

As of May 13, 2019

## **Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point-of-Sale (POS) Safety Edits**

This FAQ document integrates information from the HPMS memo released on October 23, 2018, *Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point-of-Sale Safety Edits*. FAQs have been renumbered from the memo. New information has been added in red italics. This document will be updated with additional FAQs as needed.

### **All Opioid POS safety edits:**

#### **Q1: Are the new edits described in the 2019 Final Call Letter<sup>1</sup> safety edits?**

A1: Yes. The care coordination *soft* edit and opioid naïve 7 days supply limit hard edit are safety edits, used to help fulfill concurrent drug utilization (DUR) requirements outlined in 42 CFR § 423.153(c)(2). The hard morphine milligram equivalent (MME) edit, soft concurrent opioid and benzodiazepine edit, and soft duplicative long-acting (LA) opioid therapy edit are also safety edits.

The purpose of the edits is to prompt prescribers and pharmacists to conduct additional safety review to determine if the enrollee's opioid use is appropriate and medically necessary. The edits should not be implemented as a prescribing limit or as a substitute for clinical judgment. Plan sponsors are expected to implement the edits in a manner that minimizes any additional burden on prescribers, pharmacists, and beneficiaries.

In addition, the edits are not intended to be a fraud, waste, and abuse tool, although they may identify such activities.

#### **Q2: Are PACE organizations expected to apply the opioid safety edits?**

A2: Yes. PACE organizations are expected to comply with the opioid safety edit guidance unless they do not adjudicate claims at POS.

#### **Q3: Can the opioid safety edits be applied during a beneficiary's transition period?**

A3: Yes. Since the opioid edits are safety edits, they can be applied during transition. See Section 30.4.8, "Edits for Transition Fills", Chapter 6, Part D Drugs and Formulary Requirements, Medicare Prescription Drug Benefit Manual. We encourage plan sponsors to utilize the opioid safety edits during transition fills.

#### **Q4: Are Part D sponsors permitted to include buprenorphine products *for medication assisted treatment (MAT)* in the opioid safety edits at POS?**

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<sup>1</sup> <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf>

A4: No. It is very important that beneficiaries' access to MAT, such as buprenorphine, is not impacted. Sponsors should not include buprenorphine for MAT in the opioid safety edits. However, sponsors may establish separate safety edits (or prior authorization and quantity limits upon approval by CMS) for buprenorphine products based on the maximum daily dose in the FDA labeling. Sponsors are also encouraged to implement a soft POS edit when an opioid prescription is presented following the initiation of buprenorphine for the treatment of opioid use disorder. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims *for MAT*.

**Q5: Which beneficiaries should be excluded from the opioid safety edits?**

A5: Part D sponsors are expected to develop specifications that exclude beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain from all of the opioid safety edits. Sponsors should use all information available to them to reasonably exclude these beneficiaries from triggering the edits at POS in the first place. *As announced in the 2020 Final Call Letter, CMS also recommends that beneficiaries with sickle cell disease be excluded from the opioid safety edits.* The CDC Guideline for Prescribing Opioids for Chronic Pain<sup>2</sup> stated that “given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute’s Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease”.<sup>3</sup> CMS also recently released a report on the challenges of pain management for beneficiaries with Sickle Cell Disease.<sup>4</sup> Sponsors are also encouraged to work with their P&T committees to identify other vulnerable patient populations for exclusion from the edits to avoid impeding critical access to needed medication.

Sponsors should also apply specifications to account for known exceptions, such as reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills; and high-dose opioid usage previously determined to be medically necessary such as through coverage determinations, prior authorization, case management, or appeal processes.

**Q6: Are pharmacists expected to do extra work to determine if a beneficiary who triggered one of the opioid safety edits at POS should be excluded?**

A6: No. We expect Part D plan sponsors to use available information to remove excluded beneficiaries prior to a POS rejection, but we recognize that sponsors may not always be able to automatically apply exclusions through claims data in all cases. In addition, for the opioid naïve

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<sup>2</sup> See <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

<sup>3</sup> National Heart Lung and Blood Institute. Evidence-based management of sickle cell disease. Expert Panel report.

Washington, DC: National Institutes of Health; 2014.

<sup>4</sup> <https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/information-products/data-highlights/Understanding-Pain-Management-in-Medicare-Beneficiaries-with-Sickle-Cell-Disease-.html>

edit, sponsors may be limited in their ability to identify initial versus continuing use for new enrollees at the beginning of the plan year.

Pharmacists are not expected to do extra work contacting prescribers or patients to find exclusions outside of the normal pharmacy workflow. Rather, pharmacists may have existing knowledge or information that a beneficiary is not opioid naïve or meets one of the opioid safety edit exclusions (such as through pharmacy drug claims history, knowledge of the enrollee's diagnosis and/or the prescriber's specialty). Also, the pharmacist may learn through a care coordination consult with the prescriber that a beneficiary should be excluded.

Sponsors should instruct pharmacists on how to communicate to the plan that the enrollee is excluded (e.g., through a transaction response code or by contacting the pharmacy help desk) to override the edit or to avoid the beneficiary or their prescriber from having to request a coverage determination on this particular fill. Plans are expected to accept this information in real-time so the claim can adjudicate. The NCPDP *released* updated telecommunications standards guidance to support the new Part D opioid safety edits:

<https://www.ncdp.org/NCPDP/media/pdf/VersionDQuestions.pdf>

**Q7: Are Part D sponsors permitted to require that specific criteria or requirements be met, such as a referral to a pain specialist, prior to approving a coverage determination request related to an opioid safety edit?**

A7: No. The opioid safety edits are not intended to be a means to apply additional clinical criteria for the use of opioids, such as being managed by a pain specialist, having a signed pain contract, or having a treatment plan in place. In the absence of other submitted and approved utilization management requirements, the sponsor should allow the beneficiary to access his/her medication(s) once the prescriber(s) attests that the identified cumulative MME level or days supply is the intended and medically necessary amount for the beneficiary.

For the MME edits, the exception should apply to the cumulative MME level for the beneficiary, not just one specific drug, or one prescriber. In order to minimize unnecessary disruptions in therapy, Part D sponsors should consult with the prescriber(s) to determine whether dose escalation for the beneficiary is imminent, and authorize an increased MME accordingly. For the hard opioid naïve edit, a request for a longer supply for an opioid naïve patient would be considered an exception request. If during the coverage determination process it becomes known that the patient is not opioid naïve, he or she should be excluded from the opioid naïve edit. *See the Coverage determinations and appeals section in this document for more information.*

The sponsor should also remove the edit if it is determined that the beneficiary meets their established criteria for opioid safety edit exclusions (such as cancer, palliative or end-of-life care, long-term care or hospice) discussed above.

**Q8: Could multiple opioid POS rejections occur at the same time?**

A8: Yes. For example, it is possible that a claim could trigger both the opioid naïve edit and the care coordination 90 MME edit. It is also possible that an opioid claim may be subject to a Part D sponsor's CMS-approved formulary utilization management edits. We recommend that

sponsors' P&T committees determine a hierarchy to manage multiple opioid claim rejects to reduce confusion. *See FAQ 26 for information about processing coverage determination and appeal requests involving multiple safety edits or plan coverage limitations.*

**Q9: When an opioid safety edit is triggered and the issue cannot be resolved at the pharmacy, is the pharmacy required to provide the enrollee with a copy of the notice “Medicare Prescription Drug Coverage and Your Rights” (CMS-10147)?**

A9: Yes. Consistent with 42 CFR § 423.128(b)(7)(iii) and Section 40.12.3 *of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance*<sup>5</sup>, the sponsor is required to notify their network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee (“Medicare Prescription Drug Coverage and Your Rights”, CMS-10147, OMB Approval No. 0938-0975). This notice instructs enrollees on how to contact their plan and explains their right to obtain a coverage determination from the plan, including information about the exceptions process.

This includes situations when the beneficiary does not receive a covered fill of the full days supply as written on the prescription due to the opioid naïve 7 days supply limit edit, or when the hard MME edit or care coordination edit is triggered and cannot be resolved at the pharmacy (e.g., prescriber cannot be reached for care coordination edit consultation, prescriber consulted due to care coordination edit but does not confirm the medical necessity of the prescription, pharmacist does not fill the prescription based on clinical judgment or other reasons, or due to hard edit reject).

*This also includes situations involving other opioid safety edits that are generally resolvable at POS (soft edits) such as the concurrent opioid and benzodiazepine use soft edit and the duplicative LA therapy soft edit, when the dispensing pharmacist does not fill the prescription.*

**Q10: What is the expectation for Part D sponsors if a dispensing pharmacist does not fill a prescription based on clinical judgment or other reasons (e.g. suspected fraud or opioid abuse)?**

A10: As discussed above, if the pharmacist chooses not to fill a prescription that triggers one or more *of the* opioid safety edits, the pharmacy notice must be provided to the enrollee. CMS also expects plan sponsors to assist enrollees in locating a network pharmacy that will fill prescriptions for all medications covered under the plan’s Part D benefit.

**Q11: What is CMS’ expectation with respect to training and outreach about the opioid safety edits?**

A11: As outlined in 42 CFR § 423.120(b)(7), a Part D sponsor that uses a formulary under its qualified prescription drug coverage must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary. Accordingly, CMS expects sponsors’ network pharmacies and customer service representatives to be adequately trained with

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<sup>5</sup> <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html>

regard to these edits to ensure affected beneficiaries are given timely and appropriate information and instruction. Pharmacists should also be instructed how they can override the opioid safety edits at POS using the appropriate codes.

CMS also expects sponsors to ensure that their staff are trained to appropriately identify and process enrollee requests for a coverage determination. This includes verbal coverage determination requests made by enrollees, which should not be misclassified as inquiries or grievances. Plans are not permitted to instruct an enrollee who is requesting a coverage determination that only their prescriber can initiate that request.

**Q12: Should sponsors submit opioid safety edits via HPMS even though CMS considers them to be safety edits?**

**A12:** Yes. While safety edits typically are not submitted, in the absence of dosing limits in the FDA-approved labeling for opioids, we expect Part D sponsors to submit information on their opioid naïve safety edit, care coordination safety edit, and optional hard MME edit using a template through HPMS. Guidance memos related to the HPMS submission of the opioid safety edits are provided annually. See most recent HPMS memo, *Submission Template - CY 2019 Opioid Safety Edit and Participation in Drug Management Programs*, from August 8, 2018. The memo also includes instructions if a sponsor wishes to revise their CY 2019 template after the initial submission window.

**Opioid naïve 7 days supply limit hard edit:**

**Q13: After a first fill of a 7 days supply, would the opioid naïve edit still apply if the beneficiary attempts to fill another opioid prescription?**

**A13:** No. For a beneficiary who attempts to fill another opioid prescription after the initial 7 days fill and is still within the lookback window designated by the Part D sponsor, CMS does not expect the opioid naïve edit to trigger again. The beneficiary may be subject to additional edits and CMS-approved formulary utilization management criteria.

In the case of the opioid naïve edit, we generally expect that either:

- The beneficiary will receive an initial fill for a 7 days supply. Upon reassessment by the prescriber, if the beneficiary needs additional acute pain treatment, the prescriber will write another opioid prescription. The opioid naïve edit would not trigger again if additional prescriptions are presented within the plan's lookback period; OR
- The beneficiary will not receive any medication and instead will request a coverage determination from the plan for the full amount as written.

**Q14: If an opioid prescription's smallest available marketed package size exceeds a 7 day supply, does CMS expect plans to allow more than the 7 day supply?**

**A14:** No. As stated in the 2019 Draft Call Letter, we are not aware of any State laws or labeling that would prohibit prescription opioids from being dispensed in a smaller quantity.

**Q15: How does the daily cost-sharing rate regulation at 42 CFR § 423.153(b)(4) relate to the opioid naïve edit?**

A15: When a prescription is dispensed for less than the approved month's supply, a daily cost-sharing rate applies. Thus, if a solid, oral opioid prescription is written for 30 days, and the beneficiary receives a 7 days supply due to the opioid naïve edit, the daily cost-sharing rule applies. If the copayment for a month's supply is \$30, the copayment for a 7 days supply would be \$7.

**Concurrent opioid and benzodiazepine use soft edit:**

**Q16: Does CMS intend for a soft reject to also occur for a benzodiazepine claim if concurrent history of an opioid exists?**

A16: Yes. We expect the concurrent use of opioid and benzodiazepine soft edit to be bidirectional, meaning that edit would be applied to both opioid and benzodiazepine claims.

**Opioid care coordination 90 MME edit:**

**Q17: What are CMS's expectations for pharmacists when the care coordination edit is triggered, including documentation of the care coordination consultation with the prescriber?**

A17: Outside of a known exclusion, when the care coordination edit is triggered, the pharmacist is expected to consult with the beneficiary's prescriber to confirm intent. We generally expect the consultation to be consistent with current pharmacy practice to verify the prescription with the prescriber and to validate its clinical appropriateness.

These consultations are also an opportunity for pharmacists to inform the prescriber of other opioid prescribers or increasing level (MME) of opioids. As such, they may help reinforce CDC Guideline recommendations for improved clinician and patient communications about the risks and benefits of opioid therapy, and create an opportunity for prescribers to reassess the patients' opioid use and look for opportunities for opioid discontinuation or alternative treatment options.

One of the following is likely to occur at POS when consulting with the prescriber:

- Prescriber confirms intent.
- Prescriber provides information that the enrollee is excluded.
- Prescriber does not confirm medical necessity of the prescription.
- Pharmacist is unable to reach prescriber.

Pharmacists should be provided the appropriate override codes without needing to contact the plan sponsor, or sponsors should allow the pharmacist to call the plan's help desk for the plan to put in an override in real-time if the plan sponsor does not have the capability to utilize automated codes. While Part D plan sponsors are required to oversee and monitor their network pharmacies to ensure compliance with Part D program rules, any documentation requirements established by plans related to care coordination consultations are expected to be minimally burdensome and consistent with current pharmacist workflow and professional practices. For

example, the documentation may include the date, time, name of prescriber, and brief note that the prescriber confirmed intent, did not confirm intent, provided information on beneficiary exclusion, or could not be reached after ‘X’ number of attempts.

*Regardless of whether a prescription triggers the care coordination edit or whether the prescriber confirms intent, a pharmacist retains the ability to not fill a prescription based on their clinical judgment.*

**Q18: If the pharmacist recently consulted with the beneficiary’s prescriber when verifying the prescription, is an additional care coordination consultation necessary?**

A18: Generally, no. If the pharmacist recently consulted with the prescriber and the pharmacist has up to date clinical information (e.g. Prescription Drug Monitoring Program (PDMP) system or other records), an additional consultation with the prescriber is not expected. Pharmacies should maintain documentation of the recent consultation and enter the appropriate override code.

It is also possible that a beneficiary may meet the conditions of the care coordination edit multiple times in a given month or year. We expect sponsors to implement reasonable logic to remove the likelihood of redundant or duplicative coordination edits from triggering multiple times and necessitating repeated pharmacist-prescriber consultations (e.g., after they receive the prescriber attestation via a coverage determination request or confirmation from the pharmacy that the prescriber was consulted).

**Q19: May sponsors continue to use message-only alerts with the same parameters as the care coordination edit after the resolution of the care coordination edit?**

A19: Yes. We encourage the use of 90 MME message-only alerts similar to sponsors’ care coordination edit parameters once the care coordination edit has been resolved; that is, has been overridden at the POS or no longer triggers as the result of a coverage determination or appeal. The use of message-only alerts at POS avoids duplicating the care coordination effort. At this time, we do not recommend additional soft cumulative 90 MME edits after resolution of the care coordination edit.

*Q20: When a dispensing pharmacist attempts to consult with a prescriber to resolve the care coordination edit, is the pharmacist permitted to rely on information provided by someone other than the prescriber, such as an on-call physician in the same practice or another member of the prescriber’s staff?*

*A20: CMS guidance allows the pharmacist to override the care coordination edit at the POS upon consultation with the prescriber to confirm intent. We believe this reasonably extends to physician office staff or a covering physician who attempts to provide such confirmation, at the discretion of the dispensing pharmacist.*

**Coverage determinations and appeals:**

**Q21: When an enrollee or their prescriber contacts the plan to dispute the application of an opioid safety edit, how should the request be processed?**

**A21:** The request must be processed as a coverage determination. *As noted above, sponsors should ensure that their staff are trained to appropriately recognize and process enrollee requests for a coverage determination when the beneficiary contacts the plan about opioid safety edit issues.*

An enrollee, the enrollee's representative, or the enrollee's prescriber on the enrollee's behalf has the right to request a coverage determination for a drug or drugs subject to the opioid safety edits, including the right to request an expedited coverage determination. A coverage determination may be requested at any time, including prior to the enrollee presenting a prescription at the pharmacy (for example, if the enrollee is filling a prescription for pain medication in advance of a surgical procedure).

*When an enrollee or their prescriber contacts the plan to dispute the application of an opioid safety edit that hasn't been resolved at the POS, including when the enrollee does not receive the full day's supply as written due to the opioid naïve 7 days supply limit, or a soft edit that was not overridden at the point of sale, the request must be processed as a coverage determination.*

**Q22:** *If an opioid safety edit is resolved at POS while a coverage determination is already in progress, how should the plan proceed?*

*A22: As with any other request for benefits, if a beneficiary has requested a coverage determination related to an opioid safety edit, the plan is required to issue and effectuate a decision within the applicable regulatory timeframe. CMS does not expect pending coverage determination requests to be dismissed subsequent to a pharmacist override or partial fill. However, in making its determination, the plan may rely upon information communicated by the pharmacist, included with the submitted claim, or included by the prescriber with the prescription, when available, to avoid the need to seek additional information from the prescriber. For example, a transaction response from its network pharmacy that resolves the care coordination edit based on pharmacist consultation with the prescriber that confirms the higher MME is medically necessary may be taken into consideration when adjudicating a coverage determination.*

**Q23:** **Must all coverage determination requests seeking an exception to an opioid safety edit be expedited?**

**A23:** No. Part D plan sponsors are required to process a coverage determination request under the expedited timeframe when the prescriber indicates, or the plan decides, that applying the standard timeframe may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. Generally, *CMS* expects coverage determinations related to any opioid safety edits to meet the criteria for expedited review. However, there is no blanket requirement that all of these requests must be expedited. It is based on the facts and circumstances of the individual case. If the request meets the criteria for expedited review by the plan, the plan must make its decision and notify the enrollee as expeditiously as their health condition requires, but no later than 24 hours after receipt of the prescriber's supporting statement. See *Section 40.8 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance* for more information.

***Q24: Should approved exceptions related to the opioid naïve 7 day supply limit be effectuated through the end of the plan year?***

*A24: Once a prescriber attests that the days supply is the intended and medically necessary amount for the enrollee, sponsors may decide the duration of the approval based on the facts and circumstances of the case. Generally, CMS would expect plans to effectuate a one time fill for approved opioid naïve exception requests as there may be a legitimate safety concern with continued use for the remainder of the plan year. However, as with any exception request, there may be a medical need for continued use of the drug. For example, an enrollee may demonstrate a medical need for periodic use of the drug beyond 7 days or for the remainder of the plan year.*

***Q25: How should a sponsor process a direct member reimbursement (DMR) request for a days supply of an opioid longer than 7 days?***

*A25: Under 42 CFR §423.566(b), a request for payment for any drug the enrollee believes may be covered by the plan must be processed as a coverage determination. If the enrollee making the request was not opioid naïve, the plan should not apply the 7 day supply limit and process the request based on any other applicable plan rules and the facts and circumstances of the case. If the enrollee was opioid naïve, CMS expects the plan to process the DMR as an exception request, and solicit a supporting statement from the prescriber (verbal or written) attesting that the longer days supply was medically necessary. Absent any other plan limitation on coverage, even if the longer days supply is denied, CMS expects the plan to cover up to a 7 days supply, consistent with state and federal law. For additional information on processing DMRs, refer to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, §40.5 and Chapter 14, §50.4.3 of the Medicare Prescription Drug Benefit Manual.*

***Q26: How does CMS expect Part D sponsors to process coverage determination or appeal requests for opioids that involve multiple coverage limitations and may have, or would, result in multiple reject codes at the POS?***

*A26: If a coverage determination is requested for a drug that involves multiple opioid-related or other plan coverage rules, the plan sponsor must address each issue as part of the coverage determination. For example, if the request involves a drug subject to prior authorization (PA), where the claim also rejected or would reject at the POS because it triggered the care coordination edit, the adjudication of the case must involve both issues. As with any other request for benefits, if such a request is denied in whole or in part, the written denial notice must explain the reason(s) for the denial, including information about any applicable plan coverage rule. Where appropriate, CMS expects such notice to indicate that outreach to the provider for a needed attestation related to an opioid safety edit was attempted, and not to direct the enrollee back to the pharmacy.*