

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

TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: CMS Part D Utilization Management Policies and Requirements

DATE: October 22, 2010

The Centers for Medicare & Medicaid Services (CMS) is issuing this memorandum to remind Part D sponsors of our policies and requirements relating to the submission of utilization management (UM) edits for CMS review and the implementation of point-of-sale (POS) safety edits that are not reviewed by CMS. We find it necessary to issue this reminder because our audits of Part D sponsors have revealed the use of utilization management edits that do not comply with our policies, resulting in the failure of Part D sponsors to appropriately administer CMS-approved formularies.

As outlined in 42 CFR 423.153(c)(2), Part D sponsors must perform drug utilization review (DUR) before each prescription is dispensed to a Part D enrollee. This concurrent DUR includes, but is not limited to:

- Screening for potential drug therapy problems due to therapeutic duplication.
- Age/gender-related contraindications.
- Over-utilization and under-utilization.
- Drug-drug interactions.
- Incorrect drug dosage or duration of drug therapy.
- Drug-allergy contraindications.
- Clinical abuse/misuse.

Part D sponsors are not required to submit all POS safety edits that are implemented to satisfy these requirements. For example, if a drug is only FDA-approved for patients aged 18 years and older, a Part D sponsor is not required to submit an edit that they may have in place that rejects the claim for patients less than 18 years of age. Similarly, if a drug is only indicated for use in woman, a sponsor does not need to submit as part of their Health Plan Management System (HPMS) formulary submission an edit that rejects claims for male beneficiaries.

Some Part D sponsors also utilize a POS high cost edit as a component of their comprehensive fraud, waste, and abuse program. These edits can assist the Part D sponsor in identifying input errors by the dispensing pharmacist. CMS expects that these types of edits can be overridden by the pharmacist once the correct quantity or dosage is confirmed with the prescriber and Part D sponsor. A Part D sponsor must not, however, apply any additional types of clinical restrictions once the high cost edit is resolved for those drugs that do not otherwise require prior authorization (PA). CMS expects sponsors to consider the usual and customary price of drugs when establishing a dollar threshold for the edit to reduce unnecessary burden associated with valid claims for drugs subject to high cost edits.

Part D sponsors are required to submit to CMS all other clinical requirements or limitations that are applied at POS, such as PA, step therapy (ST), and quantity limits (QL). For example, CMS recognizes that dose optimization edits can be utilized as part of a drug utilization management program as means to reduce costs. Nonetheless, these types of edits must also be included in the HPMS formulary submission for review and approval. While QL would not need to be submitted that allows for the dispensing of a given drug up to the maximum daily dose, any QLs enforced on lower strengths of the drug would need to be submitted to CMS. With respect to PAs and STs, sponsors must clearly submit all requirements as part of the respective HPMS files. CMS expects that, with rare exceptions, the sponsor's approval of PA or ST for one strength of a drug for a beneficiary will apply to all strengths. If the criteria is not submitted to and approved by CMS at a dose-specific level, sponsors must not implement dose-level requirements, as this causes undue burden for the beneficiary, pharmacy, and prescriber.

During audits of Part D sponsors, CMS has also identified sponsors' failure to appropriately effectuate requirements relating to the drugs within the classes of clinical concern (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection). The non-compliance has commonly involved the application of PA and ST requirements to beneficiaries who are currently taking the drug. As discussed in section 30.2.5 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, any applicable PA or ST requirements may only be applied to members who are not currently taking the affected drug. If a Part D sponsor cannot determine at POS whether new enrollees are taking the affected drug, the sponsor must treat these enrollees as currently taking the drug and thus cannot require PA or ST.

The following are examples of audit findings relating to these Part D UM policies. These findings have resulted from improper coding of approved UM edits, implementation of unapproved edits, and misinterpretation of CMS policy and requirements.

1. High cost edits resulting in clinical PA. One Part D sponsor utilized a high cost edit to reject claims for Part D drugs exceeding a certain cost threshold. Rather than allowing the pharmacist to resolve the edit once the dosage was verified for drugs on the formulary without PA, the sponsor required that additional clinical requirements be met and denied coverage in several cases. This resulted in interruption of

- continued access to critical drugs, including antineoplastic and antiretroviral therapies. Any clinical requirements must be submitted to CMS as a PA.
2. Inappropriate coding of PA edits. Some sponsors coded UM edits in a manner that required beneficiaries to satisfy the PA requirement with each successive dose change of a drug. For example, one sponsor approved a PA request and entered the authorization using coding at the drug name, dosage form, and strength level. A beneficiary was required to go through the PA process again, even for subsequent dose reductions. This was inconsistent with the PA information submitted to CMS. If a Part D sponsor identifies a drug for which they believe a strength-level PA is clinically appropriate, the HPMS formulary submission must be reflective of this requirement.
 3. Failure to “grandfather” current users of drugs within the classes of clinical concern. There have been a variety of errors identified affecting beneficiaries taking drugs within the classes of clinical concern that required PA or step ST. One sponsor re-applied PA to drugs during the plan year upon expiration of the initial approval, thus violating the requirement that enrollees currently taking a drug be exempt from PA or ST. Another sponsor programmed a step therapy look-back for antipsychotics at the drug, dosage form, and strength level. As a result, a beneficiary taking one strength of an antipsychotic drug was denied access to a higher strength on the basis of step therapy requirements not being met. Other sponsors did not have processes in place to determine whether new enrollees were already taking a drug within the classes of clinical concern. Thus, PA and ST requirements were being applied to all members, regardless of whether they were already taking the drugs.
 4. Unapproved components of PA. In one case, CMS discovered that the sponsor was requiring laboratory tests and other medical procedures that were not included in the PA criteria submitted to CMS. Part D sponsors must only implement PA requirements that are contained within the CMS-approved formulary submission.
 5. Unapproved quantity limit restrictions. One sponsor had implemented a variety of dispensing limitations on drugs. Many of these drugs had no quantity limit restrictions included on the CMS-approved formulary, and the restrictions were set lower than the FDA-approved dosing. Any quantity limit restrictions below the FDA-approved maximum daily dose, or below the days supply entered in the Part D plan benefit package (PBP), must be submitted to CMS.
 6. Additional miscellaneous edits. A sponsor implemented gender and age edits for certain drugs on their formulary. Even though there were no approved PAs for the drugs, the sponsor was rejecting claims for age and gender edits that were not supported by the FDA-approved label. These types of restrictions must be included as part of the PA criteria submitted to CMS.

More important than audit findings, these types of errors have the potential to cause beneficiary harm due to delayed or denied access to Part D drugs. It is the responsibility of Part D sponsors to ensure that they are administering the CMS-approved benefit. Some of these areas of non-compliance were the result of errors at the PBM level. As such, Part D sponsors must perform adequate oversight of their PBMs and other delegated entities to ensure that they are complying with all CMS requirements. CMS encourages sponsors to adequately test the adjudication of the approved formulary in advance of and during the plan year to help identify errors. In addition, sponsors should routinely review rejected claims to assist in the identification of discrepancies between the benefit that has been approved by CMS and what is being adjudicated at POS.

If you have any questions relating to this memorandum, please contact Brian Martin at brian.martin@cms.hhs.gov.