

# Trulicity: Upper Payment Limit Framework

## Summary

Under the Policy Review process for Establishing an Upper Payment Limit (UPL) (COMAR 14.01.05.06A), Board staff shall recommend at least one framework for use in developing a UPL and may recommend certain contextual information for use in developing a UPL for the subject prescription drug product.

Staff explored numerous frameworks for developing a UPL for Trulicity. Based on the frameworks explored, staff recommends further exploring and developing methodologies for two frameworks: Therapeutic Class Reference Upper Payment Limit (*see* COMAR 14.01.05.06B(2)) and Domestic Reference Upper Payment Limit (*see* COMAR 14.01.05.06B(5)). This may result in the Board selecting either a methodology that uses one or a combination of these frameworks. Consistent with the regulatory criteria, additional frameworks that may impact statutory or regulatory amounts are not recommended. *See* COMAR 14.01.05.02.D(1).

Finally, the Board may establish a UPL for eligible governmental entities that represents the system net ingredient cost (*see* COMAR 14.01.05.01B(8)).

This document is not the methodology document. The estimates below are rough estimates based on publicly available data that are not intended as final. After the Board has selected a framework, staff will publish methodology documents for public comment.

## Staff Recommendations for Trulicity

### Recommended UPL Framework(s):

If the Board wishes to develop a UPL for Trulicity for Eligible Governmental Entities, staff recommends that the Board use the Therapeutic Class Reference Upper Payment Limit (COMAR 14.01.05.06B(2)) framework.

### Contextual Information:

Under COMAR 14.01.05.06C, staff recommends that the Board utilize the following Contextual Information in setting the UPL for Trulicity:

- Information gathered during the cost review study process or the policy review process; COMAR 14.01.05.06C(1)
- Net costs for:
  - o State health plan;
  - o County, bicounty, and municipal health plans;
  - o Direct government purchases; and
  - o Medicaid; COMAR 14.01.05.06C(2)
- Current coverage status of the drug in:
  - o State health plan;
  - o County, bicounty, and municipal health plans; and
  - o Medicaid; COMAR 14.01.05.06C(4)
- Utilization in the following program by patients and prescriptions:
  - o State health plan;
  - o County, bicounty, and municipal health plans; and
  - o Medicaid; COMAR 14.01.05.06C(5)
- Amount of direct government purchases by units and patients served; COMAR 14.01.05.06C(6); and
- Budget impact analysis. COMAR 14.01.05.06C(8).

## Framework Recommendations

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

#### **Description:**

Under this framework, the Board may set a UPL using the lowest net price or net cost among competitor products in the same therapeutic class. The Board may limit the prescription drug products used for analysis to a subset of drugs in the same therapeutic class. When determining whether to use a product in the same therapeutic class as a reference product, the Board may consider a difference in indication including a difference in the patient population and disease severity, and comparative effectiveness research (*see* COMAR 14.01.05.06B(2)).

There are several key parameters that determine the potential therapeutic class reference UPL, such as the subset of the products in the class to consider and the prices to examine. Given these variables, staff may draft multiple methodologies for the Board to consider with different estimates if the Board decides to go forward with this framework.

### COMAR 14.01.05.06B(5) National Domestic Reference Pricing

#### **Description:**

Under the domestic reference framework, a UPL value may be set using the estimated net cost of a prescription drug product to other purchasers and payors for the same prescription drug product within the United States or the net price received by the manufacturer.

There are several National Domestic References prices available for consideration, including Average Net Price, National Average Drug Acquisition Cost (NADAC), State Actual Acquisition Cost (SAAC), the Federal Supply Schedule (FSS), and, as applicable, the Medicare Maximum Fair Price (MFP).