NovaRest, Inc.

Summary of Final CY 2025 Part D Redesign Program Instructions

NovaRest
ACTUARIAL CONSULTING

Contents

Executive Summary

The Centers for Medicare and Medicaid Services (CMS) released the Final CY 2025 Part D Redesign Program Instructions[1] and Fact Sheet,[2] which includes detailed changes to the structure of the Medicare Part D Defined Standard as a result of the implementation of the Inflation Reduction Act (IRA). The guidance also includes some information on provisions that already took effect in CY2023 or CY2024, but primarily focuses on CY2025 provisions.

For CY 2025, the Defined Standard benefit will now have three benefit phases due to the removal of the Coverage Gap Phase. True out-of-pocket (TrOOP)-eligible costs are used to determine a member's progression through the coverage phases (Deductible Phase, Initial Coverage Phase, and the Catastrophic Phase). Previously TrOOP costs were used to determine whether deductible or catastrophic limits were met, while total drug costs were used to determine whether the initial coverage limit (ICL) was met. As the Coverage Gap Phase has been removed, the ICL has also been removed.

Enhanced Alternative (EA) and Basic Alternative (BA) plans will continue to have the ability to offer a lower deductible. However, EA plans can offer a lower deductible as supplemental coverage, where the plan's cost share would count towards the TrOOP and a member would progress towards the DS deductible (and Discount Program eligibility) at roughly the same rate as the DS. However, BA plans cannot offer supplemental coverage, therefore the plan's cost share of Part D covered drugs does not count towards the TrOOP, and members will incur more total drug costs than either the EA or DS plans to satisfy the DS deductible and become eligible for the Discount Program (where manufacturers discount drug costs).

The Coverage Gap Discount Program (CGDP) is ending. It has been replaced by a new Discount Program that provides for manufacturer discounts in the initial coverage phase (ICP) as well as the catastrophic phase. Eligibility for the Discount Program is contingent on sufficient TrOOP costs to meet the DS deductible, even if an EA or BA plan offers a lower deductible.

TrOOP Costs

TrOOP is spending on covered Part D drugs by the beneficiary or on their behalf by certain third parties. Generally, third party costs not considered TrOOP eligible prior to 2025 would not be considered TrOOP eligible, except for the Inflation Reduction Act (IRA) requirements, which made Part D drugs that are reimbursed through insurance or a group health plan, excluding basic (not-supplemental) prescription drug coverage as TrOOP-eligible.

Examples of TrOOP eligible third party costs are LIS cost-sharing support, qualified State Pharmacy Assistance Programs, Indian Health Service and certain other Native American organizations, and AIDS Drug Assistance Programs. Additionally, supplemental Part D coverage provided by enhanced alternative (EA) Part D plans and other health insurance (OHI) will be counted as incurred costs and included in the calculation of TrOOP. While covered insulin products are not subject to the deductible, only the

[1] https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf
[2] https://www.cms.gov/newsroom/fact-sheets/final-cy-2025-part-d-redesign-program-instructions-fact-sheet

applicable copayment amount (typically $35) is TrOOP-eligible. The Medicare Prescription Payment Plan[3] does not impact what counts toward TrOOP costs.

Non-Part D covered costs would not be considered TrOOP-eligible. Manufacturer payments under the Discount Program are also not TrOOP-eligible costs, which is a change from prior years where manufacturer discounts under the Coverage Gap Discount Program counted towards TrOOP-eligible costs. Primary payer amounts paid on Medicare as secondary payer (MSP) will also remain excluded from TrOOP.

Deductible Phase

Under the DS benefit beneficiaries would generally pay 100% of their gross covered prescription drug costs (GCPDC) until the deductible ($590 for CY2025, up from $545 in CY2024) is met. If TrOOP costs meet the DS deductible limit, the deductible will be considered satisfied.

Benefits not subject to the deductible include $0 cost sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and the $35 limit per month's supply of a covered insulin product begin prior to the deductible being met, consistent with CY2024.

Initial Coverage Phase (ICP)

Under the DS benefit, beneficiary coinsurance is 25% percent coinsurance for covered Part D drugs, until they reach the annual OOP spending threshold of $2,000 (down from $8,000 in CY2024). The remainder of the cost is split between the plan sponsor (65% to 75%) and the manufacturer (0% to 10%) depending on multiple factors, including eligibility in the Discount Program, type of drug, and type of manufacturer.

If a member has sufficient TrOOP costs to satisfy the DS deductible and is eligible for the Discount Program, then a participating manufacturer[4] will discount applicable drugs[5] by 10%. However, small manufacturers[6] may receive a reduction in the discount offered. The plan sponsor is responsible for the difference.

Catastrophic Phase

The beneficiary coinsurance in the catastrophic phase is 0% for covered Part D drugs, consistent with 2024. Plan sponsors are responsible for 60% of covered Part D drugs. Consistent with discussed in the ICP, a participating manufacturer would pay a discount of typically 20% for applicable drugs, with small manufacturers potentially receiving a reduction in the discount offered. CMS would be responsible for the remainder through a reinsurance subsidy of typically 20% for applicable drugs and 40% for non-

[3] The Medicare Prescription Payment Plan is a new program created under the Inflation Reduction Act that requires Part D plan sponsors to provide their enrollees with the option to pay out-of-pocket prescription drug costs in the form of monthly payments over the course of the plan year instead of all at once to the pharmacy. This program will begin in 2025 and will give people with Medicare prescription drug coverage (Medicare Part D) the option to pay out-of-pocket costs in monthly payments spread out over the year rather than requiring they pay in full at the pharmacy counter each time they fill a prescription.

[4] Manufacturer with agreement and contract with CMS and will provide discounts.

[5] Based on Food and Drug Administration (FDA's) National Drug Code Data Elements (NSDE) file.

[6] Specified Manufacturer or Specified Small Manufacturer - Low relative expenditure participating manufacturers.

applicable drugs. This is a reduction from the 80% federal reinsurance paid in the Catastrophic Phase in CY2024.

Discount Program

The Discount Program replaces the Coverage Gap Discount Program (CGDP), which sunsets on January 1, 2025. Under the Discount Program, participating manufacturers provide discounts on applicable drugs in both the initial coverage and catastrophic phases, for applicable beneficiaries. For CY 2025, the manufacturer discounts would be approximately 10% of negotiated price for beneficiaries in the initial coverage phase (ICP) and 20% in the catastrophic phase. Certain manufacturers may be considered Specified or Specified Small Manufacturers, which would be eligible for a multi-year phase in for the discount amount, and therefore would pay a lesser discount in CY 2025.

TrOOP-eligible costs must meet the Defined Standard deductible to become an applicable beneficiary.

For alternative benefit plans with lower deductibles than the DS, while a beneficiary may enter the initial coverage phase earlier than in a DS plan, they would not be considered an applicable beneficiary until sufficient TrOOP-eligible costs are incurred to satisfy the DS deductible. TrOOP-eligible costs include the amounts paid by the beneficiary and the amounts paid by the plan sponsor or 100% of the drug costs. In this case, the plan would be responsible for covering the portion of costs that would be covered by the manufacturer discount under the Discount Program until the beneficiary becomes an applicable beneficiary.

For example, if an EA plan has a $0 deductible and 25% beneficiary cost sharing, then a beneficiary will receive first-dollar coverage and immediately enter the initial coverage phase. Therefore, on an applicable drug in this case, the beneficiary would pay a 25% coinsurance, and the plan sponsor would pay 75%. When sufficient TrOOP costs to meet the DS deductible are met (and the beneficiary is eligible for the Discount Program), the beneficiary would pay a 25% coinsurance, but the plan sponsor would typically be responsible for 65% coinsurance, and the manufacturer would typically be responsible for 10%. So, while a beneficiary is in the initial coverage phase in both cases (both before and after they are eligible for the Discount Program), the plan sponsor would be responsible for an additional amount until sufficient TrOOP costs are incurred to enter the Discount Program.

Enhanced Alternative (EA) Benefit Design

Due to the IRA provisions, which removed the gap coverage phase and set the annual OOP spending threshold to $2,000, EA are more limited in their ability to provide enhanced coverage for CY2025. Specifically, the only possible enhancement features for 2025 are as follows:

- Coverage of Part D excluded drugs
- Reduction (or elimination) of the DS deductible
- Reduction of cost-sharing in the initial coverage phase

CMS indicated they will not be establishing a specific threshold regarding the additional value EA plans must offer relative to the DS benefit. They will require the EA plan must have more value than the DS benefit, which they will analyze using the Part D OOPC model. They will consider more rigorous analyses going forward.

Basic Alternative (BA) Benefit Design

After soliciting comments, CMS will allow BA plans with lower deductibles to be offered in 2025 but will consider whether to allow in future years.

CMS noted that if a BA plan does not reduce the deductible, they would never be able to offer a different benefit from actuarially equivalent (AE) plans due to the changes due to the IRA. However, CMS noted they believe it is unlikely plan sponsors would offer a BA plan with a reduced deductible over an EA plan with a reduced deductible due to guidance on TrOOP-eligible costs. Specifically, an EA plan can reduce the plan deductible as part of its Part D supplemental benefit, which are TrOOP-eligible in 2025. A BA plan could reduce the deductible as part of its basic prescription drug coverage, which does not count plan cost sharing towards the TrOOP. Therefore, beneficiaries in BA plans with lower deductibles will take longer (more total covered drug costs) before the Discount Program discounts are available.

For example, under the DS a member would pay 100% of covered drug costs until they reach the deductible (with the exception of insulin and ACIP recommended vaccines), where they would enter the ICP and become eligible for the Discount Program. Under the BA, a plan can reduce the deductible, and therefore the member would no longer pay 100% of covered drug costs. Therefore, it would take the member more total drug costs to meet the DS deductible and receive eligibility in the Discount Program, during which time the plan would pay the remainder of the cost sharing.

PDP Meaningful Difference

CMS will use an absolute percent threshold approach for evaluating PDP meaningful difference for CY 2025, as opposed to the outlier approach used since CY2023. A threshold of 15 percent was determined by analyzing the historic annual dollar meaningful difference thresholds used in recent years and considering the CY 2024 differential achieved without a set target. CMS indicated concern about the analysis being impacted by what they call formulary robustness as opposed to benefit design/tier placement and will conduct a sub-analysis to ensure the meaningful difference is not solely being driven by the addition of benefits that are not expected to be utilized.

PACE Organizations

In CY 2025, PACE organizations will be responsible for paying 100% of the drug's costs below the annual OOP threshold after accounting for manufacturer discounts under the Discount Program and any amount of the basic Part D beneficiary premium that is greater than the regional low-income premium subsidy amount for dual-eligible beneficiaries.

While the annual OOP threshold was reduced to $2,000 for CY2025, CMS indicated the methodology for determining the PACE cost-sharing add-on amount will not change for CY2025.

Part D EGWP Sponsors

Consistent with prior years, CMS intends to make prospective reinsurance payments to all Part D EGWP sponsors. However, considering the changes to the reinsurance percentages described above as CMS waiving bid submission requirements for Part D EGWP sponsors in recent years, CMS issued new guidance surrounding the calculation methodology for prospective reinsurance payments. Specifically, for CY 2025 the prospective reinsurance payments are proposed to be calculated using the weighted

average of PMPM prospective reinsurance amounts from Part D EA plan bids. The payments are expected to be announced with the annual release of the Part D National Average Monthly Bid Amount (NAMBA), Part D base beneficiary premium (BBP), and related Part D bid information in the summer of 2024.

CMS also issued guidance regarding non-calendar year (NCY) EGWPs, which are permitted by waiver to have their plan year begin sometime in 2024 and continue into 2025. Specifically, a NCY EGWP must map the EGWP benefit to the 2024 Part D DS benefit for the portion of its NCY plan year that falls in 2024 and to the 2025 Part D DS benefit for the portion of its NCY plan year that falls in 2025. Additionally, Part D sponsors must carry over and utilize beneficiary TrOOP balances from 2024 to determine a beneficiary's DS benefit phase and TrOOP as of January 1, 2025.

Other Reporting Items

- The changes made by the IRA require CMS to revise the existing regulatory definition of creditable prescription drug coverage due to the differences in plan sponsor liability.
- Regarding the minimum MLR of 85%, CMS indicated Discount Program payments and Inflation Reduction Act Subsidy Amount (IRASA)[7] are considered pass-through payments collected by a plan on behalf of a third party, and not revenue (similar to LICS and CGDP payments), therefore are excluded from the MLR calculation.
- No changes were made to the risk corridor methodology or thresholds.
- Because there are differences in the calculation of the reinsurance subsidy for applicable and non-applicable drugs in CY 2025, CMS issued guidance on calculating the reinsurance subsidy and allocating direct and indirect remuneration (DIR) towards reinsurance. Essentially, CMS will calculate the reinsurance subsidy separately for applicable and non-applicable drugs and allocate the share of DIR for applicable and non-applicable drugs based on their respective share of gross drug costs that fall in the catastrophic phase.

[7] Part D plans for the reduction in cost sharing and elimination of the deductible for ACIP-recommended adult vaccines and covered insulin products

Appendix: DS Coverage Phase Comparison CY 2024 and CY 2025

This appendix was taken directly from the Final CY 2025 Part D Redesign Program Instructions, page 68.

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Part D Benefit Parameters for Defined Standard Benefit for CY 2024 and CY 2025 for Non-LIS Beneficiaries

<table>
<tr><th></th><th colspan="2">2024</th><th colspan="2">2025[57]</th></tr>
<tr><td>Deductible Phase</td><td colspan="2">Cost sharing: 100%</td><td colspan="2">Cost sharing: 100%</td></tr>
<tr><td></td><td colspan="2">Deductible: $545</td><td colspan="2">Deductible: $590</td></tr>
<tr><td>Initial Coverage Phase</td><td colspan="2">Cost sharing: 25%
Plan Pays: 75%</td><td>Applicable Drugs
Cost sharing: 25%
Plan Pays: 65%
Manufacturer Discount: 10%</td><td>Non-Applicable Drugs
Cost sharing: 25%
Plan Pays: 75%</td></tr>
<tr><td></td><td colspan="2">Initial Coverage Limit: $5,030</td><td colspan="2">Initial Coverage Limit: Not Applicable</td></tr>
<tr><td>Coverage Gap</td><td>Applicable Drugs
Cost sharing: 25%
Plan Pays: 5%
Manufacturer Discount: 70%</td><td>Non-Applicable Drugs
Cost sharing: 25%
Plan Pays: 75%</td><td colspan="2">N/A</td></tr>
<tr><td></td><td colspan="2">Out-of-Pocket Threshold: $8,000</td><td colspan="2">Out-of-Pocket Threshold: $2,000</td></tr>
<tr><td>Catastrophic Phase</td><td colspan="2">Plan Pays: 20%
Reinsurance: 80%</td><td>Applicable Drugs
Plan Pays: 60%
Manufacturer Discount: 20%
Reinsurance: 20%</td><td>Non-Applicable Drugs
Plan Pays: 60%
Reinsurance: 40%</td></tr>
</table>

[57] Note that the IRA provides for lower applicable discounts for certain manufacturers' applicable drugs marketed as of August 16, 2022, during a multi-year phase-in period, which concludes by 2031. For drugs that are subject to a phased-in discount, plans are responsible for covering the difference between the phased-in discount and the full discount that otherwise would have applied (10 percent in the initial coverage phase and 20 percent in the catastrophic phase). As such, the liability of plan sponsors and manufacturers for applicable drugs in the initial coverage and catastrophic phases may vary based on whether a drug is subject to a phase-in discount.