

Medicare coverage of opioids: Drug management lock-in programs and safety edits

Opioids are medications that can help treat pain after injury or surgery. These medications carry the risk of addiction, overdose, and death. As a result, Medicare has begun to implement policies to help Part D prescription drug plans address opioid misuse among Medicare beneficiaries. Two of these policies are drug management lock-in programs and new safety edits.

Drug management lock-in programs

Beginning in 2019, Part D plans can implement special drug management programs to limit opioid access for at-risk beneficiaries. Plans use clinical guidelines to identify a beneficiary who may be at risk for misuse or abuse of frequently abused drugs, such as opioids.

At-risk beneficiaries:

- May be required to use one provider and one pharmacy to get flagged medications (known as pharmacy or provider lock-in)
- Cannot use the Extra Help Special Enrollment Period (SEP) to make coverage changes

If a plan finds a beneficiary to be at risk, it must send two notices. The first notice declares the beneficiary potentially at risk. The second notice declares the beneficiary at risk and gives the beneficiary the option to select provider and pharmacy preferences.

If a beneficiary or their doctor disagrees with the at-risk designation, they can appeal by following instructions on the second notice.

Certain beneficiaries will not receive the at-risk label:

- Individuals who elect hospice care or receive palliative end-of-life care
- Individuals who reside in long-term care facilities
- Individuals being treated for active cancer-related pain

Safety edits

A safety edit is a general term that refers to any alert at the pharmacy caused by communication between the plan's and the pharmacy's computer systems. Safety edits are intended to promote safe and effective use of medications.

When a beneficiary encounters a safety edit, they may need to contact their plan or provider. This may lead to the beneficiary or provider submitting an exception request or coverage determination request and beginning an appeal.

Safety edits related to opioid prescriptions include edits for opioid-naïve patients and for care coordination alerts.

Safety edits for opioid-naïve patients

This safety edit places a limit of a seven-day supply for individuals who have not filled an opioid prescription recently (within the past 60 days). The pharmacist can dispense a partial quantity of the prescription but cannot fill the full prescription until authorized by the plan. This safety edit should not affect people already taking opioids.

If a beneficiary has this safety edit at the pharmacy and needs more than a seven-day supply, they should ask their provider to request a coverage determination from the drug plan for more than a seven-day supply.

This safety edit is related to the Centers for Disease Control and Prevention (CDC) prescribing guideline that says opioid prescriptions for acute pain should be limited to a supply for three days or fewer, and a seven-day supply is rarely necessary.

Safety edits for care coordination alerts

This safety edit limits the opioid dosage that a beneficiary can receive at the pharmacy. It may apply to:

- Potentially unsafe opioid dosages
- Potentially negative opioid interaction with benzodiazepines (such as Xanax® or Valium®)

Depending on the situation, a pharmacist may be able to contact the prescriber to confirm that a higher dosage or opioid use with benzodiazepines is medically necessary. The pharmacist can then override the safety edit and fill the prescription.

In other cases, if the opioid dosage is above a certain limit, the pharmacist will need plan authorization to override the safety edit. A beneficiary should ask their provider to request a coverage determination from the plan, providing proof of medical necessity for the higher opioid dosage. Providers are also encouraged to discuss opioid overdose risk and prevention with the beneficiary.

This safety edit is related to the CDC prescribing guideline that states opioid dosages should not exceed certain amounts per day.

For more information on this topic, visit the Centers for Medicare & Medicaid Services (CMS) resource page:
[Improving Drug Utilization Review Controls in Part D](#)