CMSDEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

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TO: All Part D Sponsors

FROM: Vanessa S. Duran
Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year 2022 Cost Sharing Administration Analysis (CSAA) – Results and Lessons Learned

Part D sponsors are responsible for ensuring that prescription drug coverage is adjudicated consistent with their CMS approved plan benefit design. The purpose of the Cost Sharing Administration Analysis (CSAA) is to evaluate whether Part D sponsors are adhering to this requirement. Many beneficiaries use published cost sharing levels to make plan selections and estimate annual drug costs. Thus, it can be significantly impactful if the cost sharing on a prescription drug claim is adjudicated incorrectly. Consistent with 42 CFR § 423.505(n)(1), CMS may determine that a Part D plan sponsor is out of compliance with a Part D requirement when a sponsor fails to meet performance standards articulated in the Part D statutes, regulations, or guidance.

The Contract Year (CY) 2022 CSAA examined prescription drug events (PDE) for claims filled at retail pharmacies during the initial coverage phase and compared the adjudicated beneficiary cost to the expected cost sharing based on the approved plan formulary and benefit design. For this version of the analysis, CMS focused on the cost sharing beneficiaries experienced for approved non-formulary (NF) drug exceptions during the initial coverage phase. For purposes of the CSAA, a PDE was considered to be for a drug provided via a formulary exception if:

1. The drug was included on the CMS Formulary Reference File (FRF), and
2. The corresponding RxNORM Concept Unique Identifier (RxCUI) was not included on the Health Plan Management System (HPMS) approved formulary for the identified month of service.

To account for potential lag time between adjudication and HPMS updates, we also checked the HPMS submissions for the subsequent two months.

For more information on the methodology and initial results of the CY 2022 analysis, refer to the HPMS memorandum titled “Contract Year 2022 Cost Sharing Administration Analysis (CSAA)” released May 25, 2023.

CY 2022 CSAA Final Results

For the CY 2022 CSAA, CMS communicated with parent organizations that had PDE(s) identified as inappropriate either due to being considered a significant outlier by volume and/or those that had any high value discrepancies. These sample PDEs were shared with the applicable plan sponsors. We requested that sponsors address why the identified PDE(s) appeared to contain a cost-sharing discrepancy whereby the adjudicated beneficiary amount appeared to be different from the expected cost-sharing amount, based on the approved formulary and benefit. Table 1 provides a summary of the results following CMS' review of the plan sponsor responses.

Table 1. Summary of CY 2022 CSAA Results

Findings	**# of selected PDEs**	**% of selected PDEs**
Appropriate Cost Sharing Applied	198	35.4%
Inappropriate Cost Sharing Applied for NF drug	140	25.0%
Midyear LIS Status Changes	77	13.8%
Formulary Submission Error	68	12.2%
Incorrect PBP Submission	61	10.9%
Day Supply Error	15	2.7%
Total	**559**	

CMS determined that 198 (35.4%) of PDEs were associated with appropriate cost sharing and no additional action was necessary.

One-hundred and forty (25.0%) PDEs were found to have applied inappropriate cost sharing for a NF drug.

- CMS identified PDEs for NF drugs that were adjudicated at cost shares other than the exception tier(s) approved in the plan's CY 2022 formulary and benefit design.
    - All NF drugs approved via a formulary exception should be adjudicated at the identified formulary exception tier(s).
- CMS observed inconsistent application of cost sharing for generic (Abbreviated New Drug Application [ANDA] approved) drugs. Identified plans applied the first exception tier for generic drugs when they identified a second generic exception tier in their approved CY 2022 formulary and benefit design.
    - For plans that identified a second generic exception tier, sponsors must uniformly apply the second level of cost sharing to all ANDA approved drugs.
    - For low-income subsidy (LIS) enrollees, cost sharing for generic drugs can be no more than the annually determined copayments for all ANDA approved drugs, published in the final Announcement of Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies for the applicable calendar year being analyzed.
- CMS observed unallowed application of tiering exceptions in addition to formulary exceptions for NF drugs.
    - Application of a tier exception is not allowable for NF drugs. All NF drugs can only be approved via a formulary exception and should be adjudicated at the identified formulary exception tier(s).

Seventy-seven (13.8%) of PDEs were found to be discrepant due to midyear LIS status changes. When estimating the expected beneficiary cost share, CMS applied the beneficiary's LIS status at the end of CY 2022. In these identified cases, sponsors provided information indicating the beneficiary was receiving a different LIS level at the time of the claim. Sponsors are expected to process retroactive adjustments for midyear LIS status changes upon notice of LIS status change.

Sixty-eight (12.2%) of PDEs were identified as a non-formulary based on CMS review of HPMS formulary submissions. However, responses from sponsors for these samples indicated that the PDE was for a formulary drug. CMS determined that these claims were not adjudicated properly because an FRF RxCUI was available for inclusion on the HPMS formulary, but the sponsors failed to include the RxCUI. While plan sponsors are permitted to enhance their formularies, including the addition of drugs, at any time during the year, sponsors are required to submit the formulary addition during the next available formulary update window. As above, CMS examined HPMS formulary files during the month of service (i.e. fill date) and the two months that subsequently followed in order to confirm a drug's formulary status. This would have accounted for any potential lag between the HPMS formulary file and the adjudication file.

Sixty-one (10.9%) of PDEs adjudicated at the second generic exception tier. However, the approved annual benefit submission for CY 2022 did not identify a second generic exceptions tier. In order to adjudicate and advertise a second less expensive cost level of cost sharing for approved formulary exceptions for generic drugs, the plan should indicate this benefit design in their PBP for CMS review and approval.

Fifteen (2.7%) of PDEs were calculated with applied daily cost sharing that was different than the daily cost sharing amount approved in their annual benefit submission. The identified plan specified that their one-month supply was 30 days in the PBP but adjudicated PDEs that applied daily cost sharing with a 31-day supply for a one-month period.

CY 2022 CSAA Lessons Learned

Midyear LIS Status Changes

As mentioned in the HPMS memorandum titled "Contract Year 2022 Cost Sharing Administration Analysis (CSAA)" released May 25, 2023, as best practice, sponsors should have procedures in place to identify midyear LIS status changes**.** Per 42 CFR § 423.800(e), sponsors must process retroactive adjustments to cost sharing for low-income subsidy eligible individuals and any resulting refunds and recoveries within 45 days of the sponsor's receipt of complete information regarding claims adjustment.

Monthly Formulary Submission

Per guidance in the CY 2022 Formulary Information HPMS memorandum from December 27, 2021, formulary enhancements, such as adding a Part D drug to the formulary, may be implemented at any time. Consistent with formulary and formulary change notice requirements, these enhancements must be included in the Part D sponsor's communication materials. The posted formulary enhancements must then be reflected in the next HPMS formulary submission. For an RxCUI included on the FRF to be considered a formulary drug, we expect the Part D

sponsor's HPMS formulary file and coverage to accurately reflect the formulary status of the RxCUI. Submissions should also include each formulation, strength, and dosage form that will be a covered formulary drug. CMS expects accurate mapping from the sponsor's NDC drug database to RxCUIs on the FRF. Further, generic and brand products of the same drug have separate RxCUIs and they need to be included on the formulary submission to accurately reflect coverage. For example, if there are separate RxCUIs on the FRF for a generic and brand drug and a plan sponsor intends for both to be on formulary, both RxCUIs must be included on the formulary file.

Non-Formulary Exceptions

All NF drugs approved via a formulary exception should be adjudicated at the identified formulary exception tier(s). In addition, for plans that identify a second generic exception tier, sponsors must uniformly apply the second level of cost sharing to all ANDA approved drugs. Per section 40.5.2 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, "a plan sponsor is limited to choosing a single cost-sharing level that applies to one of its existing formulary tiers. Sponsors may also elect to apply a second less expensive level of cost sharing for approved formulary exceptions for generic drugs, so long as the second level of cost sharing is associated with an existing formulary tier and is uniformly applied to all approved formulary exceptions for generic drugs. Under 42 CFR § 423.578(c)(4)(iii), an enrollee is prohibited from requesting a tiering exception for a non-formulary drug approved under the formulary exception process. If an enrollee requests a tiering exception for an approved non-formulary drug, the request is invalid and is dismissed by the plan." If a formulary drug becomes non-formulary, all tiering exceptions approved while the drug was formulary are no longer applicable.

If this is a transition fill, per section 30.4.9 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, for non-LIS enrollees, a sponsor must charge "the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with §423.578(b)." If a non-formulary exception is approved, the sponsor must apply the defined exception tier(s) to all non-formulary drugs. This also applies for transition fills if a drug is removed from the formulary.

Cost Sharing for Generic Drugs

For sponsors that elect to apply a second, less expensive level of cost sharing for non-formulary exceptions for generic drugs (drugs marketed under an ANDA) per 42 CFR § 423.4, they must uniformly apply the second level of cost sharing.

For LIS eligible enrollees, the sponsor must ensure that individuals pay no more than the copayment for generic drugs as listed in the annual Announcement of Medicare Advantage Capitation Rates and Part C and Part D Payment Policies (also referred to as the Rate Announcement). Per section 60.4.1 of Chapter 13 of the Medicare Prescription Drug Benefit Manual, "if a drug product approval is based upon an ANDA, that drug is a generic drug."

Daily Cost Sharing

Prescriptions dispensed at less than a month's supply are subject to the daily cost-sharing rule at 42 CFR 423.100 and 423.153 (b)(4). Under this rule, a beneficiary who receives less than the

approved month's supply of a solid oral dose drug (except antibiotics and pre-packaged drugs) that is subject to a copayment pays a copayment that is adjusted for the reduced days' supply dispensed. The adjusted daily cost-sharing rate is calculated using the monthly copayment under the enrollee's Part D plan, divided by the number of days in the approved month's supply for the drug dispensed, and rounded to the nearest cent.

Next Steps

We will notify Part D plan sponsors found to have a cost-sharing discrepancy. Sponsors must reprocess these claims and any other claims that are identified as a result of this analysis to ensure that appropriate cost-sharing is applied. When applicable, Part D plan sponsors must refund beneficiaries who overpaid cost-sharing and attempt to collect underpayments when beneficiaries underpaid cost-sharing.

CMS thanks sponsors selected for the analysis for their prompt attention to their workbook responses. We encourage all Part D plan sponsors to closely review the lessons learned described in this memorandum to ensure their adjudication systems are compliant with CMS requirements. This memorandum serves as the completion of the CY 2022 CSAA analysis. Action required or lessons learned from any future analyses will be shared at a later date. For questions regarding the Cost Sharing Administration Analysis please contact the Part D Formularies mailbox at PartDFormularies@cms.hhs.gov.