

# Medicare Formulary Coverage and Restrictions for Opioid Potentiators from 2013 to 2017

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## INTRODUCTION

In 2015, 38% of adults used prescription opioids, with slightly higher rates among older adults.<sup>1</sup> Risks of opioids have been well-described and are greater among older adults and when used concurrently with three commonly prescribed “opioid potentiator” drug classes: benzodiazepines, non-benzodiazepine sedative hypnotics, and gabapentinoids.<sup>2, 3</sup> These drugs also have risks when used on their own; in particular, there has been an increasing risk of death associated with benzodiazepine use.<sup>4</sup>

Medicare formulary coverage and utilization management strategies, including quantity limits, prior authorization, and step therapy, offer opportunities to limit potentially unsafe use of opioid potentiators, similar to coverage restrictions of opioids.<sup>5</sup> Based on Centers for Disease Control guidelines that propose more limited opioid availability and the fact that formulary restrictions are infrequently used to control opioid prescribing, Medicare recently proposed formulary changes to restrict opioid availability based on maximum daily dosage and initial fill quantity.<sup>6</sup> Many states have also legislated quantity limits for opioids.

However, coverage of opioid potentiator medications is unknown. Medicare began covering benzodiazepines in 2013 for select conditions, broadening coverage in 2014 for any medically accepted indication. We characterized Medicare formulary coverage of benzodiazepines, non-benzodiazepine sedative-hypnotics, and gabapentinoids from 2013 to 2017.

## METHODS

We used 2013, 2015, and 2017 Medicare Prescription Drug Formulary Files, which include data on all Medicare Advantage and Stand-alone Part D plan formularies. We identified all

benzodiazepines, non-benzodiazepine sedative-hypnotics, and gabapentinoids available in oral formulations. We characterized median formulary coverage of the lowest dose of the generic version of each drug, or the brand-name version when generics were unavailable. We focused on generics since they are used more commonly than the bioequivalent brand-name version, and on the lowest dose because higher doses can be created from lower doses. We excluded two brand-name drugs (Rozerem and Lunesta) that became available as a generic between 2013 and 2017, as generic availability impacts brand-name formulary coverage.

For each drug in each year, we determined the proportion of formularies not providing coverage; providing restrictive coverage using one or more utilization management strategy (quantity limit, prior authorization, or step therapy); or providing unrestrictive coverage (no utilization management). We summarized median coverage across all drugs in all three years. Analyses were conducted in R Studio version 3.2.3.

## RESULTS

There were 12 benzodiazepines, 3 non-benzodiazepine sedative hypnotics, and 3 gabapentinoids eligible for the study. The median proportion of formularies not providing coverage across all drugs was 21.8% (interquartile range [IQR], 0.3–64.8%) in 2013, 14.4% (IQR, 0.0–66.3%) in 2015, and 17.6% (IQR, 0.0–68.7%) in 2017 (Table 1). The median proportion of formularies providing restrictive coverage was 63.3% (IQR, 49.6–69.4%) in 2013, 70.1% (IQR, 65.8–81.2%) in 2015, and 66.8% (IQR, 54.4–77.9%) in 2017, with the largest growth in use of quantity limits, a smaller increase in prior authorization, and infrequent use of step therapy. The median proportion of formularies providing unrestrictive coverage in the 3 years was 33.3% (IQR, 27.1–43.7%), 27.0% (IQR, 16.3–32.2%), and 27.9% (IQR, 18.0–41.6%), respectively. In 2017, 47.9% of formularies provided unrestrictive coverage of at least 1 benzodiazepine, 39.9% of at least 1 non-benzodiazepine sedative-hypnotic, and 67.2% of at least 1 gabapentinoid.

**Table 1 Median Medicare Prescription Drug Plan Formulary Coverage and Use of Utilization Management Strategies for Benzodiazepines, Non-benzodiazepine Sedative Hypnotics, and Gabapentinoids, 2013–2017**

	Median formulary coverage (interquartile range), %		
	2013 formularies (n = 314)	2015 formularies (n = 389)	2017 formularies (n = 378)
No coverage	21.8 (0.3–64.8)	14.4 (0.0–66.3)	17.6 (0.0–68.7)
Restrictive coverage	63.3 (49.6–69.4)	70.1 (65.8–81.2)	66.8 (54.4–77.9)
Imposes a quantity limit	44.8 (34.6–54.8)	58.7 (39.1–68.4)	59.8 (41.5–70.0)
Requires prior authorization	16.4 (11.8–23.5)	31.9 (17.2–38.8)	21.0 (14.0–39.0)
Requires step therapy	0 (0–0)	0.0 (0.0–2.7)	0 (0–0.8)
Coverage with no restrictions	33.3 (27.1–43.7)	27.0 (16.3–32.2)	27.9 (18.0–41.6)

12 benzodiazepines, 3 non-benzodiazepine sedative-hypnotics, and 3 gabapentinoids were included

Medicare coverage in 2017 of each drug varied (Table 2). Quazepam and gabapentin enacarbil were not covered by any plan, whereas lorazepam, diazepam, clonazepam, doxepin, pregabalin, and gabapentin were covered by all. Among benzodiazepines, hypnotics (estazolam, flurazepam, and triazolam) had lower rates of coverage, whereas anxiolytics (alprazolam, diazepam, and lorazepam) had higher rates, albeit usually with restrictions.

## DISCUSSION

From 2013 to 2017, Medicare prescription drug plan formularies had relatively unchanged rates of benzodiazepine, non-benzodiazepine sedative hypnotic, and gabapentinoid coverage with small increases in the use of quantity limits. More than a quarter of formularies provided unrestrictive coverage of these potentially unsafe opioid potentiators in 2017, and

approximately 20% provided unrestrictive coverage of alprazolam and lorazepam, the two most commonly prescribed benzodiazepines. Furthermore, despite concern about the potential for prescription abuse, gabapentin was covered without restrictions by almost 60% of formularies.

The CMS overutilization monitoring system currently flags co-prescription of benzodiazepines and opioids, and CMS has proposed flagging co-prescription of other potentiator drugs with opioids.<sup>6</sup> Although we could not examine co-restriction of opioids and opioid potentiators using Medicare formulary data, our findings suggest opportunity for greater use of utilization management strategies to reduce use of these potentially unsafe medications.

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**Table 2 Medicare Prescription Drug Plan Formulary Coverage and Use of Utilization Management for Individual Benzodiazepines, Non-benzodiazepine Sedative Hypnotics, and Gabapentinoids, 2017 Second Quarter**

Formulary coverage <sup>a</sup>	No coverage (%)	Unrestrictive coverage (%)	Restrictive coverage <sup>a</sup> (%)	Imposes a quantity limit (%)	Requires prior authorization (%)	Requires step therapy (%)
Benzodiazepines						
Alprazolam	11.9	21.9	67.1	75.7	7.5	0
Chlordiazepoxide	48.9	37.6	13.5	57.4	17.7	0
Clonazepam	0	28.8	71.2	62.2	22.5	2.1
Clorazepate	0	27.2	72.8	63.8	37.0	0
Diazepam	0	19.6	80.4	72.0	39.7	0
Estazolam	59.4	33.6	7.0	55.9	23.4	0
Flurazepam	56.9	38.2	4.9	45.2	17.9	0
Lorazepam	0	17.5	82.5	74.6	19.6	0
Oxazepam	33.9	28.6	37.5	34.6	28.3	0
Quazepam <sup>b</sup>	100					
Temazepam	45.2	22.8	32.0	63.8	58.5	0
Triazolam	60.3	36.5	3.2	53.3	13.3	0
Non-benzodiazepine sedative hypnotics						
Doxepin	0	39.4	60.6	0	57.1	3.4
Zaleplon	23.3	3.8	72.9	78.6	54.8	10.0
Zolpidem	4.5	1.4	94.1	84.5	65.4	8.3
Gabapentinoids						
Gabapentin	0	59.8	40.2	40.2	0	0
Gabapentin enacarbil <sup>b</sup>	100					
Pregabalin	0	28.6	71.8	64.0	16.1	1.1

<sup>a</sup>Restrictive coverage defined as use of one or more utilization management strategy: quantity limit, prior authorization requirement, and step therapy requirement

<sup>b</sup>Drug was not covered by any formulary over the study period

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**Compliance with Ethical Standards:**

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