

Trulicity Upper Payment Limit Framework

PDAB Meeting

January 26, 2026

PDAB Staff



14.01.05.02 Criteria for Setting UPL

Guiding Principles

B. The Board shall:

- (1) Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;**
 - (2) Determine whether an upper payment limit is an appropriate tool to address the drivers of the affordability challenge identified for the prescription drug product;**
 - (3) Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences;**
- and**
- (4) Prioritize drugs that have a high proportion of out-of-pocket costs compared to the system net cost of the drug.**

C. The Board shall not set an upper payment limit if:

- (1) Spending on the prescription drug product by the eligible governmental entities is less than the administrative cost to implement an upper payment limit; or**
- (2) The prescription drug product is a generic and there are nine or more marketed therapeutic equivalents for the product.**

D. The Board shall not set an upper payment limit at an amount that:

- (1) Impacts statutory or regulatory amounts, such as Medicaid Best Price; or**
- (2) Is lower than the Medicare Maximum Fair Price.**



14.01.05.06A. Policy Review—Process for Establishing a UPL.

A. Staff Recommends Frameworks and Contextual Information.

(1) Board staff shall recommend at least one framework, identified in §B of this regulation, for use in developing a UPL for the subject prescription drug product.

(2) Board staff may recommend certain contextual information identified in §C of this regulation for use in developing a UPL for the subject prescription drug product.



Frameworks

- (1) Cost Effectiveness Analysis**
- (2) Therapeutic Class Reference**
- (3) Launch Price-Based**
- (4) Small Molecule Reference Based**
- (5) Domestic Reference**
 - Maximum Fair Price**
 - Other Domestic Reference Prices**
- (6) International Reference**
- (7) Budget Impact Based**
- (8) Blend of Multiple Frameworks**



14.01.05.06B(1) Frameworks- Cost Effectiveness Analysis

Cost Effectiveness Analysis- Uses a cost-effectiveness analysis to model how much additional health outcome is gained per dollar of additional spending when using a drug product compared to an alternative; is the drug cost effective at the current net price.

Literature review (Exhibit 5A) disclosed mixed results, but some literature supports finding the drug cost effective at existing net prices.



14.01.05.06B(2)- Therapeutic Class Reference Upper Payment Limit.

Therapeutic Class Reference Upper Payment Limit- Uses the lowest net price or net cost among competitor products in the same therapeutic class.

There are several key parameters that will determine the potential therapeutic class reference UPL, including which subset of the products in the class to consider and which prices to examine.



14.01.05.06B(3)- Launch Price-Based Upper Payment Limit.

Launch Price-Based Upper Payment Limit- Uses the initial price at which the drug was first marketed (launch price) adjusted for inflation.

The launch price analysis is based on WAC, and is available to the Board. The launch price-based UPL did not provide savings compared to net price.



14.01.05.06.B(4)- Same Molecule Reference Upper Payment Limit.

Same Molecule Reference Upper Payment Limit- Uses prices of the same molecule.

Trulicity does not have qualifying molecules for reference.



14.01.05.06.B(5)- Domestic Reference Upper Payment Limit.

Domestic Reference Upper Payment Limit - Uses the estimated net cost of a prescription drug product within the U.S. or the net price received by the manufacturer.

- **Average Net Price- Based on proprietary data and available to the Board**
- **National Actual Acquisition Cost (NADAC)**
30-day supply: \$1010.85
- **State Actual Acquisition Cost**
30-day supply: \$1003.05
- **Federal Supply Schedule**
30-day supply: \$972.31



14.01.05.06.B(6)- International Reference Upper Payment Limit.

International Reference Upper Payment Limit- Uses international reference prices based on the lowest price received by manufacturers for sales in the United Kingdom, Germany, France, and Canada, converted to U.S. dollars.

United Kingdom 30-day supply: \$97.82 - \$268

Germany 30-day supply: \$111 - \$229

France 30-day supply: \$94.12

Canada 30-day supply: \$121.16



14.01.05.06.B(7)- Budget Impact-Based Upper Payment Limits.

Budget Impact-Based Upper Payment Limits- Uses a payment amount for a drug that does not exceed a certain threshold of a certain budget.

Given the current and long standing use of this drug, and the lack of a methodology for setting appropriate budget spending goal(s), staff does not recommend using a budget-impact analysis to establish a UPL.



14.01.05.06.B(8)- Blend of Multiple Frameworks.

(8) Blend of Multiple Frameworks- Uses a blend of frameworks or a variation in implementing a framework.

Not recommended for this drug.



Summary of Frameworks

Reg Citation	Price	Monthly Cost
	List Price	Not publicly available
14.01.05.06.B.(1)	Cost Effectiveness Analysis	N/A
14.01.05.06.B.(2)	Therapeutic Class Reference	TBD
14.01.05.06.B.(3)	Launch Price-Based	N/A
14.01.05.06.B.(4)	Same Molecule Reference	N/A
14.01.05.06.B.(5)	Medicare Maximum Fair Price-Domestic Reference	N/A
14.01.05.06.B.(5)	NADAC- Domestic Reference	\$1010.85
14.01.05.06.B.(5)	SAAC- Domestic Reference	\$1003.05
14.01.05.06.B.(5)	FSS- Domestic Reference	\$972.31
14.01.05.06.B.(6)	UK- International Reference	\$97 - \$268
14.01.05.06.B.(6)	Germany- International Reference	\$111 - \$229
14.01.05.06.B.(6)	France- International Reference	\$94.12
14.01.05.06.B.(6)	Canada- International Reference	\$121.16
14.01.05.06.B.(7)	Budget Impact-Based	N/A



Staff Recommended Contextual Information - COMAR 14.01.05.06C

- (1) Information gathered during the cost review study process or the policy review process;
- (2) Net costs for:
 - (a) State health plan;
 - (b) County, bicounty, and municipal health plans;
 - (c) Direct government purchases; and
 - (d) Medicaid;
- (4) Current coverage status of the drug in:
 - (a) State health plan;
 - (b) County, bicounty, and municipal health plans; and
 - (c) Medicaid;
- (5) Utilization in the following program by patients and prescriptions:
 - (a) State health plan;
 - (b) County, bicounty, and municipal health plans; and
 - (c) Medicaid;
- (6) Amount of direct government purchases by units and patients served;
- (8) Budget impact analysis;



Staff Recommendations

Staff Recommended Framework: National Domestic Reference Pricing - (COMAR 14.01.05.06B(2)) - Therapeutic Class Reference Upper Payment Limit

Staff Recommended Contextual Information: COMAR 14.01.05.06C(1), (2), (4), (6), and (8)





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