



CENTER FOR MEDICARE

DATE: December 9, 2019

TO: All Prescription Drug Plans, Medicare Advantage- Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE plans

FROM: Amy Larrick Chavez-Valdez, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year (CY) 2020 Opioid Safety Edit Reminders and Recommendations

This memorandum provides helpful reminders and recommendations as Part D sponsors prepare to implement opioid point-of-sale (POS) safety edit(s) for CY 2020 and summarizes trends in the types of edits sponsors have implemented. Updated educational materials are available (such as slide decks and tip sheets for prescribers, pharmacists, and patients, including a beneficiary fact sheet) on the CMS Part D Overutilization website at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html> which sponsors may use to supplement their outreach efforts.

Background

Medicare Part D sponsors must have concurrent drug utilization review (DUR) systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale (POS) or point of distribution as described in 42 CFR 423.153(c)(2). To help prevent and address prescription opioid overuse through improved concurrent DUR, sponsors can fulfill 42 CFR 423.153(c)(2) by implementing opioid safety edits at the POS¹, including:

- Care coordination edit at 90 morphine milligram equivalents (MME) per day,
- Hard edit at 200 MME per day or more (optional),
- Hard edit for 7 day supply limit for initial opioid fills (opioid naïve),
- Soft edit for concurrent opioid and benzodiazepine use, and
- Soft edit for duplicative long-acting (LA) opioid therapy.

¹ Refer to the [2019 Final Call Letter](#) and [2020 Final Call Letter](#), as well as the October 23, 2018 HPMS memo: *Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point-of-Sale Safety Edits* and a Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point-of-Sale (POS) Safety Edits document, available on the CMS Part D Overutilization website: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>.

Important Reminders

- The purpose of the opioid safety 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. Plan sponsors are expected to implement the edits in a manner that minimizes any additional burden on prescribers, pharmacists, and beneficiaries.
- The opioid safety edits should not be implemented as prescribing limits or as a substitute for clinical judgment. Rather, the opioid safety edits aim to strike a better balance between identifying potential opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.
- Decisions by clinicians to taper opioid dosages should be carefully considered and individualized, if appropriate. Opioids should not be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal, unless there is a life-threatening issue confronting the individual patient. Tapering is most likely to be effective when there is patient buy-in and collaboration, tapering is gradual, and clinicians provide support².
- Part D sponsors are expected to develop opioid safety edit 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. For 2020, we also recommend that beneficiaries with sickle cell disease be excluded from the opioid safety edits. Sponsors are encouraged to work with their P&T committees to identify other vulnerable patient populations for exclusion from the opioid safety edits.
- The care coordination and hard MME edits may also include prescriber counts, pharmacy counts, or both. We recommend including a threshold of 2 or more opioid prescribers in these edit specifications.
- Coordinated, repetitive, and well-timed outreach to prescribers, pharmacies, and enrollees is strongly recommended ahead of the new contract year and throughout the year to reinforce the opioid safety edit policies. As noted above, updated educational resources are available on the CMS Part D Overutilization website. Part D sponsors should repeat their education and outreach efforts to ensure that clinicians are aware of the policies, pharmacists are aware of the options to resolve rejected claims at POS if appropriate, and beneficiaries are aware of their rights to request a coverage determination when a prescription cannot be filled at the pharmacy as written.

² More information on the risks of rapid tapering and guidance for gradual, individualized tapering can be found with the [HHS Joint statement on tapering](#) and the [HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics](#).

Trends in Implementation of Opioid Safety Edits and Other Recommendations

Annually, Part D sponsors provide information to CMS on the opioid safety edits they implement using a template³. Based on this information, trends in the types of edits sponsors implemented for 2019 and will implement for 2020 are summarized in this section. We also share other recommendations based on first year experience and feedback.

Cumulative MME safety edits

For 2019 and 2020, most Part D contracts have included either a prescriber count, pharmacy count, or both in the specifications for the 90 MME care coordination edit. As seen in Table 1, contracts were more likely to use prescriber counts than pharmacy counts for the care coordination edit in both 2019 and 2020.

Table 1: Contract specifications of care coordination edits, 2019 and 2020

Year	Total contracts	No prescriber or pharmacy count	Prescriber count only	Pharmacy count only	Both prescriber and pharmacy count
	Number	Number (% of contracts)	Number (% of contracts)	Number (% of contracts)	Number (% of contracts)
2020	820	170 (20.7%)	515 (62.8%)	0 (0.0%)	135 (16.5%)
2019	722	125 (17.3%)	453 (62.7%)	1 (0.1%)	143 (19.8%)

For both years, over 99% of prescriber and pharmacy counts ranged from 2 to 4 and the distributions of prescriber and pharmacy counts were about the same for both years (data not shown). Contracts were most likely to implement criteria with 2 prescribers, then 4 and 3 prescribers, in descending order of frequency. Of those contracts with pharmacy counts, most implemented either 3 or 4 pharmacies and a smaller number of contracts submitted criteria with 2 pharmacies.

About half of contracts have included an optional MME hard edit in 2019 and 2020 (Table 2), the vast majority of which have been at 200 MME.

Table 2: Contracts with optional hard MME edits, by MME thresholds, 2019 and 2020

Year	Contracts with Hard Edits (% of Contracts)	200 MME	>200-300 MME	360 MME	>360 MME
2020	415 (50.6%)	410	3	1	1
2019	339 (47.0%)	335	3	0	1

Opioid naïve edits

Part D sponsors specified the number of days that they applied for their opioid naïve edit look-back period. From 2019 to 2020, the look-back periods shifted from 90 day to 60 and 120 day windows. Additionally, the most common look-back window used by Part D sponsors was 108 days for both 2019 and 2020.

³ See August 1, 2019 HPMS memo: *Submission Template – Contract Year (CY) 2020 Opioid Safety Edits*

Table 3: Contract specifications of opioid naïve edits, look-back windows (days), 2019 and 2020

Year	Total contracts	≤ 30 days	60 days	90 days	108 days	120 days	> 120 days
2020	820	2 (0.2%)	107 (13.0%)	133 (16.2%)	367 (44.7%)	206 (25.1%)	5 (0.6%)
2019	722	1 (0.1%)	71 (9.8 %)	166 (23.0%)	332 (46.0%)	152 (21.0%)	0 (0.0%)

Recommendations

- Monitor the override rates for soft edits by pharmacy to identify outliers or educational opportunities.
- Review the volume of claims that are rejected at POS and override rates for the care coordination edit. If the vast majority of rejections are being overridden, consider adding a prescriber and/or pharmacy count.
- Assess coverage determination request volume and approval rates (e.g., attestation from the prescriber) for the hard MME edit. For example, sponsors who implemented edit specifications with a minimum of one prescriber may experience a higher number of rejections and/or approvals. The single prescriber will likely attest that the opioid dosage was medically necessary, potentially delaying beneficiary access.
- Conversely, identify low rejection rates based on contract enrollment which may be indicative of ineffective opioid safety controls at POS and reassess the edit specifications as needed.
- Reinforce to pharmacists and customer service representatives that the plan may not have opioid claims history for new enrollees, especially at the start of a new contract year, and they may experience a claim rejection due to the opioid naïve edit with their first opioid prescription over 7 days supply. Pharmacists often have existing knowledge or information that a beneficiary is not opioid naïve and may submit an override code to the plan to avoid an interruption in treatment.
- Instruct pharmacists on how to communicate to the plan when an enrollee should be excluded from any of the opioid safety edits.

Conclusion

Since the beginning of 2019, CMS has monitored complaints data, appeals data, and other sources of information to identify potential issues with the enhanced opioid safety edits. While no systemic issues have been identified, CMS has identified educational opportunities and has met with certain plan sponsors to address implementation concerns. In 2020, CMS will continue to gain experience with these strategies and closely monitor their impact on Medicare Part D prescription opioid overuse to evaluate the need for potential modifications or development of alternative or additional approaches in the future.

For questions related to Medicare Part D opioid safety edits, please email PartD_OM@cms.hhs.gov.