

Medicare Coverage of Buprenorphine-Naloxone Film Surrounding Generic Entry

Hao Zhang, PhD; Yuhua Bao, PhD; and Shashi N. Kapadia, MD

The opioid epidemic in the United States shows no sign of subsiding, with opioid overdose deaths more than doubling since 2015.¹ Buprenorphine-naloxone is an effective medication for opioid use disorder (MOUD) and is 1 of the 3 medications approved by the FDA for this indication.^{2,3} In contrast to methadone, buprenorphine-naloxone can be more accessible because of the potential for office-based prescriptions.⁴ Despite this, buprenorphine-naloxone treatment uptake remains low in the United States.^{5,6}

Suboxone, the brand-name version of buprenorphine-naloxone film, accounted for the bulk of the buprenorphine market in the past decade, despite the entry of generic buprenorphine-naloxone tablets in 2013.⁷ The mean cost for a 30-day supply of Suboxone films ranged from \$160 to \$570 without insurance in 2022, which poses a significant financial barrier among low-income populations. Qualitative research among buprenorphine prescribers has suggested that issues related to cost and insurance reimbursement have restricted accessibility to Suboxone treatment.⁸⁻¹⁰ One study also reported that the high price of Suboxone has led to the use of nonprescribed buprenorphine for opioid withdrawal management or self-detoxification.¹¹ The regulatory exclusivity for Suboxone films expired in 2013, but numerous patents associated with the film formulation prevented generic versions from entering the market.¹² However, this situation changed in 2018, when the FDA approved a generic version of buprenorphine-naloxone films, introducing competition to the Suboxone brand.¹³

Although Suboxone film is covered by most Medicare Part D plans,¹⁴ some Medicare patients may still face financial barriers due to the “donut hole,” co-pays, or coinsurance. In addition, access to opioid use disorder (OUD) treatment is essential for the Medicare population, which saw OUD prevalence more than triple from 2013 to 2018,¹⁵ with more than 777,000 adults 65 years or older misusing opioids in 2017.¹⁶ Opioid-related hospitalizations among older adults went up by 54% between 2010 and 2015.¹⁷ Prevalence of opioid misuse/abuse was higher in the Medicare population compared with populations insured by commercial plans or Medicaid, driven primarily by the high prevalence among those

ABSTRACT

OBJECTIVES: To investigate trends in Medicare coverage of buprenorphine-naloxone film before and after the FDA approval of its first generic versions.

STUDY DESIGN: This study used data from the Part D Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information Files from 2015 to 2022, which provide information on all stand-alone Medicare/Medicare Advantage Prescription Drug Plans.

METHODS: We examined the percentage of plans that provided coverage of brand-name and generic buprenorphine-naloxone films with strength 8 mg/2 mg during 2015-2022. Median out-of-pocket (OOP) cost for a 30-day supply was estimated among all plans that provided coverage.

RESULTS: Generic buprenorphine-naloxone film was covered by 82% of Medicare Part D plans in 2020, 2 years after market entry. Coverage of brand-name Suboxone film decreased from 76% in 2019 to 42% in 2020. The median OOP cost of buprenorphine-naloxone films faced by Medicare enrollees decreased from \$99 in 2019 to \$42 in 2020, driven by the lower price of generic films. In contrast, the OOP cost for brand-name buprenorphine-naloxone film increased gradually from \$85 in 2015 to \$100 in 2022.

CONCLUSIONS: Medicare Part D plan formularies replaced brand-name buprenorphine-naloxone films with the newly approved generic versions. This was accompanied by a substantial decrease in estimated OOP cost faced by Part D enrollees. These changes could potentially increase access to buprenorphine among Medicare enrollees with opioid use disorder.

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TAKEAWAY POINTS

- ▶ Generic buprenorphine-naloxone film was covered by 82% of Medicare Part D plans 2 years after its approval, whereas coverage of the brand-name Suboxone film decreased to 42%.
- ▶ Generic entry significantly drove down the out-of-pocket cost of buprenorphine-naloxone film.
- ▶ The low price of generic buprenorphine-naloxone film could potentially reduce the financial barrier to accessing opioid use disorder treatment.
- ▶ Substitution of brand-name buprenorphine-naloxone film with a generic version in coverage may lead some patients to change formulation, resulting in unintended harms.

younger than 65 years (disabled enrollees).¹⁸ Given this high and increasing prevalence, understanding factors affecting access to MOUD treatment in the Medicare population is critical.

In this study, we examined Medicare Part D coverage of buprenorphine-naloxone film before and after FDA approval of generic versions. We focused on products with strength 8 mg/2 mg because it is one of the most frequently used products, and physicians frequently titrate this formulation to a target dose of 16 mg/4 mg or higher as daily dosing.

METHODS

Data

We used data from the Part D Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information Files, which provide information on stand-alone Medicare Prescription Drug Plans (PDPs) and Medicare Advantage PDPs. We used data from the first quarter of each year from 2015 to 2022. Plans operating solely in US territories were excluded. Buprenorphine-naloxone films with strength 8 mg/2 mg (branded, generic, and overall) were identified using National Drug Codes (NDCs). We further examined changes in coverage of buprenorphine-naloxone tablets, which constitute important alternatives to Suboxone and its generic versions. Notably, Suboxone discontinued its tablet formulation in 2012; therefore, only generic buprenorphine-naloxone tablets with strength 8 mg/2 mg were covered by plans during the study years. The brand-name Zubsolv tablets 5.7 mg/1.4 mg are equivalent to buprenorphine-naloxone tablets 8 mg/2 mg and were additionally examined in this study. See the [eAppendix Table](#) (eAppendix available at ajmc.com) for the full list of NDCs.

Measures

Study outcomes included percentage of plans that provided coverage for buprenorphine-naloxone 8 mg/2 mg films and tablets, including branded (Suboxone and Zubsolv), generic, and overall. We also estimated median out-of-pocket (OOP) cost for a 30-day supply among all plans that provided coverage. OOP cost was calculated using either co-pay information in the data set, with the amount directly tied to a tier, or coinsurance information, calculated as the product of coinsurance rate and mean retail price for 30-day supply at all in-area retail pharmacies. This estimate represents

OOP cost in the postdeductible, pre-coverage gap phase of Medicare Part D coverage, without low-income subsidy. When multiple NDCs were covered by a plan, we assigned the lowest OOP cost to the plan.

Estimates were weighted by monthly plan enrollment for each Part D plan, obtained from Medicare Advantage/Part D Contract and Enrollment Data from CMS. Enrollment counts for plans with 10 or fewer enrollees were suppressed in the data. We randomly

assigned an integer value between 1 and 10 to impute enrollment in these plans. We provided unweighted results in [eAppendix Figures 1 and 2](#).

We use descriptive statistics to report the measured outcomes. All analyses were performed using SAS version 9.4 (SAS Institute).

RESULTS

Coverage

The number of Medicare Part D plans increased from 3237 in 2015 to 5301 in 2022. Part D plans that provided coverage of Suboxone films decreased from 97% in 2015 to 33% in 2022. We observed 2 substantial decreases: 1 in 2018 and the other in 2020. Generic buprenorphine-naloxone films were first covered in 2020, with 82% of all plans providing coverage. This percentage gradually increased to 86% in 2022. The opposite trends for Suboxone and generic films resulted in a U-shaped curve of coverage for buprenorphine-naloxone films overall ([Figure 1](#)). Similar findings were observed in unweighted analysis ([eAppendix Figure 1](#)).

OOP Costs

With the entry of generic films, the median OOP cost faced by patients for any buprenorphine-naloxone film dropped from \$99 in 2019 to \$42 in 2020. The drop was primarily driven by the low OOP cost of generic films, which was approximately \$10 to \$12. In contrast, the median OOP cost of Suboxone films increased from \$85 in 2015 to \$100 in 2022 ([Figure 2](#)). Similar findings were observed in unweighted analysis ([eAppendix Figure 2](#)).

Buprenorphine-Naloxone Tablets

Coverage of generic buprenorphine-naloxone tablets 8 mg/2 mg increased continuously from 68% in 2015 to 85% in 2022. Coverage of Zubsolv 5.7 mg/1.4 mg increased from 15% in 2017 to 34% in 2018, followed by a slight drop since 2021. We observed large decreases in the OOP costs for both Zubsolv and generic buprenorphine-naloxone tablets during the study period ([eAppendix Figures 3 and 4](#)).

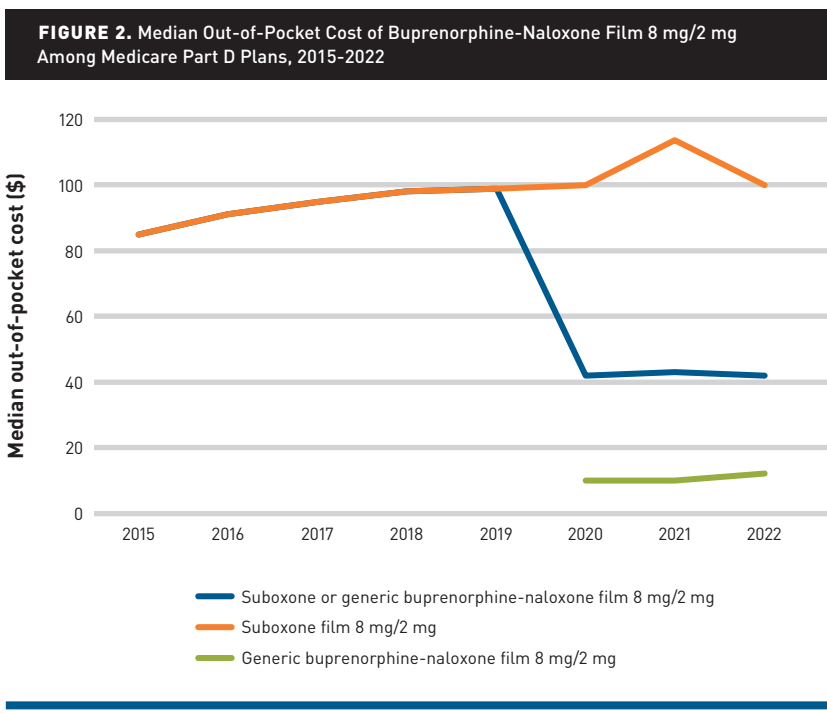
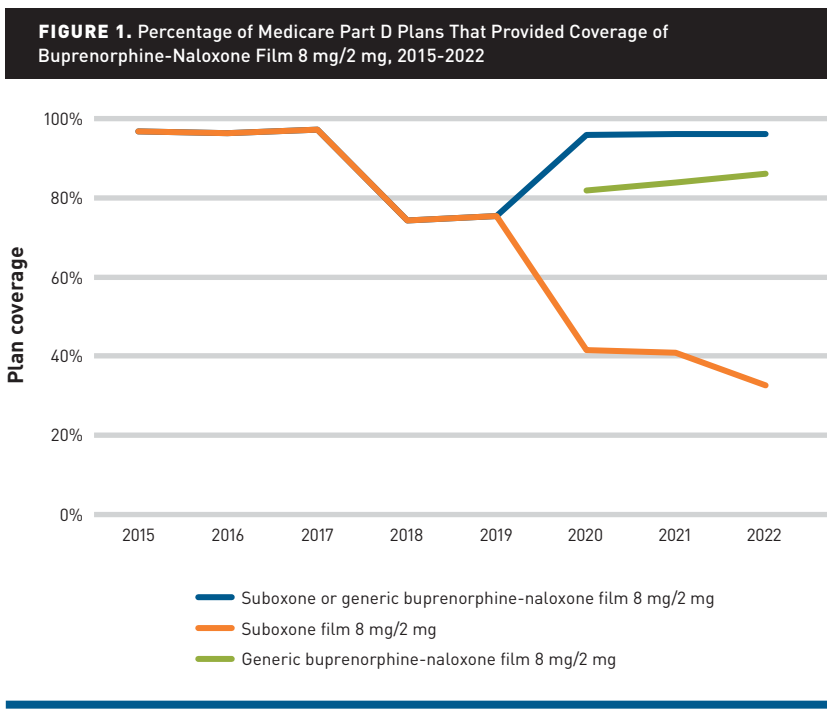
DISCUSSION

In this study, we examined trends in coverage of buprenorphine-naloxone films among Medicare Part D plans, comparing the

brand-name products, the newly approved generic films, and the tablet formulation. We found that the percentage of Part D plans providing coverage of Suboxone decreased rapidly after generic films entered the market. This resulted in large reductions in OOP costs faced by Medicare enrollees when using buprenorphine-naloxone films for OUD treatment.

The abrupt decrease in coverage of Suboxone coincided with the time when generic buprenorphine-naloxone film became available, indicating that Medicare plans are replacing Suboxone with the newly approved generic versions in the formularies. This is consistent with previous reports that Medicare seldom covers brand-name drugs when their generic counterparts are available.¹⁹ This finding suggests that, with the coverage change, some patients previously on Suboxone may be forced to switch to a generic formulation. The prevalence and implications of such a change need to be examined. Although the expectation is that branded and generic products are equivalent, there have been case series and qualitative studies suggesting that patients may experience withdrawal and/or cravings when switching to the newly approved generic formulations.²⁰⁻²² A study reported that among 24 Suboxone-maintained patients with OUD who were forced to switch to a generic, 9 experienced withdrawal symptoms or cravings, dosage adjustment, or positive urine toxicology tests.²⁰ Thus, although improved generic availability in plan formularies would serve to increase access overall, patients who have to switch formulations may require additional monitoring for the effectiveness of the new formulation. The extent to which unintended consequences such as withdrawal or relapse occur in this setting is not known and should be closely studied.

It is worth noting that the rapid formulary coverage of generic buprenorphine-naloxone films coincided with the COVID-19 pandemic, which may have had a complex and varied impact on generic buprenorphine-naloxone use and acceptance. COVID-19 caused disruptions in access to OUD treatment, drug supplies, and shortages of health care personnel,²³ potentially reducing access to buprenorphine-naloxone. On the other hand, policy changes in response



TRENDS FROM THE FIELD

to the COVID-19 emergency allow authorized providers to initiate buprenorphine using telemedicine (including phone visits) without the requirement for an in-person evaluation.²⁴ These policy changes may have made generic buprenorphine-naloxone more accessible and affordable to patients. Future studies should investigate the implications of the public health emergency for generic adoption of and access to buprenorphine.

We did not find the entry of generic products to be associated with a lower retail price or OOP cost for Suboxone films. Because OOP cost is a function of retail price, this may suggest that the retail price did not decrease after generic entry. This is consistent with other literature. In a study that examined 49 top-selling brand-name medications, 48 displayed regular annual or biannual price increases and the price changes did not differ between drugs with and without generic equivalents.²⁵ Prescribing inertia and patient loyalty built during the patent period may hinder patients from changing formulations. The magnitude of overall cost savings associated with the introduction of generic formulations would thus depend on the extent to which prescribers and patients maintain preferences for branded products.

Limitations

First, because we used the lowest OOP cost if a plan covered multiple NDCs, our estimate of median OOP cost should be treated as representing the lower bound for patients without the low-income subsidy. The real OOP cost faced by patients will depend on their benefit phase and low-income subsidy status. Second, we used data only from the first quarters of 2015–2022. Therefore, our finding that Part D coverage of generic buprenorphine-naloxone film started in 2020 should not be interpreted as total absence of coverage in 2019. Third, although we found increasing generic film coverage and decreasing OOP cost over time, our data provided no information on the volume of medications dispensed. We were thus not able to determine the extent to which access to buprenorphine changed after Part D plan coverage of generic buprenorphine-naloxone films.

CONCLUSIONS

Medicare Part D plans have been replacing Suboxone with its newly approved generic equivalents in their formularies, lowering costs and reducing barriers faced by prescribers and patients to prescribing and accessing buprenorphine-naloxone. How these changes affect the number of buprenorphine prescriptions is an important subject for future studies. ■

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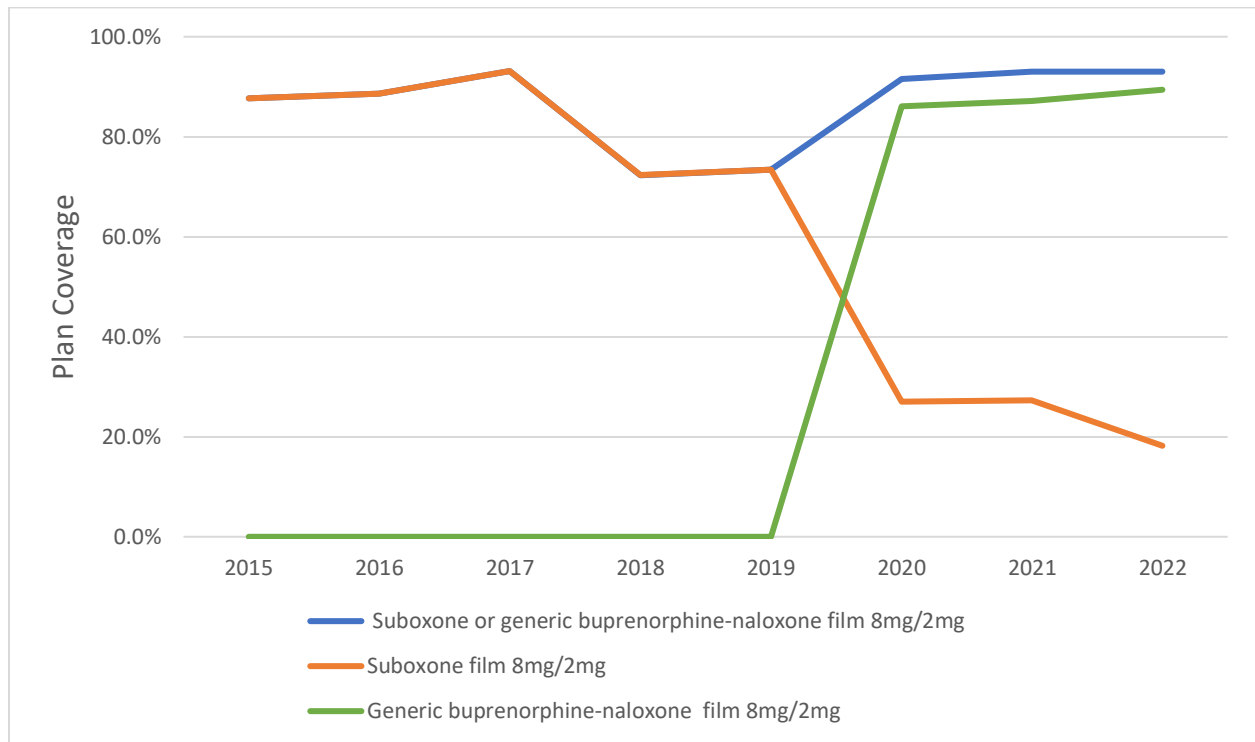
Medicare Coverage of Buprenorphine-Naloxone Film Surrounding Generic Entry.

eAppendix Materials

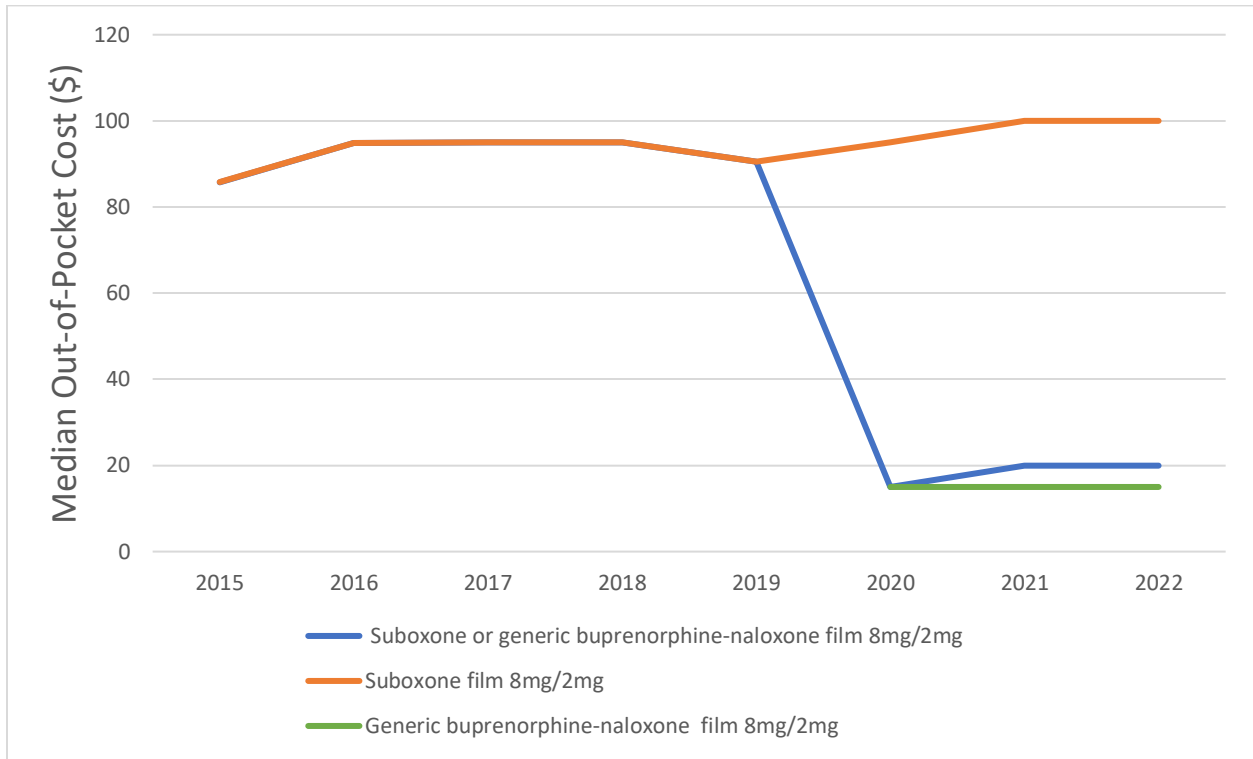
eAppendix Table. List of National Drug Codes (NDCs) of Buprenorphine-Naloxone 8mg/2mg included in the study

| | National Drug Code (NDC) |
|---|---|
| Suboxone Sublingual Film, 8 mg/ 2 mg | 12496120801, 12496120803, 54569639900, 55700014730 |
| Generic Buprenorphine-naloxone Film, 8 mg/ 2 mg | 00378876716, 00378876793, 00781723806, 00781723864, 43598058201, 43598058230, 47781035703, 52427069803, 52427069811 |
| Zubsolv Tablet, 5.7 mg/ 1.4 mg | 54123095730 |
| Generic Buprenorphine-naloxone Tablet, 8 mg/ 2 mg | 00054018913, 00093572156, 00228315503, 00228315567, 00228315573, 00406192403, 00406192409, 00406802003, 42291017530, 50268014511, 50268014515, 50383028793, 53217013830, 54569640800, 60429058730, 60429058733, 60846097103, 62175045832, 62756097064, 62756097083, 63629507401, 65162041503, 65162041509 |

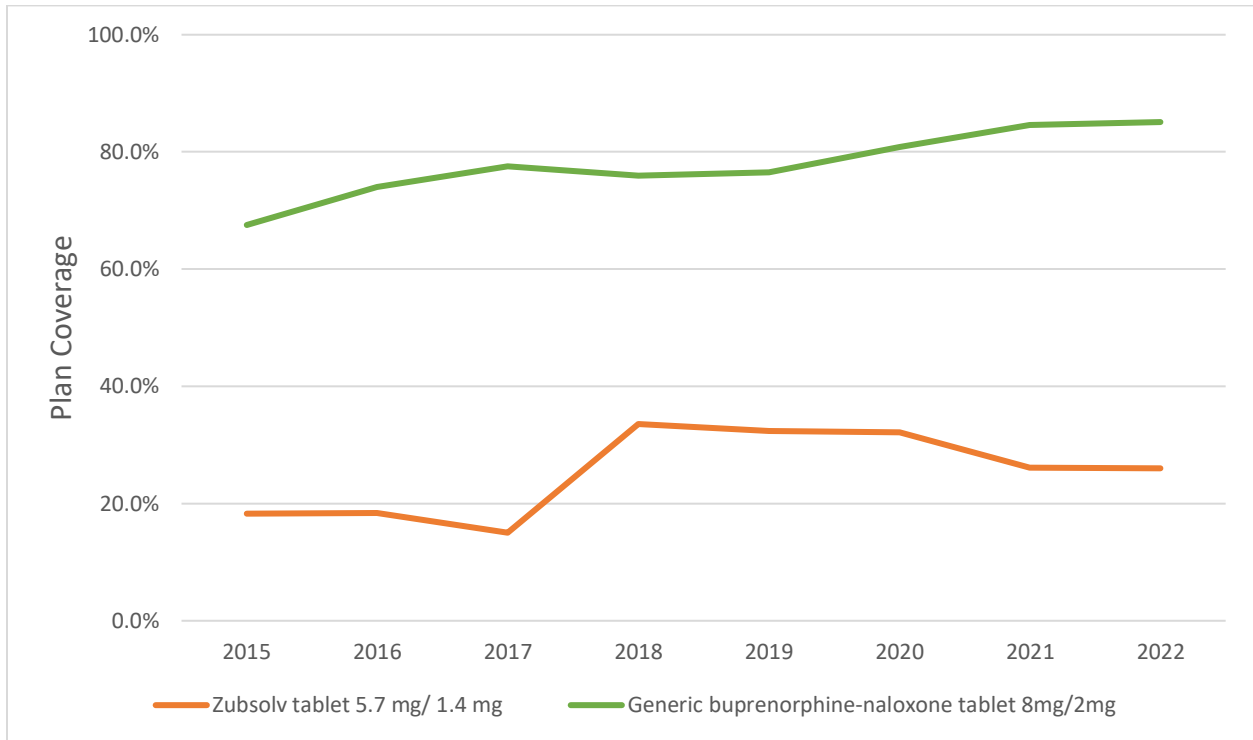
eAppendix Figure 1. Medicare Part D plan coverage of buprenorphine-naloxone film 8mg/2mg 2015-2022, unweighted results



eAppendix Figure 2. Median Out-of-Pocket cost of buprenorphine-naloxone film 8mg/2mg among Medicare Part D plans 2015-2022, unweighted results



eAppendix Figure 3. Medicare Part D plan coverage of buprenorphine-naloxone tablet 8mg/2mg, 2015-2022



eAppendix Figure 4. Median Out-of-Pocket cost of buprenorphine-naloxone tablet 8mg/2mg among Medicare Part D plans, 2015-2022

