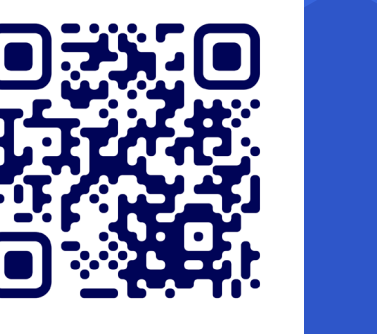


Type 1 and Type 2 Diabetes Mellitus Identification Using ICD-10-CM Codes Among New Users of Antidiabetics: A Real-World Study From Komodo Research Dataset

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Introduction

- ▶ Differentiating between type 1 (T1D) and type 2 (T2D) diabetes in observational research remains a persistent challenge due to mixed coding¹
- ▶ While the transition to ICD-10-CM¹ in 2015 was designed to improve diagnostic specificity in the U.S., the extent to which clinical practice has adopted these enhancements is unclear

Objectives

- ▶ To evaluate the real-world practice of T1D/T2D-specific ICD-10-CM codes
- ▶ Assess T1D/T2D-specific ICD-10-CM codes utility in improving patient classification for large-scale database analyses

Methods

- ▶ **Design:** A retrospective observational study
- ▶ **Data Source:** De-identified administrative claims from the Komodo Research Dataset

Komodo Research Dataset (KRD): Composed of administrative data and claims, KRD captures routinely collected health services utilization records for over 330 million de-identified unique individuals in the United States. Native to HIPAA-compliant, privacy-preserving tokens, KRD offers extended patient-level observations of medical encounters and outpatient pharmacy dispensings via linkage across medical and pharmacy insurance plans. Data availability is as early as 2016. Specialty datasets such as genomics, laboratory test results, and electronic health records are readily accessible via additional linkage. KRD is the optimized schema of the underlying Healthcare Map[®] from Komodo Health[®] for real-world evidence generation.

- ▶ **Study Population:** New users of common antidiabetics between January and December 2024, including:
 - ▶ Dipeptidyl peptidase-4 (DPP-4) inhibitors, sulfonylureas, sodium-glucose cotransporter-2 (SGLT-2) inhibitors, glucagon-like peptide-1 (GLP-1) receptor agonists, and insulin
- ▶ **Inclusion Criteria:**
 - ▶ At least 12 months of continuous medical and pharmacy health plan enrollment prior to index date (baseline period)
 - ▶ No prior use of the respective drug class
- ▶ **Exclusion:**
 - ▶ Patients with gestational diabetes codes (ICD-10: O24*)
- ▶ **Study Outcomes:**
 - ▶ Summarized baseline diagnoses for T1D (E10)* and T2D (E11*)
 - ▶ Evaluated mixed diagnosis patterns using a modified Klompas algorithm² isolated to the diagnostic coding criterion (>50% T1D-specific ICD-10 codes) while excluding medication and laboratory parameters

Figure 1: Study Design Diagram

Index Date

First claim of DPP-4 inhibitors, sulfonylureas, SGLT-2 inhibitors, GLP-1 receptor agonists, or insulin from January 1, 2024 to December 31, 2024

Days [0, 0]

Enrollment Assessment Window

Continuous medical and prescription drug insurance plan enrollment on index date and 365 days prior to index date (baseline period)
Days -365, 0

Exposure Washout Assessment Window

No claims for index treatment during the baseline period
Days -365, -1

No Gestational Diabetes:

Patients without ICD-10-CM codes for gestational diabetes during the baseline period or on index date
Days -365, 0

Diagnosis Patterns Assessment Window

T1/T2DM coding patterns and modified Klompas algorithm during the baseline period or on index date
Days -365, 0

January 1, 2023

December 31, 2024

¹International Classification of Diseases, Tenth Revision, Clinical Modification.

Results

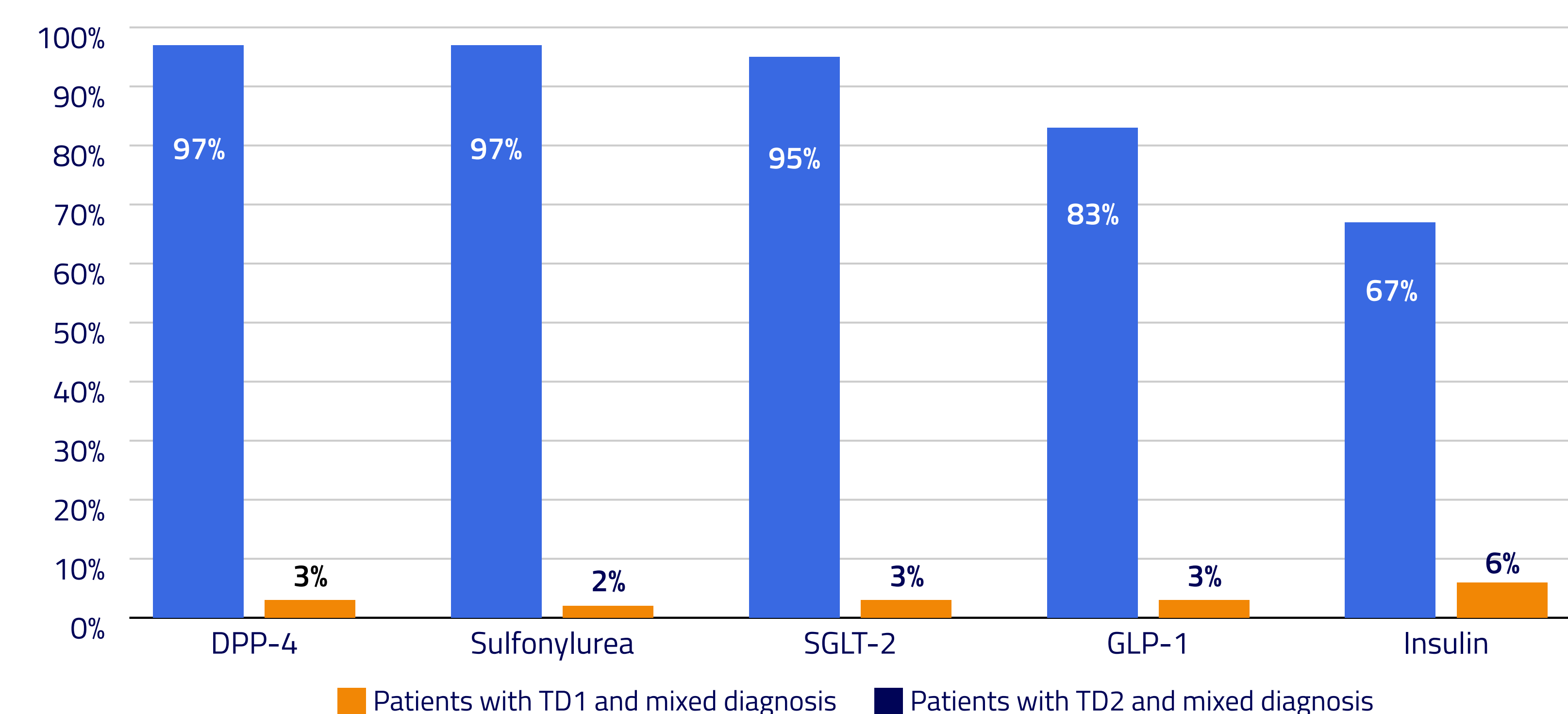
Table 1: Patient Counts

Criteria/Step	DPP-4 (N, %)	Sulfonylurea (N, %)	SGLT-2 (N, %)	GLP-1 (N, %)	Insulin (N, %)
1. Patients with antidiabetic treatment between January and December 2024; index date is first prescription fill date	1,730,707	5,121,134	7,140,705	8,641,116	7,627,477
2. Continuous medical and pharmacy enrollment during the 12 months prior to index date (baseline period) and on the index date	279,317 (16%)	769,114 (15%)	1,233,825 (17%)	1,653,099 (19%)	1,258,462 (17%)
3. No prior fills for respective antidiabetic treatment in step 1 during the 12-month baseline period	76,517 (27%)	146,741 (19%)	415,574 (34%)	709,805 (43%)	308,876 (25%)
4. No ICD-10-CM codes for gestational diabetes (O24*) during the 12-month baseline period or on the index date	76,375 (100%)	145,598 (99%)	414,792 (100%)	705,858 (99%)	292,993 (95%)

Table 2: Diagnosis Patterns During the Baseline Period or on Index Date

Diagnosis Patterns	DPP-4 (N, %)	Sulfonylurea (N, %)	SGLT-2 (N, %)	GLP-1 (N, %)	Insulin (N, %)
Total Patients (N)	76,375 (100%)	145,598 (100%)	414,792 (100%)	705,858 (100%)	292,993 (100%)
Neither T1D nor T2D codes	4,088 (5%)	9,961 (7%)	90,835 (22%)	331,862 (47%)	70,012 (24%)
T1D ICD-10-CM Assessment					
Patients with at least 1 T1D diagnosis	2,252 (3%)	3,116 (2%)	11,167 (3%)	14,222 (2%)	19,025 (7%)
Patients with at least 1 T2D diagnosis	2,188 (97%)	3,019 (97%)	10,585 (95%)	11,818 (83%)	12,788 (67%)
Patients with no T2D diagnosis	64 (3%)	97 (3%)	582 (5%)	2,404 (17%)	6,237 (33%)
T2D ICD-10 Assessment					
Patients with at least 1 T2D diagnosis	72,223 (95%)	135,540 (93%)	323,375 (78%)	371,592 (53%)	216,744 (74%)
Patients with at least 1 T1D diagnosis	2,188 (3%)	3,019 (2%)	10,585 (3%)	11,818 (3%)	12,788 (6%)
Patients with no T1D diagnosis	70,035 (97%)	132,521 (98%)	312,790 (97%)	359,774 (97%)	203,956 (94%)
Modified Klompas Algorithm					
Patients with mixed T1D/T2D diagnosis	2,188 (3%)	3,019 (3%)	10,585 (3%)	11,818 (2%)	12,788 (4%)
Modified Klompas algorithm: T1D:T2D ratio > 50%	246 (11%)	371 (12%)	2,206 (21%)	5,537 (47%)	10,509 (82%)

Figure 2: Patients With Mixed T1D/T2D Coding Among Initiators



Results

Figure 3: Klompas Algorithm — Confirmed T1D Among Patients With Mixed (T1D/T2D) Coding

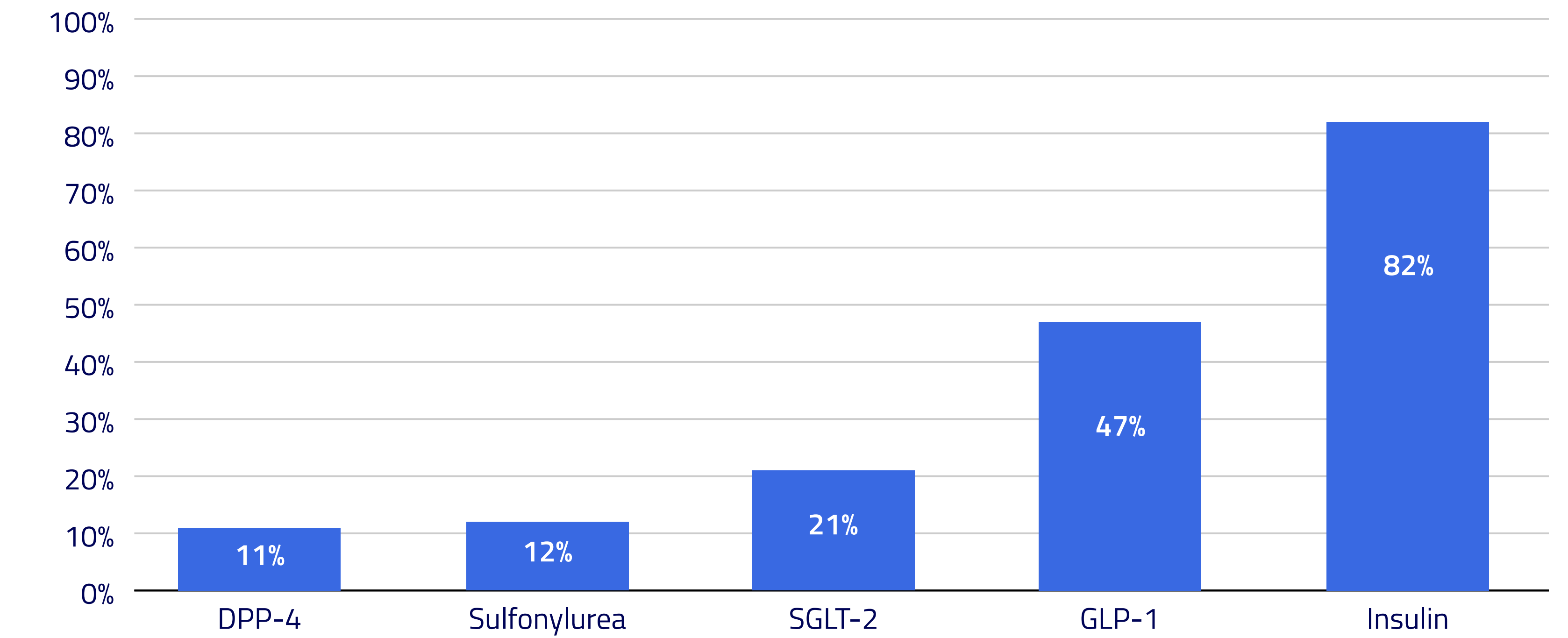
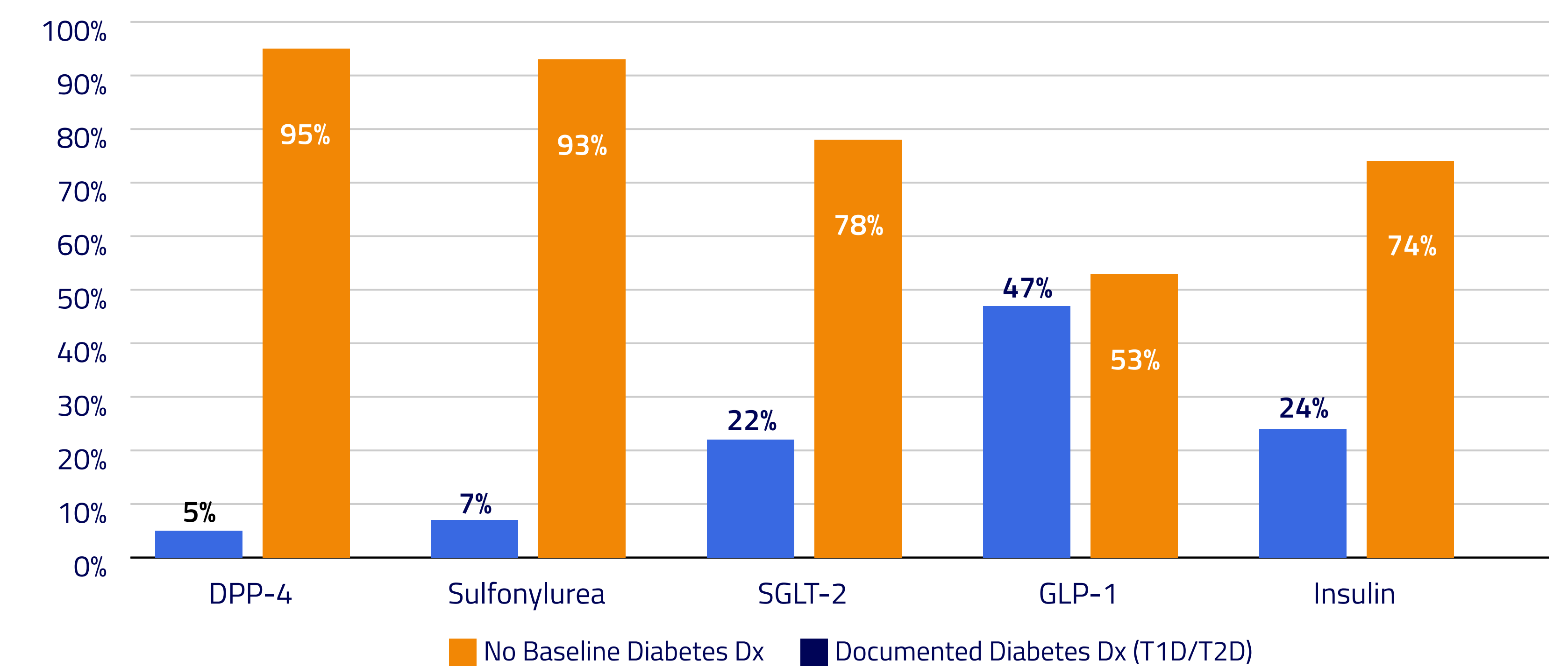


Figure 4: Baseline Diabetes Diagnosis Among Initiators



- ▶ Following all exclusion criteria, the final study cohorts consisted of **76,375** DPP-4 users, **145,598** sulfonylurea users, **414,792** SGLT-2 users, **705,858** GLP-1 users, and **292,993** insulin new users (Table 1).
- ▶ Respectively, **97%**, **97%**, **95%**, **83%**, and **67%** with T1D diagnosis were also coded with T2D diagnosis at baseline (Table 2, Figure 2).
 - ▶ Conversely, **3%**, **2%**, **3%**, **3%**, and **6%** with T2D diagnosis were also coded with T1D diagnosis at baseline (Table 2, Figure 2).
 - ▶ Among the mixed-diagnosed initiators, the modified Klompas algorithm narrowed down T1D assignment to **11%**, **12%**, **21%**, **47%** and **82%** (Table 2, Figure 3).
- ▶ Almost half (**47%**) of GLP-1 initiators had neither diabetes diagnosis at baseline, reflecting recent uptake for indications other than diabetes (Table 2, Figure 3).

Conclusions

- ▶ Compared with a similar assessment of ICD-9-CM in the literature,¹ mixed diagnosis patterns for diabetes patients remain in the U.S. healthcare system after the introduction of ICD-10-CM despite being observed significantly less often for patients with T2D diagnosis.
- ▶ Reasons other than code accuracy, such as off-label treatment intention, may be the driving factors behind the limited practice change among healthcare practitioners making a T1D diagnosis.

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