

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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OBSERVATION: BRIEF RESEARCH REPORT

Medicare Formulary Coverage Restrictions for Prescription Opioids, 2006 to 2015

Background: Over the past 2 decades, prescription opioid sales and overdose deaths have quadrupled (1). Risk for unintentional overdose is increased when longer-acting opioids 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 prescribing 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 prescribing dosages greater than 50 morphine milligram equivalents (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 opioids 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 medications 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 intended to restrict opioid prescribing, it creates a financial barrier 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 quantity 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 increased 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 (Figure). 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 formulations, 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 prescribing 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 opioids, especially at high doses, including for drugs commonly associated with overdose. Although the overall number of formularies with available data varied across years, changes in how many formularies provided information are unlikely to have affected this general trend.

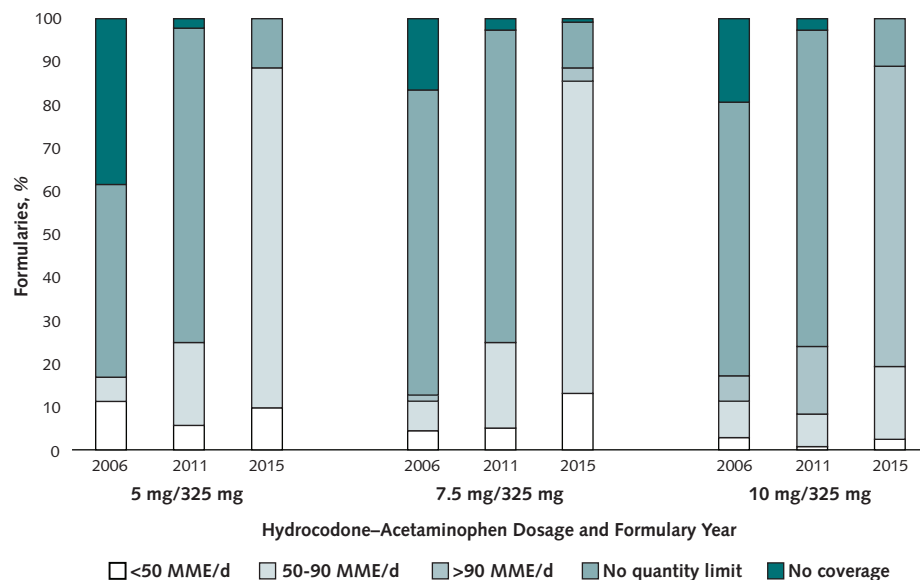
As shown by formulary coverage of hydrocodone-acetaminophen, formularies tended to be less restrictive at higher doses, largely because they maintained identical quantity limits regardless of dose. This factor allowed for higher prescribed MME per day. Given that higher doses are associated with higher 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 (n = 324)	2011 Formularies (n = 244)	2015 Formularies (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.

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

MME = morphine milligram equivalents.

for Disease Control and Prevention prescribing recommendations. 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.edu). Data set: Available for purchase from the Centers for Medicare & Medicaid Services (www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PrescriptionDrugPlanFormularyPharmacyNetworkandPricingInformationFiles.html).

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References

- Centers for Disease Control and Prevention. Prescribing data. Updated 30 August 2017. Accessed at www.cdc.gov/drugoverdose/data/prescribing.html on 1 July 2017.
- Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2016. *MMWR Recomm Rep*. 2016;65:1-49. [PMID: 26987082] doi:10.15585/mmwr.rr6501e1
- Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*. 2011;305:1315-21. [PMID: 21467284] doi:10.1001/jama.2011.370
- Saunders KW, Dunn KM, Merrill JO, Sullivan M, Weisner C, Braden JB, et al. Relationship of opioid use and dosage levels to fractures in older chronic pain patients. *J Gen Intern Med*. 2010;25:310-5. [PMID: 20049546] doi:10.1007/s11606-009-1218-z
- García MC, Dodek AB, Kowalski T, Fallon J, Lee SH, Iademarco MF, et al. Declines in opioid prescribing after a private insurer policy change—Massachusetts, 2011-2015. *MMWR Morb Mortal Wkly Rep*. 2016;65:1125-31. [PMID: 27764082] doi:10.15585/mmwr.mm6541a1