# Statin Use and Titration Patterns in the First Year Following a T2DM Diagnosis in Commercially Insured Populations

Anne C. Beaubrun, PhD,¹ Keri L. Monda, PhD,¹ Deborah Kim, MS,¹ Katherine Mues, PhD,¹ Charles A. Herzog, MD,² Robert S. Rosenson, MD³

<sup>1</sup>Center for Observational Research, Amgen Inc, Thousand Oaks, CA; <sup>2</sup>Chronic Disease Research Group, Minneapolis, MN; <sup>3</sup>Mount Sinai Icahn School of Medicine, New York, NY

# BACKGROUND

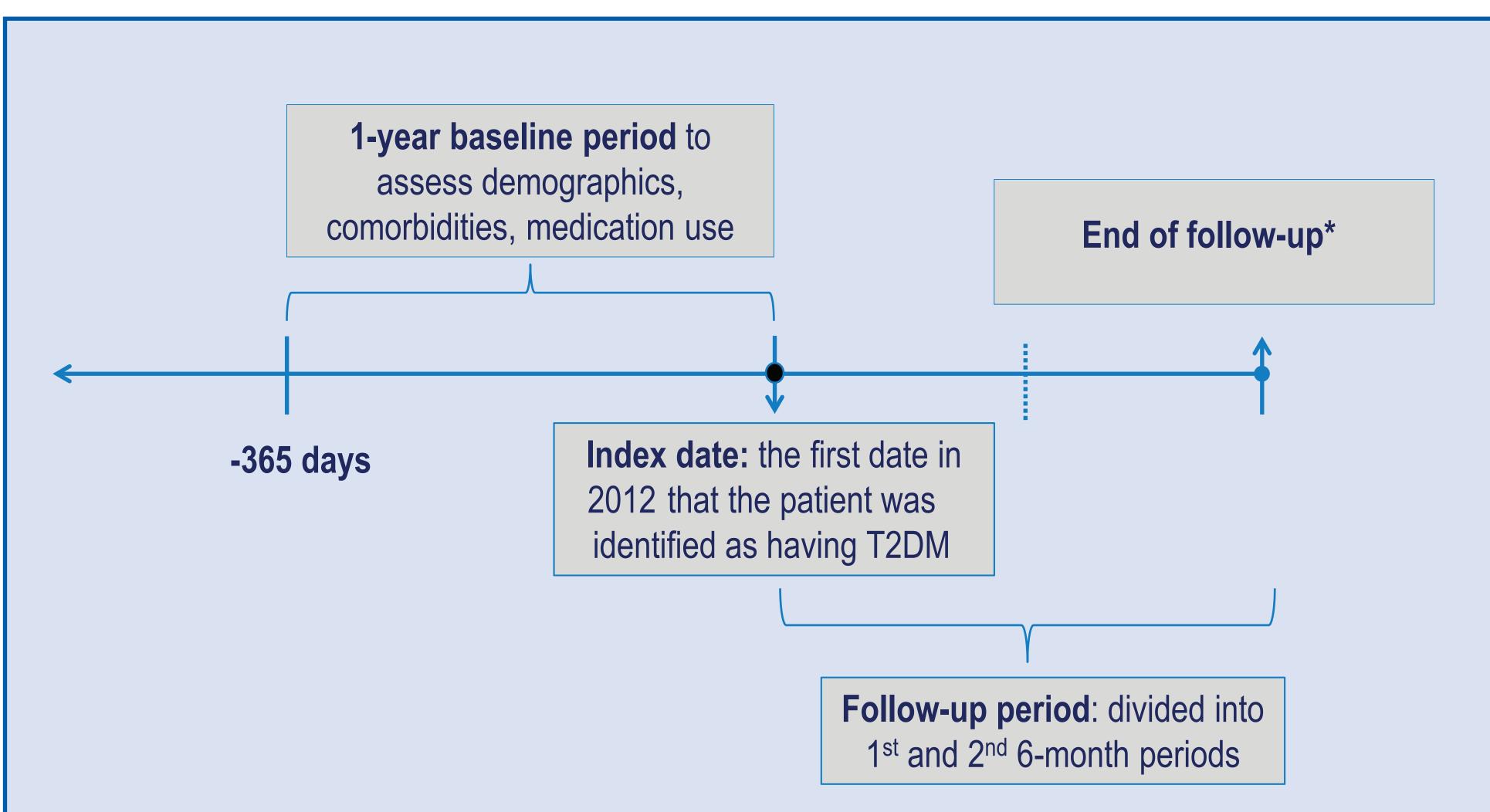
- Patients with type 2 diabetes mellitus (T2DM) are considered at high-risk of cardiovascular disease (CVD), yet little is known about statin use and titration patterns following T2DM diagnosis.
- Characterizing the real-world use and titration of statins can help to guide treatment strategies in this patient population.

# OBJECTIVES

- To identify and characterize the baseline demographics and comorbidities of beneficiaries from two commercial claims database who have been diagnosed with T2DM
- To describe real-world patterns of statin use and titration in the first year following T2DM index date (divided into the 1st and 2nd 6-month periods)

# METHODS

Figure 1. Study Design Schema



- The earliest of death, end of enrollment, or 365 days
- Retrospective Cohort Study Design
- Data source: MarketScan and Optum commercial claims databases
- Beneficiaries: > 18 years of age with ≥ 1 year of continuous coverage as of their index T2DM date
- ICD-9 diagnosis codes and National Drug Codes (NDC) were used to identify patients with T2DM:
- ≥ 1 inpatient or ≥ 2 outpatient ICD-9 Code (250.x0, 250.x2); and
- Medication fill for T2DM therapy (insulin and non-insulin)
- T2DM diagnoses were not restricted to incident diagnoses
- Low-density lipoprotein cholesterol (LDL-C) lowering therapy was defined as use of a statin, ezetimibe (alone or in combination with a statin), bile acid sequestrant, mipomersen, or lomitapide (identified using NDCs).
- Prevalent users of LDL-C lowering therapy were defined as using therapy at the time of their T2DM index date via overlapping days supply.
- Patients were followed for up to 365 days post-T2DM index date.
- Patients were followed for statin use and titration in the 1<sup>st</sup> and 2<sup>nd</sup> 6-month time periods following their T2DM index event.
- Intensity of statin therapies were determined using ACC-AHA guidelines1 (Table 1).

# METHODS (Continued)

Table 1. Statin Therapy Intensity

Statin Therapy	Low (mg/day)	Moderate (mg/day)	High (mg/day)
Atorvastatin	N/A	< 40	≥ 40
Rosuvastatin	< 10	$\geq$ 10 to < 20	≥ 20
Simvastatin	< 20	≥ 20 to < 80	≥ 80
Fluvastatin	< 80	≥ 80	N/A
Lovastatin	< 40	≥ 40	N/A
Pitavastatin	< 2	≥ 2	N/A
Pravastatin	< 40	≥ 40	N/A

### RESULTS

Table 2. Baseline Demographic Characteristics for Commercial Beneficiaries

with T2DM, 2012

	MarketScan		Optum	
	Overall population (N = 1,093,695)	On LDL-C lowering therapy* (N = 558,330)	Overall population (N = 469,861)	On LDL-C lowering therapy* (N = 240,279)
Age at index date, years, mean (SD)	60.8 (12.5)	63.2 (11.4)	64.8 (12.8)	66.7 (11.5)
Age categories, years, %				
18 – < 65	66.5	60.1	46.6	40.8
65 – < 75	18.7	22.3	29.7	33.3
≥ 75	14.8	17.6	23.7	25.9
Male, %	53.4	56.5	50.2	52.1
Geographic region, %				
Midwest	28.0	29.3	23.5	24.6
Northeast	15.7	16.2	9.9	10.7
South	38.8	36.5	49.5	47.2
West	16.0	16.5	15.6	16.0
Missing	1.6	1.5	0.0	0.0

\*Among those on LDL-C lowering therapy as of T2DM index date

Table 3. Baseline Comorbidities for Commercial Beneficiaries with T2DM, 2012

Comorbidities, %	Marke	MarketScan		Optum	
	Overall population (N = 1,093,695)	On LDL-C lowering therapy* (N = 558,330)	Overall population (N = 469,861)	On LDL-C lowering therapy* (N=240,279)	
Charlson Comorbidity Index					
< 0	16.5	14.2	10.6	8.5	
1 – 3	80.8	83.0	84.1	85.8	
≥ 4	2.7	2.8	5.4	5.7	
MI	1.0	1.3	1.2	1.5	
Unstable angina	0.9	1.1	0.6	0.8	
Ischemic stroke	1.0	1.2	1.2	1.3	
Hemorrhagic stroke	0.2	0.2	0.2	0.2	
Cerebrovascular disease	2.5	3.0	3.8	4.5	
TIA	0.7	0.8	0.7	8.0	
CABG/PCI	1.6	2.2	1.8	2.4	
PAD	2.5	2.8	4.5	5.1	
Previous T2DM diagnosis	81.5	84.1	87.6	89.9	
Hypertension	43.5	45.8	66.4	70.8	
Heart failure	4.3	4.8	7.3	7.9	
VTE	1.2	1.2	1.6	1.5	
Cancer**	5.0	5.2	5.7	5.8	
CKD (all stages)	8.2	9.1	13.0	14.2	

\*Among those on LDL-C lowering therapy as of the T2DM index date

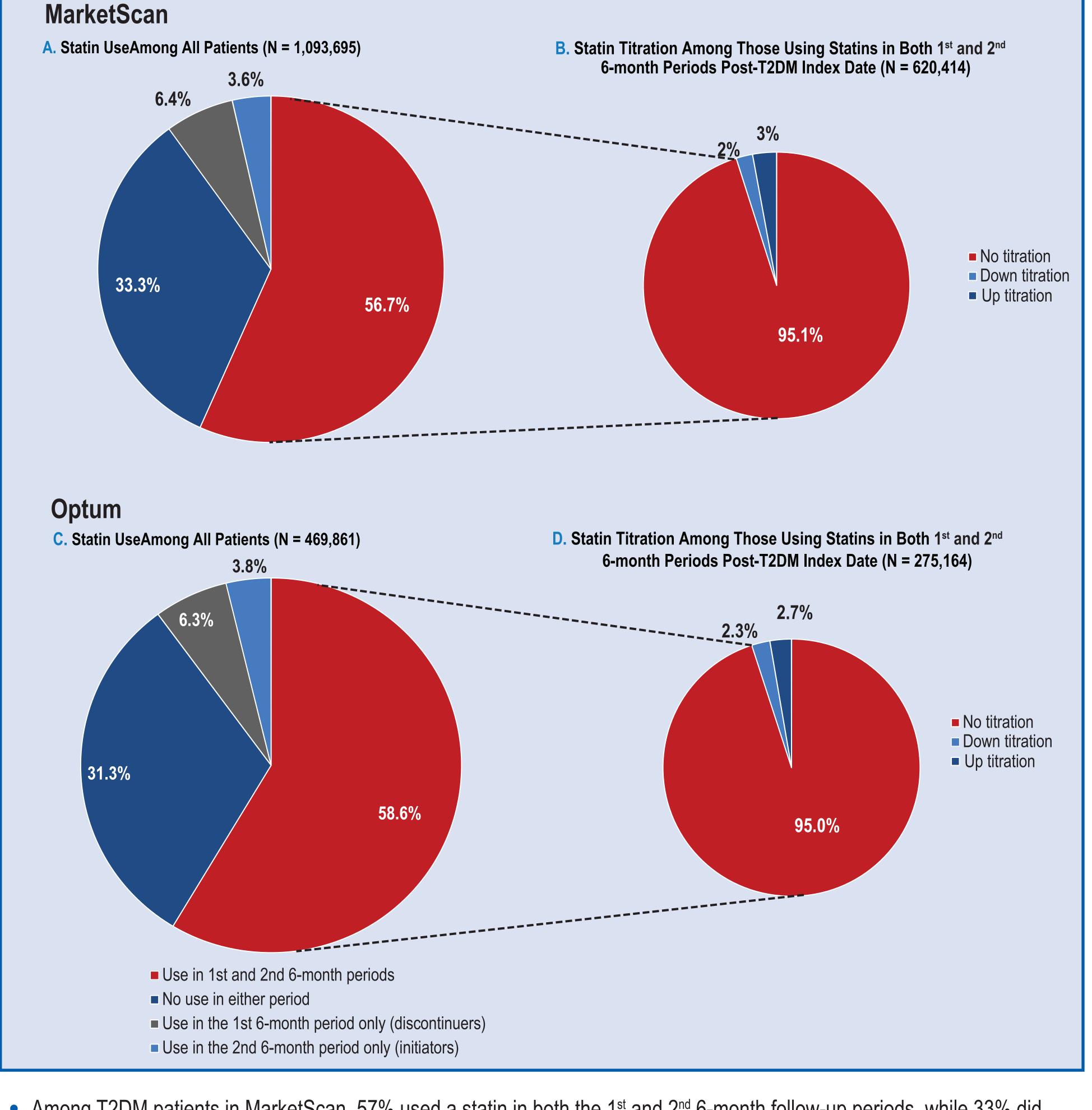
\*\*Excludes non-melanoma skin cancer

CABG/PCI, coronary artery bypass grafting/percutaneous coronary intervention; CKD, chronic kidney disease; MI, myocardial infarction; PAD, peripheral artery disease; TIA, transient ischemic attack; VTE, venous thromboembolism

# RESULTS (Continued)

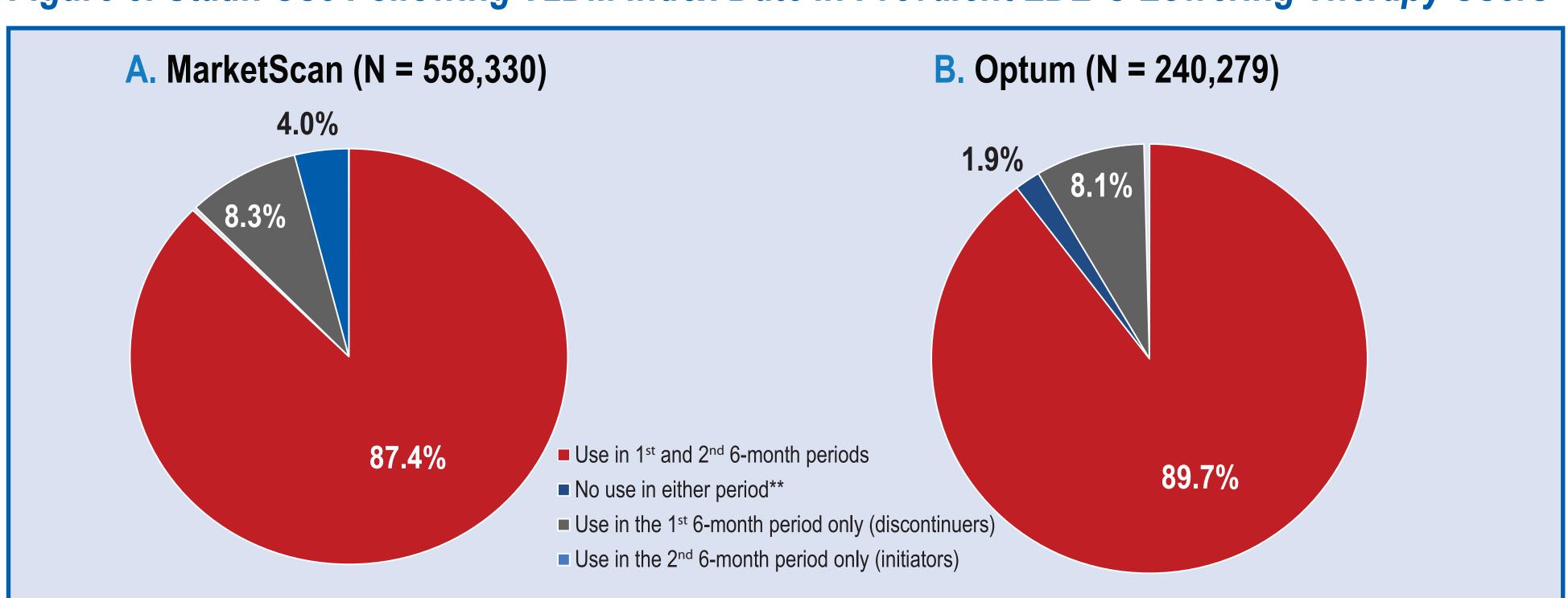
- In 2012, there were 1,093,695 and 469,861 patients identified with T2DM in MarketScan and Optum respectively.
- Those in MarketScan were slightly younger than those in Optum (mean age 60.8 years vs. 64.8 years, respectively).
  53.4% of T2DM patients in MarketScan and 50.2% in Optum were male (Table 2).
- Among T2DM patients, 558,330 (51%) in MarketScan and 240,279 (51%) in Optum were on an LDL-C lowering therapy as of the index date.
- 82% of T2DM patients in MarketScan and 88% of patients in Optum had a previous diagnosis of T2DM in the one-year baseline period (Table 3).
- The most commonly identified comorbidities were (Table 3):
- Hypertension: 44% in MarketScan and 66% in Optum
- CKD: 8% in MarketScan and 13% in Optum

Figure 2. Statin Use and Titration Patterns Among Beneficiaries with T2DM, MarketScan and Optum



- Among T2DM patients in MarketScan, 57% used a statin in both the 1<sup>st</sup> and 2<sup>nd</sup> 6-month follow-up periods, while 33% did
  not use a statin during either period (Figure 2A).
- Among T2DM patients in Optum, 59% used a statin in both the 1<sup>st</sup> and 2<sup>nd</sup> 6-month follow-up periods, while 31% did not use a statin during either period (Figure 2C).
- Among beneficiaries who used statins during both the 1st and 2nd 6-month follow-up periods:
- 95% showed no evidence of statin titration in either database (Figures 2B and 2D).
- Titration results were similar among patients already on an LDL-C lowering therapy as of their index date (data not shown).

#### Figure 3. Statin Use Following T2DM Index Date in Prevalent LDL-C Lowering Therapy Users\*



\* Prevalent users of LDL-C lowering therapy were defined as using therapy at the time of their index T2DM date via overlapping days supply.

\*\* Patients with no use in either period had no additional fills following the T2DM index date.

- Among T2DM patients who were on LDL-C lowering therapy as of their index date:

  87% in MarketScap and 90% in Optum used a statin during both follow-up periods (Figures 3A and
- 87% in MarketScan and 90% in Optum used a statin during both follow-up periods (Figures 3A and 3B).
- A small percent (4% in MarketScan, 2% in Optum) of those already on an LDL-C lowering therapy did not use a statin in either follow-up period.

### STRENGTHS AND LIMITATIONS

- Strengths
- These data cover ~1.5M covered individuals with T2DM in 2012, allowing researchers an opportunity to understand the real-world treatment patterns among a large commercially insured population.
- Follow-up time in the12 months following identification of T2DM allows for detailed investigation of use and titration patterns in relevant treatment intervals.
- Limitations
- Data among the commercial population may not be generalizable to beneficiaries covered by federal or state insurance programs.
- The algorithm may not accurately identify all patients with T2DM.
- We did not distinguish incident from prevalent T2DM patients, in whom treatment patterns may differ.
- While prescription drug fills are captured, it is not known whether the drug was actually taken by the intended recipient.
- LDL-C values are only available for a subset of patients with a T2DM in the database; thus, we were unable to
  evaluate whether the absence of titration in the follow-up period was consistent with guideline recomendations
  based on LDL-C levels.

#### CONCLUSIONS

- The results from this study highlight a potential treatment gap in a commercially insured T2DM population at high risk of CVD.
- Patients who were prevalent users of a LDL-C lowering therapy at the time of the T2DM index date were much more likely to use a statin in the follow-up period.
- Regardless of prevalent LDL-C lowering therapy use, the vast majority of patients receive no titration of their statin in the follow-up period, although a lack of titration may be appropriate.

# REFERENCES

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# DISCLOSURES

Anne C. Beaubrun, Keri L. Monda, Deborah Kim, Katherine Mues, Brian D. Bradbury: current or former employees and stockholders of Amgen; Charles A. Herzog: fees or honorarium from Amgen; consultancy from Amgen, Affymax, AbbVie, BMS, Fibrogen, GSK, Keryx, Matinas Bio Pharma, Medtronic, Relypsa, ZS Pharma, ClearView Healthcare; grants from Affymax, Amgen, Gilead, J&J, Zoll, DaVita; royalties from UpToDate; stock from Boston Scientific, J&J, GE, Merck; Robert S. Rosenson: grants from Amgen, AstraZeneca, Catabasis, Sanofi; advisory boards for Amgen, AstraZeneca, Eli Lilly, Regeneron, Sanofi; royalties from UpToDate

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