

# Ozempic Upper Payment Limit Framework

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PDAB Meeting

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PDAB Staff



## 14.01.05.02 Criteria for Setting UPL

### Guiding Principles

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#### **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.**

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### **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

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- (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**

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**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.**

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**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.**

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**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.**

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

**Ozempic does not have qualifying molecules for reference.**



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

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**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**
- **Medicare Maximum Fair Price (MFP)**  
30-day supply: \$274.00
- **National Actual Acquisition Cost (NADAC)**  
30-day supply: \$1002.25
- **State Actual Acquisition Cost**  
30-day supply: \$999.43
- **Federal Supply Schedule**  
30-day supply: \$987.49



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

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**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.**

|                       |                                     |
|-----------------------|-------------------------------------|
| <b>United Kingdom</b> | <b>30-day supply: \$174 - \$241</b> |
| <b>Germany</b>        | <b>30-day supply: \$115 - \$229</b> |
| <b>France</b>         | <b>30-day supply: \$90</b>          |
| <b>Canada</b>         | <b>30-day supply: \$140.44</b>      |



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

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**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.**

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**(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                                     | \$959.00      |
| 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 | \$274.00      |
| 14.01.05.06.B.(5) | NADAC- Domestic Reference                      | \$1002.25     |
| 14.01.05.06.B.(5) | SAAC- Domestic Reference                       | \$999.43      |
| 14.01.05.06.B.(5) | FSS- Domestic Reference                        | \$987.49      |
| 14.01.05.06.B.(6) | UK- International Reference                    | \$174 - \$242 |
| 14.01.05.06.B.(6) | Germany- International Reference               | \$115 - \$229 |
| 14.01.05.06.B.(6) | France- International Reference                | \$90          |
| 14.01.05.06.B.(6) | Canada- International Reference                | \$140.44      |
| 14.01.05.06.B.(7) | Budget Impact-Based                            | N/A           |



## **Staff Recommended Framework: Domestic Reference Pricing (COMAR 14.01.05.06B(5))- Medicare Maximum Fair Price (MFP)**

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**Calendar Year (CY27) Negotiated Maximum Fair Price for 30-day supply:** \$274.00

**Data and Data Sources:** Published Medicare Maximum Fair Price; Centers for Medicare & Medicaid Services

**Calculation:** Using the MFP as a pricing benchmark, the Board sets a UPL no lower than the MFP. The negotiated MFP is \$274.00 for a 30-day supply.

**Assumptions:** Medicare plans may negotiate additional discounts and rebates off of the published Medicare MFP.



# Staff Recommended Framework: Domestic Reference Pricing (COMAR 14.01.05.06B(5))- Medicare Maximum Fair Price (MFP)

## Savings Estimates:

Equation 1.

$$\text{Units per 30 day supply} = \frac{\text{Price}}{\text{30 Day Supply}} \times (\text{Unit Price})$$

Equation 2.

$$\text{Unit Price} = \frac{\text{Price}}{(\text{30 Day Supply})} \times \frac{(\text{30 Day Supply})}{(\text{Units Dispensed})}$$

Equation 3.

$$\text{Total Net Spend} = (\text{Unit Price}) \times (\text{Units Dispensed})$$



# Staff Recommended Framework: Domestic Reference Pricing (COMAR 14.01.05.06B(5))- Medicare Maximum Fair Price (MFP)

## Savings Estimates:

| National Drug Code (11-Digit) | MFP Per 30 Day | MFP Per Unit | Units Per 30-Day Supply | Estimated Current Net Per 30 Day | Current Net Per Unit | Units Dispensed | Gross Spend             | Net Spend Under MFP    | Current Net Spend      |
|-------------------------------|----------------|--------------|-------------------------|----------------------------------|----------------------|-----------------|-------------------------|------------------------|------------------------|
| 00169-4130-01                 | \$274.00       | \$92.26      | \$2.97                  | \$428.00                         | \$144.11             | 93              | \$26,267.00             | \$8,580.21             | \$13,402.66            |
| 00169-4130-13                 | \$274.00       | \$92.26      | \$2.97                  | \$428.00                         | \$144.11             | 43,653          | \$12,857,706.00         | \$4,027,439.44         | \$6,291,036.79         |
| 00169-4132-12                 | \$274.00       | \$177.83     | \$1.54                  | \$428.00                         | \$277.78             | 5,457           | \$ 2,653,728.00         | \$970,407.42           | \$1,515,818.89         |
| 00169-4136-11                 | \$274.00       | \$92.26      | \$2.97                  | \$428.00                         | \$144.11             | .               | .                       |                        |                        |
| 00169-4181-13                 | \$274.00       | \$92.26      | \$2.97                  | \$428.00                         | \$144.12             | 35,061          | \$ 10,774,847.00        | \$3,234,790.06         | \$5,052,883.74         |
| 00169-4772-11                 | \$274.00       | \$92.22      | \$2.97                  | \$428.00                         | \$144.06             |                 |                         |                        |                        |
| 00169-4772-12                 | \$274.00       | \$92.22      | \$2.97                  | \$428.00                         | \$144.06             | 22,364          | \$ 7,085,183.00         | \$2,062,515.47         | \$3,221,739.50         |
| <b>Total</b>                  |                |              |                         |                                  |                      |                 | <b>\$ 33,397,731.00</b> | <b>\$10,303,732.61</b> | <b>\$16,094,881.59</b> |



# Staff Recommended Contextual Information - COMAR 14.01.05.06C

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- (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**

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**Staff Recommended Framework: Domestic Reference Pricing (COMAR 14.01.05.06B(5))- Medicare Maximum Fair Price (MFP)**

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





**MARYLAND**  
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