Medicare Part D Prescription Opioid Policies for 2019

Information for Pharmacists

Background

- Opioid medications are effective at treating certain types of pain, but have serious risks such as increasing tolerance, development of opioid use disorder, and overdose.

- CMS understands the magnitude of the nation's opioid epidemic and its impact on communities and published a roadmap with a three-pronged approach to combating the opioid epidemic:
  - Prevention of new cases of opioid use disorder (OUD).
  - Treatment of patients who have already become dependent on or addicted to opioids.
  - Utilization of data from across the country to better target prevention and treatment activities.

- CMS finalized new policies for Medicare drug plans to follow starting on January 1, 2019.

Opioid Policy Summary

- The new policies include improved **safety edits** when opioid prescriptions are dispensed at the pharmacy and **drug management programs** for patients determined to be at-risk for misuse or abuse of opioids or other frequently abused drugs.

- CMS tailored its approach to help distinct populations of Medicare Part D opioid users:
    - New opioid users (opioid naïve),
    - Chronic opioid users,
    - Users with potentially problematic concurrent medication use, and
    - High risk opioid users.

Opioid Policy Exclusions

- The policies are not "one size fits all".

- Residents of long-term care facilities, those in hospice care, patients receiving palliative or end-of-life care, and patients being treated for active cancer-related pain should be excluded from these interventions.

- These policies also should not impact patients' access to medication-assisted treatment (MAT), such as buprenorphine.

Myth #1

MYTH:

"Medicare is requiring that patients fill opioid prescriptions for 7 days supply at a time."

FACT:

- A fill for a prescription opioid will be limited to a 7 days supply only for Medicare Part D patients who have not filled an opioid prescription recently (such as within the past 60 days).

- This does not apply to patients already taking opioids.

Myth #2

MYTH:

"Medicare is forcing all patients to taper their prescription opioids below a certain amount."

FACT:

- Decisions to taper or stop prescription opioids must be carefully considered and are individualized between the patient and prescriber.
    - The opioid policies are not prescribing limits.
    - Plans are implementing edits when a patient's cumulative opioid daily dosage reaches or exceeds a designated amount to prompt additional review.
    - Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies.

Myth #3

MYTH:

 "There is nothing I can do for my patient if they need more opioids."

FACT:

- Overrides for exclusions may be communicated at point-of sale (POS) with a transaction code or by contacting the plan directly.
  - If patient is subject to a safety edit at the pharmacy, and the pharmacy can't fill the prescription as written, the patient or the prescriber on their behalf may contact the plan to ask for a coverage determination, including the right to request an expedited or standard coverage determination in advance of prescribing an opioid.

1. Opioid Safety Edits

- CMS expects Medicare Part D drug plans to implement the following opioid safety edits at point-of-sale (POS):

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

Opioid Naïve Seven-day Supply Limit

- Medicare Part D patients who have not filled an opioid prescription recently will be limited to a supply of 7 days or less.

- *This edit should not impact patients who already take opioids.*

- Subsequent prescriptions filled during the plan's review window (generally 60-90 days) will not be subject to the 7 days supply limit.

Opioid Naïve Seven-day Supply Limit

Pharmacist Role

- Provide information to the plan for override if known to pharmacist that patient has an exclusion (discussed above) or is not opioid naive.

    - Overrides may be communicated at point-of sale (POS) with a transaction code or by contacting the plan directly.
    - The National Council for Prescription Drug Programs, (NCPDP) will be releasing updated telecommunications standards guidance to support the new Part D opioid safety edits.

Opioid Naïve Seven-day Supply Limit

Pharmacist Role

- If the issue is not resolved at the POS and the prescription cannot be filled as written, including when the full days supply is not dispensed, distribute a copy of the standardized CMS pharmacy notice _Medicare Prescription Drug Coverage and Your Rights_ to the patient.

- Inform the patient that either they or their prescriber can request a coverage determination from the plan for longer days supply as written on prescription.

Care Coordination Edit

- This edit will trigger when a patient's cumulative MME per day across his/her opioid prescription(s) reaches or exceeds 90 MME.

- *Some plans have this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies.*

- In reviewing the edit, the pharmacist should consult with the prescriber.

Care Coordination Edit

- *This is not a prescribing limit.* Decisions to taper or discontinue prescription opioids are individualized and agreed upon by both the patient and prescriber.

- 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.

Care Coordination Edit

Pharmacist Role

- Provide information to the Medicare Part D plan for override if known to pharmacist that patient has an exclusion (discussed above) or if prescriber has recently been consulted and the pharmacist has up to date clinical information. Overrides may be communicated at POS.

- *Consult with the patient's prescriber to confirm intent.* The consultation should be consistent with current pharmacy practice to verify the prescription with the prescriber and to validate its clinical appropriateness.

Care Coordination Edit

Pharmacist Role

- *Document the discussion and submit the appropriate override code.* 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.

- If the issue is not resolved at the POS and the prescription cannot be filled as written, distribute a copy of the standardized CMS pharmacy notice *Medicare Prescription Drug Coverage and Your Rights* to the patient.

Additional Opioid Safety Edits

- Other soft edits will trigger when the patient is taking opioids and benzodiazepines concurrently or is taking multiple duplicate long-acting opioids.

- Pharmacists should conduct additional safety review to determine if the patient's opioid use is safe and clinically appropriate.

- If the issue is not resolved at the POS and the prescription cannot be filled as written, distribute a copy of the standardized CMS pharmacy notice _Medicare Prescription Drug Coverage and Your Rights_ to the patient.

Optional Safety Alert at 200 MME or Higher

- Some plans may implement a hard edit when a patient's cumulative opioid daily dosage reaches 200 MME or more.

- *Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies.*

- *This is not a prescribing limit.* Decisions to taper or discontinue prescription opioids are individualized and agreed upon by the patient and prescriber.

Optional Safety Alert at 200 MME or Higher

Pharmacist Role

- Provide information to the Medicare Part D plan for override if known to pharmacist that patient has an exclusion (discussed above). Overrides for exclusions from the safety edit may be communicated at POS with a transaction code or by contacting the plan directly.

- If the issue is not resolved at the POS and the prescription cannot be filled as written, distribute a copy of the standardized CMS pharmacy notice *Medicare Prescription Drug Coverage and Your Rights* to the patient.

- Inform the patient that either they or their prescriber can request a coverage determination from the plan for higher amounts.

2. Drug Management Programs

- Medicare Part D plans may have a drug management program that limits access to opioids and benzodiazepines for patients who are considered by the plan to be at risk for prescription drug abuse.

- Coverage limitations under a DMP can include:

  - Requiring the patient to obtain these medications from a specified prescriber and/or pharmacy, or
  - Implementing an individualized POS edit that limits the amount of these medications that will be covered for the patient.

Drug Management Programs

- Patients are identified for the drug management program based on opioid use involving multiple doctors and pharmacies, and case management is conducted by the plan with the patients' prescribers.

- Before a limitation is implemented, the plan must give written notice to the patient, and an opportunity to tell the plan which prescribers or pharmacies they prefer to use or provide additional information if they disagree with the plan's decision.

Drug Management Programs

- If the plan decides to limit coverage under a DMP, the patient and their prescriber have the right to appeal the plan's decision.

- Pharmacies are **<u>not</u>** expected to distribute the standardized CMS pharmacy notice *<u>Medicare Prescription Drug Coverage and Your Rights</u>* to the patient in response to a rejected claim related to a limitation under a DMP.

- The patient or prescriber should contact the plan for additional information on how to appeal.

Summary

- CMS finalized new policies for Medicare drug plans to follow starting on January 1, 2019.

- These policies involve further partnership with prescribers, pharmacists, patients, and Medicare Part D prescription drug plans.

- Pharmacists play a key role in helping patients use prescription opioid pain medications more safely, understanding the risks associated with opioids, or knowing next steps to get access to needed medications.

Additional Information

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf

- Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point-of-Sale Safety Edits or Medicare Part D Drug Management Programs at: https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html

- CMS Roadmap to Address the Opioid Epidemic at https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf

- National Institute on Drug Abuse Opioid Overdose Crisis information at: https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis

- Information about the National Opioid Crisis go to: https://www.hhs.gov/opioids/ or the Center for Disease Control (CDC) at: https://www.cdc.gov/drugoverdose/epidemic/index.html

- CDC Guideline for Prescribing Opioids for Chronic Pain at: https://www.cdc.gov/drugoverdose/prescribing/guideline.html

- Medicare Prescription Drug Coverage and Your Rights at: https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/yourrightsfactsheet.pdf