

Trulicity Cost Review Study

PDAB Meeting

November 17, 2025

PDAB Staff



History and Input on the Dossier

- **Draft Dossier for Public Comment**
 - **Posted for Comment: August 20, 2025**
 - **Comments Due: September 4, 2025**
- **Final Dossier for Consideration**
 - **Posted: November 4, 2025**



Trulicity Dossier Comments

- **PDAB staff received a total of 8 comments on the Trulicity dossier for the comment period ending on September 4, 2025. Six comments were provided by organizations, two comments were provided by a pharmaceutical company.**
- **Feedback Themes Included:**
 - Technical Changes
 - Process and Deadlines
 - Upper Payment Limit Concerns
 - Support for Upper Payment Limits
 - Consideration of Plan Design in Analysis
 - Process for Collecting Physician and Patient Input
 - Manufacturer Affordability Initiative
 - Therapeutic Alternative Interchangeability
 - Policy recommendations



Incorporated Changes

- **PDAB staff posted a Final Dossier on November 4, 2025 that incorporated changes from the August 20 version. These changes included:**
 - General Formatting and Copy Editing
 - Updated Disclaimer Explaining NDCs included in Cost Review Study



Dossier Overview

- Section 1: Background
- Section 2: Clinical Information
- Section 3: Regulatory Approval and Market Context
- Section 4: Utilization of Drug Product Under Review
- Section 5: Pricing Information and Rebates
- Section 6: Therapeutic Alternatives, Cost Comparisons, and Health Economics Outcomes and Research (HEOR)
- Section 7: Cost-Sharing and Insurance Benefit Design
- Section 8: Other Information



Dossier Overview

Table of Exhibits

Exhibit 1_REDACTED	Pricing History_REDACTED (PDF)
Exhibit 2	RFI Submissions (NON-PUBLIC--TRADE SECRET, 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) Exhibit 6C Written Comments (Request September 4, 2025) (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.



Section 1: Background



Section 1: Background

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



Section 2: Clinical Information



Factor 2.1: Clinical information- FDA indications

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

<i>Indication</i>	<i>Dosing Regimen(s)</i>
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.	<p><u>Adult dosing</u> 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)</p> <p><u>Pediatric dosing</u> 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)</p>
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.	<p>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)</p>



Factor 2.1: Clinical information- Information concerning standard medical practice

Place in Therapy for Diabetes Mellitus Type 2

- 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).

All Pricing, Spending and Utilization Data is Consistent with the labeling approved by the FDA or standard medical practice.



Factor 2.2: The disease burden of the condition that is treated by the prescription drug product- Type 2 Diabetes Mellitus (DM)

Prevalence

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

Incidence

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

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.
- 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.

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. 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.

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.
- In Maryland in 2021, total and per patient medical costs attributable to diabetes were \$6.506 billion and \$11,909, respectively.
- In Maryland in 2021, diabetes-attributable total and per-person productivity losses due to morbidity were \$3.4 billion and \$6,224, respectively.



Factor 2.2: The disease burden of the condition that is treated by the prescription drug product- Type 2 Diabetes Mellitus (DM)

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).
- 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).
- 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.

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).
- Including diabetes as a contributing cause of death, the rate increases to 120.3 per 100,000 people (399,401 death certificates).
- 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.



Section 3: Regulatory Approval and Market Context



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

- The U.S. Food and Drug Administration (FDA) initially approved Trulicity on September 18, 2014.
- On February 8th, 2017, Trulicity was approved for use in combination with basal insulin for treatment of diabetes.
- On February 21st, 2020, Trulicity was approved to reduce major adverse cardiovascular events in adults with Type 2 Diabetes.
- On September 3rd, 2020, Trulicity received FDA approval to use additional dosages for treatment of Type 2 Diabetes, after demonstrating that 3.0mg and 4.5mg doses demonstrated additional benefits.
- On November 17th, 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.



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

- Trulicity is not in shortage
- Dulaglutide products were listed as in shortage from 12/15/2022-06/13/2025, but these shortages have since been resolved

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



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

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



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

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



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

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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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

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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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

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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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

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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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

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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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

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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 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

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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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

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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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

- 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

- WAC and AWP are redacted as proprietary information
- Exhibit 1 reflects pricing history for Trulicity.



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

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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Blank spaces indicate that no data was provided.



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

- Net price and net sales are redacted as proprietary information



Factor 5.3: Information estimating manufacturer net price and net sales amounts of the prescription drug product under review

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



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

- Exhibit 2 contains information responsive to this element
- Documents are available to the Board, but not the public, as exhibits to the dossier.



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

- Exhibit 2 contains information responsive to this element
- Documents are available to the Board, but not the public, as exhibits to the dossier.



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

- WAC and AWP are redacted as proprietary information
- Exhibit 3_REDACTED TRULICITY Therapeutic Alternative Pricing_REDACTED (Excel Document)



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

- The average price concession, discount, or rebate the manufacturer provides or is expected to provide redacted as proprietary information
- Exhibit 3_REDACTED TRULICITY Therapeutic Alternative Pricing_REDACTED (Excel Document)



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

- Exhibit 4 (Trulicity Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document))



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

- Exhibit 5A Trulicity Summary of Cost Effectiveness Analyses
- General Findings
 - The results of all four studies favored Ozempic/Rybelsus over Trulicity.
 - Ozempic/Rybelsus cost was set either equal to or less than Trulicity and Ozempic/Rybelsus achieved higher proportions of target clinical outcomes, analysis outcomes favored Ozempic/Rybelsus as more cost-effective options.



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.

- Exhibit 5A Trulicity Summary of Cost Effectiveness Analyses and Exhibit 5B Trulicity Summary of Comparative Effectiveness Research
 - Overall, the choice of antihyperglycemic agent utilized for the control of Type 2 Diabetes is driven by a combination of patient-centered factors, including degree of HgbA1c lowering desired, cardiorenal protection, side effects, administration preferences (oral vs. subcutaneous injection, administration frequency), and cost.
 - Clinically, all antihyperglycemic agents are considered efficacious for lowering HgbA1c and controlling blood glucose, though absolute degree may vary between medication class.



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

- Trulicity is not a generic drug product.



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

- 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.



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

- Analyses 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:
 - One study found that as patient co-payment levels increased from low (less than \$10) to medium (\$10-\$50) and high (greater than \$50), the proportion of patients with high prescription coverage (more than 80% of days covered) decreased from 72% to 66% to 60%, respectively, without controlling for other factors.
 - A separate study on GLP-1 RA therapy found that compared to patients in the lowest out-of-pocket (OOP) cost quartile (\$0-\$21), those in the highest OOP cost quartile (\$80-\$3,375) had 1.25 times the odds of nonadherence.



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

- Staff identified two patient access programs for Trulicity. The first program is the Trulicity Savings Card. This card can allow patients to pay as little as \$25 for a 1-month, 2-month, or 3-month prescription fill of Trulicity.
 - A reasonable search failed to disclose publicly available information concerning the dollar value of the Trulicity Savings Card.
- The second program is called Lilly Cares. Qualifying patients can receive prescribed Lilly medications for free for up to 12 months.
 - 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.
 - 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.
- Between January 2023 to July 2025, 13,980 Trulicity prescriptions filled in Maryland received Lilly-provided assistance. About 83% of those claims reached an OOP cost of between \$25 and \$30, with OOP costs of \$50 or less for 91% of claims.



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

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

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

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

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%	***	

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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

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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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

- Claims data did not include demographic information for the vast majority of patients
 - Staff were unable to make a conclusive assessment
- Literature Review:
 - Utilization
 - Female sex patients had consistently higher utilization Odds Ratios (ORs 1.18 to 1.22) compared to male sex patients.
 - Asian, Black, and Hispanic patients were found to have consistently lower odds of GLP-1 RA use compared to White patients (ORs for use as low as 0.59 for Asian patients).
 - Higher median household incomes (\geq \$50,000) were associated with higher utilization compared to lower-income groups.
 - Initiation
 - Asian, Black, and Hispanic Medicare patients were all associated with lower odds of initiating GLP-1 RA therapy compared to White patients (ORs as low as 0.73 for Black patients).
 - Patients in the highest income bracket (\geq \$100,000) were more likely to initiate GLP-1 RA therapy (OR 1.21), while the lowest income bracket (\leq \$34,999) was less likely (OR 0.87).



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

- This data was calculated based on the number of patients using an NDC multiplied by the annual WAC, which is redacted as proprietary information.



Section 8: Other Information



Factor 8.1: Input from the Public

- Staff received comments during the following comment periods:
 - INITIAL 60-DAY COMMENT PERIOD
 - 60-Day Written Comment: Notice Posted on 5/23/2024
 - WRITTEN COMMENT REQUEST
 - Written Comment Request: Posted 10/28/2024
 - WRITTEN COMMENT REQUEST ON DRAFT DOSSIER
 - Written Comment Request: Posted 08/20/2025



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

- 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

- Board staff did not receive input from state and local government entities for the cost review study of Trulicity.



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

- Documents received in response to the request for information are available to the Board, but not the public, as Exhibit 2 to the dossier.
- 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.





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