Obesity with Preexisting Cardiovascular Disease without Diabetes: Current Glucagon-Like Peptide-1 (GLP-1) Agonist Treatment Prevalence among 16 Million Commercially Insured Members

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BACKGROUND

- Glucagon-like peptide-1 (GLP-1) agonists have been shown to reduce weight, improve glycemia, and decrease the risk of adverse cardiovascular events in patients with diabetes.[1,2]
- All GLP-1s are FDA approved for type 2 diabetes mellitus (DM), and the GLP-1s semaglutide, liraglutide and, most recently, tirzepatide have products approved for weight loss treatment. Despite these approvals, there is still off-label use of DM specific GLP-1s for weight loss.[3]
- As GLP-1 indications for obesity grow, little is known about their impact on improving health outcomes. The SELECT study was the first cardiovascular outcomes study demonstrating superiority in major adverse cardiovascular events reduction for an antiobesity medication, semaglutide.[1,2]
- With the recent SELECT findings, little is known about commercially insured individuals' prevalence of the SELECT study target population: those with obesity and cardiovascular disease, without DM.[1] Even less is known about GLP-1 utilization within this subgroup. To address this gap in knowledge, the development of real-world evidence is necessary. This information helps inform health care decision makers of treatment prevalence and future-use potential, as GLP-1s treatment for secondary cardiovascular disease (CVD) prevention may receive an FDA approved indication.

OBJECTIVE

To identify the GLP-1 treatment prevalence and future-use potential among commercially insured members with obesity and cardiovascular disease, without DM, via integrated pharmacy and medical claims data.

Academy of Managed Care Pharmacy (AMCP) Annual Meeting, April 15 – 18, 2024, New Orleans, LA

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Sponsorship: Prime Therapeutics LLC

METHODS

- To obtain GLP-1 overall claims expenditure monthly trend from November 2022 to October 2023, all GLP-1 paid claims from the Prime Therapeutics' 16.3 million commercially insured member database were identified. The GLP-1 monthly claims allowed dollar amount per member per month (PMPM) was calculated by totaling the allowed amount paid to pharmacies, by month, divided by the overall membership. The allowed paid amount to the pharmacy is inclusive of all network discounts and member share; however, rebates or coupons are not included.

Identifying obesity with preexisting CVD without DM prevalence and GLP-1 treatment

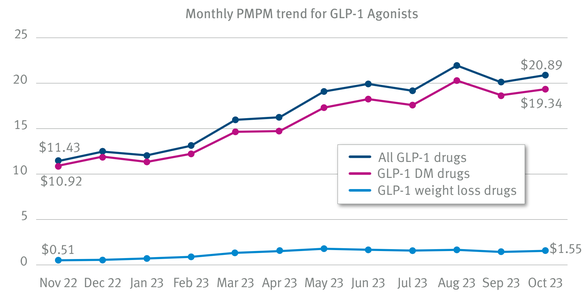
- Integrated medical and pharmacy claims from 16.3 million commercially insured members enrolled in November 2023 were queried from 07/01/2020 to 11/15/2023 to identify the current GLP-1 treatment prevalence among a population closely matched to the SELECT study criteria: age ≥45 years old, with obesity and CVD, without DM.
- Obesity was defined as one or more medical claims with an ICD-10 code for obesity or a Z-code with BMI ≥27. This definition of obesity includes those who are overweight with a BMI of 27 – 29, creating a more all-encompassing definition of obesity closely matching the SELECT study population.
- Further identification of study population included presence of one or more SELECT study specific CVD ICD-10 medical claims and the absence of any DM ICD-10 medical claims. Obesity ICD-10 medical claims include: E660, E661, E662, E668 and E669. BMI Z-code claims include Z68. DM ICD-10 medical claims include codes beginning with: E08, E09, E10, E11, E12 and E13. CVD ICD-10 medical claims include: ischemic heart disease (codes beginning with I20, I21, I22, I23, I24, I25, G45 and G46), cerebrovascular disease (codes beginning with I60, I61, I62, I63, I64, I65, I66, I67, I68 and I69), peripheral artery disease (codes beginning with I739), or a procedure code for percutaneous coronary intervention, drug eluting stent, or coronary artery bypass.
- A member currently utilizing a GLP-1 was defined as a weight loss specific GLP-1 product or DM specific GLP-1 product claim within 120 days of the 11/15/2023 analysis date. The specific products included in this analysis are the DM GLP-1 products dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide and tirzepatide and the weight loss GLP-1 products semaglutide and liraglutide. In addition to reporting current utilization within 120 days, GLP-1 utilization was expanded to report from 07/01/2021 through the 11/15/2023 analysis date.

LIMITATIONS

- Findings are limited to commercially insured members and may not be representative of members insured through government programs.
- Pharmacy and medical claims have the potential to be miscoded and include assumptions of members' actual drug use and diagnoses.
- Inclusion of specific CVD-related ICD-10 medical claims may differ slightly from the inclusion criteria of the SELECT study design.
- GLP-1 utilization may have been impacted by drug shortages.

FIGURE 1

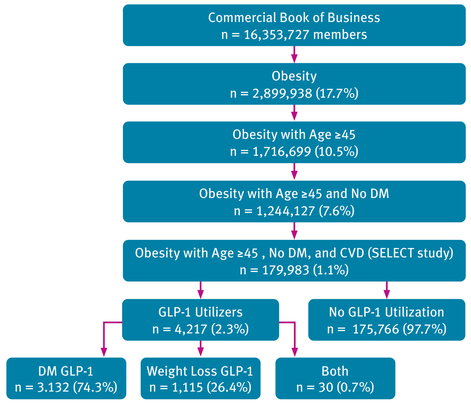
Monthly Per Member Per Month (PMPM) Trend for GLP-1 Agonists, November 2022 – October 2023



Monthly per member per month (PMPM) calculated for the Prime Therapeutics' 16.3 million commercially insured book of business from November 2022 to October 2023, by summing total paid amount for each indication-specific glucagon-like protein-1 (GLP-1) drug class in each month for enrolled members and dividing by the monthly membership. Diabetes mellitus (DM) GLP-1 drugs include products: dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide (injectable and oral formulations) and tirzepatide. Weight loss GLP-1 drugs include semaglutide and liraglutide. Total paid amount defined as amount paid pharmacy after network discount and member share, not inclusive of rebates or coupons.

FIGURE 2

SELECT Study[1] Population Member Identification and Current GLP-1 Utilization (within 120 days)



Medical claims were utilized to identify presence of obesity, diabetes mellitus (DM), and cardiovascular disease (CVD). Obesity was defined as one or more medical claims with an ICD-10 code for obesity or a Z-code with a body mass index (BMI ≥27), creating a more all-encompassing definition of obesity, including those who are overweight and closely matching the SELECT study population. See Methods for condition identification specifications. Diabetes glucagon-like peptide-1 (GLP-1) drugs include products: dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide (injectable and oral formulations) and tirzepatide. Weight loss GLP-1 drugs include semaglutide and liraglutide. Both DM and weight loss GLP-1 utilization was identified using paid pharmacy claims 120 days from analysis date, November 15, 2023. A member could potentially have multiple current claims for both a DM GLP-1 and weight loss GLP-1 as seen in the 0.7% utilization overlap.

TABLE 1

Population Characteristics

	N = 16,353,727 Commercially Insured Members
Age	
<45 years old ≥45 years old	10,201,049 (62.4%) 6,152,678 (37.6%)
Gender (male)	8,137,615 (49.8%)
DM	1,162,593 (7.1%)
Obesity	2,899,938 (17.7%)
CVD	789,264 (4.8%)
Obesity with Age ≥45	1,716,699 (10.5%)
Obesity with Age ≥45 without DM	1,244,127 (7.6%)
Obesity with Age ≥45, without DM, with CVD (SELECT study criteria)[1]	179,983 (1.1%)

Medical claims were utilized to identify presence of obesity, diabetes (DM) and cardiovascular disease (CVD). Obesity was defined as one or more medical claims with an ICD-10 code for obesity or a Z-code with a body mass index (BMI ≥27), creating a more all-encompassing definition of obesity, including those who are overweight and closely matching the SELECT study population. See Methods for condition identification specifications. The final SELECT study matched population included obesity with age ≥45, without DM, and with CVD.

TABLE 2

GLP-1 Utilization within SELECT Study[1] Specific Population

	07/01/2021 to Analysis Date, November 15, 20 23 (n = 179,922 matching SELECT Study Criteria)	Current or Within 120 Days of Analysis Date, November 15, 2023 (n = 179,983 matching SELECT Study Criteria)
GLP-1 Utilizers	**7,300 (4.1%)**	**4,217 (2.3%)**
DM GLP-1	5,330 (73.0%)	3,132 (74.3%)
Weight loss GLP-1	2,207 (30.2%)	1,115 (26.4%)
Both	234 (3.2%)	30 (0.7%)
No GLP-1 Utilization	**172,622 (95.9%)**	**175,766 (97.7%)**

DM glucagon-like peptide-1 (GLP-1) drugs include products: dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide (injectable and oral formulations) and tirzepatide. Weight loss GLP-1 drugs include semaglutide and liraglutide. Both DM and weight loss GLP-1 utilization was identified using either paid pharmacy claims from 07/01/2021 to analysis date, November 15, 2023 (column 1) and current paid pharmacy claims 120 days from analysis date, November 15, 2023 (column 2). A member could potentially have multiple current claims for both a DM GLP-1 and weight loss GLP-1 as seen in the 3.2% and 0.7% utilization overlap, respectively.

REFERENCES

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RESULTS

GLP-1 drug therapy utilization and overall expenditures among a commercial population (Figure 1)

- Overall GLP-1 utilizers among a monthly average membership of 16,316,811 commercially insured members grew from 174,519 (1.1%) in November 2022 to 304,385 (1.9%) in October 2023. This translates to a 77.4% increase in utilization over the span of one year.
- Overall GLP-1 PMPM increased from $11.43 in November 2022 to $20.89 in October 2023, an 82.8% increase over the span of the year.
- Diabetes specific GLP-1s comprised the majority of the total PMPM at the beginning and end of the time frame at 95.6% and 92.6%, respectively.
- Weight loss specific GLP-1s only comprised 4.4% and 7.4% of the total PMPM at the beginning and end of the time frame, respectively.

Study population characteristics and member identification (Table 1, Figure 2)

- Among 16,353,727 commercially insured members:
  - Obesity meeting SELECT study definition was identified in 2,899,938 (17.7%) members.
  - Obesity with age ≥45 years old was identified in 1,716,699 (10.5%) members.
  - Obesity with age ≥45 years old and without DM was identified in 1,244,127 (7.6%) members.
  - 179,983 (1.1%) of all members met the complete SELECT study criteria: obesity with age ≥45 years old, without DM, and with CVD.

GLP-1 utilization among SELECT study subgroup population (Table 2)

- GLP-1 utilization was found in 7,300 (4.1%) of the 179,922 members meeting SELECT study inclusion criteria (Age ≥45, Obesity, with CVD, without DM) at any time from 07/01/2021 to 11/15/2023.
  - 5,330 members (73.0%) utilized a DM specific GLP-1.
  - 2,207 members (30.2%) utilized a weight loss specific GLP-1.
  - 234 members (3.2%) had claims for both a DM and weight loss specific GLP-1. Note: Sum was greater than 100% due to some members with overlapping claims for both DM specific and weight loss specific GLP during the two+ year analysis period.
- GLP-1 utilization within the most recent 120 days was found in 4,217 (2.3%) of the 179,983 members meeting SELECT study inclusion criteria (Age >45, Obesity, with CVD, without DM).
  - 3,132 members (74.3%) were utilizing a DM specific GLP-1.
  - 1,115 members (26.4%) were utilizing a weight loss specific GLP-1.
  - 30 members (0.7%) had claims for both a DM and weight loss specific GLP-1. Note: Sum was greater than 100% due to some members with overlapping claims for both DM specific and weight loss specific GLP during the 120 day analysis period.

CONCLUSIONS

- In this large commercially insured population, 1 in 100 members meet the SELECT study criteria of age ≥45 years and BMI ≥27 or obesity diagnosis, with preexisting CVD and without DM.[1] Currently, only 1 in 43 of these members are receiving GLP-1 treatment.
- If all untreated SELECT study qualifying members receive treatment, at a $10,000 annual GLP-1 cost per individual treated, there would be $8.96 in new per member per month (PMPM) expenditures. Health plans and self-insured employers should plan for substantial new PMPM costs due to the SELECT study findings and potential expanded role in secondary CVD prevention.
- At more than $20 PMPM, the GLP-1 drug class expenditure has increased drastically, by over 80%, from late-2022 to late-2023, with the majority contributor being DM specific GLP-1 drugs. GLP-1 drug products indicated exclusively for DM have shown increasing utilization in the off-label treatment of obesity, as evidenced in this study.