CENTERS FOR MEDICARE & MEDICAID SERVICES

CY 2025 PART D

BID REVIEW OUT-OF-POCKET COST MODEL

METHODOLOGY

APRIL 2024

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Changes in the CY 2025 Part D Bid Review Out-of-Pocket Cost (OOPC) Model

The Contract Year (CY) 2025 Part D Bid Review OOPC Model described in this document is an update of the CY 2024 Part D Baseline OOPC Model. For the CY 2025 Part D Bid Review OOPC Model, the items listed below summarize the changes that have been made.

1. Updated the Part D policy parameters (deductible, out-of-pocket threshold, etc.) to CY 2025 values.

2. Updated the 0.1% sample of Part D beneficiary drug utilization to a 2023 sample.

3. Updated Prescription Drug Event (PDE) data for use in the drug price calculation. The CY 2025 Part D Bid Review OOPC Model uses 2023 PDE data.

4. Updated the Part D input data using the initial CY 2025 Formulary Reference File (FRF), released in March 2024.

5. Updated the SAS programs to account for the 2025 Plan Benefit Package (PBP) data structure and variable name changes, which includes the elimination of the coverage gap phase and the reduction of the annual out-of-pocket (OOP) threshold to $2,000.

6. Updated the SAS programs to account for the implementation of 2025 Inflation Reduction Act (IRA) policy changes to True-Out-Of-Pocket Costs (TrOOP).

7. Updated the SAS programs to progress a beneficiary through the benefit phases based on TrOOP. Previous versions of the model relied on gross covered drug cost accumulation to move the beneficiary through the phases.

8. Updated the model to allow for plans to run the formulary tied to non-DS plans through a DS benefit design.

1. Introduction

The Center for Medicare & Medicaid Services (CMS) uses Out-of-Pocket-Cost (OOPC) estimates to evaluate Medicare Advantage Organizations (MAOs) and Prescription Drug Plan (PDP) submitted bids. The estimates are generated by the OOPC software available on the OOPC Resources, CMS.gov website (https://www.cms.gov/medicare/coverage/prescription-drug-coverage/out-of-pocket-costs).

For Contract Year (CY) 2025 OOPC estimates, a random 0.1% sample of all Part D beneficiaries and their associated Prescription Drug Event (PDE) data is identified. The event data for these cohorts are combined with CY 2025 Plan Benefit Packages (PBP) to produce the estimates.

The Part D calculations apply average prices from the Medicare Prescription Drug Event claims data for 2023.

This document describes the general methodology underlying the CY 2025 Part D Bid Review OOPC Model. The *CY 2025 Part D Bid Review Out-of-Pocket Cost Model User Guide April 2024* provides the information on how to run the model and generate the output.

2. Selection of the OOPC Cohort Based on the 2023 Medicare Population

A random 0.1% sample of Part D beneficiaries are selected from the Common Medicare Environment (CME) Database and then associated with their 2023 PDE selected from the Medicare Part D Claims database. The CMS documentation that includes a basic description of Part D Claims Data used for the model development is provided at https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-claims-data

The sample is further screened to ensure only beneficiaries enrolled in Medicare Part D are included by using the following screening criteria:

- Removing beneficiaries that have one or more months of Part A and B Entitlement but are not enrolled in a Part D contract for that month
- Removing beneficiaries that have one or months where there is not Part A and B Entitlement and they are enrolled in a Part D contract in that month
- Removing beneficiaries that have a gap of enrollment in a Part D contract (e.g., Part A or B Entitlement January - December 2023 but enrollment in a Part D contract in January-March and July-December)

The 0.1% PDE sample resulted in approximately 50,000 beneficiaries, and their drug utilization, being included in the calculations.

3. Development of OOPC Estimates

Average monthly Part D OOPC values are calculated for each plan offering Part D benefits. The model uses the data entered into the PBP and the associated plan's formulary to calculate the OOPC.

To calculate OOPC values the following steps are performed:

- National Drug Codes (NDCs) from PDE records are mapped into RxCUI (RxNorm Concept Unique Identifiers) codes to apply a particular plan's tier-formulary based cost sharing.

- PDE records reflect the utilization of the 0.1% cohort.

- PDE records were used to calculate average drug prices.

- Each PDE record is considered a one-month (30-day) prescription or multiple thereof, and the prescription is filled at an in-network retail pharmacy. If a plan has a preferred and standard pharmacy network structure, the prescription is assumed to be filled at the preferred pharmacy.

- The model incorporates the Free First Fill benefits offered by selected plans.

- The model incorporates the deductible applied by a plan.

- The model incorporates an algorithm for EA plans that calculates, for each prescription drug event, the beneficiary costs under the plan benefit structure and as well as what the beneficiary cost sharing would be under the defined standard benefit structure. The higher of these costs is included in the TrOOP accumulator to determine the beneficiary movement through the benefit phases.

- To assist Part D plan sponsors in bid preparations ahead of the CY 2025 bid deadline, the CY 2025 Bid Review OOPC Model will incorporate functionality for plans to run the formularies tied to the non-DS plans through a DS benefit design.

- The model incorporates substitution, such that when a generic or authorized generic version of a brand drug exists on the plan's formulary, the model assigns the cost sharing associated with the generic or authorized generic version of the drug in the calculations, provided it has lower cost sharing.

- The model incorporates an algorithm to assign alternative outcomes for calculating the cost of a drug that is not on a plan's formulary; assignment includes a non-covered status (i.e., cash price); an exception tier status (based on plan specific exceptions tier); or to a therapeutic alternative status, as described below.

4. Part D OOPC

The estimated OOPC values are based upon the drug information found in the PDE file provided for the individual sample beneficiaries. The beneficiary cohort used to identify the drug utilization come from a random 0.1% sample of all Part D beneficiaries and their associated 2023 PDE data. The data are used in conjunction with the CY 2025 PBPs submitted by plans that detail the drug benefit cost sharing and plan coverage as well as the CY 2025 plan-level formulary submissions. The NDC on each PDE record is mapped into an RxCUI using the appropriate CY 2025 CMS formulary reference file (FRF) released in March 2024. The model will be refreshed prior to the bid deadline to incorporate changes from the May 2024 FRF.

An average price for each RxCUI is calculated using 2023 PDE claims data. The average price is calculated as the total gross expenditure (ingredient cost + dispensing fee + taxes + vaccination fee) divided by the number of 30-day equivalent prescriptions.

Using each plan's drug coverage status and PBP-based cost-sharing information (deductible, copayments and/or coinsurance in the initial coverage phase, free first fill, etc.), the beneficiary's OOPCs are calculated. The calculations are performed according to the type of Part D plan (Defined Standard, Basic Alternative, Actuarially Equivalent Standard, or Enhanced Alternative) and the associated cost share structure. The calculations are based on the assumption that each prescription is for a one-month (30-day) supply of drugs (rather than a 60- or 90-day supply) from an In-Network Retail Pharmacy.

In the event that both a preferred and a non-preferred pharmacy exist, the calculations are based on the preferred pharmacy cost-sharing. If a particular PDE record in the 0.1% cohort reflects an extended day supply, this would be considered as multiple one-month fills.

Substitution is assumed, such that when a generic or authorized generic version of a drug exists on the plan's formulary, the model assigns the cost sharing associated with the generic or authorized generic version of the drug in the calculations, provided it has lower cost sharing. In addition, Food and Drug Administration (FDA) application type is utilized to determine the applicable/nonapplicable status of drugs for purposes of cost-sharing estimates.

If the RxCUI is not on a plan's formulary, this drug is assigned non-covered status. Non-formulary drugs are randomly assigned to one of the following weighted outcomes:

1) Beneficiary pays the full retail cost, based on national average price [there is a 49% probability of this outcome],
2) Beneficiary pays the cost sharing for a therapeutic alternative covered on the formulary, [there is a 36% probability of this outcome], or
3) Beneficiary pays the cost sharing for the formulary exception tier(s) [there is a 15% probability of this outcome].

These proportions were quantified through a 2018-2019 PDE analysis to determine the outcomes of non-formulary covered drugs that were offered by their plan in 2018 but were dropped from coverage in 2019.

The beneficiary/prescription event level data is then aggregated to the plan level using beneficiary sample weights and the associated prescription level cost estimates.

Appendix A: 2025 Part D Benefit Assumptions – MA-PD & PDP Plans

Appendix A Table 1				
CY 2025 Medicare Part D Cost Share and Cost Limit Parameters	**Defined Standard**	**Actuarially Equivalent**	**Basic Alternative**	**Enhanced Alternative**
Annual Deductible	100%	100%	100%	100%
Initial Coverage Phase	25%	25% or Tiers	25% or Tiers	25% or Tiers or No Cost Sharing
Deductible	$590	$590	$590 or Plan-specified or No Deductible	$590 or Plan-specified or No Deductible
Deductible Exemption	No Coverage	No Coverage	Designate tiers that will not be subject to the deductible, optional	Designate tiers that will not be subject to the deductible, optional
Out of Pocket Threshold (TrOOP)	$2,000	$2,000	$2,000	$2,000
Post-Threshold Cost Shares	No cost sharing	No cost sharing	No cost sharing	No cost sharing
Charge Lesser of Copayment or Cost of the Drug	N/A	Yes, optional.	Yes, optional	Yes, optional

List of Acronyms	
API	Application Programming Interface
CMS	Centers for Medicare & Medicaid Services
CY	Contract Year
CME	Common Medicare Environment
FDA	Food and Drug Administration
FRF	Formulary Reference File
JSON	JavaScript Object Notation
NDC	National Drug Code
OOPC	Out-Of-Pocket Cost
PDE	Prescription Drug Event
PDP	Prescription Drug Plan
PBP	Plan Benefit Package
RXCUI	RxNorm Concept Unique Identifiers