Association Between Medicare and FDA Policies and Prior Authorization Requirements for Buprenorphine Products in Medicare Part D Plans

Approximately 1.2% of Medicare beneficiaries misused opioid prescriptions in 2016, double the prevalence in 2006. Buprenorphine, either alone or with naloxone, is an effective medication for opioid use disorder and is covered under Medicare Part D. As of January 2018, 57% of Medicare Part D plans required prior authorization to prescribe buprenorphine-naloxone for opioid use disorder, and 66% required prior authorization to prescribe buprenorphine. Health plans use prior authorization to encourage appropriate medication use and contain spending; however, it can also reduce the probability that a patient receives prescribed medications and lead to worse outcomes.

In September 2017, the US Food and Drug Administration (FDA) announced a labeling change for buprenorphine products that emphasized the importance of preventing barriers to obtaining medications for opioid use disorder. In April 2018, the Centers for Medicare & Medicaid Services (CMS) announced that it would not approve Part D formularies that required prior authorization for buprenorphine products more frequently than once per year, citing the FDA labeling change. We analyzed whether prior authorization requirements for buprenorphine products under Medicare Part D changed after these announcements.

Methods | We used formulary files for stand-alone Medicare Part D and Medicare Advantage prescription drug plans for the 2017, 2018, and 2019 plan years, which began in October of the previous calendar year. Formulary files indicate whether a Part D plan covers a medication, and whether a medication requires prior authorization. We examined brand-name buprenorphine-naloxone (Suboxone films, Bunavail films, and Zubsolv tablets), generic buprenorphine-naloxone, and generic buprenorphine monotherapy for opioid use disorder.

We calculated the number of plans that covered each product and required prior authorization. We analyzed the differences before and after the FDA and CMS announcements (from 2017/2018 to 2019). The reported proportions were weighted by plan enrollment so that the proportions represent enrollees who have coverage or are exposed to prior authorization. We used Cochran-Armitage tests to determine statistical significance with a 2-tailed P < .05 indicating significance. Analyses were conducted using Stata version 15.1 (StataCorp).

Results | There were 2485 plans in 2017, 2889 in 2018, and 3415 in 2019 (Table). Coverage for brand-name buprenorphine-naloxone was 99% during all plan years. The percentage of plans that required prior authorization decreased from 88% (95% CI, 85%-90%) for 2017 to 74% (95% CI, 71%-77%) for 2018 to 3% (95% CI, 3%-4%) for 2019 (P < .001).

The proportion of plans providing coverage for generic buprenorphine-naloxone increased (55% for 2017 and 2018 and 63% for 2019) and the proportion requiring prior authorization decreased from 96% (95% CI, 95%-97%) to 73% (95% CI, 70%-77%) to 0.09% (95% CI, 0.04%-0.13%) (P < .001). Generic buprenorphine without naloxone was covered by 96% to 100% of plans. Prior authorization requirements

| Table. Coverage and Prior Authorization of Buprenorphine Medications for Opioid Use Disorder, 2017-2019 |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| **Coverage and Prior Authorization**            | **2017 Plan Year (n = 2485)**                    | **2018 Plan Year (n = 2889)**                    | **2019 Plan Year (n = 3415)**                    | **P Value**                                     |
|                                                 | **Unweighted No. of Plans**                     | **Weighted Proportion of Plans (95% CI)**        | **Unweighted No. of Plans**                     | **Weighted Proportion of Plans (95% CI)**        |
| **Brand-name Buprenorphine-Naloxone (Film and Tablet)** |                                                 |                                                 |                                                 |                                                 |
| Prior authorization                             | 1979                                            | 87.51 (85.04-89.99)                              | 1662                                            | 74.10 (71.22-76.98)                              |
| **Generic Buprenorphine-Naloxone (Tablet)**     |                                                 |                                                 |                                                 |                                                 |
| Coverage                                        | 1882                                            | 55.17 (50.83-59.52)                              | 2115                                            | 54.63 (50.80-58.45)                              |
| Prior authorization                             | 1555                                            | 95.80 (94.66-96.95)                              | 1122                                            | 73.48 (69.89-77.07)                              |
| **Generic Buprenorphine (Tablet)**              |                                                 |                                                 |                                                 |                                                 |
| Coverage                                        | 2170                                            | 96.39 (95.80-96.98)                              | 2774                                            | 99.74 (99.68-99.81)                              |
| Prior authorization                             | 1714                                            | 86.85 (84.28-89.42)                              | 1725                                            | 73.72 (70.85-76.60)                              |

* Data represent the Part D marketplace as of October of the previous calendar year, which is the first month in the plan year.
* Data are a proportion of all Part D plans after weighting by plan enrollment to represent the proportion of beneficiaries with coverage or prior authorization.
* Obtained from Cochran-Armitage tests to determine whether there were significant changes in the proportion of plans covering or requiring prior authorization for buprenorphine medications for opioid use disorder.
* The denominator for this row is the number of plans that provide coverage as opposed to all plans.
Discussion | The proportion of Part D plans requiring prior authorization for buprenorphine products decreased between 2017 and 2019, with a steep decline between 2018 and 2019 that was associated with policy changes made by the FDA and CMS. The 2017 to 2018 reduction that occurred prior to the FDA and CMS policy announcements may have been stimulated by other efforts such as the New York attorney general’s investigation of health plans for parity violations related to their use of prior authorization for opioid use disorder medications. The data are important because Medicare policy is often viewed as a standard that is subsequently adopted by private health plans and Medicaid.

This study is limited in that it does not analyze the effect of prior authorization policies on buprenorphine use and subsequent outcomes. Additional research regarding the benefits of requiring prior authorization compared with the risk of imposing barriers to opioid use disorder treatment is needed.

Tami L. Mark, PhD
William Parish, PhD
Gary A. Zarkin, PhD

Author Affiliations: RTI International, Rockville, Maryland (Mark); RTI International, Research Triangle Park, North Carolina (Parish, Zarkin).

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Corresponding Author: Tami L. Mark, PhD, RTI International, 6110 Executive Blvd, Ste 903, Rockville, MD 20857 (tmark@rti.org).

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Self-reported Medical and Nonmedical Cannabis Use Among Pregnant Women in the United States

Cannabis use increased among pregnant women in the United States from 2002 to 2014. However, changes in cannabis use and frequency by trimester over time and national prevalence of medical cannabis use during pregnancy are unknown. Data from the National Survey on Drug Use and Health (NSDUH) were examined to address these knowledge gaps.

Methods | Data were from women aged 12 to 44 years who participated in the 2002-2017 NSDUH, a representative survey of the US civilian, noninstitutionalized population. Collection of NSDUH data was approved by the institutional review board at RTI International. Data were collected by interviewers during personal visits. Oral informed consent was received from respondents. The annual mean weighted response rate of the 2002-2017 NSDUH was 63.6%. Although methods to assess nonresponse bias vary, NSDUH trends have been comparable with trends from other population surveys.

The NSDUH collected sociodemographic characteristics, current pregnancy status, past-month cannabis use, past-month number of days of use, and daily/near daily use (≥20 days in the past month). Respondents who answered “yes” to “Are you currently pregnant?” were asked “How many months pregnant are you?” Starting in 2013, respondents reporting past-year and past-month cannabis use were asked if any cannabis use was recommended by health care professionals. If answering “no,” respondents were classified as having past-month “nonmedical-only cannabis use.” If answering “yes,” they were asked if all cannabis use was recommended, and if answering “yes” to that question, they were classified as having past-month “medical-only cannabis use.” Using logistic and linear regressions, we examined changes in adjusted (controlling for age, race/ethnicity, and family income) past-month cannabis use and use frequency and prevalence of past-month medical-only and nonmedical-only cannabis use by pregnancy status. Statistical significance was set at $P < .05$ by 2-sided t test. Analyses used SUDAAN software, release 11.0.1 (RTI International), to account for the NSDUH’s complex design and sampling weights.