Enhancements and Clarifications on Improving Utilization Review Controls

In this section we describe the results of sponsors' implementation of improved drug utilization controls and case management to prevent overutilization of medications in Part D in 2013,the findings of the Overutilization Monitoring System (OMS), and our additional expectations for further reductions of overutilization based on enhancements and clarifications of the policy. We appreciate the comments and suggestions submitted by sponsors, PBMs, and other organizations about the proposals to strengthen the overutilization policy in order to reduce the unsafe overutilization of medications by Part D beneficiaries.

Background

In the section entitled, "Improving Drug Utilization Review Controls in Part D" of the Final CY 2013 Call Letter issued on April 2, 2012 and in supplemental guidance issued on September 6, 2012, CMS described how Medicare Part D sponsors can comply with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of opioids. In addition, sponsors were reminded to prevent the dispensing of acetaminophen (APAP) above the U.S. Food and Drug Administration (FDA) daily maximum dose of 4 grams to any beneficiary. In general, the guidance addressed the following expectations for sponsors to address overutilization of opioids effective January 1, 2013:

- Appropriate controls at point of sale (POS), including safety edits and quantity limits.
- Improved retrospective drug utilization review (DUR) to identify at-risk beneficiaries.
- Case management with the beneficiaries' prescribers.
- Data-sharing between Part D sponsors regarding beneficiary overutilization.

Under the guidance, sponsors may implement beneficiary-specific POS edits as appropriate after case management to control access to medications containing opioids. Sponsors are expected to send 30-day advance written notice of the planned POS edit to the beneficiary, the beneficiary's prescribers who request the results of case management, and to the CMS account manager and the central office mailbox PartDPolicy@cms.hhs.gov in a secure manner. The written email notices to CMS containing personally identifiable information (PII) must be encrypted and password protected to be considered secure.

That guidance also stated that CMS would develop monitoring protocols to ensure sponsors were implementing effective but appropriate controls to prevent opioid overutilization. Subsequently, on July 31, 2013, CMS implemented the Overutilization Monitoring System (OMS) to operationalize our monitoring protocols and ensure that sponsors have established reasonable and appropriate drug utilization management programs to prevent the overutilization of prescribed medications as described above (see HPMS memo, Medicare Part D Overutilization Monitoring System, released on July 5, 2013). Additional information about the OMS and the CMS overutilization policy are available on the CMS website at:

http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.

Acetaminophen (APAP)

The use of more than 4 grams of APAP daily is contraindicated by the FDA due to the significant potential for severe liver injury and death. We remind sponsors that they are expected to implement sufficient controls to prevent the cumulative dispensing to any beneficiary of more than 4 grams of APAP per day across all products containing APAP. Analysis of 2011 Part D prescription drug event (PDE) data indicated that nearly 650,000 beneficiaries may have exceeded the maximum APAP dose for at least 5 consecutive days, 221,000 beneficiaries received more than 4 grams per day for at least 10 consecutive days, and 150,760 received more than 4 grams per day for at least 30 total days. From January through December 2013, the OMS identified 56,414 potential APAP overutilization tickets (a "ticket" is a combination of contract ID and HICN), representing 54,569 unique beneficiaries (0.14% of Part D enrollees) who received more than 4 grams of APAP per day for at least 30 days within a six-month period.

Although the use of improved DUR edits in 2013 may have reduced overutilization of APAP, CMS expects Part D sponsors to implement soft[9] formulary-level safety edits at POS at a minimum to further reduce cumulative APAP overutilization among their enrollees. Sponsors may implement hard formulary-level safety edits; however, most commenters were opposed to CMS expecting the use of hard formulary-level safety edits at this time due to the difficulty of programmatically preventing false positives (e.g., early refills, take as-needed dosing, and medication changes due to allergy or intolerance) through the POS claims processing system and the resulting delays in beneficiary access to needed medications. Therefore, sponsors' P&T committees should develop the specifications for formulary-level POS edits to prevent cumulative APAP overutilization based upon their own enrollee data, while minimizing false positives by accounting for known exceptions, such as reasonable early refills. A soft POS edit may still result in a rejected claim, but the pharmacist may exercise professional judgment to override the rejection if clinically appropriate. If the pharmacist does not override the reject, the beneficiary may request a coverage determination. We note that P&T committees may consider a mix of a formulary-level soft edits designed compel the pharmacist's clinical evaluation of APAP usage, and hard edits to prevent APAP doses at and above amounts for which there would be no reasonable medical or dispensing explanation. In addition, as sponsors become more effective at reducing overutilization of APAP among their enrollees, their P&T committees

[9] More information about soft and hard rejects and edits is available from the National Council for Prescription Drug Programs: "Telecommunication Version D and Above Questions, Answers and Editorial Updates," *NCPDP*, February 2014, http://www.ncpdp.org/NCPDP/media/pdf/VersionD-Editorial.pdf (accessed 3/20/2014).

should periodically re-evaluate the type of formulary-level APAP POS edits that are in place and the APAP amounts at which they are triggered.

While we are concerned about the risk of APAP overdose in beneficiaries, we recognize that there are circumstances that justify dispensing a prescription that would otherwise appear to be inappropriate based solely on claims data. However, we remind sponsors that a pattern of overutilization related to repetitive early refills or other reasons may be an indication of actual overutilization, stockpiling, or diversion, which should prompt additional investigation by the sponsor and verification of the ongoing medical necessity with the prescribers. For example, a beneficiary who receives an original prescription plus five refills of a 30-day supply of medication and refills the prescription each time after 75% of the days' supply has expired from the date of dispensing will actually receive 180 days' supply within 111 days. In this example, if each fill is for 100 tablets, the cumulative excess supply is potentially 133 tablets.

While sponsors may determine how to define the allowance for early refills, sponsors should identify, address, and resolve potential overutilization issues, including developing criteria for evaluating if a beneficiary's pattern of early refills warrants additional review. In addition, in the event that formulary-level safety edits at POS for all enrollees fail to address all cases of potential APAP overutilization, we remind sponsors that they may apply case management principles and implement a beneficiary-specific hard POS edit to address overutilization of APAP, as they may for any other medication. However, formulary-level safety edits based on FDA dosage limits may be implemented by sponsors without advance written notice to the beneficiary or submission to CMS.

CMS expects the use of additional POS edits will reduce the overutilization of APAP. Through the OMS we will continue to monitor sponsors' efforts to prevent overutilization of APAP and opioids based on criteria described in the Overutilization Monitoring System User Guide, which is available to all plan sponsors through the Patient Safety Analysis Website. If the soft formulary-level POS edits do not significantly reduce overutilization of APAP, CMS will re-consider the use of hard edits for contract year 2016.

Finally, we remind Part D sponsors of FDA's additional APAP safety initiatives (http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm165107.htm). The FDA asked manufacturers of approved prescription drug products containing more than 325 mg of APAP to request the withdrawal of approval of the product's application by January 14, 2014. According to their Federal Register Notice (http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0021-0001), FDA intends to utilize their authority to initiate withdrawal proceedings for the combination products that contain greater than 325 mg of APAP that remain on the market after January 14, 2014. The FDA also has recommended that health care professionals discontinue prescribing and dispensing combination drug products containing more than 325 mg of APAP. As a result of these safety initiatives, CMS will be removing all

combination prescription drug products that contain more than 325 mg of APAP from the CY 2015 Formulary Reference File.

Opioids

In the supplemental guidance issued in September 2012 (HPMS memo, September 7, 2012, Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html), CMS described a drug utilization review methodology based on morphine equivalent dose (MED) to identify beneficiaries who are at high risk for an adverse drug event due to their use of opioids and for whom focused case management may be appropriate. Analysis of 2011 Part D PDE with this methodology identified 22,222 Part D beneficiaries (0.07% of Part D enrollees) at high risk for an opioid-related adverse drug event. CMS also indicated that each sponsor's targeting criteria should be set by its P&T committee to identify patterns of apparent duplicative therapy over sustained periods of time from multiple prescribers and at high daily doses using MED methodology.

CMS' current opioid overutilization methodology identifies beneficiaries whose daily MED is greater than 120 mg for at least 90 consecutive days, and who used more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims. In January 2014, the OMS identified 27,275 potential opioid overutilization tickets for beneficiaries who exceeded the opioid threshold between January 1, 2013 and December 31, 2013. While direct comparison of these data to the 2011 findings does not show a significant positive trend, the 2013 methodology would be expected to identify a larger number of potential opioid overutilizers than the initial 2011 methodology, primarily due to the significantly expanded list of opioids and the count of beneficiaries' prescribers and pharmacies for their opioid fills through the entire year in the 2013 methodology. When applying the 2013 opioid methodology and comparable PDE cut-off dates to 2011 data, the OMS identified 29,358 beneficiaries (0.093% of enrollees) in 2011 who exceeded the current threshold for opioid overutilization, as compared to 25,246 (0.065%) in 2013. CMS appreciates the efforts of sponsors to reduce the overuse of opioids in Part D, but we believe more can be done.

CMS is concerned by responses received from some sponsors in OMS that a beneficiary's opioid use does not meet the sponsor's internal criteria for review, when that beneficiary's opioid utilization is clearly in excess of the methodology CMS described. For the January 2014 OMS reports, 67% of the potential opioid overutilization responses were BSC - No further review planned; Beneficiary did not meet the sponsor's internal criteria. It appears that some sponsors' criteria or processes to identify and address potential opioid overutilization may be insufficient.

Recent studies referenced in educational materials from the Centers for Disease Control and Prevention indicate that morphine equivalent doses as low as 100mg per day are associated with

a significant increased risk for opioid overdose and death (see http://www.cdc.gov/primarycare/materials/opoidabuse/ and http://www.cdc.gov/primarycare/materials/opoidabuse/docs/managingpain-508.pdf). Further, a recent study in Tennessee indicated that there is an increased risk of opioid-related overdose death associated with the use of 4 or more prescribers, 4 or more pharmacies, and a mean daily dosage greater than 100mg morphine equivalents.[10] Although some commenters opposed a reduction in the MED value for targeting purposes, in light of the potential safety issues for beneficiaries, Part D sponsors should lower their internal opioid criteria for retrospective identification of opioid overutilization and subsequent case management to be no less restrictive than 120mg MED daily dose over at least 90 consecutive days as used by CMS. Sponsors may use lower MED (e.g., 100mg MED suggested by CDC) and/or consecutive day thresholds to be more inclusive, and may vary other criteria including the number of prescribers and pharmacies. CMS will consider adopting 100mg MED in our threshold as early as contract year 2016. One commenter suggested that CMS collaborate with organizations such as the Pharmacy Quality Alliance to develop measure specifications which include criteria such as the 100mg MED threshold; CMS appreciates this comment and will consider new measures when developed and endorsed.

Revisions to Outlier Methodology and Policy

In January 2014, the OMS was enhanced to collect potential opioid overutilization issues that were identified through Part D sponsors' own internal criteria and reviewed, but not previously identified by CMS. No later than January 1, 2015, sponsors should begin submitting their internally-identified potential overutilization issues to the OMS quarterly along with the response code indicating the status of each beneficiary case. The overutilization issues submitted with response codes that are known exceptions may be excluded from future OMS reports.

Improved Drug Utilization Controls for Other Drug Classes

Sponsors are reminded that if they choose to implement improved drug utilization controls and case management for medications that do not contain opioids, the sponsor should apply the same level of diligence and internal documentation with respect to those medications that we expect for medications containing opioids. At this time, our guidance applies only to opioids, and thus it should not be characterized as applying to overutilization of other medications.