# We are writing in full support of CMS’ new strategies to tackle the overuse of opioids, which will help to reduce the health risks that these medications pose to Medicare beneficiaries.

Specifically, both (1) implementation of formulary-level cumulative opioid restrictions to 90 morphine milligram equivalents (MME) per day with a 7 day supply and (2) a supply limit for initial opioid fills of 7 days with a daily dose maximum (e.g. 50 MME/day) would be important steps forward. As the 2016 Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain (Dowell D, Haegerich TM, Chou R. *JAMA*. 2016;315(15):1624-1645) recommends carefully reassessing individual risks and benefits for opioid prescriptions of 50 MME/day or more and to avoid increasing dosage to 90 MME/day or more (or to carefully justify such a decision), both of CMS’ proposed changes are consistent with these guidelines.

We recently conducted a study examining Medicare prescription drug formulary coverage of opioids in 2006, 2011, and 2015 (including both Medicare Advantage and stand-alone prescription drug plans). We found that while Part D formularies have increased restrictions through increased use of quantity limits and prior authorization by 2015, a substantial number of Medicare prescription drug formularies continue to provide unrestrictive coverage to many opioids. Specifically, in examining 45 opioid drug- dose combinations in 2015, we found that a median 33.3% of formularies provided coverage without any restrictions (which means no prior authorization, no step therapy, and no quantity limits). While quantity limits were applied by a median 71.1% of Medicare prescription drug formularies in 2015, only 13.3% of quantity limits restricted opioid prescriptions to <50 MME/day and only 24.4% restricted to between 50 and 90 MME/day.

Our publication is attached below.

These data show that formularies remain an important, although underutilized, lever to improving safer prescribing of opioids for Medicare prescription drug beneficiaries. CMS’ proposed strategies represent an important step to using formulary utilization management tools to reduce opioid overuse and related harm. In addition, to complement these strategies, we also urge CMS to ensure that there is broad coverage of a spectrum of non-opioid analgesics as well as non-pharmacologic methods to achieve pain control for beneficiaries.

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**Annals of Internal Medicine** LETTERS

**OBSERVATION: BRIEF RESEARCH REPORT**

**Medicare Formulary Coverage Restrictions for Prescription Opioids, 2006 to 2015**

*Background:* Over the past 2 decades, prescription opi- oid sales and overdose deaths have quadrupled (1). Risk for unintentional overdose is increased when longer-acting opi- oids and higher dosages are prescribed (2, 3). Older patients are particularly vulnerable to opioid-related complications and injury (4). Addressing these risks, the 2016 opioid pre- scribing guidelines from the Centers for Disease Control and Prevention (2) suggest a trial of nonopioid therapies before opioid initiation, use of opioids only when expected beneﬁts outweigh risks, reassessment of risks and beneﬁts when pre- scribing dosages greater than 50 morphine milligram equiva- lents (MME) per day, and prescribing no more than 90 MME/d.

Restricting formulary coverage for prescription drugs is 1 strategy to decrease opioid prescribing. A private insurer showed that implementing prior authorization, quantity limits, and provider–patient agreements was associated with a 15% decrease in opioid prescribing (5). The extent to which opi- oids are covered and/or restricted among formularies serving Medicare beneﬁciaries is unknown.

*Objective:* To characterize the extent to which utilization management strategies have been used to restrict access to prescription opioids among Medicare Part D formularies over the past decade.

*Methods and Findings:* We used the Centers for Medicare & Medicaid Services prescription drug plan formulary ﬁles to compare coverage in 2006, 2011, and 2015 for all available doses of commonly used short- and long-acting opioid med- ications except for methadone, which was excluded. These ﬁles include data on all Medicare Advantage and standalone Part D plan formularies that have submitted complete and accurate information to the Centers for Medicare & Medicaid Services. Although lack of formulary coverage may not be in- tended to restrict opioid prescribing, it creates a ﬁnancial bar- rier to prescription opioid access.

We determined the median proportion of drug– dosage combinations that formularies did not cover; covered but did not restrict; and restricted through prior authorization, step therapy, or quantity limits. We also calculated whether prescribed dosages were limited to less than 50 MME/d

or 50 to 90 MME/d or whether those greater than 90 MME/d were permitted. We graphed results for hydrocodone– acetaminophen, a commonly prescribed short-acting opioid frequently implicated in overdose-related deaths, to show our ﬁndings at the individual drug level.

Data were available for 324, 244, and 389 formularies in 2006, 2011, and 2015, respectively. In 2006 and 2011, more than two thirds of drug– dosage combinations had no opioid prescribing restrictions; in 2015, approximately one third had no restrictions (Table). Few formularies required step therapy, but requirements for prior authorization increased over time (from a median of 0% in 2006 and 2011 to 4.4% in 2015). The median proportion of drug– dosage combinations with quan- tity limits increased from 8.9% in 2006 to 22.2% in 2011 and 71.1% in 2015. Dose restrictions to less than 50 MME/d in- creased from a median of 2.2% of drug– dose combinations in 2006 to 4.4% in 2011 and 13.3% in 2015.

Formularies increased coverage for hydrocodone– acetaminophen at all dosages between 2006 and 2015 (Fig- ure). Although no formularies required prior authorization or step therapy for this drug, the daily dosage was increasingly restricted for the 5 mg/325 mg and 7.5 mg/325 mg formula- tions, with a greater proportion limiting prescriptions to less than 90 MME/d between 2006 and 2015. Restrictions on MME per day for the 10 mg/325 mg formulation increased slightly from 2011 to 2015, with approximately 80% permitting pre- scribing greater than 90 MME/d in 2015.

*Discussion:* Medicare Part D formularies increasingly used quantity limits and, to a lesser extent, prior authorization to restrict daily allowable prescribed dosing of prescription opioids between 2006 and 2015. Despite increased formulary restrictiveness, unrestrictive coverage persisted for many opi- oids, especially at high doses, including for drugs commonly associated with overdose. Although the overall number of for- mularies with available data varied across years, changes in how many formularies provided information are unlikely to have affected this general trend.

As shown by formulary coverage of hydrocodone– acetaminophen, formularies tended to be less restrictive at higher doses, largely because they maintained identical quan- tity limits regardless of dose. This factor allowed for higher prescribed MME per day. Given that higher doses are associ- ated with higher overdose rates (3), limiting prescribed MME per day or requiring prior authorization or step therapy for high-dose opioids may facilitate better adherence to Centers

***Table.*** Median Medicare Part D Formulary Requirements for Prior Authorization, Step Therapy, Quantity Limits, and MME per Day of 45 Opioid Drug–Dose Combinations in 2006, 2011, and 2015\*

|  |  |  |  |
| --- | --- | --- | --- |
| **Formulary Coverage** | **2006 Formularies** | **2011 Formularies** | **2015 Formularies** |
|  | **(*n*** = **324)** | **(*n*** = **244)** | **(*n*** = **389)** |
| No coverage | 20 (13.3–35.6) | 15.6 (4.4–24.4) | 17.8 (11.1–33.3) |
| Coverage with no restrictions | 66.7 (51.1–80.0) | 66.7 (53.5–77.8) | 33.3 (28.9–44.4) |
| Requires prior authorization | 0 (0–4.4) | 0 (0–8.9) | 4.4 (0–11.1) |
| Requires step therapy | 0 (0–0) | 0 (0–0) | 0 (0–0) |
| Imposes any quantity limit | 8.9 (0–28.9) | 22.2 (8.9–40.6) | 71.1 (60.0–84.4) |
| Imposes a speciﬁc quantity limit  <50 MME/d | 2.2 (0–6.7) | 4.4 (2.2–6.7) | 13.3 (8.9–17.8) |
| 50–90 MME/d | 2.2 (0–8.9) | 6.7 (4.4–13.3) | 24.4 (20.0–33.3) |
| >90 MME/d | 4.4 (0–13.3) | 11.1 (2.2–24.4) | 31.1 (26.7–37.8) |

MME = morphine milligram equivalents.

\* Values are percentages, and values in parentheses are interquartile ranges.

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***Figure.*** Medicare formulary daily dosage restrictions of hydrocodone–acetaminophen: 2006, 2011, and 2015.

100



90

80

70

60

**Formularies, %**

50

40

30

20

10

0

2006

2011 2015 2006 2011 2015 2006 2011 2015

**5 mg/325 mg 7.5 mg/325 mg Hydrocodone–Acetaminophen Dosage and Formulary Year**

**10 mg/325 mg**

**<50 MME/d**

MME = morphine milligram equivalents.

* 1. **MME/d >90 MME/d No quantity limit No coverage**

for Disease Control and Prevention prescribing recommenda- tions. Because formulary coverage directly affects prescribing, our study suggests that formularies present an underutilized opportunity to restrict opioid prescribing.

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**Reproducible Research Statement:** *Study protocol and statistical code:* Available from Dr. Samuels (e-mail, [elizabeth.samuels@yale](mailto:elizabeth.samuels@yale.edu)

[.edu).](mailto:elizabeth.samuels@yale.edu) *Data set:* Available for purchase from the Centers for Medicare & Medicaid Services [(www.cms.gov/Research-Statistics-Data-and-](http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PrescriptionDrugPlanFormularyPharmacyNetworkandPricingInformationFiles.html) [Systems/Files-for-Order/NonIdentiﬁableDataFiles/PrescriptionDrug](http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PrescriptionDrugPlanFormularyPharmacyNetworkandPricingInformationFiles.html) [PlanFormularyPharmacyNetworkandPricingInformationFiles.html).](http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PrescriptionDrugPlanFormularyPharmacyNetworkandPricingInformationFiles.html)

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