CENTERS FOR MEDICARE & MEDICAID SERVICES

CY 2023 PART D

BID REVIEW OUT-OF-POCKET COST MODEL – NON-FORMULARY UPDATE

METHODOLOGY

NOVEMBER 2022

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Changes in the CY 2023 Part D Bid Review Out-of-Pocket Cost (OOPC) Model – Non-Formulary Update

The Contract Year (CY) 2023 Part D Bid Review OOPC Model – Non-Formulary Update described in this document, is an update of the CY2023 Part D Bid Review OOPC Model. The CY 2023 Part D Bid Review OOPC Model – Non-Formulary Update has been modified on how the tool calculates cost estimates for non-formulary drugs to account for formulary exceptions and potential therapeutic alternative scenarios.

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/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources).

For Contract Year (CY) 2023 OOPC estimates, a random 0.1% sample of all Part D beneficiaries and their associated PDE data is identified. The event data for these cohorts are combined with CY 2023 Plan Benefit Packages to produce the estimates.

The Part D calculations apply average prices from the Medicare Prescription Drug Event claims data for 2021.

This document describes the general methodology underlying the CY 2023 Part D Bid Review OOPC Model – Non-Formulary Update. The *CY 2023 Part D Bid Review Out-of-Pocket Cost Model – Non-Formulary Update User Guide November 2022* provides the information on how to run the model and generate the output.

2. Selection of the OOPC Cohort Based on the 2021 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 2021 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/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PartDData

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 (i.e. Part A or B Entitlement January - December 2021 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 OOPCs are calculated for each plan (including plans offering and not 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 OOPCs 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 Senior Savings benefits offered by selected plans.
- The model incorporates the deductible applied by a plan.
- The model incorporates generic 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(s)); 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 2021 PDE data. The data are used in conjunction with the CY 2023 PBPs submitted by plans that detail the drug benefit cost sharing and plan coverage as well as the CY 2023 plan-level formulary submissions. The NDC on each PDE record is mapped into an RxCUI using the appropriate CY 2023 CMS formulary reference file (FRF) released in March 2022.

An average price for each RxCUI is calculated using 2021 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, initial coverage limit, co-copayments and/or coinsurance, gap coverage, free first fill, senior savings 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, 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.

Generic 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 coverage gap cost-sharing estimates.

If the RxCUI is not on a plan's formulary, this drug is assigned non-covered status. Historically, the cost of non-covered drugs are calculated as the full cost of the RxCUI, based on the average national price for the RxCUI. CMS recognized this as a potential limitation of the Part D OOPC model, and stakeholders have expressed concern that the model does not account for other possible outcomes. These outcomes include beneficiary requesting a formulary exception for the non-formulary drug, or the beneficiary switching to a therapeutic alternative. As part of our continual efforts for process improvements, CMS is updating the Part D OOPC methodology used to calculate non-formulary drug costs in the model. Specifically, CMS is incorporating an approach whereby 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 behavior of enrollees when faced with non-formulary coverage of drugs that were offered by their plan in 2018 but were dropped from coverage in 2019. This enhancement of the Part D OOPC methodology will enable the model to better predict real-world occurrences and will provide for a more accurate reflection of the estimated Part D OOPC.

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

The CY 2023 Part D Bid Review OOPC Model – Non-Formulary Update is being made available to plan sponsors to allow sponsors the opportunity to gain familiarity with the enhancement changes before implementing them for bid review purposes.

Appendix A: 2023 Part D Benefit Assumptions – MA-PD & PDP Plans

Appendix A Table 1				
CY 2023 Medicare Part D Cost Share and Cost Limit Parameters	**Defined Standard**	**Actuarially Equivalent**	**Basic Alternative**	**Enhanced Alternative**
Pre-ICL Cost Shares	25%	25% or Tiers	25% or Tiers	25% or Tiers or No Cost Sharing
Deductible	$505	$505	$505 or Plan-specified or No Deductible	$505 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
ICL	$4,660	$4,660	$4,660 or Plan-specified or No ICL	$4,660 or Plan-specified or No ICL
Gap Coverage	25% Generic Beneficiary Cost 25% Brand Beneficiary Cost	25% Generic Beneficiary Cost 25% Brand Beneficiary Cost	25% Generic Beneficiary Cost 25% Brand Beneficiary Cost	25% Generic Beneficiary Cost 25% Brand Beneficiary Cost
Additional Gap Coverage	N/A	N/A	N/A	No Additional Coverage or Gap Tiers
Threshold (TROOP)	$7,400	$7,400	$7,400	$7,400
Catastrophic Coverage Threshold	$11,206.28	$11,206.28	$11,206.28	$11,206.28
Post-Threshold Cost Shares	Greater of 5% or $4.15 (Generic/Preferred Multi-Source Drug) or $10.35 (Other)	Greater of 5% or $4.15 (Generic/Preferred Multi-Source Drug) or $10.35 (Other)	Greater of 5% or $4.15 (Generic/Preferred Multi-Source Drug) or $10.35 (Other)	Greater of 5% or $4.15 (Generic/Preferred Multi-Source Drug) or $10.35 (Other)
Excluded Drugs Maximum Benefit Coverage Limit	N/A	N/A	N/A	Yes, optional*. *Coverage limit applies to Excluded Drugs tier only.
Charge Lesser of Copayment or Cost of the Drug	N/A	Yes, optional.	Yes, optional	Yes, optional

List of Acronyms	
CMS	Centers for Medicare & Medicaid Services
CY	Contract Year
CME	Common Medicare Environment
FDA	Food and Drug Administration
FRF	Formulary Reference File
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