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Buprenorphine Treatment For Opioid Use Disorder: Comparison Of Insurance Restrictions, 2017–21

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Abstract

Buprenorphine is a treatment medication that decreases mortality risks among people with opioid use disorder (OUD). Despite its efficacy, buprenorphine is underused in the US. Insurance restrictions are commonly cited as barriers to buprenorphine prescribing. Using Medicaid, Medicare Advantage, and commercial insurance formulary files, we examined insurance-imposed utilization restrictions for buprenorphine for OUD for each year from 2017 to 2021 by insurance type. Almost all plans covered immediate-release buprenorphine in 2021, with a general trend of decreasing prior authorization requirements and quantity limits since 2017. In contrast, two payers had relatively low coverage of extended-release buprenorphine, with only 46 percent of commercial plans and only 19 percent of Medicare Advantage plans covering this formulation. Even though most Medicaid plans covered extended-release buprenorphine in 2021, 37 percent required prior authorization. Policy makers and researchers concerned with buprenorphine insurance barriers should shift their attention to extended-release buprenorphine. State lawmakers could help address these barriers by mandating that insurers include extended-release buprenorphine on their preferred drug lists.

More people died from opioid overdoses in the US in 2021 than any other year in history.[1] Buprenorphine is considered to be among the pharmaceutical gold standards for treating opioid use disorder (OUD) and is associated with a 50 percent decrease in mortality among people with OUD.[2,3] Unfortunately, buprenorphine is underused in the US,[4] with insurance restrictions frequently cited as barriers to prescribing.[5–7]

Even if buprenorphine is included on health plans' drug formularies, insurers may impose utilization restrictions, such as quantity limits, prior authorization, or step therapy. Such restrictions for buprenorphine are associated with worse health outcomes for patients with OUD[8] and do not improve the quality of care.[9] In response to growing concerns

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about opioid overdoses in the US, it is possible that insurers have recently decreased their buprenorphine utilization restrictions. Some recent studies have examined longitudinal changes in insurance-imposed buprenorphine utilization restrictions, but those studies have not compared these restrictions across Medicaid, Medicare Advantage, and commercial insurers.[10–16] Patients may change insurer types over time (for example, because of job loss), so policy makers and researchers need information about the landscape of utilization restrictions across insurance types. Furthermore, OUD has increased among many different populations, including among people older than age sixty-five.[17]

Moreover, few studies have compared differences between utilization restrictions for immediate-release buprenorphine and extended-release injectable buprenorphine, and none has explored differences in coverage of the two formulations across Medicaid, Medicare Advantage, and commercial insurers. One prior study examined differences in coverage of an implantable version of buprenorphine and immediate-release versions,[12] but the implantable version is no longer available on the US market.[18] Unlike immediate-release buprenorphine, which is oral or sublingual and taken daily, extended-release buprenorphine is a once-per-month injection administered by a clinician, which could help address some buprenorphine treatment adherence barriers, as well as concerns about immediate-release buprenorphine diversion or misuse.[19,20]

To help address these knowledge gaps, we used formulary files for Medicaid, Medicare Advantage, and commercial insurance plans to explore changes to prior authorization requirements and quantity limits for immediate-release and extended-release buprenorphine from 2017 to 2021 by insurer type.

Study Data And Methods

DATA SOURCES

We analyzed annual formulary data from Ideon, a health information technology company that provides standardized plan design data from insurers to employee benefit managers and health technology companies. According to Ideon's documentation, the database covers all Medicare Advantage formularies and all commercial formularies used by individual and small-group Marketplace plans. In addition, the database includes all standard commercial formularies used by midsize- and large-group plans. Ideon's formulary database also provides virtually the complete set of Medicaid traditional fee-for-service and managed care formularies (Dan Langevin, cofounder and chief technology officer, Ideon, personal communication, January 30, 2023). We were able to confirm that our list of 395 Medicaid formularies included at least one formulary from all fifty states; Washington, D.C.; and Puerto Rico.

The formulary data provide National Drug Code (NDC)–level detail about drug coverage by plan, tier level, and nonprice restrictions, such as prior authorization. The formulary database provides comprehensive coverage of drug formularies. For example, the 2021 data contain 419,288,021 records at the formulary-NDC level of 168,146 NDCs, representing approximately 80 percent of all NDCs listed by the Food and Drug Administration (FDA).[21] The Ideon database has also been used in prior studies.[22–24]

Buprenorphine for OUD treatment in this analysis included buprenorphine hydrochloride, buprenorphine and naloxone hydrochloride, and generic forms of buprenorphine-naloxone.[25] Buprenorphine brands used to treat pain were excluded.[26] Because the database lacks patient information, Institutional Review Board approval was not required for this study.

MEASURES AND STATISTICAL ANALYSES

This analysis was conducted at the formulary level. We used formulary names to classify payer types corresponding to formularies. The sample of analyzed formularies included balanced panels of 395 Medicaid formularies, 656 Medicare Advantage formularies, and 870 commercial formularies appearing in the database in each year from 2017 to 2021 (see online appendix 4 for the full list of included formularies).[27]

We calculated the annual proportion of formularies covering at least one immediate-release buprenorphine product. Among these formularies, we calculated the proportion without prior authorization requirements or quantity limits for at least one such product. We stratified the data by type of formulary (Medicaid, Medicare Advantage, and commercial) and conducted similar analyses for immediate-release buprenorphine tablets (including generic and brand-name buprenorphine-naloxone tablets and generic buprenorphine tablets), immediate-release buprenorphine films (generic and brand-name buprenorphine-naloxone films), and extended-release buprenorphine. Data from 2018 to 2021 were used for the latter because it was approved in December 2017, so 2018 was the first full year in which it was available. We used Pearson's chi-square test to compare proportions in 2017 and 2021. We conducted the statistical analysis using Stata, version 17.0.

LIMITATIONS

This study had several limitations. First, the database does not contain data on enrollment in the insurance plans that used the formularies in this study. The findings might underestimate or overestimate changes in formulary generosity toward buprenorphine if changes in formularies covering more enrollees did not increase in generosity compared with changes in formularies covering fewer enrollees. Second, beyond the existence of prior authorization status and quantity limits in the database, we did not have exact quantity thresholds or other details. Quantity thresholds restrict the amount of medication covered during a predefined period (for example, one month), but the meaning of quantity thresholds for extended-release buprenorphine is unclear in the database. Third, our findings might underestimate coverage for extended-release buprenorphine, depending on whether plans covered this drug as a medical benefit instead of as a pharmacy benefit and whether the formulary database captures only drugs covered under the pharmacy benefit. Payment guidance from the extended-release buprenorphine manufacturer to prescribers suggests that the drug would be covered under both a pharmacy and a medical benefit, except in the case of opioid treatment programs, where payments are bundled[28] and buprenorphine is rarely dispensed.[29] However, it is unclear whether insurers would follow manufacturers' payment recommendations.

Study Results

CHANGES IN BUPRENORPHINE COVERAGE

From 2017 through 2021 almost all formularies across payers covered at least one immediate-release buprenorphine product (see panel A of exhibit 1 and appendix1).[27] The proportion of formularies covering specific immediate-release buprenorphine formulations significantly changed between 2017 and 2021, from 95.4 percent to 98.0 percent for immediate-release films among Medicaid formularies, from 91.3 percent to 94.7 percent for immediate-release films among commercial formularies, and from 93.4 percent to 97.0 percent for immediate-release tablets among commercial formularies. The proportion of formularies covering extended-release buprenorphine increased across Medicaid, Medicare Advantage, and commercial formularies, from 63.3 percent in 2018 to 82.8 percent in 2021 among Medicaid formularies, from 14.6 percent to 19.4 percent among Medicare Advantage formularies, and from 24.7 percent to 46.2 percent among commercial formularies.

CHANGES IN PRIOR AUTHORIZATION REQUIREMENTS

Among Medicaid formularies covering one or more immediate-release buprenorphine products, the proportion without prior authorization requirements for such products increased from 80.6 percent in 2017 to 94.9 percent in 2021 (see panel B of exhibit 1 and appendix 2),[27] owing largely to a considerable increase in the removal of prior authorization requirements for immediate-release buprenorphine films (from 41.4 percent to 74.4 percent; exhibit 1). Among Medicaid formularies covering extended-release buprenorphine, the proportion without prior authorization requirements increased substantially, from 6.8 percent in 2018 to 63.3 percent in 2021.

Sizable increases in the proportion of Medicare Advantage formularies without prior authorization requirements for immediate-release buprenorphine products were observed (from 42.7 percent in 2017 to 84.9 percent in 2021). Among Medicare Advantage formularies covering extended-release buprenorphine, the proportion without prior authorization requirements modestly increased, from 71.9 percent in 2018 to 82.7 percent in 2021.

Among commercial formularies covering one or more immediate-release buprenorphine products, the proportion without prior authorization requirements for such products increased, from 83.8 percent in 2017 to 94.6 percent in 2021. The proportion without prior authorization requirements for extended-release buprenorphine increased considerably, from 57.7 percent in 2018 to 82.6 percent in 2021.

CHANGES IN QUANTITY LIMITS

In 2021, although almost all Medicaid formularies (97.2 percent) and commercial formularies (91.0 percent) did not impose quantity limits for immediate-release buprenorphine products, more than 50 percent of Medicare Advantage formularies still did so (see panel C of exhibit 1 and appendix 3).[27] Among formularies covering one or more immediate-release buprenorphine products, the proportion of formularies without quantity limits for such products modestly increased, from 95.4 percent in 2017 to 97.2

percent in 2021 for Medicaid and from 88.1 percent to 91.0 percent for commercial formularies. Although the proportion of formularies removing quantity limits for immediate-release buprenorphine tablets was stable across insurers during this period (except for a decline among Medicare Advantage formularies), the proportion for immediate-release buprenorphine film formulations considerably increased, from 77.5 percent in 2017 to 83.2 percent in 2021 among Medicaid, 24.9 percent to 35.0 percent among Medicare Advantage, and 67.1 percent to 72.3 percent among commercial formularies.

In 2021 there were more Medicaid and commercial formularies without quantity limits for one or more extended-release buprenorphine products relative to 2018 (from 225 to 281 formularies for Medicaid and from 192 to 361 formularies for commercial versus from 92 to 88 formularies for Medicare Advantage; data not shown). Given the considerable growth in Medicaid and commercial formularies covering extended-release buprenorphine, there were modest changes in the proportion of Medicaid and Medicare Advantage formularies without quantity limits for these products between 2018 and 2021 (from 90.0 percent to 85.9 percent for Medicaid and from 89.3 percent to 89.8 percent for commercial) (exhibit 1).

Discussion

Buprenorphine treatment lowers mortality risks for people with OUD by approximately 50 percent,[2,3] but the medication remains underused in the US.[4,30] Given increasing opioid overdose deaths and national attention to the benefits of buprenorphine, we examined changes in insurance-imposed utilization restrictions for buprenorphine, examining differences by insurer type as well as between immediate-release and extended-release formulations.

Fortunately, we found decreasing prior authorization requirements for buprenorphine in recent years, with only a small percentage of formularies still requiring prior authorization. Tami Mark and colleagues found similar trends in Medicare Part D, where only 2–3 percent of plans required prior authorization for buprenorphine (with some variation depending on whether buprenorphine was generic or brand name).[31] Prior authorization requirements are a known barrier to prescribing buprenorphine,[5,32] with clinicians and clinics less likely to offer buprenorphine[33] and patients less likely to fill buprenorphine prescriptions when prior authorization requirements are present.[8] Furthermore, evidence suggests that prior authorization requirements do not result in higher quality of care for patients treated with buprenorphine,[10] whereas removal of the requirements is associated with lower likelihood of return to drug use[34] and lower rates of hospital and emergency department admissions among people with OUD.[8]

Even though quantity limits for immediate-release buprenorphine were relatively rare throughout the study period among Medicaid and commercial insurers, approximately half of Medicare Advantage formularies had quantity limits on immediate-release buprenorphine tablets. Furthermore, a higher proportion of Medicare Advantage formularies had quantity limits on these tablets in 2021 than in 2017, possibly as a cost-saving mechanism to counteract decreases in prior authorization requirements. Interestingly, one study published in 2013 found that significantly more patients preferred immediate-release buprenorphine

film to tablets.[35] Therefore, compared with quantity limits on films, quantity limits on tablets may be less likely to affect patients' satisfaction with treatment. Mark and colleagues also found increasing use of quantity limits in Medicare Part D plans for buprenorphine-naloxone from 2017 to 2019.[31]

As compared with Medicaid or commercial formularies, a higher proportion of Medicare Advantage formularies had prior authorization requirements and quantity limits. This result might reflect that Medicare Advantage revenue is capped per enrollee, so Medicare Advantage plans may try to contain costs to increase profit.[36] Medicare beneficiaries' access to OUD treatment is critical, as rates of older Americans with OUD have risen in recent years.[17] For example, the proportion of older adults seeking treatment for OUD rose by 41 percent from 2004 to 2013 and then by 54 percent from 2013 to 2015.[17]

To our knowledge, this is the first study to compare immediate-release and extended-release buprenorphine utilization restrictions across three insurers. We found that prior authorization requirements are significantly more common for extended-release than for immediate-release buprenorphine across all insurers. Compared with Medicare Advantage or commercial insurers, a higher proportion of Medicaid formularies covered extended-release buprenorphine—an important finding, given that Medicaid was the predominant insurer among people with OUD in the US as of 2019.[37,38] Problematically, however, 37 percent of Medicaid formularies covering extended-release buprenorphine still required prior authorization.

Unlike immediate-release buprenorphine, no generic version of extended-release buprenorphine currently exists, so insurers are likely to have a stronger incentive to impose utilization restrictions as a cost-maintenance mechanism for extended-release buprenorphine. Reducing potential access barriers for this formulation, including prior authorization requirements, is important for several reasons. First, because it is administered by clinicians, it has no misuse or diversion risks, which could assuage fears that other studies have found among judges, corrections officers, and other justice professionals of immediate-release buprenorphine diversion and misuse.[39–42] Second, multiple prior studies have found that clinicians' concerns about buprenorphine diversion and misuse are a prescribing barrier, possibly because of perceived prescriber liability risks.[5,7,43–47] From the patient perspective, one study found that 68 percent of patients felt that their treatment experience with extended-release buprenorphine was more positive than their experience with immediate-release buprenorphine,[48] which could have important implications for treatment retention. Also, the use of extended-release buprenorphine could help address patient access barriers resulting from low immediate-release buprenorphine stock in independent and rural pharmacies.[49–51]

Conclusion

More than twenty years have passed since immediate-release buprenorphine was approved by the FDA, and studies have documented unintended harms associated with poor insurance coverage of buprenorphine, as well as few (if any) benefits to stringent buprenorphine utilization restrictions.[10,34] Given the severity of the ongoing opioid overdose crisis, the

relative safety of immediate-release buprenorphine among opioids,[52] the medication's cost-effectiveness,[53,54] and its high efficacy for treating OUD,[3] we are unsurprised that immediate-release buprenorphine coverage has improved and utilization barriers have become less common. Policy makers should apply the lessons of the past twenty years of immediate-release buprenorphine treatment to extended-release buprenorphine treatment —namely, that significant public health benefits exist to expanding access to it.

Our findings suggest that much progress has occurred during the past decade with respect to removing prior authorization requirements and quantity limits for immediate-release buprenorphine. Policy makers and researchers concerned with insurance restrictions for buprenorphine should now pivot their attention to expanding coverage of extended-release buprenorphine and removing prior authorization requirements for this formulation. Importantly, we found that only approximately half of commercial formularies and fewer than one-fifth of Medicare Advantage formularies covered it in 2021. State legislators and regulators could lead this effort by requiring insurers operating in their states to cover extended-release buprenorphine. Several states have recently passed laws prohibiting prior authorization for or requiring coverage for medication for OUD.[55] Finally, it is important for policy makers and researchers to monitor immediate-release and extended-release buprenorphine coverage and utilization barriers across all insurer types. Although people with OUD in the US primarily use Medicaid to pay for treatment, rates of OUD have risen across many populations, including people older than age sixty-five.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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EXHIBIT 1

Coverage and insurance requirements for buprenorphine products across payers in the US, 2017–21

	Medicaid formularies			MA formularies			Commercial formularies		
	2017	2021	*p* value[a]	2017	2021	*p* value[a]	2017	2021	*p* value[a]
Panel A: formularies covering the product									
IR buprenorphine									
Any product	99.2%	99.2%	1.00	100.0%	100.0%	—[b]	97.7%	98.6%	0.15
Film	95.4	98.0	0.046	89.9	90.1	0.93	91.3	94.7	0.005
Tablet	99.2	99.2	1.00	99.8	100.0	0.32	93.4	97.0	<0.001
ER buprenorphine[c]	63.3	82.8	<0.001	14.6	19.4	0.023	24.7	46.2	<0.001
Panel B: formularies without prior authorization among formularies in panel A									
IR buprenorphine									
Any product	80.6	94.9	<0.001	42.7	84.9	<0.001	83.8	94.6	<0.001
Film	41.4	74.4	<0.001	30.8	80.4	<0.001	59.6	86.3	<0.001
Tablet	78.3	87.5	<0.001	39.2	81.2	<0.001	82.3	94.1	<0.001
ER buprenorphine[c]	6.8	63.3	<0.001	71.9	82.7	0.054	57.7	82.6	<0.001
Panel C: formularies without quantity limits among formularies in panel A									
IR buprenorphine									
Any product	95.4	97.2	0.19	52.4	52.3	0.96	88.1	91.0	0.049
Film	77.5	83.2	0.045	24.9	35.0	<0.001	67.1	72.3	0.023
Tablet	94.9	94.4	0.75	51.9	45.4	0.019	87.1	87.2	0.94
ER buprenorphine[c]	90.0	85.9	0.14	95.8	69.3	<0.001	89.3	89.8	0.85

SOURCE Authors' analysis of annual formulary data from the Ideon database.

NOTES The sample included 395 Medicaid formularies, 656 Medicare Advantage (MA) formularies, and 870 commercial formularies appearing in the database each year from 2017 to 2021. Panel A presents the proportion of formularies covering at least one of the listed products. Panels B and C present the proportion of formularies without prior authorization and quantity limits, respectively, for at least one of the listed products among formularies in panel A. IR is immediate-release. ER is extended-release.

[a]Pearson's chi-square test was used to assess differences in proportions between 2017 and 2021.

[b]Not applicable, as there was no variation.

[c]Data from the period 2018–21 were used for injectable ER buprenorphine because the drug was approved in December 2017, meaning that 2018 was the first full year in which this drug was available. We did not assess implantable ER buprenorphine, as this product was discontinued in 2020.