Adherence and Persistence to Initial Add-On Type 2 Diabetes Therapy in Metformin-Experienced Patients

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Background

- According to the World Health Organization (WHO), the prevalence of diabetes has quadrupled globally, with the number of adults affected rising from 108 million in 1980 to 422 million in 2014, significantly impacting public health and healthcare costs.[1]
- Diabetes is ranked first in U.S. public healthcare spending, with the annual cost of diagnosed diabetes in the U.S. estimated at $413 billion in 2022, including $307 billion in direct healthcare costs.
- People with diagnosed diabetes incur an average medical expenditure of ~$16,750 per year, of which ~$9,600 is attributed to diabetes. Individuals with diabetes incur 2.3 times higher medical expenses compared to those without the disease.[2]
- In addition to socioeconomic considerations, high diabetes care costs contribute to medication nonadherence, with one in five adults with diabetes reporting skipping doses or delaying prescriptions due to financial constraints.
- Nonadherence to the American Diabetes Association (ADA) guidelines is linked to increased healthcare expenditures, highlighting the need for care aligned with these guidelines to manage type 2 diabetes effectively.[3]Patients who receive nonadherence care have $4,031 higher total annual healthcare expenditures compared with their baseline year, whereas patients who received adherent care have $128 lower total annual healthcare expenditures compared with their baseline year.
- Improving medication adherence could lead to substantial cost savings, with estimates ranging from $661 million to $1.16 billion annually.[4]
- Current studies often overlook the economic burden of adherent diabetic patients, particularly in populations disproportionately affected by socioeconomic challenges. In addition, many studies do not address what other social determinants of health outside of socioeconomic status may affect adherence to diabetic medications.

Objective

To demonstrate the differences in adherence and persistence of ADA recommended add-on therapies to metformin monotherapy for the treatment of T2DM.

Methods

Study Design	Retrospective Cohort Study
Data Source	Moda Health Database
Study Cohorts	Based on add-on therapy: • Dipeptidyl Peptidase IV Inhibitors (DPP) • Glucagon-like Peptide-1 Agonist (GLP) • Sodium-Glucose Cotransporter-2 Inhibitors (SGLT) • Sulfonylureas (SU) • Thiazolidinediones (TZD)
Inclusion Criteria	All members with at least one claim for a targeted antidiabetic medication during the claim evaluation window
Exclusion Criteria	• Index date outside of the enrollment period • Multiple target medications on the index date • No claims for metformin during the baseline period • Claims for other antidiabetic medications during the baseline period • Non-continuous pharmacy benefit enrollment during the baseline period • Non-continuous pharmacy benefit enrollment during the follow up period • Third party primary insurance coverage • Enrollment in Medicare supplemental insurance, discount card, or other unmanaged formulary plans • Under 18 years old at the beginning of the baseline period • Second line therapy other than those recommended by current ADA treatment guidelines • Has only one service date for the index agent during the follow up period
Baseline Characteristics	• Included age at index date, gender, ethnicity, geography, line of business (Commercial, Medicare, Medicaid), and health plan funding type. • The formulary tier and mean copay amounts for index agents were also reported, as well as the chronic disease score (CDS) and total baseline claims. • Atherosclerotic cardiovascular disease (ASCVD) risk, heart failure (HF), and chronic kidney disease (CKD) risks were assessed using outpatient pharmacy claim based on the presence of claims for medications in Table 1, as well as the total days supply. Per ADA guidelines, these disease states are important clinical characteristics to determine the appropriate selection of T2DM medication for patients. • ARNi, Ivabradine, and PSCK9 medications were initially included, but are not reported due to low patient counts.
Primary Outcomes	**Adherence:** • Proportion of Days Covered (PDC) was calculated as described by the PQA. The denominator was the number of days in the treatment period. The numerator is the number of days covered by at least one outpatient pharmacy claim for the index medication during the treatment period. Coverage is determined using the service date as the start of coverage. The end of coverage is the calculated by adding the days supply to the service date and subtracting one. • PDC Tier: PDC 0-50%: Low PDC >50%, <80%: Moderate PDC > 80%: High Persistence: Persistence to therapy was defined as the number of days from the first date of service to the end of the treatment period (time to discontinuation).
Data Analysis	All statistical testing was performed using BASE SAS software 9.4M8 and SAS/STAT 15.3. Differences in continuous variables were evaluated using ANOVA with Tukey's Honest Significant Difference test and differences in categorical variables were evaluated using the chi-squared test.

Figure 1. Claims Evaluation Window Timeline

Table 1. Cardiovascular Medications

Classification	Medications
ACE	Benazepril HCl, Captopril , Enalapril Maleate, Enalaprilat, Fosinopril Sodium, Lisinopril, Moexipril HCl, Perindopril Erbumine, Quinapril HCl, Ramipril, Trandolapril
ARB	Azilsartan Medoxomil, Candesartan Cilexetil, Irbesartan, Losartan Potassium, Olmesartan Medoxomil, Telmisartan, Valsartan
BBNonHF	Acebutolol HCl, Atenolol, Betaxolol HCl, Esmolol HCl, Esmolol HCl-Sodium Chloride, Labetalol HCl, Labetalol HCl-Dextrose, Labetalol HCl-Sodium Chloride, Metoprolol Tartrate, Nadolol, Nebivolol HCl, Pindolol, Propranolol HCl, Propranolol HCl Sustained-Release Beads, Sotalol HCl, Sotalol HCl (AFIB/AFL), Timolol Maleate
HTNCombo	Aliskiren-Hydrochlorothiazide, Amlodipine Besylate-Benazepril HCl, Amlodipine Besylate-Olmesartan Medoxomil, Amlodipine Besylate-Valsartan, Amlodipine-Valsartan-Hydrochlorothiazide, Atenolol & Chlorthalidone, Azilsartan Medoxomil-Chlorthalidone, Benazepril & Hydrochlorothiazide, Bisoprolol & Hydrochlorothiazide, Candesartan Cilexetil-Hydrochlorothiazide, Captopril & Hydrochlorothiazide, Enalapril Maleate & Hydrochlorothiazide, Fosinopril Sodium & Hydrochlorothiazide, Irbesartan-Hydrochlorothiazide, Lisinopril & Hydrochlorothiazide, Losartan Potassium & Hydrochlorothiazide, Methyldopa & Hydrochlorothiazide, Metoprolol & Hydrochlorothiazide, Olmesartan Medoxomil-Amlodipine-Hydrochlorothiazide, Olmesartan Medoxomil-Hydrochlorothiazide, Perindopril Arginine-Amlodipine Besylate, Propranolol & Hydrochlorothiazide, Quinapril-Hydrochlorothiazide, Telmisartan-Amlodipine, Telmisartan-Hydrochlorothiazide, Trandolapril-Verapamil HCl, Valsartan-Hydrochlorothiazide
HTNOther	Amlodipine Benzoate, Amlodipine Besylate, Chlorothiazide, Chlorothiazide Sodium, Chlorthalidone, Clonidine, Clonidine HCl, Doxazosin Mesylate, Hydrochlorothiazide, Indapamide, Metolazone, Nifedipine
Nitro	Nitroglycerin
Platelet	Aspirin, Cangrelor Tetrasodium, Clopidogrel Bisulfate, Prasugrel HCl, Ticagrelor
ARNi	Sacubitril-Valsartan
BBHF	Bisoprolol Fumarate, Carvedilol, Carvedilol Phosphate, Metoprolol Succinate
IDH	Isosorbide Dinitrate-Hydralazine HCl
Ivabradine	Ivabradine HCl
Loop	Bumetanide, Ethacrynate Sodium, Ethacrynic Acid, Furosemide, Furosemide in Sodium Chloride, Torsemide
MRA	Eplerenone, Spironolactone
NDHPCCB	Diltiazem HCl, Diltiazem HCl Coated Beads, Diltiazem HCl Extended Release Beads, Diltiazem HCl in Dextrose, Diltiazem HCl in Sodium Chloride
Statin	Atorvastatin Calcium, Rosuvastatin Calcium, Fluvastatin Sodium, Lovastatin, Pitavastatin Calcium, Pitavastatin Magnesium, Pravastatin Sodium, Simvastatin
PCSK9	Inclisiran, Alirocumab, Evolocumab

Results

Table 2. Baseline Characteristics and Demographics

	Overall (n=3,357)	DPP (n=118)	GLP (n=1,514)	SGLT (n=733)	SU (n=868)	TZD (n=124)		
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	P	Pairwise
Line of business								
Commercial	2,912 (86.74%)	96 (81.36%)	1,377 (90.95%)	655 (89.36%)	690 (79.49%)	94 (75.81%)		
Managed Medicaid	226 (6.73%)	10 (8.47%)	92 (6.08%)	39 (5.32%)	69 (7.95%)	16 (12.90%)	**<.0001**	**DPP - GLP p 0.0001 GLP - SU p <.0001 GLP - TZD p <.0001 SGLT - SU p <.0001 SGLT - TZD p 0.0001**
Medicare	219 (6.52%)	12 (10.17%)	45 (2.97%)	39 (5.32%)	109 (12.56%)	14 (11.29%)		
Gender*								
Female	1,872 (55.76%)	66 (55.93%)	1,032 (68.16%)	327 (44.61%)	395 (45.51%)	52 (41.94%)	**<.0001**	**GLP - SGLT (-0.1767:-0.2565) p <.0001 GLP - SU (-0.1792:-0.2578) p <.0001 GLP - TZD (-0.0512:-0.1127) p <.0001**
Male	1,485 (44.24%)	52 (44.07%)	482 (31.84%)	406 (55.39%)	473 (54.49%)	72 (58.06%)		
Age								
Mean (Median) [SD]	56.0 (56.0) [13.1]	60.7 (60.0) [13.8]	52.0 (52.0) [12.2]	59.0 (58.0) [12.3]	59.7 (59.0) [13.3]	57.6 (56.0) [12.2]		
18-29	69 (2.06%)	1 (0.85%)	50 (3.30%)	6 (0.82%)	10 (1.15%)	2 (1.61%)		
30-39	276 (8.22%)	6 (5.08%)	186 (12.29%)	34 (4.64%)	45 (5.18%)	5 (4.03%)		
40-49	699 (20.82%)	21 (17.80%)	396 (26.16%)	124 (16.92%)	134 (15.44%)	24 (19.35%)	**<.0001**	**DPP - GLP p <.0001 GLP - SGLT p <.0001 GLP - SU p <.0001 GLP - TZD p 0.0023**
50-59	1,035 (30.83%)	28 (23.73%)	477 (31.51%)	229 (31.24%)	258 (29.72%)	43 (34.68%)		
60-64	426 (12.69%)	13 (11.02%)	169 (11.16%)	106 (14.46%)	120 (13.82%)	18 (14.52%)		
65 and older	852 (25.38%)	49 (41.53%)	236 (15.59%)	234 (31.92%)	301 (34.68%)	32 (25.81%)		
Index Agent Copay								
Mean (Median) [SD]	73.4 (75.0) [84.5]	73 (75) [74]	100 (75) [81]	114 (75) [92]	3 (0) [5]	5 (1) [8]	**<.0001**	**DPP - SU(51.388 :89.299) DPP - TZD(43.187 :92.879) GLP - DPP(8.2088 : 45.14) GLP - SU(88.792 :105.24) GLP - TZD(76.661 :112.75) SGLT - DPP(21.37 :59.697) SGLT - GLP(5.1656 :22.552) SGLT - SU(101.19 :120.57) SGLT - TZD(89.806 :127.33)**
Chronic Disease Score (CDS)								
Mean (Median) [SD]	6.70 (6.00) [3.15]	7.15 (7.00) [3.49]	6.48 (6.00) [3.20]	7.18 (7.00) [3.14]	6.65 (6.00) [3.00]	6.44 (6.00) [2.89]	**<.0001**	**SGLT - GLP(0.3181:1.0884) SGLT - SU(0.1083 : 0.967)**

*Nonbinary was not reported due to individuals in this category not meeting inclusion criteria

Table 3. Cardiovascular Pharmacy Claims

	Overall (n=3,357)	DPP (n=118)	GLP (n=1,514)	SGLT (n=733)	SU (n=868)	TZD (n=124)	
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	P
ACE	**1,007 (30.00%)**	**41 (34.75%)**	**370 (24.44%)**	**248 (33.83%)**	**303 (34.91%)**	**45 (36.29%)**	**<.0001**
ARB	795 (23.68%)	27 (22.88%)	338 (22.32%)	194 (26.47%)	209 (24.08%)	27 (21.77%)	0.2818
Beta Blocker HF	**552 (16.44%)**	**13 (11.02%)**	**184 (12.15%)**	**201 (27.42%)**	**136 (15.67%)**	**18 (14.52%)**	**<.0001**
HTNCombo	390 (11.62%)	17 (14.41%)	174 (11.49%)	87 (11.87%)	107 (12.33%)	5 (4.03%)	0.0800
HTNOther	329 (9.80%)	11 (9.32%)	140 (9.25%)	71 (9.69%)	95 (10.94%)	12 (9.68%)	0.7626
Loop Diuretics	**269 (8.01%)**	**5 (4.24%)**	**84 (5.55%)**	**99 (13.51%)**	**75 (8.64%)**	**6 (4.84%)**	**<.0001**
MRA	**197 (5.87%)**	**5 (4.24%)**	**89 (5.88%)**	**61 (8.32%)**	**38 (4.38%)**	**4 (3.23%)**	**0.0086**
NDHPCCB	80 (2.38%)	1 (0.85%)	30 (1.98%)	27 (3.68%)	21 (2.42%)	1 (0.81%)	0.0635
Nitro	71 (2.11%)	1 (0.85%)	30 (1.98%)	24 (3.27%)	15 (1.73%)	1 (0.81%)	0.1136
Platelet	197 (5.87%)	6 (5.08%)	75 (4.95%)	56 (7.64%)	53 (6.11%)	7 (5.65%)	0.1533
Statin	**2,033 (60.56%)**	**82 (69.49%)**	**746 (49.27%)**	**556 (75.85%)**	**572 (65.90%)**	**77 (62.10%)**	**<.0001**

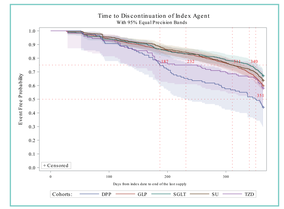
Table 4. Pairwise Comparisons for Significant Cardiovascular Pharmacy Claims

	Overall (n=3,357)	DPP (n=118)	GLP (n=1,514)	SGLT (n=733)	SU (n=868)	TZD (n=124)		
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	P	Pairwise
Any claims	2,808 (83.65%)	106 (89.83%)	1,167 (77.08%)	673 (91.81%)	759 (87.44%)	103 (83.06%)	**<.0001**	**GLP - SGLT (0.059:0.1481) p <.0001 GLP - SU (0.0759:0.1633) p <.0001 GLP - TZD (0.0109:0.0768) p 0.0035**
ACE	1,007 (30.00%)	41 (34.75%)	370 (24.44%)	248 (33.83%)	303 (34.91%)	45 (36.29%)	**<.0001**	**DPP - SGLT (0.061:0.1472) p 0.0001 GLP - SGLT (0.1824:0.2902) p <.0001 SGLT - SU (-0.235:-0.117) p <.0001 SGLT - TZD (-0.13:-0.038) p 0.0023**
Beta Blocker HF	552 (16.44%)	13 (11.02%)	184 (12.15%)	201 (27.42%)	136 (15.67%)	18 (14.52%)	**<.0001**	**DPP - SGLT (0.0547:0.1517) p 0.0043 GLP - SGLT (0.1589:0.3087) p <.0001 GLP - SU (0.0349:0.1951) p 0.0036 SGLT - SU (-0.203:-0.047) p 0.0018**
Loop Diuretics	269 (8.01%)	5 (4.24%)	84 (5.55%)	99 (13.51%)	75 (8.64%)	6 (4.84%)	**<.0001**	**SGLT - SU (-0.268: -0.07) p 0.0011**
MRA	197 (5.87%)	5 (4.24%)	89 (5.88%)	61 (8.32%)	38 (4.38%)	4 (3.23%)	**0.0086**	**DPP - GLP (-0.079:-0.029) p <.0001 GLP - SGLT (0.2031:0.2763) p <.0001 GLP - SU (0.1178:0.1938) p <.0001 SGLT - SU (-0.171:-0.066) p <.0001 SGLT - TZD (-0.147:-0.029) p 0.0013**
Statin	2,033 (60.56%)	82 (69.49%)	746 (49.27%)	556 (75.85%)	572 (65.90%)	77 (62.10%)	**<.0001**	**GLP - SGLT (0.059:0.1481) p <.0001 GLP - SU (0.0759:0.1633) p <.0001 GLP - TZD (0.0109:0.0768) p 0.0035**

Table 5. Adherence and Persistence to Index Agent

	Overall (n=3,357)	DPP (n=118)	GLP (n=1,514)	SGLT (n=733)	SU (n=868)	TZD (n=124)		
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	P	Pairwise
Adherence (PDC)								
Mean (Median) [SD]	0.824 (0.904) [0.206]	0.851 (0.928) [0.179]	0.792 (0.866) [0.211]	0.861 (0.940) [0.192]	0.839 (0.930) [0.206]	0.858 (0.950) [0.199]	**<.0001**	**DPP - GLP(0.0062 :0.1126) SGLT - GLP(0.0443 :0.0944) SU - GLP(0.0239 :0.0713) TZD - GLP(0.014 : 0.118)**
Adherent (PDC ≥ 80%)	2,361 (70.33%)	89 (75.42%)	981 (64.80%)	570 (77.76%)	625 (72.00%)	96 (77.42%)	**<.0001**	**GLP - SGLT (0.0937:0.1729) p <.0001 GLP - SU (0.0356:0.1164) p 0.0003 GLP - TZD (0.0144: 0.064) p 0.0044**
Persistence								
Mean (Median) [SD]	315 (365) [90]	281 (352) [103]	315 (365) [90]	320 (365) [90]	319 (365) [85]	299 (365) [104]	**<.0001**	**GLP - DPP(10.677 :57.536) SGLT - DPP(14.304 :62.934) SU - DPP(14.565 :62.668)**

Figure 2. Survival Plot: Persistence to Index Agent



Baseline & Demographic Characteristics (Table 2)

- A total of 3,357 patients were included, with 124 (3.69%) TZD, 868 (25.86%) SU, 118 (3.52%) DPP, 733 (21.83%) SGLT, and 1,514 (45.10%) GLP.
- There was a significant difference in line of business across cohorts, with 88.74% of included patients had commercial insurance, with 8.73% having Medicaid and 8.52% having Medicare (p <.0001). The GLP cohort had a significantly higher percentage of patients with commercial insurance compared to DPP, SU, and TZD (p <.0001). The SGLT cohort had significantly higher percentages of patients with commercial insurance compared to SU and TZD (p <.0001).
- A significant difference in gender was observed across cohorts, with a total of 1,872 (55.76%) of patients identifying as female and 1,485 (44.24%) of patients identifying as male (p<.0001). The GLP cohort had a significantly higher percentage of female patients compared to SGLT, SU, and TZD (p<.0001).
- Mean age and the distribution of age showed a significant difference across cohorts (p<.0001). The GLP cohort had a significantly lower mean age and difference in distribution of age compared to all other cohorts, including significantly higher percentages of patients between the ages of 18 and 49 (p<.0001).
- There was a significant difference in index agent copay across cohorts (p <.0001). The DPP cohort had significantly lower copays compared to SU and TZD. The GLP cohort has significantly higher copays compared to DPP, SU, and TZD. The SGLT cohort had a significantly higher copay compared to all other cohorts.
- A significant difference in chronic disease score (CDS) across cohorts was observed (p <.0001), with the SGLT cohort had significantly higher scores compared to GLP and SU cohorts.

Cardiovascular Pharmacy Claims (Tables 3 & 4)

- Significant differences in cardiovascular medications were observed across cohorts including ACE inhibitors (p<.0001), Beta Blockers indicated for heart failure (p <.0001), loop diuretics (p <.0001), mineralocorticoid receptor antagonists (MRA, p=.0086), and statins (p<.0001).
- A significant difference in percentage of patients having any cardiovascular pharmacy claims was observed across cohorts, (p <.0001), with the GLP cohort having a significantly lower percentage of patients with cardiovascular claims compared to DPP (p=.0013), SGLT (p <.0001), and SU (p <.0001), and the SGLT having a significantly higher percentage of patients with any cardiovascular claims compared to SU (p=0.0046) and TZD (p=.0021).
- The GLP cohort had significantly lower rates of ACE inhibitor pharmacy claims compared to SGLT (p <.0001), SU (p <.0001), and TZD (p=0.0035), significantly lower rates of loop diuretics compared to SU (p=0.0036), and significantly lower rates of statin claims compared to DPP, SGLT, and SU (p <.0001).
- The SGLT cohort had significantly higher rates of beta blocker pharmacy claims compared to DPP (p<.0001), GLP (p <.0001), SU (p <.0001), and TZD (p=0.0023), significantly higher rates of loop diuretics compared to DPP (p=0.0043), GLP (p<.0001), and SU (p=.0018), significantly higher rates of MRA claims compared to SU (p=.0011), and significantly higher rates of statin claims compared to GLP (p <.0001), SU (p <.0001), and TZD (p=.0013).

Adherence & Persistence (Table 5 and Figure 1)

- Mean PDC varied significantly across the cohorts (p <.0001) with the GLP cohort having a significantly lower mean PDC compared to all other cohorts, and a significantly lower proportion of members with a PDC >= 80% vs. SGLT (p <.0001), SU (p=.0003), and TZD (p=.0044).
- Mean persistence varied significantly across the cohorts (p <.0001), with the DPP cohort having significantly lower mean persistence compared to GLP, SGLT, and SU. Survival analysis of persistence suggests non-significant variance across groups.

Discussion

- Baseline characteristics, including cardiovascular agent use, significantly differ between cohorts, indicating diverse patient populations for different second-line diabetes therapies.
- GLP-1 receptor agonists had significant differences in demographic factors compared to the other cohorts including more frequent female gender, and lower mean age, lower rate of cardiovascular pharmacy claims suggesting that prescribing may depend on other factors outside of type 2 diabetes.
- High index agent copays were seen in GLP and SGLT cohorts, suggesting that cost may be a barrier to access for these agents for patients with a low socioeconomic status.
- Statistically significant differences in chronic disease scores may not be clinically significant due to the narrow range of values.
- Lower rates of cardiovascular pharmacy claims in the GLP cohort provides an opportunity to further explore why GLP users are not being prescribed first-line ASCVD medications that are usually recommended by the ADA guidelines.
- The similar rates of ACE inhibitors and ARBs between SGLT2 inhibitor and sulfonylurea users suggest that ADA guidelines for second-line therapy may not be the primary consideration, with other factors like cost, prescriber perception, and drug access potentially playing a role.
- Lower adherence rates in the GLP cohort provide an opportunity to further explore what demographic and nonclinical factors may affect lower adherence in GLP users compared to other second-line agents.
- Although statistically different, the survival analysis of persistence suggests that the persistence between the cohorts may not be clinically different.

Limitations

- Moda Health is a regional health plan and may not be representative of the entire U.S. population.
- Although medical claims were not used to confirm type 2 diabetes diagnosis, one or more pharmacy claims for T2DM medication have been shown to have high positive predictive value (97.3%) and specificity (99.8%) for T2DM, but lacks sensitivity (50.7%).5
- An analysis on behavioral and socioeconomic data and its relationship to adherence was not conducted but provides an area for future research to determine what factors may affect agent selection and adherence.

Conclusion

Adherence and persistence varied significantly among second-line add-on therapies for metformin-experienced patients. Baseline characteristics and demographic differences suggest that nonclinical factors may influence treatment selection and adherence. Further research is needed to understand how these factors impact adherence to add-on therapy. In addition, further research is needed to explore whether certain demographics or baseline characteristics drive the observed lower adherence rates with GLP-1 therapy, or if this is a broader issue inherent to the treatment class.

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