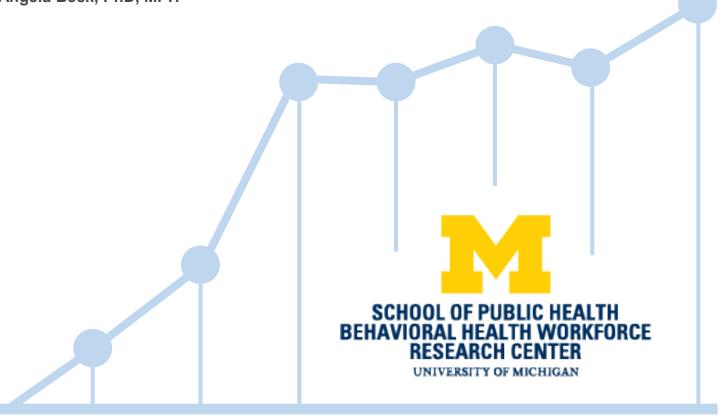
Coverage of Buprenorphine Medications That Treat Opioid Use Disorder by State Medicaid Programs

January 2021

Project Team

Amanda I. Mauri, MPH
Victoria Shoebel, MPH
Caitlyn Wayment, MPH
Jessica Buche, MPH, MA
Angela Beck, PhD, MPH



ACKNOWLEDGEMENTS

This publication was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$900,000. The contents are those of the author and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.

SUGGESTED CITATION

University of Michigan Behavioral Health Workforce Research Center. Coverage of Buprenorphine Medications That Treat Opioid Use Disorder by State Medicaid Programs. Ann Arbor, MI: UMSPH; 2021.

Table of Contents

Abstract	4
Background	5
Methods	
Results	6
Discussion	
Conclusions	
References	

Abstract

Objectives

This project explores the application of prior authorization (PA) requirements to buprenorphine, 1 of 3 Food and Drug Administration–approved medications used in the treatment of opioid use disorder, by Medicaid programs in 2019.

Methods

Investigators reviewed 45 Medicaid preferred drug lists in 2019 to determine coverage of 8 buprenorphine forms, and if coverage required PA. The authors calculated the proportion of plans that covered, covered with PA, and covered without PA at least one buprenorphine product, as well as the percentage of plans that covered at least 1 buprenorphine form.

Results

An overwhelming proportion of Medicaid programs covered buprenorphine alone and buprenorphine/ naloxone combination forms in the preferred drug list. However, with the exception of Suboxone™, all other buprenorphine formulations were subject to PA by more than two thirds of PDLs. Although all plans (100%) covered at least 1 buprenorphine form, almost 30% of plans did not cover at least 1 buprenorphine form without PA.

Conclusions

Although Medicaid programs largely cover buprenorphine products, many continue to apply PA requirements. In the midst of the opioid epidemic, it is challenging to justify the exclusion of buprenorphine coverage and imposition of burdensome utilization management requirements. As policymakers consider strategies to decrease opioid-related morbidity and mortality, they should consider opportunities to mandate the removal of PA. Researchers can expand upon this project by exploring how to define adequate buprenorphine access.



Background

Buprenorphine is an effective medication for the treatment of opioid use disorder (OUD). It promotes long-term recovery and decreases the risk of mortality. 1-6 Buprenorphine treatment increases engagement in addiction treatment, reduces emergency department admissions, 8,9 and is cost effective compared with brief intervention or referral treatments. 10

Buprenorphine is 1 of 3 medications, along with methadone and naltrexone, approved for the treatment of OUD. Buprenorphine is a partial opioid agonist, meaning it does not completely bind to the µopioid receptor. As a partial agonist, it has a ceiling effect, meaning its euphoric effects plateau and do not heighten with increased dosing. 11-13 Buprenorphine is currently available as a daily medication or in longacting forms. It is also available alone or in combination with naloxone. Experts recommend buprenorphinenaloxone forms over other buprenorphine products because naloxone attenuates the partial agonist effect, reducing its euphoric capacity. Naloxone is contraindicated for patients who are pregnant or have co-occurring conditions. Buprenorphine prescribing is limited to gualified office-based prescribers who have a demonstrated or certified ability to treat and manage patients with opioid dependence.¹⁴

Federal and state governments have implemented policies to increase access to buprenorphine and other medications approved for the treatment of OUD.¹¹ For instance, policymakers mandated mental health and substance use disorder coverage by public and private payers, 15-18 and expanded the type of providers eligible to prescribe buprenorphine for OUD to include nurse practitioners and physician assistants. 19 However, a persistent barrier to buprenorphine access is prior authorization (PA).

The utilization management practice of PA is employed by insurers and requires healthcare providers to obtain approval from a health plan before a service is delivered to the patient in order to qualify for payment coverage. Existing literature demonstrates that PA policies reduce prescribing of the targeted prescription. 20-24 Research on PA applied to buprenorphine confirms these findings, demonstrating that PA reduces buprenorphine prescribing.²⁵ A 2020 study using Medicare Part D claims showed plans that removed PA for buprenorphine-naloxone products had an associated increase in the number of buprenorphine-naloxone prescriptions filled, and that PA removal was associated with a decrease in healthcare utilization and expenditures.²⁶ Furthermore. PA is also associated with reduced likelihood of addiction treatment programs offering buprenorphine products,²⁷ and providers confirm that PA creates barriers to obtaining reimbursement.²⁸

Owing to PA creating barriers to medication access, some public and private programs have removed PA for medications used in the treatment of OUD. 25,29,30 However, PA requirements remain common in Medicaid and private insurance. 25,31,32 Research on Medicaid programs show that although states have increased coverage of medications used in the treatment of OUD, many continue to impose or increase coverage limitations, including PA, that create potential barriers to medication utilization. 33,34 In 2017, although >85% of marketplace plans covered at least 1 buprenorphine formulation, 60% of plans also required PA for at least 1 buprenorphine form.³⁵

This study analyzes how state Medicaid programs apply PA to buprenorphine products. As Medicaid is the dominant payor for behavioral health services in the U.S., an analysis of Medicaid PA requirements for buprenorphine products is essential to understanding how states use insurance policies to impact access to medications essential to the treatment of OUD. Existing research does not speak to the prevalence of PA requirements for specific buprenorphine formulations. To help fill this gap, this paper aims to take a formulation-level approach to compare how PA requirements are applied to buprenorphine products by Medicaid programs. We first review how Medicaid programs apply PA to buprenorphine products and then assess how formulation-level requirements impact overall buprenorphine access for Medicaid beneficiaries at the plan-level.

Methods

As of October 2019, there were 8 buprenorphine products available (Table 1). The list includes brand name and generic versions of buprenorphine and buprenorphine/naloxone combination forms, as well as long-acting and daily methods of administration.

Table 1. Available buprenorphine products approved for the treatment of opioid use disorder (October 2019)							
Proprietary Name	Buprenorphine or Buprenorphine / Naloxone	Long-acting / Daily	Dosage Form	Approval Date			
Probuphine™	Buprenorphine	Long-acting	Implant	2016			
Sublocade™	Buprenorphine	Long-acting	Solution	2017			
Bunavail™	Buprenorphine / naloxone	Daily	Film	2014			
Suboxone™	Buprenorphine / naloxone	Daily	Film	2010			
Zubsolv™	Buprenorphine / naloxone	Daily	Tablet	2013			
N/A – generic	Buprenorphine / naloxone	Daily Tablet		2013			
N/A – generic	Buprenorphine / naloxone	Daily	Film	2018			
N/A – generic	Buprenorphine	Daily	Tablet	2009			

Note: Subutex is excluded because it was discontinued at the time of analysis.

In October 2019, a researcher reviewed 45 online accessible Medicaid preferred drug lists (PDLs) for buprenorphine coverage requirements. The research team did not review Medicaid PDLs for 5 states (California, Connecticut, Hawaii, Kansas, and New Mexico) because the formulary was associated with a broken link. A researcher determined if the PDL covered a buprenorphine form, and if coverage required PA. For each buprenorphine product, researchers calculated the proportion of PDLs that covered, covered with PA, and covered without PA, as well as the percentage of plans that covered at least 1 buprenorphine formulation.

Results

Table 2 displays state Medicaid coverage of buprenorphine products in 2019. An overwhelming proportion of Medicaid programs included brand name buprenorphine/naloxone forms in their PDL; 100% of formularies reviewed covered Suboxone™ and Zubsolv™, and 98% of PDLs covered Bunavail™. Although the percentage of PDLs that included tablet buprenorphine/naloxone on the Medicaid formulary was >90%, the proportion including film buprenorphine/naloxone was <65%. Long-acting buprenorphine forms were less likely to be covered by state Medicaid programs with just over half of PDLs covering Probuphine™ (53%) and more than three quarters covering Sublocade™ (75%).

With the exception of Suboxone™, all other buprenorphine formulations were subject to PA by more than two thirds of PDLs. PDLs applied PA frequently to Probuphine™ (92%) and Sublocade™ (82%), both of which are long-acting forms of buprenorphine. Suboxone™ was subject to PA by only 36% of PDLs as compared with Bunavail™ (86%), Zubsolv™ (80%), buprenorphine/naloxone film (79%), and buprenorphine/ naloxone tablet (71%).

Although all plans covered at least 1 buprenorphine form, PDLs varied on whether they applied PA to covered products. More than 25% of plans did not cover any buprenorphine product without PA. When

examining buprenorphine/naloxone forms, 66.6% of PDLs covered at least 1 product without PA. Only 7 PDLs covered at least 1 long-acting buprenorphine form without PA, meaning that almost 80% of PDLs imposed a

Table 2. Buprenorphine coverage by state Medicaid programs, 2019							
Buprenorphine formulation	Plans that cover the drug n (%)	Plans that cover without prior authorization	Plans that cover with prior authorization				
Versions of drug preferred for opioid use disorder maintenance treatment							
Long-acting implant (Probuphine™)	24 (53.3%)	2 (8.33%)	22 (91.67%)				
Long-acting injection (Sublocade™)	34 (75.56%)	6 (17.65%)	28 (82.35%)				
Buprenorphine/naloxone (Bunavail™)	44 (97.78%)	6 (13.64%)	38 (86.36%)				
Buprenorphine/naloxone (Suboxone™)	45 (100.00%)	29 (64.44%)	16 (35.56%)				
Buprenorphine/naloxone (Zubsolv™)	45 (100.00%)	9 (20.00%)	36 (80.00%)				
Buprenorphine/naloxone (generic tab- let)	42 (93.33%)	12 (28.57%)	30 (71.43%)				
Buprenorphine/naloxone (generic film)	29 (64.44%)	6 (20.69%)	23 (79.31%)				
Versions of drug recommended only for select opioid use disorder populations							
Buprenorphine (generic tablet)	45 (100.00%)	11 (24.44%)	34 (75.56%)				
At least 1 buprenorphine form	45 (100.00%)	33 (73.3%)	44 (97.78%)				
At least 1 long-acting form	34 (75.56%)	7 (20.59%)	28 (82.35%)				
At least 1 buprenorphine/naloxone form	45 (100.00%	30 (66.67%)	41 (91.11%)				

Note: The percentage of plans that cover the drug is the proportion of all reviewed preferred drug lists (45). The percentage of plans that cover the drug with and without prior authorization is the proportion of plans that cover the drug, so the denominator varies by buprenorphine formulation and equals the n calculated for the number of plans that cover the drug.

PA requirement to either Probuphine™ or Sublocade™.

Discussion

This study examined Medicaid coverage of buprenorphine products in 2019, and highlights important state-level differences in access to buprenorphine. Although Medicaid programs largely cover buprenorphine products, many continue to apply PA requirements. Even Suboxone™, the buprenorphine form least associated with PA requirements, is subject to PA in more than one third of state Medicaid programs. Though all PDLs cover at least 1 buprenorphine product, more than 25% of the reviewed Medicaid formularies impose a PA restriction to all covered buprenorphine products.

In the midst of the opioid epidemic, it is challenging to justify the exclusion of buprenorphine from Medicaid coverage, as well as the imposition of burdensome utilization management practices on essential medications used in the treatment of OUD. Indeed, these findings demonstrate that Medicaid continues to diverge from other health insurance markets that experienced a recent decline in PA requirements as a response to the opioid crisis, 26 and confirms the legacy of stringent PA requirements to buprenorphine applied by Medicaid programs. 25,31,32,34

As policymakers consider strategies to decrease opioid-related morbidity and mortality, they should consider opportunities to mandate the removal of PA. Government policies that decrease the proportion of plans requiring PA for buprenorphine products can lead to increases in prescribing rates and decreases in healthcare utilization and expenditures.²⁶ This is particularly important among state Medicaid programs. Medicaid is not only the dominant payer of behavioral health services, but Medicaid enrollees are more likely than their peers with other health coverage to experience an OUD.³⁶

This study has limitations and highlights opportunities for future research. First, the authors are unable to make any statements about the implications of applying PA to buprenorphine forms in relation to treatment access. Future research should expand upon this project by examining how variation in PA requirements applied to buprenorphine products impacts prescribing, availability of buprenorphine, and healthcare utilization and expenditures. Second, this research does not shed light on why Suboxone™ is the preferred buprenorphine form. However, the findings may be another symptom of the documented anti-competitive practices of Reckitt Benckiser, Suboxone's™ parent company, which include product hops, citizen petitions, and Risk Evaluation and Mitigation Strategy abuses aimed to sustain high prices for Suboxone™ by extending brand exclusivity and impeding generic entry.^{37,38} Future research should explore the hypothesis that pharmaceutical companies, in this case Reckitt Benckiser, may strategically lobby for the application of utilization management techniques to promote their products and limit prescribing of competitor forms. Finally, the data do not offer insights into how to define adequate buprenorphine access. Researchers should explore how the application of PA to different types and quantities of buprenorphine products impacts the ability of Medicaid beneficiaries to access and adjust the medication form most appropriate to their healthcare needs.

Conclusions

This study expands upon existing literature by examining the application of PA requirements to buprenorphine products by Medicaid programs. It found that although many states cover buprenorphine

forms, many limit access to buprenorphine through PA practices.

References

- National Institute on Drug Abuse. How effective are medications to treat opioid use disorder? National Institute on Drug Abuse. https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder. Published June 2018. Accessed November 11, 2020.
- 2. Sordo L, Barrio G, Bravo MJ, et al. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. BMJ. 2017;357:j1550. doi:10.1136/bmj.j1550.
- Nielsen S, Larance B, Degenhardt L, Gowing L, Kehler C, Lintzeris N. Opioid agonist treatment for pharmaceutical opioid dependent people. Cochrane Database Syst Rev. 2016;May 9 (5):CD011117. doi:10.1002/14651858.CD011117.pub2.
- 4. 4. Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database Syst Rev. 2014;Feb 6(2):CD002207. doi:10.1002/14651858.CD002207.pub4.
- 5. Ma J, Bao Y-P, Wang R-J, et al. Effects of medication-assisted treatment on mortality among opioids users: a systematic review and meta-analysis. Mol Psychiatry. 2019;24(12):1868-1883. doi:10.1038/s41380-018-0094-5.
- 6. Larochelle MR, Bernson D, Land T, et al. Medication for opioid use disorder after nonfatal opioid overdose and association with mortality. Ann Intern Med. 2018;169(3):137-145. doi:10.7326/M17-3107.
- 7. 7. D'Onofrio G, O'Connor PG, Pantalon MV, et al. Emergency department–initiated buprenorphine/naloxone treatment for opioid dependence. JAMA. 2015;313(16):1636-1644. doi:10.1001/jama.2015.3474.
- 8. Mohlman MK, Tanzman B, Finison K, Pinette M, Jones C. Impact of medication-assisted treatment for opioid addiction on Medicaid expenditures and health services utilization rates in Vermont. J Subst Abuse Treat. 2016;67:9-14. doi:10.1016/j.jsat.2016.05.002.
- 9. Schwarz R, Zelenev A, Bruce RD, Altice FL. Retention on buprenorphine treatment reduces emergency department utilization, but not hospitalization among treatment-seeking patients with opioid dependence. J Subst Abuse Treat. 2012;43(4):451-457. doi:10.1016/j.jsat.2012.03.008.
- 10. 10. Busch SH, Fiellin DA, Chawarski MC, et al. Cost effectiveness of emergency department-initiated treatment for opioid dependence. Addiction. 2017;112(11):2002-2010. doi:10.1111/add.13900.
- 11. 11. Haffajee RL, Bohnert ASB, Lagisetty PA. Policy pathways to address provider workforce barriers to buprenorphine treatment. Am J Prev Med. 2018;54(6 Suppl 3):S230-S242. doi:10.1016/j.amepre.2017.12.022.
- 12. 12. Schuckit MA. Treatment of opioid-use disorders. N Engl J Med. 2016;375(4):357-368. doi:10.1056/NEJMra1604339
- 13. 13. The PEW Charitable Trusts. Medication-Assisted Treatment Saves Lives While Increasing the Chances a Person Will Remain in Treatment and Learn the Skills and Build the Networks Necessary for Long-Term Recovery. 2016:8.
- 14. 14. Drug Addiction Treatment Act of 2000. 2000.
- 15. 15. Davis CS, Carr DH. Legal and policy changes urgently needed to increase access to opioid agonist therapy in the United States. Int J Drug Policy. 2019;73:42-48. doi:10.1016/j.drugpo.2019.07.006.
- 16. 16. Burak EW. Behavioral health services in separate state CHIP programs: is your state in compliance? Center For Children and Families. https://ccf.georgetown.edu/2020/05/29/behavioral-health-services-in-separate-state-chip-programs-is-your-state-in-compliance/. Published May 29, 2020. Accessed November 11, 2020.
- 17. 17. National Conference of State Legislatures. Mental health benefits: state laws mandating or regulating. https://www.ncsl.org/research/health/mental-health-benefits-state-mandates.aspx. Published December 30, 2015. Accessed November 11, 2020.
- 18. 18. Patient Protection and Affordable Care Act.; 2010.
- 19. 19. Comprehensive Addiction and Recovery Act of 2016.; 2016.
- 20. 20. Hartung DM, Kim H, Ahmed SM, et al. Effect of a high dosage opioid prior authorization policy on prescription

- opioid use, misuse, and overdose outcomes. Subst Abus. 2018;39(2):239-246. doi:10.1080/08897077.2017.1389798.
- 21. 21. Keast SL, Kim H, Deyo RA, et al. Effects of a prior authorization policy for extended-release/long-acting opioids on utilization and outcomes in a state Medicaid program. Addiction. 2018;113(9):1651-1660. doi:https://doi.org/10.1111/add.14248.
- 22. 22. Mauri Al, Townsend TN, Haffajee RL. The association of state opioid misuse prevention policies with patient-and provider-related outcomes: a scoping review. Milbank Q. 2020;98(1):57-105. doi:10.1111/1468-0009.12436.
- 23. 23. Morden NE, Zerzan JT, Rue TC, et al. Medicaid prior authorization and controlled-release oxycodone. Med Care. 2008;46(6):573-580. doi:10.1097/MLR.0b013e31816493fb.
- 24. 24. Park Y, Raza S, George A, Agrawal R, Ko J. The effect of formulary restrictions on patient and payer outcomes: a systematic literature review. J Manag Care Spec Pharm. 2017;23(8):893-901. doi:10.18553/jmcp.2017.23.8.893.
- 25. 25. Clark RE, Baxter JD, Barton BA, Aweh G, O'Connell E, Fisher WH. The impact of prior authorization on buprenorphine dose, relapse rates, and cost for Massachusetts Medicaid beneficiaries with opioid dependence. Health Serv Res. 2014;49(6):1964-1979. doi: 10.1111/1475-6773.12201.
- 26. 26. Mark TL, Parish WJ, Zarkin GA. Association of formulary prior authorization policies with buprenorphine-naloxone prescriptions and hospital and emergency department use among Medicare beneficiaries. JAMA Netw Open. 2020;3(4):e203132. doi:10.1001/jamanetworkopen.2020.3132.
- 27. 27. Andrews CM, Abraham AJ, Grogan CM, Westlake MA, Pollack HA, Friedmann PD. Impact of Medicaid restrictions on availability of buprenorphine in addiction treatment programs. Am J Public Health. 2019;109(3):434-436. doi:10.2105/AJPH.2018.304856.
- 28. 28. Andraka-Christou B, Capone MJ. A qualitative study comparing physician-reported barriers to treating addiction using buprenorphine and extended-release naltrexone in U.S. office-based practices. Int J Drug Policy. 2018;54:9-17. doi:10.1016/j.drugpo.2017.11.021.
- 29. 29. Advisory Board. Cigna drops prior authorization requirement for opioid-misuse treatment buprenorphine. http://www.advisory.com/daily-briefing/2016/10/25/cigna-prior-authorization-opioid-misuse-treatment. Published October 25, 2016. Accessed November 11, 2020.
- 30. 30. Partnership to End Addiction. Aetna is latest insurer to drop preauthorization for opioid addiction treatment Partnership to End Addiction. https://drugfree.org/drug-and-alcohol-news/aetna-latest-insurer-drop-preauthorization-opioid-addiction-treatment/. Published March 2017. Accessed November 11, 2020.
- 31. 31. Clark RE, Samnaliev M, Baxter JD, Leung GY. The evidence doesn't justify steps by state Medicaid programs to restrict opioid addiction treatment with buprenorphine. Health Aff (Millwood). 2011;30(8):1425-1433. doi:10.1377/hlthaff.2010.0532.
- 32. 32. Clark RE, Baxter JD. Responses of state Medicaid programs to buprenorphine diversion: doing more harm than good? JAMA Intern Med. 2013;173(17):1571-1572. doi:10.1001/jamainternmed.2013.9059.
- 33. 33. Burns RM, Pacula RL, Bauhoff S, et al. Policies related to opioid agonist therapy for opioid use disorders: the evolution of state policies from 2004 to 2013. Subst Abus. 2016;37(1):63-69. doi:10.1080/08897077.2015.1080208.
- 34. 34. Grogan CM, Andrews C, Abraham A, et al. Survey highlights differences in Medicaid coverage for substance use treatment and opioid use disorder medications. Health Aff (Millwood). 2016;35(12):2289-2296. doi:10.1377/hlthaff.2016.0623.
- 35. 35. Huskamp HA, Riedel LE, Barry CL, Busch AB. Coverage of medications that treat opioid use disorder and opioids for pain management in marketplace plans, 2017. Med Care. 2018;56(6):505-509. doi:10.1097/MLR.000000000000018.
- 36. 36. Orgera K, Tolbert J. The opioid epidemic and Medicaid's role in facilitating access to treatment. KFF. https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaids-role-in-facilitating-access-to-treatment/. Published May 24, 2019. Accessed November 11, 2020.
- 37. 37. Haffajee RL, Frank RG. Abuses of FDA regulatory procedures the case of Suboxone. N Engl J Med. 2020;382 (6):496-498. doi:10.1056/NEJMp1906680.
- 38. 38. Haffajee RL, Frank RG. Generic drug policy and Suboxone to treat opioid use disorder. J Law Med Ethics.