DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: September 26, 2022

TO: All Part D Sponsors

FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group

SUBJECT: PDE Reporting Instructions for Implementing the Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023

The Inflation Reduction Act (IRA) was signed into law on August 16, 2022. Effective January 1, 2023, the IRA eliminates the deductible and imposes a statutory maximum beneficiary cost sharing of $35 per month's supply for Part D covered insulins.[1] In addition, effective January 1, 2023, the IRA eliminates the deductible and imposes a statutory maximum beneficiary cost sharing of $0 for adult vaccines as recommended by the Advisory Committee on Immunization Practices (ACIP). The purpose of this memo is to present the operational approach that the Centers for Medicare & Medicaid Services (CMS) will take in implementing these provisions of the IRA in the Part D program.

Section 1860D-2(b)(9) of the Social Security Act (the Act), as added by section 11406 of the IRA, imposes a $35 monthly limit on cost sharing for covered insulin products throughout all phases of the Part D benefit. Subparagraph (E) of new section 1860D-2(b)(9) provides a three-month period (January 1, 2023 through March 31, 2023) during which a Part D sponsor may retroactively reimburse beneficiaries within 30 days for amounts paid in excess of the $35 cost sharing maximum in the event that the Part D sponsor has not yet adjusted its claims adjudication systems to implement the new insulin benefit at the point of sale. During this time, a beneficiary

[1] Per section 1860D-2(b)(9)(C) of the Social Security Act, as added by section 11406(a)(1)(E) of the IRA, a covered insulin is a covered Part D drug covered under a PDP or MA-PD plan that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act and marketed pursuant to such approval or licensure, including any covered insulin product that has been deemed to be licensed under section 351 of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section.

may pay the higher plan cost sharing at the point of sale, and the plan must refund the difference between that higher amount and $35 to the beneficiary within 30 days.

Similarly, section 1860D-2(b)(8) of the Act, as added by section 11401 of the IRA, requires the elimination of beneficiary cost sharing for ACIP-recommended adult vaccines administered in accordance with the ACIP recommendation (hereafter referred to as "ACIP-recommended vaccines") under a Part D plan throughout the entire Part D benefit beginning January 1, 2023. Unlike the insulin benefit, the statute does not incorporate a three-month grace period for plans to implement the changes to this vaccine coverage.

Section 1860D-15(h) of the Act, as added by section 11401(c) of the IRA and amended by section 11406(c), also requires that a temporary retrospective subsidy be paid to Part D plans for the reduction in cost sharing and elimination of the deductible for ACIP-recommended vaccines and covered insulin products during the 2023 plan year – the Inflation Reduction Act Subsidy Amount (IRASA). Specifically, we define IRASA as the difference between the beneficiary cost sharing for the covered insulin, or ACIP-recommended vaccine, under the plan's 2023 benefit design, and the applicable statutory maximum cost sharing ($35 for insulins and $0 for vaccines). The IRASA is available only for 2023. Per the statute, the amounts paid by the plan and reimbursed by Medicare through the retrospective subsidy must count as beneficiary incurred costs, meaning these costs count toward meeting the True-Out-of-Pocket (TrOOP) threshold. Our approach to calculating, reporting, and reconciling the IRASA seeks to balance the need for certain information to be collected on the Prescription Drug Event (PDE) record with the expedited implementation timeline, which requires sponsors to begin offering these benefits on January 1, 2023.

Please direct questions regarding this memo to PDE-Operations@cms.hhs.gov.

<u>IRASA Calculation and PDE Reporting</u>

The IRASA is determined after the plan applies the cost sharing consistent with the 2023 bid. This subsidy amount must be reported in the Other TrOOP Amount field on the PDE record. Because we are utilizing an existing field on the PDE record, we are aware that the amount reported in the Other TrOOP Amount field on a single PDE record may contain patient liability reductions from another TrOOP eligible payer, in addition to the IRASA. Therefore, if a PDE record for a covered insulin product or ACIP-recommended vaccine has a value in the Other TrOOP Amount field that partly or entirely reflects the IRASA, Part D Plans must also populate an indicator on the PDE record. We are repurposing the Type of Fill Code field for this purpose and renaming it Other TrOOP Amount Indicator.[2] PDE records that report Other TrOOP from

[2] Recall that the Type of Fill Code field was defined in an HPMS memo released on June 9, 2015 titled "Provider Enrollment, Chain, and Ownership System (PECOS) and Updates to the Prescription Drug Event (PDE) File Layout and Edits" but never used.

another TrOOP eligible payer and do not include IRASA are advised to leave the Other TrOOP Amount Indicator field blank.

The following values should be reported in the Other TrOOP Amount Indicator field (renamed from Type of Fill Code), Field 59 on the PDE record:

- Blank– This value indicates that the Other TrOOP Amount field is either blank or contains an only **non**-IRASA Other TrOOP amount
- “S” – This value indicates that the Other TrOOP Amount field contains an **only** IRASA Other TrOOP amount
- “B” – This value indicates that the Other TrOOP field contains **both** IRASA Other TrOOP and non-IRASA Other TrOOP amounts

A new version of the PDE layout will be posted on the CSSC Operations website that includes an updated description of the Other TrOOP Amount field to include IRASA for 2023 only, the renaming of the Type of Fill Code to Other TrOOP Amount Indicator, and definition of the new field’s valid values.

PDE Edit Updates

An updated Drug Data Processing System (DDPS) PDE Edit lookup tool and spreadsheet will be posted on the CSSC Operations website to reflect the edit modifications and additions discussed in this section.

Existing Edit Update:

Edit 842 will be updated to allow valid values of blank, “B” or “S” in the Other TrOOP Amount Indicator field (repurposed Type of Fill Code) when DOS is between 1/1/2023 and 12/31/2023. Must be blank for all other DOS. (M/I category, Reject edit)

New Edits:

Edit 774 – If Drug Coverage Status Code is “E” or “O”, then the Other TrOOP Amount Indicator must be blank. (Non-Covered Drug category, Reject edit)

Edit 796 – If Other TrOOP Amount Indicator is “B” or “S” and GDCA Amount = 0, then Part D Model Indicator must not equal “07”. (M/I category, Reject edit).

Edit 820 – The Other TrOOP Amount Indicator field is invalid. Must be blank on PDEs submitted by PACE plans. (PACE category, Reject edit)

Edit 900 – If DOS between 1/1/2023 and 12/31/2023, Other TrOOP Amount Indicator = “B” or “S”, and Other TrOOP is > zero, then NDC must be either a covered insulin product or ACIP recommended vaccine. (IRA category, Reject edit)

Edit 901- If Other TrOOP Amount Indicator is “B” or “S” and DOS between 1/1/2023 and 12/31/2023, the Other TrOOP Amount must be greater than zero. (IRA category, Reject edit)

Edit 902 – If NDC is an ACIP recommended vaccine, DOS is on or after 1/1/2023, the Patient Pay Amount must equal zero. (IRA category, Reject edit)

Edit 904 - If NDC is a covered insulin product, DOS is on or after 1/1/2023, the Patient Pay Amount must not exceed $35 * number of months’ supply. (IRA category, Informational edit) (NOTE: This edit will be triggered beginning on 4/1/2023.)

Grace Period for Cost Sharing Maximum at POS for Covered Insulin Products

The IRA allows for a 3-month grace period for plans to fully implement the insulin cost sharing maximum at the point of sale. This means that a beneficiary may pay at the point of sale the 2023 plan cost sharing that was previously established with the 2023 bid for the covered insulin product through March of 2023 but must be reimbursed by the plan for any amount paid above $35 for a month’s supply within 30 days post-point-of-sale. Under this scenario, plans are advised to submit an original PDE record with the cost sharing actually paid by the beneficiary at the point of sale, then submit an adjustment PDE record once the beneficiary has been reimbursed the difference. The adjustment record will update the Patient Pay Amount and the Other TrOOP Amount on the PDE record. While CMS will not be editing the cost sharing amounts of covered insulin products in the first three months of 2023, we will be conducting periodic retrospective reviews of the PDE data to ensure PDEs are consistent with beneficiary cost sharing and reimbursement requirements. Beginning with DOS on or after April 1, 2023, DDPS will issue informational Edit 904 if the Patient Pay Amount is greater than $35.00.

IRASA Reconciliation

Because the Other TrOOP Amount field on the PDE record may contain other sources of TrOOP eligible payments in addition to the IRASA, a supplemental file will be required from each Part D plan to report non-IRASA Other TrOOP amounts at the PDE level on only those PDE records coded with a “B” in the Other TrOOP Amount Indicator field. This supplemental file will be reported within 6 months of the end of a coverage year. As part of the Part D payment reconciliation for the 2023 contract year, the total from this file will be subtracted from the total Other TrOOP Amount on PDE records for covered insulin products or ACIP-recommended vaccines for which Other TrOOP Amount Indicator = “S” or “B” to determine the total IRASA to be paid to the Part D sponsor. The supplemental file format and submission method, and updates to the Part D Payment Reconciliation calculations and reports, will be released in a separate memorandum.

Interaction with Prescription Drug Senior Savings Model

Prescription Drug Senior Savings (PDSS) Model plans should continue to follow all previously published PDE calculation and reporting guidance specific to insulins covered by the PDSS

Model (i.e., Plan Selected Model Drugs). The PDE calculation and reporting guidance in this memo applies to all non-model covered insulin products provided to all beneficiaries enrolled in PDSS plans, all covered insulin products provided to LIS-eligible beneficiaries enrolled in PDSS plans, all covered insulin products provided to all beneficiaries enrolled in PDSS plans in the catastrophic phase, and ACIP-recommended vaccines covered by the PDSS plan.

PDE Examples

The following PDE examples use the 2023 benefit parameters.

Example #1: Defined Standard Plan – Deductible Phase - Insulin

This example demonstrates how to report a PDE for a $200.00 covered insulin product with an IRASA that falls within the Deductible Phase of a Defined Standard plan.

When the claim adjudication begins, the Total Gross Covered Drug Cost (TGCDC) Accumulator is $0.00 and the TrOOP Accumulator is $0.00. While the beneficiary is in the Deductible Phase of the Defined Standard benefit, the deductible cost sharing of 100% does not apply and the beneficiary pays $35. Although the deductible does not apply to covered insulin products, plans are advised to continue reporting the beginning and ending phase benefit indicators as “D”, meaning Deductible phase, in 2023 to minimize PDE record population logic changes due to the IRA.

The IRASA is calculated by subtracting the maximum copayment under the IRA from the original beneficiary payment under the plan’s 2023 benefit design consistent with the plan’s 2023 bid ($200.00 - $35.00 = $165.00). This amount is reported in the Other TrOOP Amount field, and because there are no additional non-IRASA payments reported in the Other TrOOP Amount field, the Other TROOP Amount Indicator field is populated with an “S”.

A beneficiary’s progression through the Defined Standard benefit prior to the Coverage Gap Phase is based on TGCDC for all Part D covered drugs purchased by the beneficiary. Therefore, $200.00 is counted towards the Defined Standard deductible, rather than the beneficiary payment of $35.00. The TrOOP Accumulator increases by $200 since both Patient Pay Amount and IRASA are TrOOP-eligible payments. Given that the deductible applies to covered insulin products under the plan’s 2023 benefit design consistent with the plan’s 2023 bid, the TGCDC for the insulin product in this example also counts towards the deductible that otherwise applies under the plan even though the beneficiary only pays a portion of the cost of the drug out of pocket, as the IRASA is treated as paid by the beneficiary.[3]

[3] If the deductible did not apply to the covered insulin product in this example under the plan’s 2023 benefit design consistent with the plan’s 2023 bid, consistent with our existing guidance, none of the cost of the insulin product in this example would count towards satisfying the deductible that otherwise applies under the plan for other products. See section 7.5.2.1 of the *2011 PDE Participant Guide*, which demonstrates how to populate a PDE record for a drug that is not subject to a plan’s deductible and is purchased when the beneficiary would otherwise be in the Deductible Phase under the defined standard benefit. It must also be noted that, as stated in the September 10, 2010

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$0.00
True Out of Pocket Accumulator	$0.00
Beginning Benefit Phase	D
Ending Benefit Phase	D
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$0.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$165.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #2: Defined Standard Plan – Initial Coverage Phase - Insulin

This example demonstrates how to report a PDE for a $200.00 covered insulin product with an IRASA that falls within the Initial Coverage Phase (ICP) of a Defined Standard plan.

When the claim adjudication begins, the TGCDC Accumulator is $748.00 and the TrOOP Accumulator is $565.75. The beneficiary is in the ICP of the benefit (TGCDC Accumulator > $505.00 and ≤ $4,660.00) in 2023. Therefore, the beginning and ending benefit phase indicators are "N", meaning ICP. In the ICP, the beneficiary typically pays 25 percent coinsurance ($50.00). The plan pays 75% of the total drug cost ($150.00), which is reported in the Covered Plan Paid Amount (CPP) field. Because this is a covered insulin product, the beneficiary payment is reduced to $35.00 per the IRA. The IRASA is calculated by subtracting the maximum copayment under the IRA from the original beneficiary payment under the plan's 2023 benefit design consistent with the plan's 2023 bid ($50.00 - $35.00 = $15.00). This amount

HPMS memorandum, *Additional Guidance Concerning Closing the Coverage Gap in 2011*, a Part D deductible ceases to apply once a beneficiary's TGCDC amount exceeds the initial coverage limit, irrespective of the enhanced benefit design, even if the beneficiary has not satisfied the deductible under the plan.

is reported in the Other TrOOP Amount field and because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with an “S”.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$748.00
True Out of Pocket Accumulator	$565.75
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$150.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$15.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

<u>Example #3: Defined Standard Plan – Gap Phase - Insulin</u>

This example demonstrates how to report a PDE for a $200.00 covered insulin product with an IRASA that falls within the Coverage Gap Phase of a Defined Standard plan.

When the claim adjudication begins, the TGCDC Accumulator is $5,000.00 and the TrOOP Accumulator is $1,628.75. The beneficiary is in the Coverage Gap Phase of the benefit (TGCDC Accumulator > $4,660.00, and TrOOP Accumulator < $7,400.00) in 2023. Therefore, the beginning and ending benefit phase indicators are “G”. Under the Defined Standard benefit, in the Gap, the beneficiary would typically pay 25 percent coinsurance ($50.00). The plan pays 5% of the total drug cost ($10.00), which is reported in the CPP field. The Gap Discount Amount is 70%, or $140.00. Because this is a covered insulin product, the beneficiary payment is reduced to $35.00 per the IRA. The IRASA is calculated by subtracting the maximum copayment under the IRA from the original beneficiary payment under the plan’s 2023 benefit design consistent with the plan’s 2023 bid ($50.00 - $35.00 = $15.00). This amount is reported in the Other

TrOOP Amount field and, because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indictor field is populated with an “S”.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	**Value**
Total Gross Covered Drug Cost Accumulator	$5,000.00
True Out of Pocket Accumulator	$1,628.75
Beginning Benefit Phase	G
Ending Benefit Phase	G
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$10.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$15.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$140.00

Example #4: Defined Standard Plan – Catastrophic Phase - Insulin

This example demonstrates how to report a PDE for a $200.00 covered insulin product that falls within the Catastrophic Phase of a Defined Standard plan.

When the claim adjudication begins, the TGCDC Accumulator is $15,600.00 and the TrOOP Accumulator exceeds $7,400.00. The beneficiary is in the Catastrophic Phase of the benefit (TrOOP Accumulator > $7,400.00) in 2023. Therefore, the beginning and ending benefit phase indicators are “C”, meaning Catastrophic Phase. Under the Defined Standard benefit, in the Catastrophic Phase, the beneficiary would pay the lesser of the maximum copayment under the IRA ($35.00), or the greater of $10.35 or 5% of the drug cost (see the Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies). In this case, the beneficiary would pay $10.35. The remainder of the drug cost ($189.65) is reported in the CPP field. Since the beneficiary cost sharing under the Defined Standard plan is already less than the statutory maximum of $35, the beneficiary pays the lesser amount, and there is no IRASA on this PDE record. Because there is no IRASA and no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is left blank.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	**Value**
Total Gross Covered Drug Cost Accumulator	$15,600.00
True Out of Pocket Accumulator	$7,400.00
Beginning Benefit Phase	C
Ending Benefit Phase	C
Other TrOOP Amount Indicator	<blank>
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$0.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$200.00
Patient Pay Amount	$10.35
Covered D Plan Paid Amount (CPP)	$189.65
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$0.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #5: Basic Alternative (BA) Plan – Deductible Phase - Insulin

This example demonstrates how to report a PDE for a $250.00 covered insulin product with an IRASA that falls within the Deductible Phase of a BA Plan. The BA plan does not have an alternative deductible, choosing to use the Defined Standard benefit $505.00 deductible amount.

When the claim adjudication begins, the Total Gross Covered Drug Cost (TGCDC) Accumulator is $0.00 and the TrOOP Accumulator is $0.00. While the beneficiary is in the Deductible Phase, the deductible cost sharing of 100% does not apply, and the beneficiary pays $35. Although the deductible does not apply to a covered insulin product, plans are advised to continue reporting the beginning and ending phase benefit indicators as “D” in 2023 to minimize PDE record population logic changes due to the IRA.

The IRASA is calculated by subtracting the maximum copayment under the IRA from the original beneficiary payment under the plan’s 2023 benefit design consistent with the plan’s 2023 bid ($250.00 - $35.00 = $215.00). This amount is reported in the Other TrOOP Amount field, and because there is no additional non-IRASA payments reported in the Other TrOOP Amount field, the Other TROOP Amount Indicator field is populated with an “S”.

A beneficiary’s progression through the Defined Standard benefit prior to the Coverage Gap Phase, is based on TGCDC for all Part D covered drugs purchased by the beneficiary. Therefore, $250.00 is counted towards the plan deductible, rather than the beneficiary payment of $35.00. The TrOOP Accumulator increases by $250 since both Patient Pay Amount and IRASA are TrOOP-eligible payments. Given that the deductible applies to covered insulin products under the plan’s 2023 benefit design consistent with the plan’s 2023 bid, the TGCDC for the insulin product in this example also counts towards the deductible that otherwise applies under the plan even though the beneficiary only pays a portion of the cost of the drug out of pocket, as the IRASA is treated as paid by the beneficiary.[4]

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	**Value**
Total Gross Covered Drug Cost Accumulator	$0.00
True Out of Pocket Accumulator	$0.00
Beginning Benefit Phase	D
Ending Benefit Phase	D
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$250.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$250.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$0.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$215.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

[4] See footnote 3.

<u>Example #6: Basic Alternative Plan – ICP to Coverage Gap Phase with copay in the ICP, IRASA > $0.00 – Insulin</u>

This example demonstrates how to report a PDE for a $445.00 covered insulin product, with a $442.00 ingredient cost and $3.00 dispensing fee that straddles the ICP and the Coverage Gap of an BA plan. The resulting Patient Pay Amount is compared to the statutory maximum cost sharing for a covered insulin product and the lesser amount is charged to the beneficiary. In this example, under the plan's 2023 benefit design consistent with the plan's 2023 bid, the BA plan has a $45.00 copay for this drug in the ICP.

Step 1 – Determine costs that fall within the Coverage Gap:
When claim adjudication begins the TGCDC Accumulator is $4,610.00 and the TrOOP Accumulator is $1,395.00; the beginning benefit phase is the ICP. The first $50.00 of the claim falls in the ICP. (The amount is calculated as ICL – beginning value in TGCDC Accumulator or $4,660.00 – $4,610.00.) Because the beneficiary has not met the TrOOP threshold, the remaining $395.00 of the claim falls in the Coverage Gap. The ending benefit phase is the Coverage Gap, noted by a "G" in the Ending Benefit Phase field on the PDE record.

Step 2 – Determine the discount eligible cost:
The discount eligible cost is $395.00, the Coverage Gap amount. The dispensing fee falls outside of the Coverage Gap.

Step 3 – Calculate the Gap Discount:
The gap discount is 70% of the $395.00 discount eligible cost, or $276.50.

Step 4 – Determine beneficiary cost sharing under the plan benefit design:
The beneficiary is responsible for cost sharing in each benefit phase the claim straddles because this is a copay to coinsurance straddle claim. The ICP cost sharing in this BA plan is $45.00; Coverage Gap cost sharing is 25% of the drug cost in the gap, or $98.75. Prior to the IRA, the beneficiary would have paid $143.75.

Step 5 – Calculate CPP:
The plan pays the remainder of cost falling in the ICP beyond the beneficiary copay in the ICP ($50.00 - $45.00 = $5.00) and 5% of the discount eligible cost in the Coverage Gap ($395.00 * 0.05 = $19.75). The total CPP is $24.75.

Step 6 – Calculate Patient Pay Amount and IRASA:
Because this is a covered insulin product, total beneficiary cost sharing is reduced to $35.00 per the IRA. The IRASA is calculated by subtracting the reduced beneficiary payment from the original beneficiary payment under the plan's 2023 benefit design ($143.75 - $35.00 = $108.75). This amount is reported in the Other TrOOP Amount field and because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with an "S".

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$4,610.00
True Out of Pocket Accumulator	$1,395.00
Beginning Benefit Phase	N
Ending Benefit Phase	G
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$442.00
Dispensing Fee Paid	$3.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$445.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$24.75
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$108.75
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$276.50

Example #7: Enhanced Alternative Plan – Initial Coverage Phase with Copay < $35 - Insulin

This example demonstrates how to report a PDE for a $200.00 covered insulin product that falls within the ICP of an EA plan. The plan's 2023 benefit design consistent with their bid has this insulin on a $20.00 tier in the ICP.

When the claim adjudication begins, the TGCDC Accumulator is $748.00 and the TrOOP Accumulator is $565.75. The beneficiary is in the ICP of the benefit (TGCDC Accumulator > $505.00 and ≤ $4,660.00) in 2023. Therefore, the beginning and ending benefit phase indicators are "N". In the ICP under the Defined Standard benefit, the beneficiary would typically pay 25 percent coinsurance ($50.00). According to the plan's original 2023 benefit design, the copay for this insulin product is $20, so the difference between the benefit design cost sharing and the Defined Standard cost sharing is reported as NPP ($50.00 - $20.00 = $30.00). The plan pays 75% of the total drug cost ($150.00), which is reported in the CPP field. Because the beneficiary cost sharing under the EA plan's benefit consistent with their 2023 bid is already less than the statutory maximum of $35, the beneficiary pays the lesser amount and there is no IRASA on this PDE record. Because there is no IRASA and no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is left blank.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$748.00
True Out of Pocket Accumulator	$565.75
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	<blank>
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$20.00
Covered D Plan Paid Amount (CPP)	$150.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$30.00
Other True-Out-of-Pocket (TrOOP) Amount	$0.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #8: Enhanced Alternative Plan – Initial Coverage Phase with Copay > $35 - Insulin

This example demonstrates how to report a PDE record for a $200.00 covered insulin product with an IRASA that falls within the ICP of an Enhanced Alternative (EA) plan. The plan's 2023 benefit design consistent with its bid has this insulin product on an $80.00 copay tier in the ICP.

When the claim adjudication begins, the TGCDC Accumulator is $748.00 and the TrOOP Accumulator is $565.75. The beneficiary is in the ICP of the benefit (TGCDC Accumulator > $505.00 and ≤ $4,660.00) in 2023. Therefore, the beginning and ending benefit phase indicators are "N." In the ICP under the Defined Standard benefit, the beneficiary would typically pay 25 percent coinsurance ($50.00). According to the plan's 2023 benefit design, the copay for this insulin product is $80.00, so the difference between the plan benefit design cost sharing and the Defined Standard cost sharing is reported as Non-Covered Plan Paid Amount (NPP) ($50.00 - $80.00 = -$30.00). The plan pays 75% of the total drug cost ($150.00), which is reported in the CPP field. Because this is a covered insulin product, the beneficiary payment is reduced to $35.00 per the IRA. The IRASA is calculated by subtracting the maximum copayment under the IRA from the original beneficiary payment under the plan's 2023 benefit design ($80.00 - $35.00 = $45.00). This amount is reported in the Other TrOOP Amount field, and because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with an "S".

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	**Value**
Total Gross Covered Drug Cost Accumulator	$748.00
True Out of Pocket Accumulator	$565.75
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$150.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	-$30.00
Other True-Out-of-Pocket (TrOOP) Amount	$45.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #9: Enhanced Alternative Plan – Initial Coverage Phase with Copay > $35 with SPAP payment -- Insulin

This example demonstrates how to report a PDE record for a $200.00 covered insulin product with an IRASA that falls within the ICP of an Enhanced Alternative (EA) plan. The plan's 2023 benefit design consistent with its bid has this insulin on an $80.00 copay tier in the ICP. The beneficiary also has an SPAP that reduces the beneficiary's cost sharing to $5.00.

When the claim adjudication begins, the TGCDC Accumulator is $748.00 and the TrOOP Accumulator is $565.75. The beneficiary is in the ICP of the benefit (TGCDC Accumulator > $505.00 and ≤ $4,660.00) in 2023. Therefore, the beginning and ending benefit phase indicators are "N". In the ICP under the Defined Standard benefit, the beneficiary would typically pay 25 percent coinsurance ($50.00). According to the plan's 2023 benefit design, the copay for this insulin product is $80.00, so the difference between the benefit design cost sharing and the Defined Standard cost sharing is reported as Non-Covered Plan Paid Amount (NPP) ($50.00 - $80.00 = -$30.00). The plan pays 75% of the total drug cost ($150.00), which is reported in the CPP field. Because this is a covered insulin product, the beneficiary payment is reduced to

$35.00 per the IRA. The IRASA is calculated by subtracting the reduced beneficiary payment under the plan's 2023 benefit design consistent with the plan's 2023 bid ($80.00 - $35.00 = $45.00). This amount is reported in the Other TrOOP Amount field. The SPAP further reduces the beneficiary's cost sharing from $35.00 to $5.00, and the additional $30.00 reduction is also reported in the Other TrOOP field, bringing the total reported in the Other TrOOP Amount field on the PDE record to $75.00 ($45.00 IRASA + $30.00 non-IRASA). Because there are both IRASA and non-IRASA payments reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with a "B".

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	**Value**
Total Gross Covered Drug Cost Accumulator	$748.00
True Out of Pocket Accumulator	$565.75
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	B
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$5.00
Covered D Plan Paid Amount (CPP)	$150.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	-$30.00
Other True-Out-of-Pocket (TrOOP) Amount	$75.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Because this PDE has a value of "B" in the Other TrOOP Amount Indicator field, this signifies that there is more than one type of TrOOP in the Other TrOOP field. Therefore, at the end of the year, the plan will submit a file to CMS to distinguish the Other TrOOP amounts in the Other TrOOP field for this PDE record.

Example #10: Enhanced Alternative Plan – Coverage Gap Phase with copay, IRASA = $0.00 – Insulin

This example demonstrates how to report a PDE for a $200.00 covered insulin product, with a $195.00 ingredient cost and $5.00 dispensing fee that falls entirely within the Coverage Gap of an EA plan. The resulting Patient Pay Amount is compared to the statutory maximum cost sharing for covered insulin and the lesser amount is charged to the beneficiary. In this example, under the plan's 2023 benefit design consistent with the plan's 2023 bid, the EA plan has a $40 copay for this insulin product in the Coverage Gap. Consistent with the 2023 bid and the coverage gap discount program statute, the gap discount applies after EA supplemental benefits.

Step 1 – Determine costs that fall within the Coverage Gap:
When the claim adjudication begins, the TGCDC Accumulator is $4,700.00 and the TrOOP Accumulator is $1,174.00. The beneficiary's Gross Covered Drug Cost has exceeded the Initial Coverage Limit (TGCDC > ICL), and the beneficiary's TrOOP remains below the TrOOP threshold (Accumulated TrOOP < TrOOP threshold) through the processing of the claim. The beginning and ending benefit phases are the Coverage Gap phase. Therefore, the beginning and ending benefit phase indicators are "G".

Step 2 – Determine plan liability:
The plan liability is equal to the difference between the total cost falling in the Coverage Gap and the applicable beneficiary Coverage Gap copay or coinsurance under the EA plan benefit design. In this example, the beneficiary has a $40.00 copay under the original EA plan benefit design. Therefore, the plan liability is $200 - $40.00 = $160.00. Note that the plan liability of $160.00 is inclusive of the plan's liability for its portion of the dispensing fee.

Step 3 – Determine the discount eligible cost:
In this example, the $40.00 beneficiary copay is 20% of the cost of the drug ($200.00); therefore, the beneficiary pays 20% of the ingredient cost ($195.00 * 0.2 = $39.00) and 20% of the dispensing fee ($5.00 * 0.2 = $1.00). The discount eligible cost is the drug cost in the Coverage Gap minus the plan liability and the beneficiary liability for the dispensing fee. In this example, the discount eligible cost is $200.00 - $160.00 (plan liability) - $1.00 (beneficiary cost sharing for the dispensing fee in the gap) = $39.00.

Step 3 – Calculate the Gap Discount:
The gap discount is 70% of the $39.00 discount eligible cost, or $27.30.

Step 4 – Determine beneficiary cost sharing:
The beneficiary liability is comprised of the remaining portion of the discount eligible cost and a portion of the dispensing fee. The beneficiary liability is $12.70 (= $39.00 * 0.3 + $5.00 * 0.2).

Step 5 – Calculate IRASA:
The beneficiary is already paying less than $35.00 because the gap discount reduced the beneficiary's copay in the Coverage Gap. Therefore, IRASA = $0.00, the Other TrOOP Amount field is $0.00, and the Other TrOOP Amount Indicator field is left blank.

Step 6 – Calculate CPP and NPP amounts:
To determine the portion of the $160 plan liability that is CPP, we consider this claim in light of the Defined Standard benefit where CPP is 5% of the ingredient cost and sales tax in the gap plus 75% of the dispensing fee in the gap. CPP equals ($195.00 * 0.05) + ($5.00 * 0.75) = $13.50.

NPP is determined by taking the cost falling within the Coverage Gap and subtracting the beneficiary cost sharing in the Coverage Gap, reported gap discount, and CPP amounts. NPP is $200.00 – ($12.70 + $27.30 + $13.50) = $146.50.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$4,700.00
True Out of Pocket Accumulator	$1,174.00
Beginning Benefit Phase	G
Ending Benefit Phase	G
Other TrOOP Amount Indicator	<blank>
Ingredient Cost Paid	$195.00
Dispensing Fee Paid	$5.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$12.70
Covered D Plan Paid Amount (CPP)	$13.50
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$146.50
Other True-Out-of-Pocket (TrOOP) Amount	$0.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$27.30

Example #11: Enhanced Alternative Plan – Coverage Gap Phase with coinsurance, IRASA > $0.00 – Insulin

This example demonstrates how to report a PDE for a $725.00 covered insulin product, with a $720.00 ingredient cost and $5.00 dispensing fee that falls entirely within the Coverage Gap Phase of an EA plan. The resulting Patient Pay Amount is compared to the statutory maximum cost sharing for a covered insulin product and the lesser amount is charged to the beneficiary. In this example, under the plan's 2023 benefit design consistent with the plan's 2023 bid, the EA plan has 20% coinsurance for this insulin product in the Coverage Gap. Consistent with the 2023 bid and the coverage gap discount program statute, the gap discount applies after EA supplemental benefits.

Step 1 – Determine costs that fall within the Coverage Gap:
When the claim adjudication begins, the TGCDC Accumulator is $4,950.00 and the TrOOP Accumulator is $1,120.00. The beneficiary's Gross Covered Drug Cost has exceeded the Initial Coverage Limit (TGCDC > ICL), and the beneficiary's TrOOP remains below the TrOOP threshold (Accumulated TrOOP < TrOOP threshold) through the processing of the claim. The beginning and ending benefit phases are the Coverage Gap Phase. Therefore, the beginning and ending benefit phase indicators are "G".

Step 2 – Determine plan liability:
The plan liability is equal to the difference between the total cost falling in the Coverage Gap and the applicable beneficiary Coverage Gap copay or coinsurance under the EA plan benefit design. In this example, the beneficiary has 20% coinsurance under the original EA plan benefit design. Therefore, the plan liability is $725.00 - $145.00 = $580.00. Note that the plan liability of $580.00 is inclusive of the plan's liability for its portion of the dispensing fee.

Step 3 – Determine the discount eligible cost:
The beneficiary coinsurance is 20% of the cost of the drug; therefore, the beneficiary pays 20% of the ingredient cost ($720.00 * 0.2 = $144.00) and 20% of the dispensing fee ($5.00 * 0.2 = $1.00). The discount eligible cost is the drug cost in the Coverage Gap minus the plan liability and the beneficiary liability for the dispensing fee. In this example, the discount eligible cost is $725.00 - $580.00 (plan liability) - $1.00 (beneficiary cost sharing for the dispensing fee in the gap) = $144.00.

Step 4 – Calculate the Gap Discount:
The gap discount is 70% of the $144.00 discount eligible cost, or $100.80.

Step 5 – Determine beneficiary cost sharing:
The beneficiary liability consists of the remaining portion of the discount eligible cost and a portion of the dispensing fee. The beneficiary liability is $44.20 ($144.00 * 0.3 + $5.00 * 0.2). Because this is a plan-covered insulin product, the beneficiary payment is further reduced to $35.00 per the IRA.

Step 6 – Calculate IRASA:
The IRASA is calculated by subtracting the maximum copayment under the IRA from the original beneficiary payment under the plan's 2023 benefit design ($44.20 - $35.00 = $9.20). This amount is reported in the Other TrOOP Amount field and because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with an "S".

Step 7 – Calculate CPP and NPP:
To determine the portion of this amount that is CPP, we consider this claim in light of the Defined Standard benefit where CPP is 5% of the ingredient cost and sales tax in the gap plus 75% of the dispensing fee in the gap. CPP equals ($720.00 * 0.05) + ($5.00 * 0.75) = $39.75.

NPP is determined by taking the cost falling within the Coverage Gap and subtracting the beneficiary cost sharing in the Coverage Gap, reported gap discount, IRASA, and CPP amounts. NPP is $725.00 – ($35.00 + $100.80 + $9.20 + $39.75) = $540.25.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$4,950.00
True Out of Pocket Accumulator	$1,120.00
Beginning Benefit Phase	G
Ending Benefit Phase	G
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$720.00
Dispensing Fee Paid	$5.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$725.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$39.75
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$540.25
Other True-Out-of-Pocket (TrOOP) Amount	$9.20
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$100.80

Example #12: Low Income Subsidy (Level 2) Beneficiary in a Defined Standard Plan – Initial Coverage Phase - Insulin

This example demonstrates that the low income cost sharing subsidy (LICS) applies before IRASA, and the lesser of test applies (i.e., if a low income subsidy-eligible (LIS) beneficiary would have had a copayment of $4.30 on a covered insulin product, this is below the statutory maximum copay of $35 per the IRA, so the LIS beneficiary pays $4.30 and there is no IRASA).

This example demonstrates how to report a PDE for a $200 insulin for a category 2 LIS beneficiary that is in the ICP of a Defined Standard Plan. When the claim adjudication begins, the TGCDC Accumulator is $600.00 and the TrOOP Accumulator is $528.75.

Step 1 – Calculate non-LIS beneficiary cost sharing under the plan benefit design:
The non-LIS beneficiary typically pays 25% coinsurance ($50.00) in the ICP prior to the IRA.

Step 2 – Determine LIS cost sharing prior to the application of the IRA cost sharing reduction:

A category 2 LIS beneficiary pays a $4.30 copay in 2023 for a brand drug in the ICP.

Step 3 – Compare non-LIS and LIS beneficiary cost sharing:
Determine the beneficiary's cost sharing by performing the "lesser of" test. Consider the appropriate amounts for the LIS beneficiary and non-LIS cost sharing amounts. The LIS beneficiary cost sharing amount, as calculated in Step 2, is $4.30. The non-LIS beneficiary cost sharing amount under the plan's 2023 benefit design, as calculated in Step 1, is $50.00. When comparing the non-LIS and LIS beneficiary cost sharing using the "lesser of" test, the LIS beneficiary cost sharing of $4.30 is less than the non-LIS beneficiary cost sharing of $50.00, so the beneficiary will pay the LIS beneficiary cost sharing amount of $4.30.

Step 4 – Apply LICS formula:
The LICS amount equals the difference between the non-LIS and LIS beneficiary cost sharing amounts. The LICS amount is $50.00 – $4.30 = $45.70.

Step 5 – Calculate CPP amount and IRASA:
Since the plan would have paid 75 percent ($150.00) under the Defined Standard benefit, this amount is reported as CPP.

The LIS beneficiary cost sharing of $4.30, as calculated in Step 3, is compared to the statutory maximum cost sharing of $35 for covered insulin products per the IRA. The LIS beneficiary pays the lesser of these two amounts ($4.30) and that amount is reported in the Patient Pay Amount field on the PDE record. Because the beneficiary's cost sharing is already less than the statutory maximum of $35 per the IRA, there is no IRASA. Because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is left blank.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	**Value**
Total Gross Covered Drug Cost Accumulator	$600.00
True Out of Pocket Accumulator	$528.75
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	<blank>
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$4.30

Covered D Plan Paid Amount (CPP)	$150.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$45.70
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$0.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #13: Low Income Subsidy (Level 2) Beneficiary in a Defined Standard Plan – Initial Coverage Phase with SPAP Payment - Insulin

This example demonstrates that the low income cost sharing subsidy (LICS) applies before IRASA, and the lesser of test applies (i.e., if a low income subsidy-eligible (LIS) beneficiary would have had a copayment of $4.30 on a covered insulin product, this is below the statutory maximum copay of $35 per the IRA, so the LIS beneficiary pays $4.30 and there is no IRASA). This example also demonstrates how to populate the Other TrOOP Amount Indicator when only non-IRASA Other TrOOP applies.

This example demonstrates how to report a PDE for a $200 covered insulin product for a category 2 LIS beneficiary that is in the ICP of a Defined Standard Plan. The beneficiary has an SPAP that eliminates cost sharing on this drug. When the claim adjudication begins, the TGCDC Accumulator is $600.00 and the TrOOP Accumulator is $528.75.

Step 1 – Calculate non-LIS beneficiary cost sharing under plan benefit design:
The non-LIS beneficiary typically pays 25% coinsurance ($50.00) in the ICP prior to the IRA.

Step 2 – Determine LIS cost sharing prior to the application of the IRA cost sharing reduction:
A category 2 LIS beneficiary pays a $4.30 copay in 2023 for a brand drug in the ICP.

Step 3 – Compare non-LIS and LIS beneficiary cost sharing:
Determine the beneficiary's cost sharing by performing the "lesser of" test. Consider the appropriate amounts for the LIS beneficiary and non-LIS cost sharing amounts. The LIS beneficiary cost sharing amount, as calculated in Step 2, is $4.30. The non-LIS beneficiary cost sharing amount under the plan's 2023 benefit design, as calculated in Step 1, is $50.00. When comparing the non-LIS and LIS beneficiary cost sharing using the "lesser of" test, we see that the LIS beneficiary cost sharing of $4.30 is less than the non-LIS beneficiary cost sharing of $50.00, so the beneficiary would pay the LIS beneficiary cost sharing amount of $4.30.

Step 4 – Apply LICS formula:
The LICS amount equals the difference between the non-LIS and LIS beneficiary cost sharing amounts. The LICS amount is $50.00 – $4.30 = $45.70.

Step 5 – Calculate CPP amount and IRASA, and apply the SPAP payment:

Since the plan would have paid 75 percent ($150.00) under the Defined Standard benefit, this amount is reported as CPP.

The LIS beneficiary cost sharing of $4.30, as calculated in Step 3, is compared to the statutory maximum cost sharing of $35 for covered insulins per the IRA. The LIS beneficiary would pay the lesser of these two amounts ($4.30). Because the beneficiary's cost sharing is already less than the statutory maximum of $35 per the IRA, there is no IRASA.

The LIS beneficiary has an SPAP that eliminates the beneficiary's cost sharing on this drug. The final Patient Pay Amount is $0 and the $4.30 SPAP contribution is reported in the Other TrOOP Amount field on the PDE record. Because there is only a non-IRASA payment reported in the Other TrOOP field, the Other TrOOP Amount Indicator field is left blank.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	**Value**
Total Gross Covered Drug Cost Accumulator	$600.00
True Out of Pocket Accumulator	$528.75
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	<blank>
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$0.00
Covered D Plan Paid Amount (CPP)	$150.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$45.70
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$4.30
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #14: Low Income Subsidy (Level 2) Beneficiary in a Defined Standard Plan – Initial Coverage Phase - Vaccine

This example demonstrates that the low income cost sharing subsidy (LICS) applies before IRASA, and the lesser of test applies (i.e., if a low income subsidy-eligible (LIS) beneficiary would have had a copayment of $4.30 on an ACIP-recommended vaccine, the copay is now $0 per the IRA, and the $4.30 difference is reported as IRASA).

This example demonstrates how to report a PDE for a $300 ACIP-recommended vaccine, which includes a $40 vaccine administration fee, for a category 2 LIS beneficiary that is in the ICP of a Defined Standard Plan. When the claim adjudication begins, the TGCDC Accumulator is $600.00 and the TrOOP Accumulator is $528.75.

Step 1 – Calculate non-LIS beneficiary cost sharing under plan benefit design:
The non-LIS beneficiary typically pays 25% coinsurance ($75.00) in the ICP prior to the IRA.

Step 2 – Determine LIS cost sharing prior to the application of the IRA cost sharing reduction:
A category 2 LIS beneficiary pays a $4.30 copay in 2023 for a brand drug in the ICP.

Step 3 – Compare non-LIS and LIS beneficiary cost sharing:
Determine the beneficiary's cost sharing by performing the "lesser of" test. Consider the appropriate amounts for the LIS beneficiary and non-LIS cost sharing amounts. The LIS beneficiary cost sharing amount, as calculated in Step 2, is $4.30. The non-LIS beneficiary cost sharing amount under the plan's 2023 benefit design consistent with the plan's 2023 bid, as calculated in Step 1, is $75.00. When comparing the non-LIS and LIS beneficiary cost sharing using the "lesser of" test, we see that the LIS beneficiary cost sharing of $4.30 is less than the non-LIS beneficiary cost sharing of $75.00, so the beneficiary will pay the LIS beneficiary cost sharing amount of $4.30.

Step 4 – Apply LICS formula:
The LICS amount equals the difference between the non-LIS and LIS beneficiary cost sharing amounts. The LICS amount is $75.00 – $4.30 = $70.70.

Step 5 – Calculate CPP amount and IRASA:
Since the plan would have paid 75 percent ($225.00) under the Defined Standard benefit, this amount is reported as CPP.

Beneficiaries do not have cost sharing on ACIP-recommended vaccines per the IRA, therefore, the Patient Pay Amount is reduced to $0, and this reduction ($4.30) is reported as the IRASA in the Other TrOOP Amount field. Because there is no additional non-IRASA payment reported in the Other TrOOP field, the Other TrOOP Amount Indicator field is populated with a "S".

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$600.00
True Out of Pocket Accumulator	$528.75
Beginning Benefit Phase	N
Ending Benefit Phase	N

Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$260.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$40.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$300.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$0.00
Covered D Plan Paid Amount (CPP)	$225.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$70.70
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$4.30
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #15: Low Income Subsidy (Level 2) Beneficiary in a Defined Standard Plan – Gap - Vaccine

This example demonstrates that the plan cost sharing in the Coverage Gap does not apply to low income beneficiaries because these beneficiaries are not applicable beneficiaries. Additionally, this example demonstrates that the low income cost sharing subsidy (LICS) applies before IRASA, and the lesser of test applies (i.e., if a low income subsidy-eligible (LIS) beneficiary would have had a copayment of $4.30 on an ACIP-recommended vaccine, the copay is now $0 per the IRA, and the $4.30 difference is reported as IRASA).

This example demonstrates how to report a PDE for a $200.00 ACIP-recommended vaccine, which includes a $40.00 vaccine administration fee, for a category 2 LIS beneficiary that is in the Gap phase of a Defined Standard Plan. When the claim adjudication begins, the TGCDC Accumulator is $5,000.00 and the TrOOP Accumulator is $1,628.75.

Step 1 – Determine costs that fall in the Coverage Gap: Confirm that the claim falls squarely in the Coverage Gap. The beneficiary's Gross Covered Drug Cost has exceeded the Initial Coverage Limit (TGCDC > ICL), and the beneficiary's TrOOP remains below the TrOOP threshold (Accumulated TrOOP < TrOOP threshold) throughout the processing of the claim. When claim adjudication begins the Total Gross Covered Drug Cost (TGCDC) Accumulator is $5,000.00 and the TrOOP Accumulator is $1,628.75. The beginning benefit phase is the Coverage Gap and the ending benefit phase is also the Coverage Gap.

Step 2 – Determine Discount Eligible Cost: The beneficiary is low-income and is excluded from the Coverage Gap Discount program; therefore, the discount eligible cost is $0.00.

Step 3 – Calculate Gap Discount: The beneficiary is low-income and is excluded from the Coverage Gap Discount program; therefore, the gap discount is $0.00.

Step 4 – Determine beneficiary cost sharing: The beneficiary is a category 2 low-income beneficiary and pays $4.30 for brand drugs. To determine the LICS amount in the Coverage Gap take the total cost of the drug in the gap and subtract the LICS co-pay amount. In this example, subtract $4.30 from $200.00. The LICS amount is $195.70. Beneficiaries do not have cost sharing on ACIP-recommended vaccines per the IRA, therefore, the Patient Pay Amount is reduced to $0, and this reduction ($4.30) is reported as the IRASA in the Other TrOOP Amount field. Because there is no additional non-IRASA payment reported in the Other TrOOP field, the Other TrOOP Amount Indicator field is populated with a "S".

Step 5 Calculate Covered and non-Covered Portion of Plan Paid cost sharing: Low income beneficiaries are exempt from plan cost sharing in the coverage gap; therefore, CPP is $0.00 on this PDE.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$5,000.00
True Out of Pocket Accumulator	$1,628.75
Beginning Benefit Phase	G
Ending Benefit Phase	G
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$160.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$40.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$0.00
Covered D Plan Paid Amount (CPP)	$0.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$195.70
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$4.30
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #16: Low Income Subsidy (Level 4) Beneficiary in a Defined Standard Plan – Deductible Phase - Insulin

This example demonstrates that the low income cost sharing subsidy (LICS) applies before IRASA, and the lesser of test applies (i.e., if a low income subsidy-eligible (LI-4) beneficiary would have had a coinsurance of 15% on a covered insulin product and this results in a Patient Pay Amount that is above the statutory maximum copay of $35 per the IRA, the LIS beneficiary cost sharing is reduced to $35 and the difference is reported as IRASA).

This example demonstrates how to report a PDE for a $400 covered insulin product for a category 4 LIS beneficiary that is in the Deductible Phase of a Defined Standard Plan. When the claim adjudication begins, the TGCDC Accumulator is $0.00 and the TrOOP Accumulator is $0.00.

Step 1 – Calculate non-LIS beneficiary cost sharing under plan benefit design:
The non-LIS beneficiary typically pays 100% coinsurance ($400.00) in the deductible prior to the IRA.

Step 2 – Determine LIS cost sharing prior to the application of the IRA cost sharing reduction:
In 2023, prior to the IRA cost sharing reduction, a category 4 LIS beneficiary would have paid a $104.00 deductible plus 15% of the remainder of the drug cost prior to the application of the IRA cost sharing reduction. The Patient Pay Amount prior to the IRA is $104.00 + ($400.00 - $104.00) * 0.15 = $148.40.

Step 3 – Compare non-LIS and LIS beneficiary cost sharing:
Determine the beneficiary's cost sharing by performing the "lesser of" test. Consider the appropriate amounts for the LIS beneficiary and non-LIS cost sharing amounts. The LIS beneficiary cost sharing amount, as calculated in Step 2, is $148.40. The non-LIS beneficiary cost sharing amount under the plan's 2023 benefit design consistent with the plan's 2023 bid, as calculated in Step 1, is $400.00. When comparing the non-LIS and LIS beneficiary cost sharing using the "lesser of" test, we see that the LIS beneficiary cost sharing of $148.40 is less than the non-LIS beneficiary cost sharing of $400.00, so the beneficiary would pay the LIS beneficiary cost sharing amount of $148.40.

Step 4 – Apply LICS formula:
The LICS amount equals the difference between the non-LIS and LIS beneficiary cost sharing amounts. The LICS amount is $400.00 – $148.40 = $251.60.

Step 5 – Calculate CPP amount and IRASA:
Since the plan would have paid nothing under the Defined Standard benefit, there is no CPP.

The LIS beneficiary cost sharing of $148.40, as calculated in Step 3, is compared to the statutory maximum cost sharing of $35 for a covered insulin product per the IRA. The LIS beneficiary pays the lesser of these two amounts ($35.00) and that amount is reported as the Patient Pay Amount on the PDE record. IRASA is calculated as the difference between $148.40 and $35.00, which is $113.40. This amount is reported in the Other TrOOP Amount field on the PDE record. Because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with a "S". Although the IRASA effectively eliminates the deductible on this covered insulin product for the LI-4 beneficiary, plans are advised to continue reporting the beginning and ending phase benefit indicators as "D" in 2023 to minimize PDE record population logic changes due to the IRA. Given that the LI-4 deductible would have applied to covered insulin products under the plan's 2023 benefit design consistent with the plan's 2023 bid, the first $104.00 of the drug cost of the insulin product in this example also counts towards the LI-4 deductible that otherwise applies under the plan even though the beneficiary only pays a portion of the cost of the drug out of pocket, as the IRASA is treated as paid by the beneficiary.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	**Value**
Total Gross Covered Drug Cost Accumulator	$0.00
True Out of Pocket Accumulator	$0.00
Beginning Benefit Phase	D
Ending Benefit Phase	D
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$400.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$400.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$0.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$251.60
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$113.40
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #17: Low Income Subsidy Beneficiary (Level 4) in an EA plan– Initial Coverage Phase - Insulin

This example demonstrates how to report a PDE for a $280.00 covered insulin product for a category 4 LIS beneficiary that is in the ICP of an EA plan. The EA plan has a 20% coinsurance for this drug. When the claim adjudication begins, the TGCDC Accumulator is $800.00 and the TrOOP Accumulator is $120.00.

Step 1 – Calculate non-LIS beneficiary cost sharing under plan benefit design:
A non-LIS beneficiary in this EA plan pays 20% coinsurance ($280.00 * 0.2 = $56.00) in the ICP prior to the IRA.

Step 2 – Determine LIS cost sharing prior to the application of the IRA cost sharing reduction:
A category 4 LIS beneficiary pays 15% coinsurance ($42.00) in 2023 in the ICP.

Step 3 – Compare non-LIS and LIS beneficiary cost sharing:
Determine the beneficiary's cost sharing by performing the "lesser of" test. Consider the appropriate amounts for LIS and non-LIS beneficiary cost sharing. The LIS beneficiary cost sharing amount, as calculated in Step 2, is $42.00. The non-LIS beneficiary cost sharing amount under the plan's 2023 benefit design consistent with the plan's 2023 bid, as calculated in Step 1, is $56.00. When comparing the non-LIS and LIS beneficiary cost sharing using the "lesser of" test, we see that the LIS beneficiary cost sharing of $42.00 is less than the non-LIS beneficiary cost sharing of $56.00, so the beneficiary would pay the LIS beneficiary cost sharing amount of $42.00.

Step 4 – Apply LICS formula:
The LICS amount equals the difference between the non-LIS and LIS beneficiary cost sharing amounts. The LICS amount is $56.00 – $42.00 = $14.00.

Step 5 – Calculate CPP amount, NPP amount and IRASA:
Since the plan would have paid 75 percent ($210.00) under the Defined Standard benefit, this amount is reported as CPP.

The LIS beneficiary cost sharing of $42.00, as calculated in Step 3, is compared to the statutory maximum cost sharing of $35 for covered insulins per the IRA. The LIS beneficiary pays the lesser of these two amounts ($35.00) and that amount is reported as the Patient Pay Amount on the PDE record. The patient pay reduction of $7.00 is reported as the IRASA in the Other TrOOP Amount field. Because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with an "S".

NPP is determined by taking the total drug cost and subtracting the beneficiary cost sharing, IRASA, LICS, and CPP amounts. NPP is $280.00 – ($35.00 + $7.00 + $14.00 + $210.00) = $14.00.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$800.00
True Out of Pocket Accumulator	$120.00
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$280.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$280.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$210.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$14.00
Non-Covered Plan Paid Amount (NPP)	$14.00
Other True-Out-of-Pocket (TrOOP) Amount	$7.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$0.00
Reported Gap Discount	$0.00

Example #18: Medicare Secondary Payer (MSP) PDE -- Insulin

This example demonstrates how to report an MSP PDE record for a covered insulin product, where the primary payment was $170.00, and the beneficiary is in the ICP of a Defined Standard Plan. Note that all MSP calculation steps should be performed before reducing the Patient Pay Amount to $35.00 if the calculated Patient Pay Amount in Step 5 exceeds $35.00. When the claim adjudication begins, the TGCDC Accumulator is $3,345.00 and the TrOOP Accumulator is $1,023.00. The beneficiary is in the ICP of the benefit (TGCDC Accumulator > $505.00 and ≤ $4,660.00) in 2023. Therefore, the beginning and ending benefit phase indicators are "N".

Step 1 – Price the claim according to the Part D plan's negotiated price for the drug:
The plan prices the claim at its negotiated price of $400.00 and reports this amount in the GDCB field.

Step 2 – Report the primary payment amount as Patient Liability Reduced by Other (PLRO):
The plan reports the primary payment of $170.00 in the PLRO field.

Step 3 – Determine beneficiary and plan liabilities:
Under the plan's 2023 benefit design, the beneficiary's liability is $100.00 (25%) and the plan liability is $300.00 (75%). Note that the pre-IRA cost sharing is used in this step as consistent with the plan's 2023 bid.

Step 4 – Subtract the primary payment from the negotiated price:
The difference between the negotiated price and the primary payment is $230.00 ($400.00 - $170.00).

Step 5 – Determine Patient Pay amount:
The beneficiary is responsible for the lesser of the cost sharing under the plan's 2023 benefit design ($100.00) or the difference between the negotiated price and the amount paid by the primary payer ($230.00). The plan determines $100.00 to be the interim Patient Pay Amount.

Step 6 – Calculate Part D Plan-Paid amount at the point of sale:
The Part D plan is responsible for any amount remaining after the primary payment and the beneficiary's cost sharing under the plan's 2023 benefit design have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($170.00) and the beneficiary's liability ($100.00) is $270.00. The plan pays the pharmacy the remaining $130.00 of the negotiated price ($400.00 – $270.00).

Step 7 – Calculate CPP, IRASA, and Adjusted Patient Pay Amount
This is a covered drug under a Defined Standard plan, so the remaining amount of $130.00 is reported as CPP.

The Patient Pay Amount calculated in Step 5 exceeds $35.00. Therefore, this Patient Pay Amount is reduced to the IRA statutory maximum of $35.00. This reduction ($65.00) is reported as the IRASA in the Other TrOOP Amount field. Because there is no additional non-IRASA payment reported in the Other TrOOP field, the Other TrOOP Amount Indicator field is populated with an "S".

Step 8 – Populate the Pricing Exception field:
The plan reports "M" in the Pricing Exception field.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	**Value**
Total Gross Covered Drug Cost Accumulator	$3,345.00
True Out of Pocket Accumulator	$1,023.00
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	S
Pricing Exception Code	M
Ingredient Cost Paid	$400.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$400.00

Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$130.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$65.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$170.00
Reported Gap Discount	$0.00

Example #19: Employer Group Waiver Plan (EGWP) in the ICP, OHI Benefit < $35.00 – Insulin

This example demonstrates that EGWPs determine IRASA as the final step in calculating and reporting the PDE. Additionally, it demonstrates that EGWPs must charge the lesser of the EGWP's known Other Health Insurance (OHI) benefit or the cost sharing maximum established by the IRA.

In this example, a beneficiary enrolled in an EGWP receives a $200.00 covered insulin product, with a $200.00 ingredient cost and $0.00 dispensing fee. When the claim adjudication begins, the TGCDC Accumulator is $800.00 and the TrOOP Accumulator is $510.00. The beneficiary is in the ICP of the benefit (TGCDC Accumulator > $505.00 and ≤ $4,660.00) in 2023. Therefore, the beginning and ending benefit phase indicators are "N". Under the EGWP's 2023 OHI benefit, the plan has a $20.00 copayment for this covered insulin product in the ICP.

The EGWP should follow the following steps for calculating and reporting IRASA-eligible PDEs in 2023:

Step 1 – Apply the Defined Standard Benefit to Determine CPP

To determine the CPP, this PDE must be considered in light of the Defined Standard Benefit. In the ICP, the plan pays 75% of the total drug cost ($150.00), which is reported in the CPP field.

Step 2 – Apply the EGWP OHI Benefit

The beneficiary would be responsible for a $20.00 copayment for the covered insulin product under the EGWP's OHI benefit in 2023. If the beneficiary were in a Defined Standard plan, the beneficiary would pay $50.00 ($200.00 * 0.25). To determine the PLRO amount, subtract the Patient Pay Amount under the Defined Standard Benefit ($50.00) from the Patient Pay Amount under the OHI benefit ($20.00). PLRO is $30.00.

Step 3 – Calculate Adjusted Patient Pay Amount and IRASA

The Patient Pay Amount under the EGWP OHI benefit is less than the statutory maximum for a covered insulin product under the IRA ($20.00 < $35.00). Therefore, the patient pays the lesser amount, and there is no IRASA on this PDE. The Other TrOOP Amount field is $0.00 and the Other TrOOP Amount Indicator field is left blank.

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$800.00
True Out of Pocket Accumulator	$510.00
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	<blank>
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$20.00
Covered D Plan Paid Amount (CPP)	$150.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$0.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$30.00
Reported Gap Discount	$0.00

<u>Example #20: EGWP in the ICP, OHI Benefit > $35.00 – Insulin</u>

In this example, a beneficiary enrolled in an EGWP receives a $200.00 covered insulin product, with a $200.00 ingredient cost and $0.00 dispensing fee. When the claim adjudication begins, the TGCDC Accumulator is $800.00 and the TrOOP Accumulator is $510.00. The beneficiary is in the ICP of the benefit (TGCDC Accumulator > $505.00 and ≤ $4,660.00) in 2023. Therefore, the beginning and ending benefit phase indicators are "N". Under the EGWP's 2023 OHI benefit, the plan has a $40.00 copayment for this covered insulin product in the ICP.

The EGWP should follow the following steps for calculating and reporting IRASA-eligible PDEs in 2023:

Step 1 – Apply the Defined Standard Benefit to Determine CPP

To determine the CPP, this PDE must be considered in light of the Defined Standard Benefit. In the ICP, the plan pays 75% of the total drug cost ($150.00), which is reported in the CPP field.

Step 2 – Apply the EGWP OHI Benefit

The beneficiary would be responsible for a $40.00 copayment for the covered insulin product under the EGWP OHI benefit in 2023. If the beneficiary were in a Defined Standard plan, the beneficiary would pay $50.00 ($200.00 * 0.25). To determine the PLRO amount, subtract the Patient Pay Amount under the Defined Standard Benefit ($50.00) from the Patient Pay Amount under the OHI benefit ($40.00). PLRO is $10.00.

Step 3 – Calculate Adjusted Patient Pay Amount and IRASA

The Patient Pay Amount under the EGWP OHI benefit is greater than the statutory maximum for a covered insulin product under the IRA ($40.00 > $35.00). Therefore, the Patient Pay Amount is further reduced to $35.00 per the IRA. IRASA is calculated by subtracting the maximum copayment under the IRA from the calculated Patient Pay Amount under the EGWP OHI benefit in 2023 ($40.00 - $35.00 = $5.00). This amount is reported in the Other TrOOP Amount field and because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with an "S".

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$800.00
True Out of Pocket Accumulator	$510.00
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$200.00
Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$150.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$5.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	$10.00
Reported Gap Discount	$0.00

Example #21: EGWP in the ICP, OHI Benefit > $35.00 AND, OHI Benefit > 2023 Defined Standard Benefit Coinsurance – Insulin

In this example, a beneficiary enrolled in an EGWP receives a $200.00 covered insulin product, with a $200.00 ingredient cost and $0.00 dispensing fee. When the claim adjudication begins, the TGCDC Accumulator is $800.00 and the TrOOP Accumulator is $510.00. The beneficiary is in the ICP of the benefit (TGCDC Accumulator > $505.00 and ≤ $4,660.00) in 2023. Therefore, the beginning and ending benefit phase indicators are "N". Under the EGWP's 2023 OHI benefit, the EGWP plan has a $60.00 copayment for this covered insulin product in the ICP.

EGWPs should follow the following steps for calculating and reporting IRASA eligible PDEs in 2023:

Step 1 – Apply the Defined Standard Benefit to Determine CPP

To determine the CPP, this PDE must be considered in light of the Defined Standard Benefit. In the ICP, the plan pays 75% of the total drug cost ($150.00), which is reported in the CPP field.

Step 2 – Apply the EGWP OHI Benefit

The beneficiary would be responsible for a $60.00 copayment for the covered insulin product under the EGWP's known OHI benefit in 2023. If the beneficiary were in a Defined Standard plan, the beneficiary would pay $50.00 ($200.00 * 0.25). To determine the PLRO amount, subtract the Patient Pay Amount under the Defined Standard Benefit ($50.00) from the Patient Pay Amount under the OHI benefit ($60.00). PLRO is -$10.00.

Step 3 – Calculate Adjusted Patient Pay Amount and IRASA

The Patient Pay Amount under the EGWP OHI benefit is greater than the statutory maximum for a covered insulin product under the IRA ($60.00 > $35.00). Therefore, the Patient Pay Amount is reduced to $35.00. IRASA is calculated by subtracting the maximum copayment under the IRA from the calculated Patient Pay Amount under the EGWP OHI benefit in 2023 ($60.00 - $35.00 = $25.00). This amount is reported in the Other TrOOP Amount field and because there is no additional non-IRASA payment reported in the Other TrOOP Amount field, the Other TrOOP Amount Indicator field is populated with an "S".

The table below illustrates how the plan sponsor would populate the PDE record.

PDE Field	Value
Total Gross Covered Drug Cost Accumulator	$800.00
True Out of Pocket Accumulator	$510.00
Beginning Benefit Phase	N
Ending Benefit Phase	N
Other TrOOP Amount Indicator	S
Ingredient Cost Paid	$200.00

Dispensing Fee Paid	$0.00
Sales Tax	$0.00
Vaccine Administration Fee	$0.00
Gross Covered Drug Cost Below Out-of-Pocket Threshold (GDCB)	$200.00
Gross Covered Drug Cost Above Out-of-Pocket Threshold (GDCA)	$0.00
Patient Pay Amount	$35.00
Covered D Plan Paid Amount (CPP)	$150.00
Low-Income Cost-Sharing Subsidy (LICS) Amount	$0.00
Non-Covered Plan Paid Amount (NPP)	$0.00
Other True-Out-of-Pocket (TrOOP) Amount	$25.00
Patient Liability Reduction due to Other Payer Amount (PLRO)	-$10.00
Reported Gap Discount	$0.00