).

Variable	Point Estimate	95% CI
Intercept	102.73	68.51 136.95
Exclusion DPP4	-18.91	-32.17 -5.66
Step therapy DPP4	-3.49	-13.34 6.35

Adjusted for: Age, female, race, A1C test, admission to any facility, cancer, DM management class, ambulatory visit, eye exam, flu shot, glucose test, hypoglycemia, LDL test, long term complications, neurological symptoms, physician office visit, SNF admission, short term complications, and uncontrolled DM.

### Conclusion

Formulary exclusion in the DPP4 class of antihyperglycemic agents decreased their uptake and decreased their utilization among DPP4 users.