Trulicity (dulaglutide)-Dossier

Maryland Prescription Drug Affordability Board

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MARYLAND
Prescription Drug Affordability Board

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Cost Review Study Dossier - Trulicity (dulaglutide)

Introduction

To the extent practicable, and in compliance with COMAR 14.01.04.05B, staff has assembled the data and analyses specified by Health-General Article §21-2C-09(b), Annotated Code of Maryland, and the regulations for consideration by the Board in conducting its cost review study.

Section 1: Background

The table below displays a list of all possible NDC-11 codes associated with Trulicity (proprietary name) and dulaglutide (non-proprietary name).[1] The NDC-11 codes were identified by staff through searching the RxNorm database.[2]

Table 1. NDC List

National Drug Code	Proprietary Name	Non-Proprietary Name	Dosage-Strength
54568-0433-63	Trulicity	Dulaglutide	0.75 MG/0.5 ML
54568-0433-71	Trulicity	Dulaglutide	0.75 MG/0.5 ML
54568-0434-63	Trulicity	Dulaglutide	1.5 MG/0.5 ML
54568-0434-71	Trulicity	Dulaglutide	1.5 MG/0.5 ML
00002-1433-61	Trulicity	Dulaglutide	0.75 MG/0.5 ML
00002-1433-01	Trulicity	Dulaglutide	0.75 MG/0.5 ML
00002-1433-80	Trulicity	Dulaglutide	0.75 MG/0.5 ML
50090-3484-00	Trulicity	Dulaglutide	0.75 MG/0.5 ML
50090-6453-00	Trulicity	Dulaglutide	0.75 MG/0.5 ML
00002-1434-61	Trulicity	Dulaglutide	1.5 MG/0.5 ML
00002-1434-01	Trulicity	Dulaglutide	1.5 MG/0.5 ML
00002-1434-80	Trulicity	Dulaglutide	1.5 MG/0.5 ML
50090-3483-00	Trulicity	Dulaglutide	1.5 MG/0.5 ML
50090-6456-00	Trulicity	Dulaglutide	1.5 MG/0.5 ML
00002-2236-61	Trulicity	Dulaglutide	3 MG/0.5 ML
00002-2236-01	Trulicity	Dulaglutide	3 MG/0.5 ML
00002-2236-80	Trulicity	Dulaglutide	3 MG/0.5 ML
50090-5467-00	Trulicity	Dulaglutide	3 MG/0.5 ML
50090-6571-00	Trulicity	Dulaglutide	3 MG/0.5 ML
00002-3182-61	Trulicity	Dulaglutide	4.5 MG/0.5 ML
00002-3182-01	Trulicity	Dulaglutide	4.5 MG/0.5 ML
00002-3182-80	Trulicity	Dulaglutide	4.5 MG/0.5 ML

[1] The standard practice in published literature is to refer to drugs by the name of the molecule rather than the brand name of the drug. Staff has retained that convention. As a result, when discussing literature, Trulicity is referred to as dulaglutide.

[2] https://www.nlm.nih.gov/research/umls/rxnorm/index.html

Section 2: Clinical Information

Factor 2.1: Clinical information, including FDA indications and doses and information concerning standard medical practice.

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(i)
Methodology: Literature review
Data Sources: U.S. Food & Drug Administration (FDA) labels and clinical guidelines

Summary of Clinical Information

Table 2. Trulicity® (dulaglutide): FDA-approved indications and associated dosing regimen(s)[3]

Indication	*Dosing Regimen(s)*
As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.	**Adult dosing** **Initial dose** Inject 0.75mg subcutaneously once weekly **If additional glycemic control is needed, may titrate stepwise every 4 weeks to the following once weekly subcutaneous dosages:** 1.5mg 3mg 4.5mg (max dose) **Pediatric dosing** **Initial dose** Inject 0.75mg subcutaneously once weekly **If additional glycemic control is needed, may titrate after at least 4 weeks to the following once weekly subcutaneous dosage:** 1.5mg (max dose)
To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.	**Initial dose** Inject 0.75mg subcutaneously once weekly **If additional glycemic control is needed, may titrate stepwise every 4 weeks to the following once weekly subcutaneous dosages:** 1.5mg 3mg 4.5mg (max dose)

[3] Trulicity. Indianapolis (IN): Eli Lilly and Company; 2024 Nov. Package Insert. NDC 0002-1433-80.

Standard Medical Practice Recommendations

Trulicity® (dulaglutide) Place in Therapy for Diabetes Mellitus Type 2

Diabetes mellitus (DM) describes a group of chronic metabolic disorders of blood sugar, where the body both underuses and overproduces sugar resulting in high blood sugar. Underuse of blood sugar may be caused by either an inability of the body to make sufficient (or any) insulin, such as in Type 1 DM, or resistance to insulin as found in Type 2 DM.[4]

Trulicity and other medications in the GLP-1 RA class are recommended by the American Diabetes Association (ADA) and the American Association of Clinical Endocrinology (AACE) as one of the seven medication classes which may be used to lower blood sugar in patients with Type 2 DM.[5,6] The ADA does not specify an order of use preference; choice of medication class option is based on a variety of patient specific factors such as administration preference, cost, absolute ability to lower glucose, risk of low blood sugar, dosing frequency, etc. For treatment of glycemic control only, use of Trulicity, is equal to other therapeutic options indicated for Type 2 DM (such as insulin, metformin, sodium-glucose cotransporter-2 inhibitors (SGLT2i), sulfonylurea, etc).[7] The AACE similarly considers patient specific factors and explicitly prefers GLP-1 RA (or SGLT2i) for patients with overweight or obesity or at risk of low blood sugar.[8] These guideline recommendations are in line with other major society guidelines, including the American College of Physicians and the National Kidney Foundation Kidney Disease Improving Global Outcomes.[9,10]

In adult patients with Type 2 DM and *established cardiovascular disease (CVD)* (including prior heart attack, stroke or revascularization procedure) or multiple risk factors for CVD (including obesity, high blood pressure, protein in urine, smoking, high cholesterol), the ADA and AACE recommend the use of GLP-1 RA with proven benefit [Trulicity, Ozempic (semaglutide) and

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[4] American Diabetes Association Professional Practice Committee; 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S27–S49. https://doi.org/10.2337/dc25-S002.
[5] *Id.*
[6] Samson, Susan L. et al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update. Endocrine Practice, Volume 29, Issue 5, 305 – 340.
[7] *Id.* at 4
[8] *Id.* at 5
[9] Amir Qaseem, Adam J. Obley, Tatyana Shamliyan, et al; Clinical Guidelines Committee of the American College of Physicians. Newer Pharmacologic Treatments in Adults With Type 2 Diabetes: A Clinical Guideline From the American College of Physicians. Ann Intern Med.2024;177:658-666. [Epub 19 April 2024]. https://doi.org/10.7326/M23-2788.
[10] Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2022;102 (5S):S1–S127. https://doi.org/10.1016/j.kint.2022.06.008.

Victoza (liraglutide)] or SGLT2 inhibitors with proven benefit [Jardiance (empagliflozin) and Invokana (canagliflozin)] as first line therapy.[11,12] This recommendation is independent of the patient's use of other medications or glycemic control.

Though not separately indicated, in adult patients with Type 2 DM and *chronic kidney disease (CKD)*, the ADA recommends as first line therapy the use of GLP-1 RA with proven benefit [Ozempic (semaglutide) – proven benefit; Trulicity and Victoza (liraglutide) secondarily recommended due to renal benefits in cardiovascular outcome trials] or SGLT2 inhibitors with proven benefit [Farxiga (dapagliflozin), Jardiance (empagliflozin), Invokana [canagliflozin]) for control of blood sugars and slowing progression of CKD. This recommendation is independent of the patient's use of other medications or glycemic control. GLP-1 RA is preferred for glycemic management in patients with advanced CKD, eGFR <30ml/min/m^2, due to lower risk of hypoglycemia, and for cardiovascular event reduction. SGLT2 inhibitors are not preferred for eGFR <30/min/m^2 as they do not effectively lower glucose at this stage of renal dysfunction.[13] The AACE recommends as first line therapy the use of SGLT2 inhibitors for adult patients with Type 2 DM and CKD.[14] The KDIGO guidelines also recommend GLP-1 RA as second-line therapy after SGLT2i in patients with Type 2 DM and CKD.[15] Discordance in guideline recommendations for this subpopulation may be explained by the cadence in which the guidelines are updated to incorporate new literature and evidence. The ADA guidelines update yearly in January, while AACE guidelines where most recently updated in 2023 and KDIGO guidelines are from 2022 (note: updated KDIGO guidelines are expected in 2025).

Clinical use in DM Key Takeaway: GLP-1 RA is a preferred drug class in the treatment of Type 2 DM. GLP-1 RAs are typically considered as a first line therapy option for Type 2 DM given the overall safety (low risk of hypoglycemia), effectiveness in lowering blood sugar, and CKD and CVD benefits and protection. SGLT2 inhibitors have demonstrated similar outcomes and are an alternative first-line therapy. Metformin, a biguanide, is also considered first line therapy with effectiveness in lowering blood sugar, low hypoglycemia risk, and potential CVD benefit; but has not demonstrated benefit in progression of CKD. Trulicity, Ozempic (semaglutide) and Victoza (liraglutide) are the preferred choices in this class for medical professionals given their proven benefits for CVD and CKD. Trulicity and Ozempic (semaglutide) require less frequent injections (weekly) than Victoza (liraglutide, daily).

[11] *Id.* at 4
[12] *Id.* at 6
[13] *Id.* at 4
[14] *Id.* at 6
[15] *Id.* at 10

Factor 2.2: The disease burden of the condition that is treated by the prescription drug product

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(g)(ii)
Methodology: Literature review
Data Sources: Medical literature and clinical guidelines

Summary of Clinical Impact: Type 2 Diabetes Mellitus (DM)

Prevalence

- In the United States (US), 38.4 million (11.6%) people have diagnosed or undiagnosed diabetes mellitus (DM). [16,17] , Type 2 DM accounts for 90-95% of all diagnosed cases of diabetes. [18]
- In Maryland, the total age-adjusted percentage of adults aged 18 years or older with diagnosed diabetes was 10.5% in 2022.[19]

Incidence

- In 2021, 1.2 million adults were diagnosed with diabetes (rate of 5.9 per 1000 people).[20,21] Worth noting, 98 million adults, more than 1 in 3 people, have prediabetes (38% of adult US population).[22,23] In individuals 65 years or older, 48.8% have prediabetes.[24]
- In Maryland, the age-adjusted rate of adults aged 18 years or older with newly diagnosed diabetes was 7.8 per 1000 in 2022.[25]

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[16] Centers for Disease Control and Prevention. Diabetes in the US, a US Report Card [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2022 [cited 2025 Jan 4]. Available from: https://www.cdc.gov/diabetes/images/library/socialmedia/diabetesintheus_print.pdf
[17] Centers for Disease Control and Prevention. National Diabetes Statistics Report website [Internet]Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2024 [cited 2025 Jan 4]. Available from: https://www.cdc.gov/diabetes/php/data-research/index.html.
[18] *Id.* at 16
[19] United States Diabetes Surveillance System [Internet]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention. 2000 - [cited 2025 Jan 4]. Available from: https://gis.cdc.gov/grasp/diabetes/diabetesatlas-surveillance.html#.
[20] *Id.* at 16
[21] *Id.* at 17
[22] *Id.* at 16
[23] *Id.* at 17
[24] *Id.*
[25] *Id.* at 19

Comorbid Disease

- Based on global data from 2007-2017, 32.2% of persons with Type 2 Diabetes Mellitus have cardiovascular disease (CVD). In this report, 13% and 46% of the studies analyzed were from North America and Europe, respectively.[26]
- Type 2 Diabetes Mellitus contributes to the development and worsening of CVD as well as chronic kidney disease (CKD). A 2018 study of >500,000 US adults with Type 2 Diabetes Mellitus found that <10% had no associated cardiovascular or kidney disorder. CVD and CKD can initiate and perpetuate each other, leading to increased morbidity and mortality.[27]

Disease Severity

- Diabetes is classified into categories, including Type 1 (immune destruction of insulin producing pancreatic cells), Type 2 (non-immune progressive loss of insulin secretion, frequently with an inability of the body to use available insulin), gestational (diagnosed in 2nd or 3rd trimester of pregnancy and not present pre-pregnancy) and other causes.[28] The primary tool to assess glycemic status is the A1c test as it reflects the average blood glucose value over the preceding 2-3 months and is strongly linked to diabetes complications. Higher A1c values correspond to higher complication rates of diabetes.[29]

Cost of Illness/Financial Impact

- Total direct and indirect estimated costs of diagnosed diabetes in the US were $413 billion in 2022. Excess medical costs per person associated with diabetes were $12,022 in 2022.[30]
- In Maryland in 2021, total and per patient medical costs attributable to diabetes were $6.506 billion and $11,909, respectively.[31]

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[26] Einarson TR, Acs A, Ludwig C, Panton UH. Prevalence of cardiovascular disease in type 2 diabetes: a systematic literature review of scientific evidence from across the world in 2007-2017. Cardiovasc Diabetol. 2018 Jun 8;17(1):83. doi: 10.1186/s12933-018-0728-6. PMID: 29884191; PMCID: PMC5994068.

[27] Usman MS, Khan MS, Butler J. The Interplay Between Diabetes, Cardiovascular Disease, and Kidney Disease. In: Chronic Kidney Disease and Type 2 Diabetes. Arlington (VA): American Diabetes Association; 2021 Jun. Available from: https://www.ncbi.nlm.nih.gov/books/NBK571718/doi: 10.2337/db20211-13

[28] *Id.* at 4

[29] American Diabetes Association Professional Practice Committee; 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes—2025. Diabetes Care 1 January 2025; 48 (Supplement_1): S128–S145. https://doi.org/10.2337/dc25-S006.

[30] *Id*. at 17

[31] A. Khavjou, Olga; Sun, Minglu; R. D'Angelo, Sophia; J. Neuwahl, Simon; J. Hoerger, Thomas; Cho, Pyone; et al. (2024). Economic Costs Attributed to Diagnosed Diabetes in Each US State and the District of Columbia, 2021. American Diabetes Association. Figure. https://doi.org/10.2337/figshare.26351743.v1.

- In Maryland in 2021, diabetes-attributable total and per-person productivity losses due to morbidity were $3.4 billion and $6,224, respectively.[32]

Morbidity

- *In 2020,* about 16.8 million emergency department visits were reported with diabetes as any listed diagnosis among adults aged 18 years or older. Of these, 267,000 were for hyperglycemic crisis (11.4 per 1,000 adults with diabetes) and 202,000 were for hypoglycemia (8.6 per 1,000 adults with diabetes).[33]

[32] *Id.*
[33] *Id.* at 17

Table 3. Number and rate of hospitalizations per 1,000 adults aged 18 years or older with diabetes for selected causes, United States, 2019-2020[34]

Risk factor	2019 Number	2019 Crude rate per 1,000 (95% CI)	2020 Number	2020 Crude Rate per 1,000 (95% CI)
Diabetes as any listed diagnosis	**8,341,000**	**356.1 (337.0–375.3)**	**7,856,000**	**335.4 (316.5–354.4)**
Major cardiovascular disease	1,920,000	82.0 (77.4–86.5)	1,677,000	71.6 (67.4–75.8)
Ischemic heart disease	443,000	18.9 (17.8–20.0)	368,000	15.7 (14.7–16.7)
Stoke	346,000	14.8 (13.9–15.6)	321,000	13.7 (12.9–14.5)
Lower-extremity amputation	162,000	6.9 (6.5–7.3)	160,000	6.8 (6.4–7.2)
Hyperglycemic crisis	231,000	9.9 (9.3–10.4)	232,000	9.9 (9.3–10.5)
Diabetic ketoacidosis	205,000	8.8 (8.3–9.2)	206,000	8.8 (8.3–9.3)
Hyperosmolar hyperglycemic syndrome	26,000	1.1 (1.0–1.2)	26,000	1.1 (1.1–1.2)
Hypoglycemia	60,000	2.5 (2.4–2.7)	51,000	2.2 (2.1–2.3)

Notes: CI = confidence interval. Numbers rounded to the nearest thousand. Data sources: 2019 and 2020 National Inpatient Sample; 2019 and 2020 National Health Interview Survey.

- Among adults aged 18 years or older with diagnosed diabetes (data from 2017-2020), 39.2% had chronic kidney disease (CKD, stages 1–4), based on the updated 2021 CKD Epidemiology Collaboration (CKD-EPI) equation for estimated glomerular filtration rate (eGFR).[35]
- Diabetes is the leading cause of new cases of blindness for adults aged 18-64 years. In 2021, 10.1% of adults with diagnosed diabetes reported severe vision difficulty or blindness.[36]

Mortality

- Diabetes was the 8th leading cause of death in the US in 2021, based on 103,294 death certificates with diabetes as underlying cause (rate of 31.1 per 100,000 people).[37] Including diabetes as a contributing cause of death, the rate increases to 120.3 per 100,000 people (399,401 death certificates).[38]
- In Maryland, the age-adjusted rate of diabetes death and diabetes-related death in adults aged 18 years older was 33.5 and 145.5 per 100,000 people, respectively, in 2022.[39]

[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.* At 19

Section 3: Regulatory Approval and Market Context

Factor 3.1: Analysis of the prescription drug product's approval process

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(g)(ix)
Methodology: Review of databases and sites
Data Sources: FDA databases and manufacturer website

The FDA initially approved Trulicity (dulaglutide) on September 18, 2014, indicated to improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise.[40,41] Trulicity became the fifth GLP-1 agonist indicated for use in management in patients with type 2 diabetes, and the FDA did not convene an advisory committee because the application did not raise any new efficacy or safety issues that required advisory input.[42] No evidence was found to indicate that Trulicity had an accelerated approval pathway at any stage, and no orphan drug approvals were found.

Trulicity first received approval as a 0.75mg or 1.5mg pre-filled syringe or injectable pen, for use an adjunct treatment to diet and exercise to help improve glycemic control in adults with type 2 diabetes.[43] Trulicity reported that its efficacy had been compared to four commonly used type 2 diabetes medicines: metformin, Januvia®, Byetta® and Lantus®.

The FDA required Eli Lilly to conduct post-marketing studies for Trulicity:

> FDA is requiring post marketing studies for Trulicity to include a pediatric study to evaluate dosing, efficacy, and safety in pediatric patients; a study to evaluate toxicity in immature rats; a medullary thyroid carcinoma (MTC) case registry of at least 15 years duration to identify any increase in MTC incidence related to Trulicity; a clinical trial comparing Trulicity with insulin glargine on glycemic control in patients with type 2 diabetes and moderate or severe renal impairment; and a cardiovascular outcomes trial. These have been negotiated and agreed to by the applicant and are summarized in Dr. Jennifer Pippins memorandum.[44]

Eli Lilly has two post marketing commitments that are still active: (1) a trial to evaluate the impact of temporarily withholding dulaglutide and of fasting duration on retained gastric

[40] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/125469Orig1s000ltr.pdf?utm_source
[41] Eli Lily and Company announced the drug's U.S. pharmacy availability on November 10, 2014. https://investor.lilly.com/static-files/3ee44ef3-da08-41a8-be92-92b91c19c56f
[42] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000SumR.pdf
[43] https://investor.lilly.com/news-releases/news-release-details/fda-approves-trulicitytm-dulaglutide-lillys-once-weekly-therapy
[44] *Id.* at 42

contents (GLP-1 delays gastric emptying), and to inform methods to mitigate the risk of pulmonary aspiration of gastric contents (pending); and (2) a study to measure the incidence of medullary thyroid carcinoma associated with Trulicity (study was delayed in 2015, FDA found the delay to be for good cause, and is expected to be completed by 2030).[45,46]

Since initial approval, the FDA has approved 19 supplementary applications, including twelve updates to prescription information to reflect study results or known risks, two proposed updates to FDA REMS requirements, an authorization of use expansion to pediatric patients aged 10 and older with type 2 diabetes, a new indication for cardiac health, and an approval to administer higher doses.[47]

In February 2017, Trulicity gained approval for use in combination with basal insulin for treatment of diabetes, which Eli Lilly claimed made it the only GLP-1 receptor agonist approved for use in combination with mealtime or basal insulin.[48]

In February 2020, Eli Lilly gained approval for a new indication of Trulicity for the reduction of major adverse cardiovascular events in adults with type 2 diabetes.[49]

In September 2020, Eli Lilly gained FDA approval to use additional dosages for treatment of type 2 diabetes, after demonstrating that 3.0mg and 4.5mg doses demonstrated additional benefits.[50]

In November 2022, after satisfying its post-marketing commitment to study safety in pediatric patients, Trulicity received approval for use in children older than 10 with type 2 diabetes.[51]

Trulicity has a REMS action plan to mitigate the risk of medullary thyroid carcinoma and pancreatitis associated with Trulicity by informing providers about the risk.[52]

[45] https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm
[46] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/125469Orig1s000ltr.pdf
[47] Drugs@FDA Trulicity, BLA 125469
[48] https://investor.lilly.com/news-releases/news-release-details/lillys-truS-051
[49] https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine
[50] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/125469Orig1s036ltr.pdf
[51] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/125469Orig1s051ltr.pdf
[52] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000RiskR.pdf

Factor 3.2: Analysis of the prescription drug product's shortage status

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(x)
Methodology: Review of databases
Data Sources: FDA Databases

Trulicity (dulaglutide) is not in shortage.[53]

The following dulaglutide products were in shortage from 12/15/2022 to 06/13/2025.[54]

Table 4. Resolved Dulaglutide Injection Shortages as of 07/23/2025.

National Drug Code	Proprietary Name	Non-Proprietary Name	Dosage-Strength
0002-1433-80	Trulicity	Dulaglutide	0.75MG/0.5 ML
0002-1434-80	Trulicity	Dulaglutide	1.5MG/0.5 ML
0002-2236-80	Trulicity	Dulaglutide	3MG/0.5 ML
0002-3182-80	Trulicity	Dulaglutide	4.5MG/0.5 ML

Board staff monitored the shortage while it was ongoing. Based on an inquiry submitted to the FDA, Board staff learned that the FDA routinely places all products with the same active ingredient and dosage form on the shortage list. At the time the shortage was active, the FDA published documents noting whether particular NDCs were available while the shortage was still active. Board staff had previously saved copies of the documents in April 2024, reflected in the table below.

Table 5. Sample Previous Availability Report from FDA, April 1, 2024

Presentation	Availability Information	Date of Update
Trulicity, Injection, .75 mg/.5 mL (NDC 0002-1433-80)	Available	4/17/2024
Trulicity, Injection, 1.5 mg/.5 mL (NDC 0002-1434-80)	Limited Availability	4/17/2024
Trulicity, Injection, 3 mg/.5 mL (NDC 0002-2236-80)	Limited Availability	4/17/2024
Trulicity, Injection, 4.5 mg/.5 mL (NDC 0002-3182-80)	Limited Availability	4/17/2024

[53] FDA Drug Shortage Databases. https://dps.fda.gov/drugshortages
[54] https://dps.fda.gov/drugshortages/resolved/dulaglutide-injection (Page visited on 07/23/2025)

In addition, Board Staff has attempted to find updates after this date using the internet archive.[55] This search revealed that additional presentations were listed as available over time. Based on the archive from April 18, 2025, the manufacturer listed all presentations as available on April 1, 2025, but the FDA continued to list the drug as actively in shortage.

[55] https://web.archive.org/web/20250000000000*/https://dps.fda.gov/drugshortages/activeingredient/dulaglutide-injection

Factor 3.3: Analysis of the market context of the prescription drug product including the prescription drug product's lifecycle management, patent management, regulatory exclusivities, and product hopping

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(g)(xi)
Methodology: Review of databases and sites, aggregation of claims data to understand spending and utilization of other products with the same active ingredient by the same manufacturer
Data Sources: FDA Databases; Initiative for Medicines, Access, & Knowledge (I-MAK); Manufacturer Website

Patent and Exclusivity Data

One potential source of patent information for biological products is FDA's "Purple Book." A brand-name manufacturer is required to give the FDA a list of patents and their expiration dates within 30 days after that same list is disclosed to a biosimilar applicant as part of a patent dispute resolution process. The FDA then publishes that information in the Purple Book.[56] Because of the complexities of this process, patent information for biologics is not always available from official FDA sources. In the case of Trulicity, the Purple Book did not contain patent information. Therefore, staff reviewed the I-MAK database to identify patents for Trulicity.[57]

Fourteen patents apply to Trulicity.[58] The primary patent, a drug product patent filed prior to FDA approval, expires on December 7, 2027. Two patents were also filed before FDA approval, both for the method of treatment and expiring on May 15, 2026 and December 20, 2031. A separate method of treatment patent expires on April 28, 2036. The method of production and process patent expires on October 11, 2038. The device is covered by five patents, with the last patent expiring on March 19, 2040. *See* Patent Listing Table below.

[56] https://purplebooksearch.fda.gov/faqs
[57] https://drugpatentbook.i-mak.org/
[58] Patent landscape was completed May-June 2022.

Table 6. Patent Listing Table

Patent Number	Patent Type	Submission Date	Patent Expiration
9764004B2	Product	10/14/2016	10/14/2036
11123488B2	Device	9/27/2019	9/27/2039
10627377B2	Method of Production and Process	10/11/2018	10/11/2038
10709766B2	Product	11/22/2017	8/19/2036
10987472B2	Device	12/11/2020	2/22/2038
11071831B2	Device	2/20/2019	2/20/2039
11179522B2	Device	3/19/2020	3/19/2040
11253574B2	Method of Treatment	6/5/2020	4/28/2036
11298462B2	Device	3/6/2020	3/6/2040
7452966B2	Product	6/10/2004	12/7/2027
8273854B2	Method of Treatment	10/31/2008	5/15/2026
9161953B2	Method of Treatment	12/20/2011	12/20/2031
9855318	Product	4/28/2016	4/28/2036
9884093B2	Product	10/14/2016	10/14/2036

Trulicity, having received initial FDA approval in 2014, its data exclusivity period expired in 2018.[59,60] Trulicity's exclusivity, originally set to expire in 2026, was extended by six months due to a new pediatric indication approved by the FDA in 2022. [61,62,63,64] This extension means that Trulicity's exclusivity is now set to expire in 2027.

Lifecycle Management

Trulicity has received approval for new indications, such as cardiovascular risk reduction and pediatric use.[65,66] Additionally, the Trulicity has received different delivery mechanisms and introduced higher dosage strengths (3.0 mg and 4.5 mg).[67]

[59] "Data exclusivity precludes applicants from relying on the reference product's clinical data to demonstrate the safety and effectiveness of the follow-on product." https://www.congress.gov/crs-product/IF11217#:~:text=There%20are%20two%20general%20categories,necessary%20safety%20and%20effectiveness%20data.
[60] *Id.* at 46
[61] *Id.*
[62] *Id.* at 59 "Marketing exclusivity precludes FDA from approving any other application for an identical or biosimilar product for the same use, even if the applicant has generated its own data."
[63] *Id.* at 46
[64] https://www.fda.gov/media/164320/download
[65] *Id.* at 49
[66] *Id.* at 51
[67] *Id.* at 50

Also, a result of competition in the GLP-1 market, including internal-competition from Eli Lilly's own portfolio Mounjaro (FDA approval May 13, 2022), sales of Trulicity have declined. Revenue from 2023 to 2024 increased by 124% for Mounjaro, whereas Trulicity declined by 26%. [68,69] A clinical trial conducted by Eli Lilly and published in a press release stated that "Mounjaro was associated with a 16% lower rate of all-cause death compared to Trulicity." Additionally, Mounjaro led to "greater improvements in A1C weight and cardiovascular biomarkers… compared to Trulicity." [70]

[68] https://investor.lilly.com/news-releases/news-release-details/lilly-reports-full-q4-2024-financial-results-and-provides-2025
[69] https://investor.lilly.com/news-releases/news-release-details/fda-approves-lillys-mounjarotm-tirzepatide-injection-first-and
[70] *Id.*

Section 4: Utilization of Drug Product Under Review

Factor 4.1: The total gross spending in the State for the prescription drug product under review, the total number of patients in the State using the prescription drug product, and the percentage of overall total prescription drug product spending that the product's spending represents

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05.C(1)(g)(iv)
Methodology: Calculations
Data Sources: MCDB

For each NDC, the following tables provide the gross spending and number of patients by payor type.

Table 7a. Trulicity Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Commercial (2023) Gross Spending	Commercial (2023) Patient Count	Commercial (2023) Pct Total Gross Spend
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$68,996,111.00	12,599	0.6885%
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$105,611,793.00	15,945	1.0539%
00002-2236-01	Trulicity	3 MG/0.5 ML	$104,356.00	29	0.0010%
00002-2236-80	Trulicity	3 MG/0.5 ML	$59,731,978.00	9,331	0.5960%
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$31,643,521.00	4,586	0.3158%
00002-1433-01	Trulicity	0.75 MG/0.5 ML	$200,580.00	69	0.0020%
00002-1434-01	Trulicity	1.5 MG/0.5 ML	$333,517.00	86	0.0033%
00002-3182-01	Trulicity	4.5 MG/0.5 ML	$200,428.00	34	0.0020%
50090-3484-00	Trulicity	0.75 MG/0.5 ML	***	***	***
50090-6456-00	Trulicity	1.5 MG/0.5 ML	***	***	***
50090-3483-00	Trulicity	1.5 MG/0.5 ML	***	***	***
50090-6571-00	Trulicity	3 MG/0.5 ML	***	***	***
50090-5467-00	Trulicity	3 MG/0.5 ML	$51,872.00	16	0.0005%

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.

Blank spaces indicate that no data was provided.

Table 7b. Trulicity Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	State Local Gov. Emp. (2023) Gross Spending	State Local Gov. Emp. (2023) Patient Count	State Local Gov. Emp. (2023) Pct Total Gross Spend
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$4,005,661.00	823	0.5841%
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$5,619,443.00	1,086	0.8194%
00002-2236-01	Trulicity	3 MG/0.5 ML			
00002-2236-80	Trulicity	3 MG/0.5 ML	$3,880,098.00	682	0.5658%
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$2,040,785.00	319	0.2976%
00002-1433-01	Trulicity	0.75 MG/0.5 ML	***	***	***
00002-1434-01	Trulicity	1.5 MG/0.5 ML	***	***	***
00002-3182-01	Trulicity	4.5 MG/0.5 ML			
50090-3484-00	Trulicity	0.75 MG/0.5 ML	***	***	***
50090-6456-00	Trulicity	1.5 MG/0.5 ML	***	***	***
50090-3483-00	Trulicity	1.5 MG/0.5 ML	***	***	***
50090-6571-00	Trulicity	3 MG/0.5 ML	***	***	***
50090-5467-00	Trulicity	3 MG/0.5 ML	***	***	***

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Blank spaces indicate that no data was provided.

Table 7c. Trulicity Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicaid (2022) Gross Spending	Medicaid (2022) Patient Count	Medicaid (2022) Pct Total Gross Spend
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$15,485,519.87	3,838	0.8461%
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$19,361,612.57	3,872	1.0578%
00002-2236-01	Trulicity	3 MG/0.5 ML	$40,222.69	13	0.0022%
00002-2236-80	Trulicity	3 MG/0.5 ML	$8,954,803.64	1,866	0.4893%
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$4,032,667.02	741	0.2203%
00002-1433-01	Trulicity	0.75 MG/0.5 ML	$86,766.61	30	0.0047%
00002-1434-01	Trulicity	1.5 MG/0.5 ML	$90,068.85	26	0.0049%
00002-3182-01	Trulicity	4.5 MG/0.5 ML	***	***	***
50090-3484-00	Trulicity	0.75 MG/0.5 ML			
50090-6456-00	Trulicity	1.5 MG/0.5 ML			
50090-3483-00	Trulicity	1.5 MG/0.5 ML			
50090-6571-00	Trulicity	3 MG/0.5 ML			
50090-5467-00	Trulicity	3 MG/0.5ML	***	***	***

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Blank spaces indicate that no data was provided.

Table 7d. Trulicity Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicare (2022) Gross Spending	Medicare (2022) Patient Count	Medicare (2022) Pct Total Gross Spend
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$29,429,603.02	5,686	0.8136%
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$47,293,347.01	7,319	1.3075%
00002-2236-01	Trulicity	3 MG/0.5 ML	$123,391.73	30	0.0034%
00002-2236-80	Trulicity	3 MG/0.5 ML	$18,652,313.40	3,263	0.5157%
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$8,352,570.34	1,317	0.2309%
00002-1433-01	Trulicity	0.75 MG/0.5 ML	$239,575.39	68	0.0066%
00002-1434-01	Trulicity	1.5 MG/0.5 ML	$423,700.82	94	0.0117%
00002-3182-01	Trulicity	4.5 MG/0.5 ML	$88,179.88	19	0.0024%
50090-3484-00	Trulicity	0.75 MG/0.5 ML			
50090-6456-00	Trulicity	1.5 MG/0.5 ML			
50090-3483-00	Trulicity	1.5 MG/0.5 ML			
50090-6571-00	Trulicity	3 MG/0.5 ML			
50090-5467-00	Trulicity	3 MG/0.5 ML			

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Blank spaces indicate that no data was provided.

Factor 4.2: The change in total gross spending and utilization for a prescription drug product in the State between the two most recent available calendar years and the percent change in total gross spending for a prescription drug product in the State between the two most recent available calendar years

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(v)
Methodology: Aggregation of claims to calculate the total gross spending and utilization
Data Sources: MCDB

For each NDC and payor type, the tables below show the change in total gross spending and utilization.

Table 8a. Trulicity Change in Spending and Utilization

Drug Information			Change in Commercial Data (2022-2023)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$10,125,142.00	17.20%	98	398	-14,075
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$7,831,296.00	8.01%	-395	-2,869	-38,646
00002-2236-01	Trulicity	3 MG/0.5 ML	$-7,536.00	6.74%	2	2	-52
00002-2236-80	Trulicity	3 MG/0.5 ML	$19,520,144.00	48.54%	1,714	7,315	14,698
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$14,273,637.00	82.17%	1,594	6,725	17,385
00002-1433-01	Trulicity	0.75 MG/0.5 ML	$86,461.00	75.76%	21	30	34
00002-1434-01	Trulicity	1.5 MG/0.5 ML	$-29,604.00	8.15%	1	-106	-234
00002-3182-01	Trulicity	4.5 MG/0.5 ML	$92,314.00	85.39%	14	25	114
50090-3484-00	Trulicity	0.75 MG/0.5 ML	***	***	***	***	***
50090-6456-00	Trulicity	1.5 MG/0.5 ML	***	***	***	***	***
50090-3483-00	Trulicity	1.5 MG/0.5 ML	***	***	***	***	***
50090-6571-00	Trulicity	3 MG/0.5 ML	***	***	***	***	***
50090-5467-00	Trulicity	3 MG/0.5 ML					

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Table 8b. Trulicity Change in Spending and Utilization

Drug Information			Change in State Local Gov. Emp. Data (2022-2023)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$-169,250.00	4.05%	-20	-220	-2,198
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$-1,529,696.00	21.40%	-96	-648	-5,916
00002-2236-01	Trulicity	3 MG/0.5 ML					
00002-2236-80	Trulicity	3 MG/0.5 ML	$795,185.00	25.78%	94	442	458
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$865,477.00	73.64%	113	417	1,193
00002-1433-01	Trulicity	0.75 MG/0.5 ML	***	***	***	***	***
00002-1434-01	Trulicity	1.5 MG/0.5 ML	***	***	***	***	***
00002-3182-01	Trulicity	4.5 MG/0.5 ML					
50090-3484-00	Trulicity	0.75 MG/0.5 ML	***	***	***	***	***
50090-6456-00	Trulicity	1.5 MG/0.5 ML	***	***	***	***	***
50090-3483-00	Trulicity	1.5 MG/0.5 ML	***	***	***	***	***
50090-6571-00	Trulicity	3 MG/0.5 ML	***	***	***	***	***
50090-5467-00	Trulicity	3 MG/0.5 ML	***	***	***	***	***

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Table 8c. Trulicity Change in Spending and Utilization

Drug Information			Change in Medicaid Data (2021-2022)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$3,074,758.19	24.77%	652	1,413	5,635
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$2,674,615.67	16.03%	622	1,157	4,236
00002-2236-01	Trulicity	3 MG/0.5 ML	$24,464.07	155.24%	5	10	54
00002-2236-80	Trulicity	3 MG/0.5 ML	$4,868,023.81	119.12%	854	1,894	10,857
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$3,102,077.95	333.35%	509	1,159	7,102
00002-1433-01	Trulicity	0.75 MG/0.5 ML	$30,961.08	55.48%	13	20	67
00002-1434-01	Trulicity	1.5 MG/0.5 ML	$-29,849.83	(24.89%)	2	-3	-85
00002-3182-01	Trulicity	4.5 MG/0.5 ML	***	***	***	***	***
50090-3484-00	Trulicity	0.75 MG/0.5 ML					
50090-6456-00	Trulicity	1.5 MG/0.5 ML					
50090-3483-00	Trulicity	1.5 MG/0.5 ML					
50090-6571-00	Trulicity	3 MG/0.5 ML					
50090-5467-00	Trulicity	3 MG/0.5 ML	***	***	***	***	***

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Table 8d. Trulicity Change in Spending and Utilization

Drug Information			Change in Medicare Data (2021-2022)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$3,611,941.12	13.99%	407	1,803	4,341
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$3,473,539.01	7.93%	387	392	1,630
00002-2236-01	Trulicity	3 MG/0.5 ML	$26,783.20	27.72%	1	45	44
00002-2236-80	Trulicity	3 MG/0.5 ML	$9,011,281.08	93.47%	1,207	5,250	18,388
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$6,017,652.60	257.72%	805	3,528	12,843
00002-1433-01	Trulicity	0.75 MG/0.5 ML	$-13,839.05	(5.46%)	-16	32	-58
00002-1434-01	Trulicity	1.5 MG/0.5 ML	$69,914.17	19.76%	17	223	96
00002-3182-01	Trulicity	4.5 MG/0.5 ML	$54,225.14	159.70%	10	58	111
50090-3484-00	Trulicity	0.75 MG/0.5 ML					
50090-6456-00	Trulicity	1.5 MG/0.5 ML					
50090-3483-00	Trulicity	1.5 MG/0.5 ML					
50090-6571-00	Trulicity	3 MG/0.5 ML					
50090-5467-00	Trulicity	3 MG/0.5 ML					

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data. Blank spaces indicate that no data was provided.

Factor 4.3: Impact of the utilization and spending for the prescription drug product on public budgets and comparison of the spending on the prescription drug product to relevant benchmarks

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xv)
Methodology: Research, review, and aggregation of claims data to calculate utilization and spending
Data Sources: MCDB and public budget data

Staff conducted research to understand the impact of the utilization and spending on the prescription drug product on public budgets and to compare spending on the prescription drug product to relevant benchmarks. The utilization and spending data is captured for Commercial, State and Local Government Employee, and Medicaid populations in Factor 4.1 “Pct Total Gross Spend” column in Tables 7a, 7b, and 7c.

Staff gathered budget data from local governmental entities (counties). Because the data was not uniform—some local government budgets reflect spending for employee health, some reflect employee prescriptions, and some do not contain information at that level of specificity—staff was unable to assess the impact on public budgets for specific local governments.

In future Cost Review Studies, staff will continue to work with state and local governments, and other public budgets, to identify standardized data to support this analysis or develop other methods of conducting this analysis.

Section 5: Pricing Information and Rebates

Factor 5.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(i);
COMAR 14.01.04.05.C(1)(a)(i)
Methodology: Research and calculations to convert unit prices to annual prices
Data Sources: UpToDate (MediSpan), Centers for Medicare and Medicaid Services, Myers and Stauffer, Department of Veterans Affairs, FDA Databases

This section covers various drug pricing metrics, including the Wholesale Acquisition Cost (WAC), Average Wholesale Price (AWP), National Average Drug Acquisition Cost (NADAC), State Average Acquisition Cost (SAAC), Average Sales Price (ASP), and Federal Supply Schedule (FSS) price. The WAC and AWP are proprietary and commercially licensed from UpToDate (MediSpan). The NADAC is publicly available from the Centers for Medicare and Medicaid Services.[71] The SAAC is provided by Myers and Stauffer, a contractor of the State of Maryland.[72] The ASP is publicly available from the Centers for Medicare and Medicaid Services.[73] The FSS is publicly available from the U.S. Department of Veterans Affairs.[74] Staff converted unit prices (in this case the price per pill) to annual prices based on the FDA labels (number of pills per day times 365). Because none of the identified drugs have a reported ASP, that pricing metric is not included in the attached tables.

The following tables reflect (a) the effective date, (b) the current* unit price, and (c) the estimated annual price (based on the FDA's recommended dosing regimens and current* unit prices) for each NDC-11 associated with the prescription drug product under review.

*Current prices will not reflect price changes that occurred after August 1, 2024.

NOTE: WAC, AWP, and NADAC price history plots by NDC-11 are presented in Exhibit 1 of this file.

[71] https://www.medicaid.gov/medicaid/nadac
[72] https://myersandstauffer.com/client-portal/maryland/maryland-pharmacy/
[73] https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files
[74] https://www.va.gov/opal/nac/fss/pharmprices.asp

Table 9a. Trulicity WAC and AWP Pricing

National Drug Code	WAC Unit Price	Est. WAC per Yr	AWP Unit Price	Est. AWP per Yr
00002-1433-01 (0.75 MG/0.5 ML)	[redacted]	[redacted]	[redacted]	[redacted]
00002-1433-61 (0.75 MG/ 0.5 ML)				
00002-1433-80 (0.75 MG/0.5 ML)	[redacted]	[redacted]	[redacted]	[redacted]
00002-1434-01 (1.5 MG/0.5 ML)	[redacted]	[redacted]	[redacted]	[redacted]
00002-1434-80 (1.5 MG/0.5 ML)	[redacted]	[redacted]	[redacted]	[redacted]
00002-2236-01 (3 MG/0.5 ML)	[redacted]	[redacted]	[redacted]	[redacted]
00002-2236-80 (3 MG/0.5 ML)	[redacted]	[redacted]	[redacted]	[redacted]
00002-3182-01 (4.5 MG/0.5 ML)	[redacted]	[redacted]	[redacted]	[redacted]
00002-3182-80 (4.5 MG/0.5 ML)	[redacted]	[redacted]	[redacted]	[redacted]
50090-3483-00 (1.5 MG/0.5 ML)			[redacted]	[redacted]
50090-3484-00 (0.75 MG/0.5 ML)			[redacted]	[redacted]
50090-5467-00 (3 MG/0.5 ML)			[redacted]	[redacted]
50090-6453-00 (0.75 MG/0.5 ML)			[redacted]	[redacted]
50090-6456-00 (1.5 MG/0.5 ML)			[redacted]	[redacted]
50090-6571-00 (3 MG/0.5 ML)			[redacted]	[redacted]

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Table 9b. Trulicity NADAC, SAAC, and FSS Pricing

National Drug Code	NADAC Unit Price	Est. NADAC per Yr	SAAC Rate	Est. SAAC per Yr	FSS Unit Price	Est. FSS per Yr
00002-1433-01 (0.75 MG/0.5 ML)			$ 468.09	$ 12,203.79		
00002-1433-61 (0.75 MG/ 0.5 ML)			$ 468.09	$ 12,203.79		
00002-1433-80 (0.75 MG/0.5 ML)	$ 471.65	$ 12,296.54	$ 468.09	$ 12,203.79	$ 426.39	$ 11,116.47
00002-1434-01 (1.5 MG/0.5 ML)			$ 468.02	$ 12,201.96		
00002-1434-80 (1.5 MG/0.5 ML)	$ 471.59	$ 12,295.05	$ 468.02	$ 12,201.96	$ 426.39	$ 11,116.47
00002-2236-01 (3 MG/0.5 ML)			$ 467.97	$ 12,200.62		
00002-2236-80 (3 MG/0.5 ML)	$ 471.73	$ 12,298.65	$ 467.97	$ 12,200.62	$ 453.75	$ 11,829.78
00002-3182-01 (4.5 MG/0.5 ML)			$ 468.03	$ 12,202.34		
00002-3182-80 (4.5 MG/0.5 ML)	$ 471.57	$ 12,294.61	$ 468.03	$ 12,202.34	$ 453.75	$ 11,829.78
50090-3483-00 (1.5 MG/0.5 ML)						
50090-3484-00 (0.75 MG/0.5 ML)						
50090-5467-00 (3 MG/0.5 ML)						
50090-6453-00 (0.75 MG/0.5 ML)						
50090-6456-00 (1.5 MG/0.5 ML)						
50090-6571-00 (3 MG/0.5 ML)						

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Exhibit 1 (attached) reflects pricing history for Trulicity.

Factor 5.2: Information estimating manufacturer net price and net sales amounts of the prescription drug product under review

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(a)(ii)
Methodology: Develop and apply equations to data
Data Sources: Proprietary databases including SSR Health and UpToDate (MediSpan), MCDB

The table below presents (a) the drug product under review, (b) all NDC-11s associated with the drug product, (c) the most recently available SSR rebate estimate (2024 Q2) for the drug product, (d) estimated manufacturer net prices using *equation 1*, below, (e) estimated sales amount for each APCD segment using *equation 2,* below. The previously mentioned data elements are presented at the NDC-11 level.

The proprietary data and the equations used in calculating the estimated net price are redacted to protect confidential and proprietary information in accordance with Health-General Article §§ 21-2C-10 and 21-2C-03 and applicable data and licensing agreements. The equation and estimated net sales calculation are likewise redacted to protect confidential and proprietary information.

Table 10. Trulicity Net Price and Net Spending Estimates

Drug Information			Annual Price or Sales After SSR Application[redacted]				
National Drug Code	Strength	SSR Rebate	Est. Net Price per Yr	Commercial (2023) Estimated Net Spend	State Local Govt Emp (2023) Estimated Net Spend	Medicaid (2022) Estimated Net Spend	Medicare (2022) Estimated Net Spend
00002-1434-80	1.5 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00002-1433-80	0.75 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00002-2236-80	3 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00002-3182-80	4.5 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00002-1434-01	1.5 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00002-1433-01	0.75 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00002-3182-01	4.5 MG/0.5 ML	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]
00002-2236-01	3 MG/0.5 ML	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]
50090-5467-00	3 MG/0.5 ML	[redacted]		[redacted]	***	***	
50090-6571-00	3 MG/0.5 ML	[redacted]		***	***		
50090-6456-00	1.5 MG/0.5 ML	[redacted]		***	***		
50090-3484-00	0.75 MG/0.5 ML	[redacted]		***	***		
50090-3483-00	1.5 MG/0.5 ML	[redacted]		***	***		

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Factor 5.3: The average price concession, discount, and rebate provided by the manufacturer or expected to be provided to each payor class in the State for the drug under review, expressed as a number and as a percent of the WAC

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(ii); COMAR 14.01.04.05C(1)(b)(i)
Methodology: Calculation of discount as percentage of WAC
Data Sources: Centers for Medicare and Medicaid Services

Trulicity has not been selected as a drug subject to Medicare Price Negotiation Program.

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as exhibits to the dossier.

Exhibit 2 contains information responsive to this element.

Factor 5.4: The average price concession, discount, and rebate the manufacturer provided or is expected to provide for the prescription drug product under review to each PBM operating in the State, expressed as a number and as a percent of the WAC

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(iii); COMAR 14.01.04.05C(1)(b)(ii); COMAR 14.01.04.05C(1)(g)(xviii); COMAR 14.01.04.04B(3)(b)
Methodology: Reported by entities
Data Sources: Reported by entities

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as exhibits to the dossier.

Exhibit 2 contains information responsive to this element.

Factor 5.5: Information supplied by the manufacturer, if any, explaining the relationship between the pricing of the prescription drug product and (a) the cost of development and (b) the therapeutic benefit of the prescription drug product, or information that is otherwise pertinent to the manufacturer's pricing decision

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(iii); COMAR 14.01.04.05C(1)(g)(viii); COMAR 14.01.04.05C(1)(g)(xviii); COMAR 14.01.04.04B(1)(a)
Methodology: Reported by entities
Data Sources: Reported by entities

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as exhibits to the dossier.

Exhibit 2 contains information responsive to this element.

Section 6: Therapeutic Alternatives, Cost Comparisons, and Health Economics Outcomes and Research (HEOR)

Factor 6.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS at which each therapeutic alternative has been sold in the State

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(iv); COMAR 14.01.04.05C(1)(c)(ii)
Methodology: Calculation of number of units per year and calculation pricing per year
Data Sources: Proprietary databases including UpToDate (MediSpan); and Centers for Medicare and Medicaid Services, Myers and Stauffer, Department of Veterans Affairs

Factor 6.2: The average price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans in the State for therapeutic alternatives

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(v); COMAR 14.01.04.05.C(1)(c)(i)
Methodology: Calculation using equation
Data Sources: Proprietary databases including SSR Health and UpToDate (MediSpan)

This section provides pricing and concession information for each therapeutic alternative.

Factor 6.1 (COMAR 14.01.04.05C(1)(c)(ii) and Health-General § 21-2C-09(b)(2)(iv)) address pricing metrics (WAC, AWP, NADAC, SAAC, ASP, and FSS) for therapeutic alternatives. For each therapeutic alternative, staff identified the number of units per year for each alternative based on the FDA label. For pills, the number of units per year is the number of pills per year. For injections, the units are either milliliters, vials, or autoinjectors. For most therapeutic alternatives, staff identified the unit for each drug and the number of units per year. For drugs that have initial loading doses, staff assumed a full year of use for a patient who has previously taken the loading dose.

Factor 6.2 (COMAR 14.01.04.05.C(1)(c)(i) and Health-Gen. § 21-2C-09(b)(2)(v)) address the average price concession, discount, or rebate the manufacturer provides for each therapeutic alternative. Staff calculated the estimated dollar rebate using proprietary data from SSR health.

[redacted]

Staff developed the attached supplemental excel document (Exhibit 3_REDACTED "TRULICITY Therapeutic Alternative Pricing_REDACTED") to organize these two factors and the following data for each therapeutic alternative: (a) the effective date of the price; (b) the current* unit price for WAC, AWP, NADAC, FSS and SAC; (c) the estimated annual price (based on the FDA's recommended dosing regimens and current* unit prices); and (d) calculated average dollar rebate.

Sheet 1 of Exhibit 3_REDACTED contains the information specified above for non-insulin therapeutic alternatives.

Sheet 2 of Exhibit 3_REDACTED contains the specified information for insulin therapeutic alternatives with a single exception. The insulin sheet provides estimated price metrics per 50 units (*e.g.*, WAC per 50 Units).

Sheet 3 of Exhibit 3_REDACTED provides a summary for each non-insulin therapeutic alternative, displaying the number of NDCs associated with the therapeutic alternative, along with the minimum, maximum and average annual price estimates observed among their NDCs.

*Current prices do not reflect price changes that occurred after August 1, 2024.

Factor 6.3: The utilization, costs, and out-of-pocket costs for therapeutic alternatives

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(c)(iii)
Methodology: Aggregation of claims to calculate utilization, spending, and out-pocket cost measures
Data Sources: MCDB

Staff developed the attached supplemental excel document Exhibit 4 (Trulicity Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document)) to organize the following data for each NDC-11 associated with each approved therapeutic alternative by MCDB segment: (a) patient counts; (b) total units dispensed; (c) total gross spending; (d) average, median, and 90th percentile of annual patient OOP costs; and (e) the average deductible, coinsurance, copayment, and other patient liability for applicable MCDB segments.

Factor 6.4: The incremental costs associated with a prescription drug product, including financial impacts to health, medical, or social services as can be quantified and compared to baseline effects of existing therapeutic alternatives

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(ix); COMAR 14.01.04.05C(1)(e)(i)
Methodology: Literature review
Data Sources: Published cost-effectiveness studies and literature

This subsection concerns the incremental costs associated with a prescription drug product. This includes the cost of using the drug and the cost of using other health, medical, and social services to manage other aspects of health addressed by the therapy. Staff compared these costs—cost of using the drug and the cost of using other health, medical and social services—to the same costs when using a therapeutic alternative. Staff considered the costs associated with the use of the therapeutic alternative as the baseline effect. The incremental cost of the therapy is the change in all of these costs compared to the costs associated with the therapeutic alternative.

Staff reviewed published cost-effectiveness literature in the United States to identify the potential incremental costs associated with the use of Trulicity (dulaglutide). Staff used Embase (Elsevier interface) to identify potential analyses. Staff combined the following string in Embase with the relevant drug terms: ('cost effectiveness analysis'/exp OR 'cost effectiveness':ti,ab,kw OR 'cost efficiency':ti,ab,kw OR 'incremental cost effectiveness ratio'/exp OR 'incremental cost'/exp OR 'incremental cost*':ti,ab,kw OR 'incremental cost utility ratio'/exp) AND ('dulaglutide'/exp OR 'dulaglutide':ti,ab,kw OR 'ly 05008':ti,ab,kw OR 'ly 2189265':ti,ab,kw OR 'ly05008':ti,ab,kw OR 'ly2189265':ti,ab,kw OR 'trulicity':ti,ab,kw) AND ('non insulin dependent diabetes mellitus'/exp OR 'niddm':ti,ab,kw OR 't2dm':ti,ab,kw OR 'tiidm':ti,ab,kw OR 'adult onset diabetes':ti,ab,kw OR 'diabetes mellitus type 2':ti,ab,kw OR 'diabetes mellitus type ii':ti,ab,kw OR 'diabetes type 2':ti,ab,kw OR 'diabetes type ii':ti,ab,kw OR 'dm 2':ti,ab,kw OR 'insulin independent diabetes':ti,ab,kw OR 'insulin independent diabetes mellitus':ti,ab,kw OR 'ketosis resistant diabetes mellitus':ti,ab,kw OR 'maturity onset diabetes':ti,ab,kw OR 'non insulin dependent (type 2) diabetes mellitus':ti,ab,kw OR 'non insulin dependent diabetes':ti,ab,kw OR 'noninsulin dependent (type 2) diabetes mellitus':ti,ab,kw OR 'noninsulin dependent diabetes':ti,ab,kw OR 'type 2 (insulin independent) diabetes':ti,ab,kw OR 'type 2 diabetes':ti,ab,kw OR 'type ii diabetes':ti,ab,kw) AND ('article'/it OR 'article in press'/it OR 'preprint'/it OR 'review'/it). In total, this search had 85 results.[75]

The results of these studies are summarized in Exhibit 5A.

[75] Search conducted on 24 February, 2024.

Factor 6.5: Information derived from health economics and outcomes research that may address the effectiveness of the prescription drug product in treating the conditions for which it is prescribed or in improving a patient's health, quality of life, or overall health outcomes, and the effectiveness of the prescription drug product compared with therapeutic alternatives or no treatment.

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(e)(ii)
Methodology: Literature review
Data Sources: Published cost-effectiveness studies and literature and published comparative effectiveness research and literature

Health Economics and Outcomes Research (HEOR) is a field of study that provides patients, providers, and decision makers with information concerning the effectiveness, costs, and quality of life resulting from health care interventions. This includes both cost effectiveness and comparative effectiveness research: cost effectiveness research compares the relative costs and outcomes (or effects) of different healthcare treatments or interventions; comparative effectiveness research compares different healthcare interventions or therapies to determine clinical effectiveness, benefits, and safety.

This research may be published in academic journals or by non-profit institutions and governmental entities.

Staff reviewed literature from two sources. First, staff used Embase (Elsevier interface) to combine the following string with the relevant drug and approved indications terms: ('treatment outcome'/exp OR 'patient outcome*':ti,ab,kw OR 'therapeutic outcome*':ti,ab,kw OR 'therapy outcome*':ti,ab,kw OR 'treatment outcome*':ti,ab,kw OR 'quality of life'/exp OR 'hrql':ti,ab,kw OR 'health related quality of life':ti,ab,kw OR 'life quality':ti,ab,kw OR 'quality of life':ti,ab,kw) AND ('dulaglutide'/exp OR 'dulaglutide':ti,ab,kw OR 'ly 05008':ti,ab,kw OR 'ly 2189265':ti,ab,kw OR 'ly05008':ti,ab,kw OR 'ly2189265':ti,ab,kw OR 'trulicity':ti,ab,kw) AND ('non insulin dependent diabetes mellitus'/exp OR 'niddm':ti,ab,kw OR 't2dm':ti,ab,kw OR 'tiidm':ti,ab,kw OR 'adult onset diabetes':ti,ab,kw OR 'diabetes mellitus type 2':ti,ab,kw OR 'diabetes mellitus type ii':ti,ab,kw OR 'diabetes type 2':ti,ab,kw OR 'diabetes type ii':ti,ab,kw OR 'dm 2':ti,ab,kw OR 'insulin independent diabetes':ti,ab,kw OR 'insulin independent diabetes mellitus':ti,ab,kw OR 'ketosis resistant diabetes mellitus':ti,ab,kw OR 'maturity onset diabetes':ti,ab,kw OR 'non insulin dependent (type 2) diabetes mellitus':ti,ab,kw OR 'non insulin dependent diabetes':ti,ab,kw OR 'noninsulin dependent (type 2) diabetes mellitus':ti,ab,kw OR

'noninsulin dependent diabetes':ti,ab,kw OR 'type 2 (insulin independent) diabetes':ti,ab,kw OR 'type 2 diabetes':ti,ab,kw OR 'type ii diabetes':ti,ab,kw) AND ('comparative effectiveness'/de OR 'comparative study'/de OR comparative:ti,ab,kw OR comparison:ti,ab,kw) AND ('article'/it OR 'article in press'/it OR 'preprint'/it OR 'review'/it). In total, this search has 150 results.[76] In addition, staff retrieved the cited references from the Comparative Effectiveness section of the drug's monograph in DRUGDEX (via Micromedex).[77] In total, staff retrieved 10 unique results.[78]

The principle outcome assessed for comparative effectiveness of Trulicity (dulaglutide) versus other antihyperglycemic agents is the ability to lower hemoglobin A1c (HgbA1c).

Trulicity may be more effective in lowering HgbA1c compared to agents in alternate classes, including Glucophage (metformin), Januvia (sitagliptin), Invokana (canagliflozin), and Lantus (insulin glargine). However, it may be equally as effective or less effective in lowering HgbA1c compared to Glucotrol (glipizide), and other GLP-1s [i.e., Victoza (liraglutide), Byetta (exenatide), and Ozempic (semaglutide). Reasons for mixed results include trial differences and various treatment dosages compared.

Of 14 trials evaluated, 7 were sponsored by Eli Lilly and Company, the manufacturer of Trulicity.

See Exhibits 5A and 5B for a summary of the literature.

[76] Search conducted on 24 February, 2025.
[77] The monograph was last modified 10 January, 2025.
[78] Retrieved 24 February 2025.

Factor 6.6: In the case of generic prescription drug products, the number of pharmaceutical manufacturers that produce the prescription drug product

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(iii)
Methodology: Research and review of databases
Data Sources: Drugs@FDA database, FDA Orange Book

Trulicity is not a generic drug product.

Factor 6.7: The utilization and pricing of therapeutically equivalent drug products

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xii)
Methodology: Research and review
Data Sources: FDA Orange Book

This section is not applicable to biologic products because therapeutic equivalence is a concept reserved for small-molecule drugs and associated with the FDA's Orange Book.[79]

[79] For biologic drugs with more complex structures and manufacturing processes, there are other classifications in the FDA's Purple Book (Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations) that more adequately capture the differences in products.

Section 7: Cost-Sharing and Insurance Benefit Design

Factor 7.1: The estimated impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(vii);
COMAR 14.01.04.05C(1)(d)(ii)
Methodology: Analyses using claims data (see below) and literature review
Data Sources: MCDB

MCDB Analysis

The following analysis aims to estimate the impact on patient access resulting from the cost of prescription drug products under study relative to insurance benefit design. In particular, we are interested in seeing (a) the distribution of coinsurance/copayment utilization among claims for the drug under study, and (b) whether increases or decreases in a patient's average copay/coinsurance per claim impact their utilization of the drug under study.

Methods

1. Extract claims for the prescription drug product of interest from commercial eligibility file
    a. Initial Inclusion Criteria:
        i. Patients filling claims for the prescription drug product of interest must have pharmacy coverage for at least 11 months of the calendar year
        ii. Patients must reside in Maryland as indicated on their pharmacy claims
        iii. Claims must not be denied or contain indicators that the claim was a duplicate submission from either a third-part administrator (i.e.,PBM), health plans providing Medicare Part D, Fee-For-Service, coverage, or commercial health plan providing Medicaid/Medicare managed care coverage.
        iv. Claims must have positive non-zero values for the total paid amount field (i.e., total gross spending) and values greater than 0 for cost-sharing payment fields (i.e., deductible amounts, copay amounts, coinsurance amounts, and other member liability amounts).
        v. Claims for patients whose 30-day normalized ratio (i.e., [total 30-day equivalents received]/[expected 30-day equivalents]) >1 are excluded
        vi. Claims for patients whose first instance of using the prescription drug product was in December were excluded.
2. Assign copay and coinsurance flags to each eligible claim and determine rate at which these cost sharing measures are utilized.

3. Prepare for regression analysis by summarizing patient information among eligible claims
    a. Sum all 30-day equivalents (*total 30-day equivalents)*
    b. Calculate expected 30 day equivalents as
        i. (Total Covered Months +1) – (Month of first prescription fill date)
    c. Calculate Normalized 30 Day Equivalent as
        i. (Total 30-Day Equivalents)/(Expected 30-Day Equivalents)
    d. Assign Continuous user flag for patients who received the drug in January or February of the calendar year
    e. Calculate the average coinsurance and copayment for each patient
    f. Create interaction term between average coinsurance/copayment as
        i. Interaction 1: (cont_user)*(average coinsurance)
        ii. Interaction 2 : (cont_user)*(average copay)
4. Run following regression on data
    a. $Yi= \beta 0+ \beta 1x1 + \beta 2x2 + \beta 3x3 + \beta 4x4 + \beta 5x5$ where
        i. Yi = Normalized 30 Day Equivalent
        ii. $\beta 0$= Intercept
        iii. $\beta 1$ = Patient's Average Copay per Claim
        iv. $\beta 2$= Patient's Average Coinsurance per Claim
        v. $\beta 3$= Continuous User Indicator
        vi. $\beta 4$= Interaction Term – Continuous User*Avg Copay
        vii. $\beta 5$= Interaction Term – Continuous User*Avg Coinsurance

Results

Data Characteristics

Table 11. 2023 Commercial Pharmacy Claims Characteristics for Trulicity Analysis

	Patient Count	**Claim Count**
Total Population		
Counts	31,172	156,876
Eligible Patients (≥ 11 months of pharmacy coverage)		
Counts	27769	145295
Final Summary File for Eligible Claims		
Counts	16623	72239

Trulicity

Table 12. Trulicity Out of Pocket Cost Frequency Analysis

COIN_FLAG	COPAY_FLAG	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	0	25912	35.87	25912	35.87
0	1	38907	53.86	64819	89.73
1	0	6989	9.67	71808	99.40
1	1	431	0.60	72239	100.00

Among eligible commercial claims for Trulicity, copay is used most often (54%) as part of the insurance benefit design. Use of coinsurance as part of the benefit design, either by itself or in conjunction with coinsurance payments, is observed in slightly more than 10% of claims.

Regression Analysis

Table 13. Summary statistics for regression variables

	N	NMiss	Min	Max	Mean	Std
Normalized 30 Day Equivalent	16623	0	0.08	1.00	0.64	0.30
Continuous User Indicator	16623	0	0.00	1.00	0.55	0.50
Average Coinsurance	16623	0	0.00	5148.00	14.89	86.04
Average Copay	16623	0	0.00	952.00	25.25	34.24
Continuous User*Avg. Coinsurance	16623	0	0.00	3020.0	7.26	47.78
Continuous User*Avg. Copay	16623	0	0.00	952.00	14.42	28.62

Table 14. Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	10.41787	2.08357	23.12	<.0001
Error	16617	1497.42089	0.09011		
Corrected Total	16622	1507.83876			

Table 15. Model Statistics.			
Root MSE	0.30019	**R-Square**	0.0069
Dependent Mean	0.63878	**Adj R-Sq**	0.0066
Coeff Var	46.99434		

Table 16. Parameter Estimates						
Variable	**Label**	**DF**	**Parameter Estimate**	**Standard Error**	**t Value**	**Pr > |t|**
Intercept	Intercept	1	0.61927	0.00432	143.36	<.0001
AVG_COPAY	Average Copay	1	0.00079944	0.00010227	7.82	<.0001
AVG_COIN	Average Coinsurance	1	-0.00014203	0.00003253	-4.37	<.0001
CONT_USER	Continuous User Indicator	1	0.01123	0.00592	1.90	0.0579
INTX_COIN	Continuous User*Avg. Coinsurance	1	0.00005722	0.00005920	0.97	0.3337
INTX_COPAY	Continuous User*Avg. Copay	1	-0.00035788	0.00013747	-2.60	0.0092

The analysis above suggests that while there are statistically significant relationships between average copays and coinsurance and the number of prescriptions people use in a year, any impact is small.

Literature Review

Staff conducted a literature review of the published literature to determine whether similar results exist nationally. Staff conducted a literature review using Google Scholar and PubMed for articles using the search term "Co-payment Adherence dulaglutide." Staff identified two articles after excluding articles focused solely on obesity as the indication.

The first article examined the relationship between copayments and utilization in a database of commercial insurance and Medicare Part D plans associated with Medicare Advantage.[80] The researchers categorized patients into three groups based on their copay levels: low (less than $10), medium (between $10 and $50), and high (greater than $50). They then examined the proportion of days covered by prescriptions. The researchers examined the relationship between the copayment categories and the probability of having more than 80% of the prescription days covered in a year. Without controlling for other factors, they found that 72% of patients with low copayment levels had more than 80% of prescription days covered. In comparison, 66% of those with medium and 60% of those with high copayments had 80% covered. Controlling for demographic, clinical, and socioeconomic factors, the authors found that the odds ratio for those with medium copayments was 0.62 and those with high copayments was 0.47 compared to the low copayment group.

The second study examined the association between patient out-of-pocket (OOP) costs and nonadherence to glucagon-like peptide 1 receptor agonists (GLP-1 RAs) in a commercial database.[81] After classifying patients into four OOP cost quartiles, researchers found that among adults who initiated GLP-1RA therapy, higher 30-day OOP costs were associated with decreased adherence: the odds ratio of nonadherence for patients in the highest quartile (OOP cost $80-$3,375) compared with the lowest quartile (OOP cost $0-$21) was 1.25.

[80] Essien UR, Singh B, Swabe G, et al. Association of Prescription Co-payment With Adherence to Glucagon-Like Peptide-1 Receptor Agonist and Sodium-Glucose Cotransporter-2 Inhibitor Therapies in Patients With Heart Failure and Diabetes. JAMA Netw Open. 2023;6(6):e2316290. doi:10.1001/jamanetworkopen.2023.16290

[81] Donglan Zhang, Nihan Gencerliler, Amrita Mukhopadhyay, Saul Blecker, Morgan E. Grams, Davene R. Wright, Vivian Hsing-Chun Wang, Anand Rajan, Eisha Butt, Jung-Im Shin, Yunwen Xu, Karan R. Chhabra, Jasmin Divers; Association of Patient Cost Sharing With Adherence to GLP-1RA and Adverse Health Outcomes. *Diabetes Care* 21 July 2025; 48 (8): 1329–1336. https://doi.org/10.2337/dc24-2746

Factor 7.2: The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer for the drug product under review and the policies surrounding and implementing such programs

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(viii);
COMAR 14.01.04.05C(1)(d)(iii)
Methodology: Research and review
Data Sources: Manufacturer's website

Staff identified two patient access programs for Trulicity. The first program is the Trulicity Savings Card.[82] The terms of use and eligibility for the program are expressed as follows:

> ELIGIBILITY:
>
> 1. You have been prescribed Trulicity for an approved use consistent with FDA-approved product labeling;
> 2. You are enrolled in a commercial drug insurance plan with coverage for Trulicity;
> 3. You are not enrolled in any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state prescription drug assistance program;
> 4. You are a resident of the United States or Puerto Rico; and
> 5. You are 18 years of age or older.
>
> TERMS OF USE: You must have commercial drug insurance that covers Trulicity and a prescription for an approved use consistent with FDA-approved product labeling to pay as little as $25 for a 1-month, 2-month, or 3-month prescription fill of Trulicity. One month is defined as 28-days and up to 4 pens; 2-months is defined as 56 days and up to 8 pens; 3 months is defined as 84 days and up to 12 pens. Card savings are subject to a maximum monthly savings of up to $150 per 1-month prescription, $300 per 2-month prescription, or $450 per 3-month prescription fill and separate maximum annual savings of up to $1,950 per calendar year. Card may be used for a maximum of up to 13 prescription fills per calendar year. Subject to Lilly USA, LLC's ("Lilly") right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason. Card expires and savings end on 12/31/2025.[83]

[82] https://trulicity.lilly.com/hcp/savings#savings-card
[83] *Id.* Accessed August 1, 2025.

The second program is called “Lilly Cares.” [84] According to the website:

> Lilly Cares Foundation, Inc. (Lilly Cares) is a nonprofit charitable organization that provides prescribed Lilly medications for free for up to 12 months to qualifying U.S. patients. [85]
>
> You may be eligible for the Lilly Cares Program if:
>
> - You are a permanent resident of the United States (inclusive of Puerto Rico and the U.S. Virgin Islands).
> - Your healthcare provider has prescribed a medication offered through Lilly Cares.
> - The following applies to you with regard to your insurance coverage:
>   - You are not enrolled in Medicaid, full Low Income Subsidy (LIS, “Extra Help”) or Veterans (VA) Benefits;
>   - For all Medications, you do not have an insurance plan or third party that requires you to apply to the Lilly Cares Program as a condition, requirement, or prerequisite for coverage of specific Eli Lilly and Company medications. Additional information on such ineligible programs, often referred to as alternative funding programs, for-profit patient advocacy programs, or specialty cost-containment networks (collectively known as "AFPs"), is provided below*.
>   - You meet the insurance requirements for the medication for which you are applying. Insurance requirements are listed below for each Medication Group.
> - You meet the household income guidelines for the Program.
>   - Trulicity: Household annual adjusted gross income ≤ 300% Federal Poverty Level (FPL) [86]

As of August 1st, 2025, new applications for Trulicity are not being accepted, except for limited medical circumstances.

> Medical exception eligibility:
>
> The patient must meet ALL of the following criteria, and prescriber must check all boxes that apply.
>
> - Diagnosed with type 2 diabetes mellitus
> - On Trulicity currently or within past 12 months
> - Over age 10

[84] https://www.lillycares.com/
[85] *Id.*
[86] Accessed August 1, 2025: https://www.lillycares.com/how-to-apply

- Within past 12 months previously tried and failed at least one other GLP-1 receptor agonist after at least 3 months on each therapy

AND at least one of the following:

- Has previously tried metformin and had an inadequate treatment response, intolerance, or has a contraindication to metformin
- Requires combination therapy AND has an A1C of 7.5% or greater
- Has established cardiovascular disease or multiple cardiovascular risk factors[87]

A reasonable search failed to disclose publicly available information concerning the dollar value and utilization of the Trulicity Savings Card.

Nationally, in 2024, Lilly Cares provided diabetes medications, including Trulicity, valued at $1.1 billion, supporting approximately 115,000 patients. Trulicity was the most frequently requested medication in the program with 71,094 patients.[88]

In Maryland in 2024, Lilly Cares provided diabetes medications, including Trulicity, valued at $15,900,000, calculated based on their Wholesale Acquisition Cost. These medications assisted 1,713 patients in the State.[89]

[87] https://www.lillycares.com/assets/pdf/LillyCaresMedicalExceptionRequestForm.pdf
[88] https://www.lillycares.com/assets/pdf/lilly_cares_2024_annual_report.pdf
[89] https://www.lillycares.com/assets/pdf/lilly_cares_2024_state_level_data.pdf

Factor 7.3: The average patient copay and other cost-sharing data for the prescription drug in the State

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(x);
COMAR 14.01.04.05C(1)(f)(i)

Methodology: Aggregation of claims data to calculate average by out-of-pocket cost category

Data Sources: MCDB

For each NDC-11, the following tables provide the average out-of-pocket costs by payor type. Note that the MCDB includes these fields only for the commercial sector and not Medicare or Medicaid.

Table 17a. Trulicity Average Copays and Other Cost-Sharing

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Commercial (2023) Avg Deductible	Commercial (2023) Avg Copay	Commercial (2023) Avg Coinsurance	Commercial (2023) Avg Other Member Liability
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$141.61	$82.62	$38.96	$58.14
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$91.78	$97.99	$48.97	$81.35
00002-2236-01	Trulicity	3 MG/0.5 ML	$70.76	$23.52	$8.52	$32.55
00002-2236-80	Trulicity	3 MG/0.5 ML	$84.39	$90.70	$46.03	$68.13
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$66.35	$94.39	$52.32	$73.49
00002-1433-01	Trulicity	0.75 MG/0.5 ML	$73.90	$19.77	$13.96	$31.59
00002-1434-01	Trulicity	1.5 MG/0.5 ML	$24.66	$25.63	$7.21	$1.00
00002-3182-01	Trulicity	4.5 MG/0.5 ML	$81.41	$43.79	$43.35	$22.62
50090-3484-00	Trulicity	0.75 MG/0.5 ML	***	***	***	***
50090-6456-00	Trulicity	1.5 MG/0.5 ML	***	***	***	***
50090-3483-00	Trulicity	1.5 MG/0.5 ML	***	***	***	***
50090-6571-00	Trulicity	3 MG/0.5 ML	***	***	***	***
50090-5467-00	Trulicity	3 MG/0.5 ML	$544.94	$5.94	$212.25	$53.06

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Table 17b. Trulicity Average Copays and Other Cost-Sharing

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	State Local Gov (2023) Avg Deductible	State Local Gov (2023) Avg Copay	State Local Gov (2023) Avg Coinsurance	State Local Gov (2023) Avg Other Member Liability
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$5.43	$71.10	$10.57	$1.92
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$3.85	$82.73	$9.35	$1.96
00002-2236-01	Trulicity	3 MG/0.5 ML				
00002-2236-80	Trulicity	3 MG/0.5 ML	$4.54	$75.25	$9.27	$3.58
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$9.94	$85.72	$15.97	$4.18
00002-1433-01	Trulicity	0.75 MG/0.5 ML	***	***	***	***
00002-1434-01	Trulicity	1.5 MG/0.5 ML	***	***	***	***
00002-3182-01	Trulicity	4.5 MG/0.5 ML				
50090-3484-00	Trulicity	0.75 MG/0.5 ML	***	***	***	***
50090-6456-00	Trulicity	1.5 MG/0.5 ML	***	***	***	***
50090-3483-00	Trulicity	1.5 MG/0.5 ML	***	***	***	***
50090-6571-00	Trulicity	3 MG/0.5 ML	***	***	***	***
50090-5467-00	Trulicity	3 MG/0.5 ML	***	***	***	***

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Factor 7.4: The average cost share

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(f)(ii)
Methodology: Aggregation of claims data to calculate average cost share (the average percentage of gross spending paid by patients)
Data Sources: MCDB

The table below shows the cost share for different types of payors. The table does not include Medicaid because the MCDB does not include out-of-pocket cost data for Medicaid. The cost share is the patient total out-of-pocket costs divided by gross spending, which yields the percentage of gross spending paid by the patient. The average cost share is, on average, the percentage of gross spending paid by patients.

Table 18. Trulicity Average Cost Share

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Commercial (2023) Avg. Cost Share	State Local Gov (2023) Avg. Cost Share	Medicare (2022) Avg. Cost Share
00002-1433-80	Trulicity	0.75 MG/0.5 ML	0.0005%	0.0022%	0.0008%
00002-1434-80	Trulicity	1.5 MG/0.5 ML	0.0003%	0.0017%	0.0006%
00002-2236-01	Trulicity	3 MG/0.5 ML	0.1297%		0.0404%
00002-2236-80	Trulicity	3 MG/0.5 ML	0.0005%	0.0024%	0.0013%
00002-3182-80	Trulicity	4.5 MG/0.5 ML	0.0009%	0.0057%	0.0030%
00002-1433-01	Trulicity	0.75 MG/0.5 ML	0.0694%	***	0.0171%
00002-1434-01	Trulicity	1.5 MG/0.5 ML	0.0175%	***	0.0057%
00002-3182-01	Trulicity	4.5 MG/0.5 ML	0.0954%		0.0027%
50090-3484-00	Trulicity	0.75 MG/0.5 ML	***	***	
50090-6456-00	Trulicity	1.5 MG/0.5 ML	***	***	
50090-3483-00	Trulicity	1.5 MG/0.5 ML	***	***	
50090-6571-00	Trulicity	3 MG/0.5 ML	***	***	
50090-5467-00	Trulicity	3 MG/0.5 ML	1.5735%	***	

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.

^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.

Blank spaces indicate that no data was provided.

Factor 7.5: The mean, median, and 90th percentile out-of-pocket costs per patient compared to State incomes

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(vi)
Methodology: Aggregation of claims data to determine distribution of out-of-pocket costs, research
Data Sources: MCDB, Maryland Manual On-line (derived from U.S. Census Bureau)

The table below shows out-of-pocket costs (average, median, and 90th percentile) by payor type.

Table 19. Trulicity Average Out-of-Pocket Costs

Drug Information		Commercial (2023) Statistics			State Local Gov (2023) Statistics			Medicare (2022) OOP Statistics		
National Drug Code (11-Digit)	Dosage Strength	Avg.	Median	90th Percentile	Avg.	Median	90th Percentile	Avg.	Median	90th Percentile
00002-1433-80	0.75 MG/0.5 ML	$321.33	$75.00	$892.00	$89.02	$50.00	$220.00	$337.29	$49.25	$1,364.20
00002-1434-80	1.5 MG/0.5 ML	$320.10	$100.00	$800.00	$97.88	$50.00	$250.00	$379.16	$68.95	$1,457.39
00002-2236-01	3 MG/0.5 ML	$135.34	$0.00	$300.00				$23.95	$0.00	$39.40
00002-2236-80	3 MG/0.5 ML	$289.24	$90.00	$635.00	$92.63	$50.00	$225.00	$318.98	$50.00	$1,215.32
00002-3182-80	4.5 MG/0.5 ML	$286.54	$90.00	$690.00	$115.81	$60.00	$280.00	$342.16	$49.25	$1,374.57
00002-1433-01	0.75 MG/0.5 ML	$139.22	$9.00	$437.00	***	***	***	$21.03	$0.00	$0.00
00002-1434-01	1.5 MG/0.5 ML	$58.50	$0.00	$210.00	***	***	***	$21.45	$0.00	$24.00
00002-3182-01	4.5 MG/0.5 ML	$191.18	$30.00	$410.00				$2.56	$0.00	$9.85
50090-3484-00	0.75 MG/0.5 ML	***	***	***	***	***	***			
50090-6456-00	1.5 MG/0.5 ML	***	***	***	***	***	***			
50090-3483-00	1.5 MG/0.5 ML	***	***	***	***	***	***			
50090-6571-00	3 MG/0.5 ML	***	***	***	***	***	***			
50090-5467-00	3 MG/0.5 ML	$816.19	$0.00	$4,245.00	***	***	***			

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^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

The Maryland Manual On-line provides estimates of the Maryland median household income and per capita personal income based on data from the U.S. Census Bureau.[90] The Maryland Manual reports a 2023 median household income of $101,652 and a per capita personal income of $75,391. The Maryland Manual also provides per capita personal income for each county. In 2023, personal income per capita ranged from $37,345 in Somerset County to $100,044 in Montgomery County.

[90] https://msa.maryland.gov/msa/mdmanual/01glance/economy/html/income.html

Factor 7.6: An assessment of the impact of the prescription drug product's cost to access by priority populations and the impact on equity

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(vii)
Methodology: Analysis of claims data
Data Sources: MCDB

Given that the claims data did not include demographic information for the vast majority of patients, staff were unable to make a conclusive assessment. Due to the lack of data and information for this element, staff are unable to provide the Board with this data, information, and analyses for study.

If demographic information were available, staff anticipated using linear regression techniques to assess whether there is a statistically significant difference in spending and utilization between identified priority populations for each selected drug. The priority populations to be assessed are informed by the Agency for Healthcare Research and Quality (AHRQ) reporting of priority populations.[91]

Since staff were unable to conduct the Maryland-specific analysis, staff conducted a literature review to see if any studies addressed disparities at a national level. Staff identified one study concerning differences in utilization and another study that examined differences in initiation.

In one study, researchers examined GLP-1 RA utilization among commercially insured patients with Type 2 diabetes mellitus (T2D) with or without atherosclerotic cardiovascular disease (ASCVD).[92] For GLP-1 RA use among all patients, multivariable analysis revealed the following information: Female sex was associated with higher GLP-1 RA use, with an odds ratio of 1.22. When compared with White individuals, Asian, Black, and Hispanic patients had lower GLP-1 RA use, with odds ratios of 0.59, 0.81, and 0.91, respectively. The researchers also found that higher annual median household incomes ≥$50,000 were associated with higher GLP-1 RA use compared to lower median household incomes <$50,000, with an odds ratio of 1.13.

For patients with both T2D and ASCVD, multivariable analyses provided similar results: Female sex was associated with higher GLP-1 RA use, with an odds ratio of 1.18. When compared with White individuals, Asian, Black, and Hispanic patients had lower GLP1-RA use, with odds ratios

[91] The selection of priority populations informed by AHRQ's definitions. https://www.ahrq.gov/priority-populations/index.html (last checked April 30, 2025).
[92] Eberly LA, Yang L, Essien UR, et al. Racial, Ethnic, and Socioeconomic Inequities in Glucagon-Like Peptide-1 Receptor Agonist Use Among Patients With Diabetes in the US. *JAMA Health Forum.* 2021;2(12):e214182. doi:10.1001/jamahealthforum.2021.4182

of 0.69, 0.82, and 0.94, respectively. For this subgroup, higher median household incomes were also associated with more GLP-1 RA use when compared with lower income <$50,000 (>$100,000 odds ratio: 1.06; $50,000-$99,000 odds ratio: 1.15).

A second study examined, among other things, sociodemographic and clinical factors associated with the initiation of GLP-1 RA therapy compared to sulfonylurea therapy in a Medicare fee-for-service patient population with CKD and T2D.[93] The researchers found that female sex was associated with higher GLP-1 RA therapy initiation, with an odds ratio of 1.20. Black, Asian, and Hispanic patients were associated with lower odds of GLP-1 RA therapy initiation compared to White patients, with odds ratios of 0.73, 0.74, and 0.81, respectively. When compared to patients with a household median income of $60,000-$99,000, patients with a median income of ≥$100,000 were more likely to initiate GLP-1 RA therapy (odds ratio: 1.21), whereas those with median income <$60,000 were less likely (odds ratio for income ≤$34,999: 0.87; odds ratio for income between $35,000-$59,999: 0.88).

[93] Julie Z. Zhao, Eric D. Weinhandl, Angeline M. Carlson, Wendy L. St. Peter. Disparities in SGLT2 Inhibitor or Glucagon-Like Peptide 1 Receptor Agonist Initiation Among Medicare-Insured Adults With CKD in the United States. *Kidney Medicine*. Volume 5, Issue 1, 2023, 100564, ISSN 2590-0595. https://doi.org/10.1016/j.xkme.2022.100564.

Factor 7.7: The costs to health plans based on patient access consistent with FDA-labeled indications or standard medical practice

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(vi);
COMAR 14.01.04.05C(1)(d)(i)
Methodology: Aggregation of number of unique patients in claims data and calculation potential gross spending if all patients used a full year of treatment
Data Sources: FDA Databases and MCDB

The tables below summarize the projected spending if all patients used 365 days' worth of the prescription drug product. This data was calculated based on the number of patients using an NDC multiplied by the annual WAC (as estimated in other tables). This number may be an overestimate for total spending across all NDCs because a single patient may use multiple NDCs over the course of a year. In addition, these numbers assume that patients have completed their initial doses, and all prescriptions are based on steady state doses consistent with the maximum or only dose each NDC is designed to administer.

Table 20. Trulicity Cost Consistent with FDA Label

National Drug Code (11-Digit)	Dosage Strength	Projected Yearly Spending Commerical	Projected Yearly Spending State and Local Government	Projected Yearly Spending Medicare	Projected Yearly Spending Medicaid
00002-1433-01	0.75 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]
00002-1433-61	0.75 MG/0.5 ML				
00002-1433-80	0.75 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]
00002-1434-01	1.5 MG/0.5 ML	[redacted]	***	[redacted]	[redacted]
00002-1434-80	1.5 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]
00002-2236-01	3 MG/0.5 ML	[redacted]		[redacted]	[redacted]
00002-2236-80	3 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]
00002-3182-01	4.5 MG/0.5 ML	[redacted]		[redacted]	***
00002-3182-80	4.5 MG/0.5 ML	[redacted]	[redacted]	[redacted]	[redacted]
50090-3483-00	1.5 MG/0.5 ML	***	***		
50090-3484-00	0.75 MG/0.5 ML	***	***		
50090-5467-00	3 MG/0.5 ML				
50090-6453-00	0.75 MG/0.5 ML				
50090-6456-00	1.5 MG/0.5 ML				
50090-6571-00	3 MG/0.5 ML				

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

Section 8: Other Information

Factor 8.1: Input from the Public

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xvii)
Methodology: Input received
Data Sources: Public

INITIAL 60-DAY COMMENT PERIOD

60-Day Written Comment: Notice Posted on 5/23/2024

In accordance with COMAR 14.01.04.05C(2)(a), the public may provide written comments concerning the prescription drug product within 60 days of the date the drug selected for a cost review study is posted on the Board's website. The 60-day Public Comment period for Trulicity began on May 23, 2024, and ended July 22, 2024. *See* Exhibit 6A.

WRITTEN COMMENT REQUEST

Written Comment Request: Posted 10/28/2024

In accordance with COMAR 14.01.01.05B(4), the Board requested public written comments for the cost review study process for Farxiga, Jardiance, Ozempic and Trulicity. Patient experience and clinician input regarding these drugs were of particular interest, but all comments were encouraged. Written comments were due by the close of business, Friday, November 8, 2024.

Written comments for Trulicity received in response to this request are attached as Exhibit 6B and are also available on the Board's website.[94]

[94] Trulicity Public Comment - Pages 7-8
https://pdab.maryland.gov/Documents/comments/11.8.2024%20Cost%20Review%20Comment%20Packet_updated.pdf

Factor 8.2: Analysis of the impact of state and federal regulatory and compliance issues related to the prescription drug product

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xiii)
Methodology: Research
Data Sources: Review of FDA, DEA, and State regulations

Staff did not identify any other regulatory or compliance issue that would provide additional context for the market related to this prescription drug product.

Factor 8.3: Input from state and local governmental entities and the entities' contractors such as health plans and plan administrators

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xiv)
Methodology: Outreach to state and local governmental entities
Data Sources: State and Governmental Entities

Although Board staff reached out to state and local government entities, staff did not receive input for the cost review study of Trulicity.

For future Cost Review Studies, staff will continue to work with state and local governments to develop data and mechanisms to support this factor.

Factor 8.4: Information and analyses submitted by an entity under Regulation .04 of this chapter.

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05.C(1)(g)(xviii)
Methodology: Request for Information
Data Sources: Manufacturer, health plans, PBMS, wholesalers as applicable

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as Exhibit 2 to the dossier. Under COMAR 14.01.04.05C(1)(g)(xviii), the Board may consider the "[i]nformation and analyses submitted by an entity under Regulation .04 of this chapter."

In accordance with Health-General Article § 21-2C-09 and COMAR 14.01.04.05E, the Board only considers certain categories of information and data if the Board is first unable to make an affordability challenge determination based on the other data and information provided. If the Board is unable to make an affordability determination, the Board may then consider that information. In compliance with these requirements, Board staff redacted the information that may be considered at the second step from the submitted documents provided to the Board as exhibits to the dossier. If the Board is unable to make an affordability challenge determination, staff will provide the Board with unredacted copies of the exhibits that contain the information that may be considered at the second step.

Table of Exhibits

Exhibit 1_REDACTED		Pricing History_REDACTED (PDF)
Exhibit 2		RFI Submissions **(NON-PUBLIC--TRADE SECRET,** ehi**CONFIDENTIAL, AND PROPRIETARY)**
Exhibit 3_REDACTED		TRULICITY Therapeutic Alternative Pricing_REDACTED (Excel Document)
Exhibit 4		Trulicity Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document)
Exhibit 5		
	Exhibit 5A	Trulicity Summary of Cost Effectiveness Analyses
	Exhibit 5B	Trulicity Summary of Comparative Effectiveness Research
Exhibit 6		
	Exhibit 6A	Written Comments (60-day COMAR 14.01.04.05C(2)) (PDF)
	Exhibit 6B	Written Comments (Request October 28, 2024) (PDF)

In accordance with Health-General Article §§ 21-2c-10 and 21-2c-03, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. The documents contained in Exhibit 2 are, therefore, not available to the public.