

Diabetes Mellitus (DM) Prevalence, Incidence, Drug Regimens and Insulin Therapy Cost by Type Among Four Million Commercially Insured Members Continuously Enrolled For 4.5 Years

K. L. Bowen¹, P. P. Gleason¹ ¹Prime Therapeutics LLC, Eagan, MN, United States.

No external funding provided for this research

Background

- Drug therapy for diabetes mellitus (DM) is a leading pharmacy cost category and cost driver for most insured populations. Many different therapeutic agents and possible treatment regimens are available.¹
- Health plans are now assessing the quality and cost impacts of new long-acting insulins including:
 - the first “follow-on” insulin glargine (Basaglar[®]) after Lantus[®] patent expiration,
 - a new higher-concentration form of insulin glargine (Toujeo[®]),
 - the novel insulin degludec as a single agent (Tresiba[®]) or in combination with a rapid-acting insulin (Ryxodeg[®]), and
 - two insulin/glucagon-like peptide 1 (GLP-1) receptor agonist combinations, insulin glargine/lixisenatide (LixiLan[®]) and insulin degludec/liraglutide (Xultophy[®]), whose Food and Drug Administration (FDA) approval is anticipated in mid-2016.

Objective

- To estimate the prevalence and trends in cost of drug therapy for Type 1 DM (T1) and Type 2 DM (T2) that includes insulin in order to support use and cost modeling of new insulin products.

Methods

- All commercially insured members in 12 health plans were selected who were continuously enrolled between Jan. 1, 2011 and June 30, 2015.
- All members were identified with a pharmacy claim (Rx) for any DM agent listed in Table 1.
 - Members with a medical claim ICD-9 diagnosis code (Dx) for gestational diabetes (648.0x) but none with a diagnosis code for T1 or T2 (250.xx) were excluded.
 - Members whose only DM agent was metformin (Metf) who had no DM diagnosis code were excluded.
 - The remaining members were categorized as T1 or T2 by the algorithm shown in Figure 1.²
- Incident cases of new DM drug therapy were defined as those with earliest study pharmacy claim was later than June 30, 2011.
- Diabetes pharmacy claim utilization for T1 and T2 members was characterized by the class(es) of diabetes agents for which members had pharmacy claims.
 - For each drug class, the number of members was determined by who had a pharmacy claim for any single agent drug in the class or combination drug containing an agent in the class.
 - The number of different classes of non-insulin diabetes agents (NIDAs) was determined for each member.
 - To describe cost by diabetes drug class, the cost of combination drugs was assigned to just one of the drug classes as indicated in footnote 3 of Table 2.
 - To describe diabetes drug cost as a proportion of total pharmacy cost, all pharmacy claim costs for study members was totaled in six month intervals.

Results

- There were 3,947,165 members in the sample, with a mean age of 39.4 years.
- 274,016 (6.9 percent) had a pharmacy claim for a diabetes drug during the 4.5 years. As shown in Figure 1, 15,011 (5.5 percent) were categorized as T1 and 226,639 (5.7 percent) as T2 patients who received diabetes drug therapy.
- The prevalence of drug therapy in the 4.5 year period for T1 or T2 by age groups was: under 18 years, 0.36 percent; 18 to 44 years, 2.5 percent; 45 to 64 years, 10.5 percent; and 65 to 74 years, 17.9 percent. These findings are consistent with estimates of the prevalence of diagnosed diabetes in the United States civilian non-institutionalized population from the National Health Interview Survey.³
- During quarters one and two of 2011, 13,234 T1 and 131,545 T2 patients had a diabetes pharmacy claim. The additional number treated at any point in the following four years calculates to an incidence rate per year of new T1 therapy of 12 per 100,000 and of new T2 therapy of 625 per 100,000 members.
- During quarters one and two of 2015, 15,011 of the 15,011 (100 percent) T1 patients and 190,305 of the 226,639 (84.0 percent) T2 patients had a diabetes pharmacy claim. 36,334 of the 226,639 patients (16.0 percent) with a history of diabetes pharmacy claims had none in the latest six month interval.
- Between quarters one and two of 2011 and quarters one and two of 2015:
 - The cost for all diabetes pharmacy claims for T1 and T2 patients increased 168 percent from \$106 million to \$285 million. This was an increase from 6.7 percent to 10.7 percent of the cost of all pharmacy benefit claims for the 3.9 million study members in the respective six month intervals.
 - The cost for all insulin pharmacy claims increased 200 percent from \$48 million to \$144 million. This was an increase from 3.0 percent to 5.4 percent of the cost of all pharmacy benefit claims for the 3.9 million study members in the respective six month intervals.
 - The cost for all pharmacy claims for the 3.9 million study members increased 66.5 percent from \$1.590 billion to \$2.648 billion.
 - The percentage of study members with any insulin use increased from 0.98 percent to 1.44 percent and the mean cost of insulin pharmacy claims per utilizing member increased 104.5 percent from \$1,239 to \$2,537.
- Table 2 shows the quarter one and two of 2011 and quarter one and two of 2015 percentages of study members and cost for all diabetes agents, and mean cost per utilizing member, by T1 patients vs. T2 patients using any insulin vs. T2 patients using only NIDAs, by class of diabetes agents and number of different NIDAs.

Limitations

- These results describe a continuously enrolled sample of members from a commercially insured population and may not be generalizable to other populations.
- By design, all members in the study sample aged 4.5 years over the course of the study.
- As accurate categorization of all utilizing members as T1 vs. T2 is not possible from claims data due to the high frequency of inconsistent diagnosis coding, these results reflect an unknown degree of misclassification.

Conclusions

- Over the past four years, the fraction of members in a commercially insured population using insulin increased 50 percent from about 1.0 percent to nearly 1.5 percent. The fraction of all pharmacy expense for insulin increased about 80 percent, from 3.0 percent to 5.4 percent. These increases were driven mostly by an increased number of members with type 2 diabetes treated with insulin and increased insulin cost.
- Recently approved insulins are substitutes for the observed use of basal insulin. The anticipated basal insulin/GLP-1 receptor agonist combinations would also be substitutes for current GLP-1 products. The impact of these new drugs on the cost of pharmacy benefits will be determined by their use and prices.

References

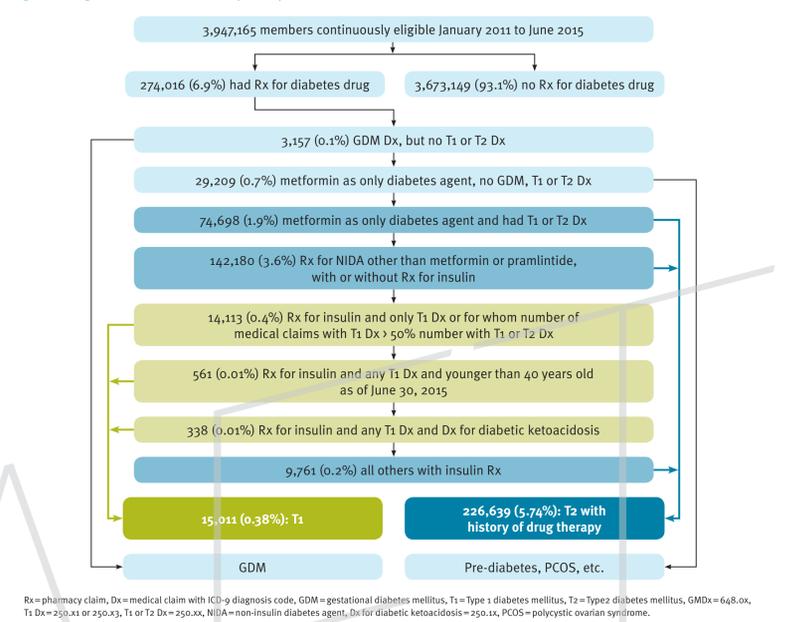
- American Diabetes Association. Approaches to glycemic treatment. Sec. 7. In Standards of Medical Care in Diabetes 2015. *Diabetes Care* 2015; 38 (Suppl. 1): S41-S48.
- Lo-Ciganic, W. et al. Identifying Type 1 and Type 2 diabetic cases using administrative data: a tree-structured model. *J Diabetes Science and Technology* 2011; 5 (3): 486-493.
- http://www.cdc.gov/diabetes/statistics/prev/national/figbyage.htm.

Table 1. Classes of Diabetes Agents Used by Study Members as Single Agents or in Combination Drugs

Drug class	
Insulins	
Basal	Insulin glargine, insulin detemir, insulin NPH
Rapid-acting	Insulin aspart, insulin lispro, insulin glulisine, inhaled regular insulin
Pre-mixed	70% NPA/30% aspart, 75% NPL/25% lispro, 70% NPH/30% regular, 50% NPL/50% lispro
Regular	Insulin regular (excluding inhaled)
Non-insulin diabetes agents	
Biguanides	Metformin*
Sulfonylureas	Glipizide*, glimepiride*, glyburide*, chlorpropamide*
Thiazolidinediones	Rosiglitazone, pioglitazone*
DPP-4 inhibitors	Sitagliptin, saxagliptin, linagliptin, alogliptin
GLP-1 receptor agonists	Exenatide, liraglutide, dulaglutide, albiglutide
SGLT2 inhibitors	Canagliflozin, dapagliflozin, empagliflozin
Meglitinides	Repaglinide*, nateglinide*
Alpha-glucosidase inhibitors	Acarbose*, miglitol
Amylin agonists	Pramlintide

NPH=Neutral Protamine Hagedorn, NPA=Neutral Protamine Aspart, NPL=Neutral Protamine Lispro, DPP-4=Dipeptidyl Peptidase IV, GLP-1=glucagon-like peptide 1, SGLT2=Sodium-glucose co-transporter 2.
*Agents available as generic drugs during all or part of the study period.

Figure 1: Algorithm Used to Classify Study Members as T1 or T2



Rx = pharmacy claim, Dx = medical claim with ICD-9 diagnosis code, GDM = gestational diabetes mellitus, T1 = Type 1 diabetes mellitus, T2 = Type 2 diabetes mellitus, GMDx = 648.0x, T1 Dx = 250.x1 or 250.x3, T1 or T2 Dx = 250.xx, NIDA = non-insulin diabetes agent, Dx for diabetic ketoacidosis = 250.1x, PCOS = polycystic ovarian syndrome.

Table 2. Percentages of Study Members and Cost for All Diabetes Agents, and Mean Cost Per Utilizing Member, by T1 vs. T2 Using Any Insulin vs. T2 Using Only NIDAs, by Class of Diabetes Agents and Number of Different NIDAs

Members' claims for diabetes drugs incurred in six month interval	T1DM or T2DM		T1DM		T2DM using any insulin		T2DM only using non-insulins	
	2011	2015	2011	2015	2011	2015	2011	2015
	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2
Any antihyperglycemic agents	100%	100%	100%	100%	100%	100%	100%	100%
Any insulin	26.6%	27.7%	100%	100%	100%	100%		
Basal insulins	18.3%	20.4%	46.8%	44.5%	80.1%	83.9%		
Rapid-acting insulins	15.1%	14.9%	94.5%	95.8%	36.8%	38.7%		
Pre-mixed insulins	3.1%	2.4%	4.2%	3.1%	15.6%	10.7%		
Regular insulin	1.0%	0.8%	3.0%	2.2%	4.3%	3.1%		
NIDA	85.7%	87.6%	4.9%	4.9%	67.6%	73.4%	100%	100%
Number of NIDAs in regimen:								
0 NIDAs	14.3%	12.4%	95.0%	95.1%	32.4%	26.6%	53.5%	53.6%
1 NIDA	45.0%	45.6%	5.0%	4.9%	30.0%	32.0%	32.3%	30.8%
2 different NIDAs	28.2%	27.7%			25.7%	26.7%	11.8%	12.2%
3 different NIDAs	10.4%	11.2%			10.0%	11.7%		
≥ 4 different NIDAs	2.1%	3.1%			1.9%	3.0%	2.4%	3.4%
Use of NIDA class:								
Biguanides	72.5%	75.6%	3.9%	4.5%	54.0%	57.6%	85.5%	87.9%
SU	30.6%	27.7%			26.2%	23.6%	35.5%	31.6%
TZD	16.6%	6.3%			15.8%	5.5%	18.9%	7.2%
DPP-4	13.5%	17.3%			12.1%	15.9%	15.5%	19.4%
GLP-1	5.9%	8.2%			7.8%	13.3%	6.2%	7.6%
SGLT2		11.0%				15.0%		11.0%
Meglitinides	0.8%	0.6%			1.4%	0.9%	0.8%	0.5%
AGI	0.3%	0.2%			0.3%	0.2%	0.3%	0.3%
Amylin agonists	0.3%	0.1%	1.1%	0.5%	1.1%	0.2%		

Members' claims for diabetes drugs incurred in six month interval	T1DM or T2DM		T1DM		T2DM using any insulin		T2DM only using non-insulins	
	2011	2015	2011	2015	2011	2015	2011	2015
	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2
Any antihyperglycemic agents	100%	100%	100%	100%	100%	100%	100%	100%
Any insulin	44.8%	50.7%	98.8%	99.4%	73.4%	74.7%		
Basal insulins	18.8%	25.1%	20.4%	22.1%	40.2%	44.7%		
Rapid-acting insulins	21.1%	20.7%	74.4%	73.7%	21.7%	21.1%		
Pre-mixed insulins	4.3%	3.7%	3.0%	2.2%	10.1%	7.0%		
Regular insulin	0.7%	1.2%	1.0%	1.3%	1.4%	2.0%		
NIDA	55.2%	49.3%	1.2%	0.6%	26.6%	25.3%	100%	100%
Number of NIDAs in regimen:								
0 NIDAs	9.1%	6.8%	1.2%	0.6%	4.7%	4.2%	15.9%	12.6%
1 NIDA	21.4%	18.5%			10.7%	9.7%	38.7%	37.4%
2 different NIDAs	18.4%	16.5%			8.6%	8.1%	33.9%	34.0%
≥ 4 different NIDAs	6.2%	7.5%			2.6%	3.2%	11.5%	16.0%
Use of NIDA class:								
Biguanides	4.0%	4.2%	0.1%	0.1%	1.6%	1.7%	7.5%	9.2%
SU	2.2%	1.0%			1.0%	0.4%	4.1%	2.3%
TZD	22.4%	0.9%			10.0%	0.3%	41.5%	2.0%
DPP-4	15.6%	18.6%			6.4%	7.2%	29.3%	40.8%
GLP-1	9.5%	12.9%			5.8%	8.9%	16.3%	23.2%
SGLT2		11.3%				6.5%		22.1%
Meglitinides	0.7%	0.2%			0.6%	0.1%	1.1%	0.3%
AGI	0.1%	0.0%			0.0%	0.0%	0.1%	0.1%
Amylin agonists	0.7%	0.2%	1.1%	0.5%	1.1%	0.2%	0.1%	

Members' claims for diabetes drugs incurred in six month interval	T1DM or T2DM		T1DM		T2DM using any insulin		T2DM only using non-insulins	
	2011	2015	2011	2015	2011	2015	2011	2015
	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2	Q1&2
Any antihyperglycemic agents	\$735	\$1,386	\$1,386	\$2,673	\$1,596	\$3,338	\$449	\$705
Any insulin	\$1,239	\$2,537	\$1,368	\$2,657	\$1,171	\$2,494		
Basal insulins	\$755	\$1,705	\$603	\$1,328	\$802	\$1,777		
Rapid-acting insulins	\$1,027	\$1,932	\$1,091	\$2,056	\$940	\$1,822		
Pre-mixed insulins	\$1,023	\$2,153	\$983	\$1,966	\$1,028	\$2,173		
Regular insulin	\$490	\$2,026	\$463	\$1,631	\$500	\$2,126		
NIDA	\$473	\$780	\$346	\$337	\$629	\$1,150	\$449	\$705
Number of NIDAs in regimen:								
0 NIDAs								
1 NIDA	\$149	\$206	\$344	\$337	\$250	\$436	\$133	\$166
2 different NIDAs	\$558	\$929			\$667	\$1,219	\$538	\$858
3 different NIDAs	\$1,307	\$2,037			\$1,379	\$2,317	\$1,292	\$1,962
≥ 4 different NIDAs	\$2,174	\$3,341			\$2,158	\$3,589	\$2,177	\$3,280
Use of NIDA class:								
Biguanides	\$40	\$78	\$47	\$84	\$46	\$100	\$39	\$74
SU	\$53	\$52			\$63	\$62	\$52	\$50
TZD	\$990	\$190			\$1,005	\$160	\$987	\$197
DPP-4	\$850	\$1,486			\$851	\$1,508	\$850	\$1,481
GLP-1	\$1,177	\$2,173			\$1,201	\$2,229	\$1,170	\$2,145
SGLT2		\$1,422				\$1,434		\$1,418
Meglitinides	\$656	\$396			\$725	\$398	\$627	\$395
AGI	\$207	\$201			\$236	\$208	\$198	\$199
Amylin agonists	\$1,528	\$3,157	\$1,377	\$2,718	\$1,583	\$3,636	\$1,787	\$2,768

- NIDA=Non-insulin Diabetes Agent; SU=sulfonylurea; TZD=thiazolidinedione; DPP-4=DPP-4 inhibitor; GLP-1=GLP-1 receptor agonist; SGLT2=SGLT2 inhibitor; AGI=alpha-glucosidase inhibitor; T1DM and T2DM=classified by claims-based algorithm as Type 1 or Type 2 diabetes mellitus, respectively; Q1 & 2=January 1 to June 30 of specified year; Utilizing Member=member with claims during the six month interval that meet our criteria.
- Use of NIDA class "% of Study Members" = the percentage with a claim for any single agent drug in the named class or combination drug containing an agent in the named class.
- Use of NIDA class "% of Total Pharmacy Cost" assigns cost for combination drugs to just one of the drug classes as follows: Metformin, all cost for combination drugs assigned to the non-metformin component of the drug; SU=cost for SU and SU-Metf combinations; TZD=cost for TZD-Metf and TZD-SU combinations; DPP-4=cost for DPP-4-Metf and DPP-4+TZD combinations; SGLT2=cost for SGLT2-Metf and SGLT2+DPP-4 combinations; Meglitinide=cost for Meglitinide-Metf combinations.
- Mean Cost for Six Months per Utilizing Member=sum of assigned cost for class divided by total number of members with a claim for any agent in the drug class.