Farxiga: 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.

Based on the criteria for setting a UPL (*see e.g.*, COMAR 14.01.05.02D), the Board shall not set a UPL that is lower than the Medicare Maximum Fair Price. Farxiga was selected for the first round of Medicare Price Negotiations[1] and has a Medicare Maximum Fair Price.[2] Staff explored numerous other frameworks for developing a UPL for Farxiga. However, most of the additional frameworks, such as therapeutic class reference pricing and international reference pricing, produced results that are below the Medicare Maximum Fair Price. Consistent with the regulatory criteria, these frameworks are not recommended by staff. *See* COMAR 14.01.05.06D(2).

Finally, the Board may establish a UPL for eligible governmental entities that represents the system net ingredient cost. (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.

[1] Selected Drugs and Negotiated Prices. https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices
[2] Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026. https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf

Staff Recommendations for Farxiga

Recommended UPL Framework(s):

If the Board wishes to develop a UPL for Farxiga for participating Eligible Governmental Entities, staff recommends that the Board use the Domestic Reference Pricing (COMAR 14.01.05.06B(5))- Medicare Maximum Fair Price (MFP) framework. The negotiated MFP for CY2026 is $178.50 for a 30-day supply, or $5.95 per pill.

Contextual Information:

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

- Information gathered during the cost review study process or the policy review process; COMAR 14.01.05.01C(1)
- Net costs for:
    - State health plan;
    - County, bicounty, and municipal health plans;
    - Direct government purchases; and
    - Medicaid; COMAR 14.01.05.01C(2)
- Current coverage status of the drug in:
    - State health plan;
    - County, bicounty, and municipal health plans; and
    - Medicaid; COMAR 14.01.05.01C(4)
- Utilization in the following program by patients and prescriptions:
    - State health plan;
    - County, bicounty, and municipal health plans; and
    - Medicaid; COMAR 14.01.05.01C(5)
- Amount of direct government purchases by units and patients served; COMAR 14.01.05.01C(6); and
- Budget impact analysis. COMAR 14.01.05.01C(8).

Framework Recommendation

COMAR 14.01.05.06B(5) National Domestic Reference Pricing - Medicare Maximum Fair Price (MFP)

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.

Under the Inflation Reduction Act of 2022 (P.L. 117-169), CMS (Medicare) was authorized to negotiate the prices of certain high-expenditure drugs directly with manufacturers. CMS selected ten drugs covered under Medicare Part D for the first cycle of negotiations. CMS reports that it "engaged in genuine, thoughtful negotiations with each participating drug company."[3] CMS also advises that it "developed an initial offer for each drug, consistent with the process described in the statute and the agency's guidance," and each manufacturer responded with a counteroffer.[4]

CMS has provided an analysis of its processes and the data considered in negotiating the Maximum Fair Price, which is available on the CMS website.[5] CMS reports that it "held three meetings with each participating drug company to discuss the offers and counteroffers, discuss evidence, and attempt to arrive at a mutually acceptable price for the drug."[6] CMS revised its offers upward for each drug in response. Some drug companies revised their counteroffers downward. Although the route by which the negotiated price was reached varied by drug, a Maximum Fair Price has been published for each drug.

Farxiga was part of the first round of negotiations. CMS has published a Maximum Fair Price (MFP) for Farxiga, effective January 1, 2026. CMS has also published an explanation of the MFP.[7]

[3] *Id.*
[4] *Id.*
[5] Medicare Drug Negotiation Program. https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program
[6] Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026. https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf
[7] CMS File for the MFP Explanation for Farxiga (ZIP) https://www.cms.gov/files/zip/mfp-explanation-farxiga.zip

Data and Data Sources:
Published Medicare Maximum Fair Price; Centers for Medicare & Medicaid Services[8]

Calculation:
Using the MFP as a pricing benchmark, the Board sets a UPL no lower than the MFP. *See also* COMAR 14.01.05.06D(2).

The negotiated MFP is $178.50 for a 30-day supply,[9] or $5.95 per pill based on the FDA-labeled use of 1 pill per day.[10]

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

Estimated Savings/Savings Comparison:
These cost savings estimates are based on publicly available data, which may not align fully with certain proprietary data. Within these limitations, these are estimates designed to leverage the available data to understand the potential for savings.

CMS reports that the CY 2023 List Price for a 30-day supply of the drug was $556 and that the negotiated MFP of $178.50 represents a 68% discount from the list price.[11] Using the number of units dispensed in the Maryland Medical Claims Database (MCDB) for State and Local Governments in 2022 (391,311),[12] divided by 30, staff calculated the number of 30-day supplies dispensed (13,044). Staff then multiplied the number of 30-day supplies dispensed (13,044) by the CY 2023 CMS List Price ($556) to approximate the amount state and local governments would have spent using the CMS List Price ($7,252,297).

Similarly, staff multiplied the number of 30-day supplies dispensed (13,044) by the CMS MFP ($178.50) to approximate the amount state and local governments would have spent using the CMS MFP ($2,328,300).

Staff then compared the amount state and local governments would have spent using the CMS List Price ($7,252,297) to the amount state and local governments would have spent using the CMS MFP ($2,328,300), which yielded an estimated $4,923,996 in reduced spending based on list price. This does not reflect the rebates and discounts received.

[8] Medicare Drug Price Negotiation Program. https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program
[9] Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026 - https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf
[10] Drugs@FDA: FDA-Approved Drugs: New Drug Application (NDA): 202293. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process

Prior studies have explored the potential discount to the net spend associated with the MFP for Farxiga.[11,1213] The studies found that the MFP for Farxiga may not result in additional discounts compared to the average discounts. It is possible that the MFP for Farxiga may not yield significant savings for State and local government health plans, purchasers, or payors, though there are likely some savings for entities that are currently paying more than the average discounts.

Table 1. Spending and Savings Estimates Based on APCD Gross Spend, CMS List Price, CMS MFP, and Estimated Net Spend

	2023 CMS List Price	CMS MFP	Hernandez Medicare Part D Est. Net Price[14]
Total Units Dispensed- 2022 State and Local Government	391,311	391,311	391,311
30-Day Supply Dispensed	13,044	13,044	13,044
Price Per 30-Day Supply	$556	$197	$197
Total Spending	$7,252,297	$2,328,300	$2,328,300
Est. Md Gov't Savings Compared to MFP	$4,923,996	$0	$0

[11] Hernandez I, Cousin EM, Wouters OJ, Gabriel N, Cameron T, Sullivan SD. Price benchmarks of drugs selected for Medicare price negotiation and their therapeutic alternatives. J Manag Care Spec Pharm. 2024 Aug;30(8):762-772. doi: 10.18553/jmcp.2024.24153. Epub 2024 Jun 21. PMID: 38905356; PMCID: PMC11293770.

[12] Hernandez I, Gabriel N, Dickson S. Estimated discounts generated by Medicare drug negotiation in 2026. J Manag Care Spec Pharm. 2023;29(8):868-872. doi:10.18553/jmcp.2023.29.8.868

[13] Hernandez I, Wouters O, et. Al. Interpreting The First Round Of Maximum Fair Prices Negotiated By Medicare For Drugs. Health Affairs Forefront. September 3, 2024. https://www.healthaffairs.org/content/forefront/interpreting-first-round-maximum-fair-prices-negotiated-medicare-drugs

[14] Hernandez I, Wouters O, et. Al. Interpreting The First Round Of Maximum Fair Prices Negotiated By Medicare For Drugs. Health Affairs Forefront. September 3, 2024. https://www.healthaffairs.org/content/forefront/interpreting-first-round-maximum-fair-prices-negotiated-medicare-drugs