



Medicare Opioid Edits and Programs

There are several opioid safety edits and programs for Medicare Part D. This impacts all Fallon Health Medicare members: Fallon Medicare Plus, Navicare, Summit ElderCare PACE, and Fallon Health Weinberg PACE.

The criteria used to identify members potentially at risk or for the point of sale pharmacy edits are not intended as prescribing limits. They are used to identify members that may be at risk for opioid overuse. The edits are not a substitute for your professional judgment and do not mean that you cannot prescribe over these limits.

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 support.

You need to attest that the identified medications and doses are intended and medically necessary for the member. Please be aware that network pharmacies, Fallon Health Pharmacy Department, our MTM vendor (Clarest Health), and/or our Opioid Drug Management vendor and PBM (Optum Rx) may outreach to you for your assistance in resolving these safety edits and opioid management cases.

Please assist us in meeting the expectation that prescribers respond to pharmacy outreach related to opioid safety alerts in a timely manner, including educating their on-call staff. Some of these issues can be completed directly with the retail pharmacy by attesting that the medications and doses are intended and medically necessary for the member. If you need to submit a Coverage Determination or an Exception request, please call 1-844-657-0494 (please call 1-844-722-1701 for Fallon Health Weinberg PACE) or fax 844-403-1028.

Below is a summary of the programs.

Point of Sale (POS) opioid safety edits

CMS requires certain prospective safety edits. These edits will occur when the member is filling the prescription at the pharmacy. These edits require resolution. The pharmacist at the pharmacy may override some of the edits with appropriate codes, may need to consult with the provider, and may need to inform the provider that a prior authorization is required. Since these are safety edits, they will still apply during a member's transition period; meaning, the claims will still reject with the edits and require resolution. Buprenorphine for medication-assisted treatment (MAT) is not included in the safety edits.

Hospice/palliative care, cancer-related pain, sickle cell disease, and LTC members are excluded from the safety edits. Members have Coverage Determination and Appeal rights under this program. The edits include:

- Soft edit for concurrent opioid and benzodiazepine use – pharmacy can override
- Soft edit for duplicative long-acting (LA) opioid therapy – pharmacy can override
- Soft edit for concurrent opioid and prenatal vitamins use – pharmacy can override
- Soft edit for concurrent opioid and Medication Assisted Therapy (MAT) use – pharmacy can override
- Care coordination edit at 90 morphine milligram equivalents (MME) and 2 prescribers – pharmacy can override only after consultation with the prescriber, documentation of the discussion, and if the prescriber confirms intent (the opioids and/or day supply is intended and medically necessary for the member), using an override code that indicates the prescriber has been consulted.
- Hard edit for a 7-day supply limit for initial opioid fills (opioid naïve) with a 120-day look-back. If the pharmacy cannot resolve at point of sale (POS), this will require a prior authorization to be submitted. Provider needs to attest that the opioids and/or day supply is intended and medically necessary for the member. Member is considered opioid naïve if there are no opioid claims in the past 120 days.
- Benzodiazepines (COB) in members who are 18 years of age or older, with concurrent use of opioid and benzodiazepine for greater than fourteen (14) days. If the pharmacy cannot resolve at point of sale (POS), this will require a prior authorization to be submitted.

Medication Therapy Management (Not applicable to PACE)

We are also including special eligibility criteria into our Medication Therapy Management Program (MTMP). In addition to traditional MTMP eligibility, members are eligible for MTMP if they have been identified as an At-Risk Beneficiary (ARB) under a Drug Management Program (DMP)

Comprehensive Addiction and Recovery Act of 2016 (CARA) - Drug Management Program (DMP)

This is a comprehensive opioid management program required under the Comprehensive Addiction and Recovery Act of 2016 (CARA). This is a retrospective DUR program to identify members at risk for frequently abused drugs and conduct case management. Frequently abused drugs are defined by CMS as opioids and benzodiazepines. Buprenorphine for medication-assisted treatment (MAT) is not included in the 90 MME accumulations. The program excludes members with cancer pain, palliative/hospice care, sickle cell disease, and in LTC. Dual/Low Income Subsidy (LIS) members are limited in ability to change plans to avoid intervention once identified as at-risk.

Criteria for identification into the program include any of the below:

- Members with opioid pharmacy claims equal to or greater than 90 MME and 3+ opioid prescribers and 3+ opioid dispensing pharmacies
- Members with opioid pharmacy claims equal to or greater than 90 MME and 5+ opioid prescribers
- Members with any MME level and 7+ opioid prescribers or 7+ opioid dispensing pharmacies
- Members identified as having a history of opioid-related overdose are also included in the DMP.
- Program includes case management and clinical outreach to providers to determine if the member is at risk for opioid overutilization, notifications to the member, potential lock-in restrictions to specific provider(s), pharmacy(ies), and/or at the drug level. Members have appeal rights under this program

Medicare Part D Opioid Policies: Information for Prescribers

Medicare Part D **opioid policies** include **safety alerts** when opioid prescriptions are dispensed at the pharmacy and **drug management programs** for Part D enrollees at risk for misuse or abuse of opioids or other frequently abused drugs.

Residents of long-term care facilities, receiving hospice, palliative or end-of-life care, being treated for active cancer-related pain, or who have sickle cell disease are exempt from these interventions. Enrollee access to medication-assisted treatment (MAT), such as buprenorphine, should not be impacted.

 Opioid Safety Alert	 Prescriber Tips
Seven-day supply limit for opioid naïve patients This hard edit alert triggers when an enrollee who has not filled an opioid prescription recently (such as within the past 60 days) attempts to fill an opioid prescription for more than a 7 day supply. This edit should not impact enrollees who already take opioids, but may occur for enrollees who enroll in a new plan that does not know their current prescription information.	Enrollee may receive up to a 7 day supply without taking any action. Enrollee or prescriber can request a coverage determination for full days supply as written. Prescriber only needs to attest that the days supply is the intended and medically necessary amount. Subsequent prescriptions filled within the plan's look back window are not subject to the 7 day supply limit, as the enrollee will no longer be considered opioid naïve.
Optional Safety Alert at 200 morphine milligram equivalent (MME) or more Some plans may implement a hard edit safety alert when an enrollee's cumulative opioid daily dosage reaches 200 MME or more. Some plans have this alert only when the enrollee uses multiple opioid prescribers and/or opioid dispensing pharmacies. This alert stops the pharmacy from processing the prescription until an override is entered or authorized by the plan.	Resolving this alert generally requires the plan to process a coverage determination which may be requested by the enrollee or prescriber. In the absence of other approved utilization management requirements, once the prescriber attests that the identified cumulative MME level is the intended and medically necessary amount, the plan should approve the higher MME, allowing the claim to adjudicate.
Opioid care coordination alert at 90 MME This alert triggers when an enrollee's cumulative MME per day across all of their opioid prescription(s) reaches or exceeds 90 MME. Some plans use this alert only when the enrollee uses multiple opioid prescribers and/or opioid dispensing pharmacies. This consultation usually occurs once per plan year.	The pharmacist may call to confirm the dose and medical need for the opioid prescription that prompts the alert, even if it's below 90 MME. The prescriber may be informed of other opioid prescribers or increasing level (MME) of opioids. Prescriber only needs to attest that the identified cumulative MME level days supply is the intended and medically necessary amount.
Concurrent opioid and benzodiazepine use or duplicative long-acting opioid therapy These soft edit alerts trigger when opioids and benzodiazepines or multiple long-acting opioids are taken concurrently.	The pharmacist will conduct additional safety reviews to determine if the enrollee's medication use is safe and clinically appropriate. The pharmacist may contact the prescriber to confirm medical necessity.

Opioid Safety Alerts

Opioid safety alerts are not prescribing limits. Part D plans are expected to implement safety alerts (pharmacy claim edits) for pharmacists to review at the time of dispensing the medication to prevent the unsafe utilization of drugs. CMS encourages prescribers to respond to plan and pharmacist outreach in a timely manner and to give appropriate information to on-call prescribers as needed to resolve opioid safety edits and avoid disruption of therapy.

CMS expects all Part D plan sponsors to have a mechanism in place which allows all opioid safety alerts, including hard edits, to be overridden at point of sale at the pharmacy based on information from the prescriber or otherwise known to the pharmacy that an enrollee is exempt.

Prescribers have the right to request a coverage determination for a drug(s) on behalf of an enrollee, including the right to request an expedited or standard coverage determination in advance of prescribing.

Drug Management Programs (DMPs)

All Part D plans must have a DMP that limits access to opioids and/or benzodiazepines for enrollees who are considered by the plan to be at risk for prescription drug abuse or misuse. The goal of a DMP is better care coordination for safer use. Enrollees are identified by opioid use involving multiple doctors and pharmacies or a recent history of opioid-related overdose, and undergo case management conducted by the plan and involving their prescribers.

DMP limitations can include requiring the enrollee to obtain these medications from a specified prescriber and/or pharmacy, or implementing an individualized point of sale edit that limits the amount that will be covered.

After case management, and at least 30 days before implementing a coverage limitation, the plan will notify the enrollee in writing. Plans are required to make reasonable efforts to notify prescribers. After 30 days, the plan must send the enrollee a second written notice confirming the details of the limitation. This notice also explains that the enrollee, their representative, or their prescriber have the right to appeal.