ASPE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION | OFFICE OF HEALTH POLICY

RESEARCH REPORT

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Estimating the Effects of the Medicare $2 Drug List on Part D Enrollees

Providing a standardized list of generic drugs for $2 or less for a month's supply to Part D enrollees would lead to $2 billion less in aggregate out-of-pocket spending on generic drugs commonly used to treat chronic conditions in the Medicare population.

KEY POINTS

- The Centers for Medicare & Medicaid Services (CMS) Innovation Center is in the process of developing the Medicare $2 Drug List (M2DL) Model. This would allow Part D plan sponsors to offer a standardized list of generic drugs for a copayment of $2 or less for a month's supply that would not be subject to prior authorization, quantity limits, or other utilization management restrictions.
- The 101 prescription drugs on the sample $2 drug list for the M2DL Model account for 60 percent of 30-day equivalent fills among Part D enrollees not receiving the low-income subsidy (LIS). These drugs treat a range of chronic conditions common among Medicare enrollees, including high cholesterol, hypothyroidism, hypertension, and diabetes.
- Currently, enrollees pay significantly more than $2 for many of the drugs on the sample $2 drug list. ASPE modeled the M2DL Model, finding that, average savings reach $55.72 per non-LIS part D enrollees, or 12.3 percent of their Part D out-of-pocket (OOP) spending in 2025. This amounts to $2 billion among all non-LIS enrollees.
- For drugs on the sample $2 drug list, a potential benefit of the M2DL Model would be more predictable cost-sharing. Under the current Part D benefit design, average OOP per 30-day equivalent in 2025 is projected to range from $1.28 to $30.71 for model drugs. Under the model, these OOP costs would be capped at $2.
- Prescription drugs included on the sample drug list with the largest reduction in OOP per 30-day equivalent among non-LIS enrollees include treatments for opioid use disorder, alcohol use disorder, asthma, and Parkinson's disease.

BACKGROUND

Part of the U.S. strategy for making prescription drugs affordable is the use of generic drugs. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Amendments), the first manufacturer to submit a certification for patent invalidation receives a 180-day

generic drug exclusivity period.[1] Once patent protection or exclusivity is lost, generic drugs enter the market leading to increased competition.

Among the Part D population, generic drugs are commonly used. In 2022, for instance, 82 percent of Part D enrollees filled at least one generic prescription.[2] And recent estimates indicate that over 90 percent of all prescriptions filled in Part D are for generic drugs.[3,4] Many of these drugs are for chronic conditions that are common among the Medicare population including hypertension, chronic obstructive pulmonary disease (COPD), diabetes, and high cholesterol.[2]

Most generic drugs in Part D are filled for relatively low out-of-pocket (OOP) cost to the patient. Lower OOP costs can lead to better adherence to prescriptions and better outcomes.[5-13] Among Part D enrollees not receiving the low-income subsidy (LIS) in 2022,[*] for instance, nearly 60 percent of 30-day equivalents for generic drugs filled through Part D were for less than $2 in OOP costs. Because of the added protection afforded through LIS, for the LIS population, 94 percent of 30-day equivalents for generic drugs were for less than $2 in OOP costs. On average, Part D enrollees filled 30-day equivalent supplies for generics for $2.92 per fill, with LIS enrollees paying $0.59, and non-LIS enrollees paying $4.00 on average.[2] While most generic drugs are filled for nominal copayments, there is still variation in OOP costs for generic drugs. Among the non-LIS population, for instance, over 19 percent of 30-day equivalents for generic drugs were filled for more than $10 in OOP costs. For individuals relying on Social Security retirement benefits, and/or those without LIS benefits, even modest OOP costs can be burdensome. This can reduce adherence to important prescription drugs and potentially lead to harms.[5-8,14]

In addition to OOP costs, confusion or misunderstanding of benefit structures is also likely to affect medication adherence. This has been well-studied in the context of insurance plan enrollment decisions – in various settings including Part D – where too many options can lead to suboptimal choices.[15-17] This kind of "choice overload" may also affect how and whether enrollees fill their prescribed medications. For instance, both beneficiaries and prescribers must determine whether a given drug is covered, at what copayment, and whether other options within the same class are available. Exacerbating this challenge, Part D plans have increasingly used tiering to cover prescription drugs at different levels of cost-sharing, including among generic drugs.[18] In August 2024 data, close to 30 percent of Part D plans had more than five cost-sharing tiers.[†] Combined with the fact that formularies can change throughout the year, potentially changing cost-sharing faced by enrollees, there are many potential sources of confusion and choice overload that can lead enrollees to not fill all of their prescriptions.

One approach to improving adherence to prescription drugs that has been successfully used in the private sector has been the use of fixed copayment drug lists. For instance, Walmart has offered a $4 drug list since 2006. Amazon has offered a similar service, with a monthly subscription that includes prescription drugs for various conditions. Though evidence is limited, one study found that the rollout of the Walmart program led to an increase in the use of antihypertensive medications and a reduction in avoidable hospitalizations.[19]

In response to an executive order issued by President Biden in October 2022,[20] the Center for Medicare and Medicaid Innovation (Innovation Center) at the Centers for Medicare & Medicaid Services (CMS) is developing a model focused on improving the use of commonly used generic drugs that treat chronic conditions.[21] This model – the Medicare $2 Drug List (M2DL) Model – creates a list of generic drugs that can be offered by Part D

[*] For eligible enrollees whose income and resources are limited, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 established the Low-Income Subsidy, also known as Extra Help. Subsidies are paid by the Federal government to drug plans and provide assistance with premiums, deductibles, and co-payments. Under the Inflation Reduction Act, beginning in 2024, the full LIS benefit is expanded to individuals with limited financial resources and incomes up to 150 percent of the Federal Poverty Limit (FPL), which is about $21,870 per individual in 2023. For more information, please see here.

[†] ASPE analysis of August 2024 Part D formulary public use files available from CMS.

plan sponsors to enrollees at a low, fixed cost. Under this model, a 30-day equivalent supply of each drug will be available for no more than $2, a 60-day supply for no more than $4, and a 90-day supply for no more than $5. Restrictions such as step therapy, prior authorization, or quantity limits would not apply.[‡]Model drugs would not be subject to the deductible, but drug expenditures would count towards true out of pocket (TrOOP) costs. The goal of this model is to test whether a simplified approach to offering low-cost, clinically important generic drugs can improve medication adherence, lead to better outcomes, and improve beneficiary and prescriber satisfaction with the Part D benefit.

In October 2024, CMS included a sample $2 drug list in a Request for Information (RFI) about the model.[22] The sample $2 Drug List shared in the RFI represents a starting point for the Innovation Center's development of the M2DL Model which, pending development, could start as early as January 2027.

In this report, we use CMS' sample $2 drug list to present results from simulating the M2DL Model across all Part D plans that would be eligible to participate in the M2DL Model. We illustrate how overall enrollee cost sharing could change under this scenario. While the M2DL Model would apply to both LIS and non-LIS enrollees, we focus our analysis on the non-LIS population,[§] as this is where OOP spending would be mostly affected.

METHODS

ASPE used a simulation model of Medicare Part D benefits that has previously been used to model various components of the Inflation Reduction Act's (IRA) changes to Medicare Part D.[23] In its current iteration, this model incorporates the most recent projections from the CMS Office of the Actuary (OACT) and relies on 2023 10% Part D Prescription Drug Event (PDE) data as a baseline for prescription drug utilization and plan benefit structure. The model assumes historical utilization based on PDE data, assumes that components of the IRA such as the $2,000 OOP cap in Part D are in place, and applies OACT's growth estimates to project utilization,[**] OOP spending, and gross drug costs in calendar year 2025.[††]

The CMS Innovation Center provided ASPE a list of 270 unique RxNorm concept unique identifiers (RxCUIs) that represent active ingredients, dosage strengths, and dosage forms included in the sample $2 drug list for the M2DL Model. These 270 RxCUIs account for 101 unique combinations of active ingredient and dosage form, and 93 unique active ingredients. Using the simulation model, OOP changes from the M2DL Model under development were applied to 2025 projections. For each unique RxCUI, OOP costs were not allowed to exceed $2 for a 30-day equivalent supply, $4 for a 60-day equivalent supply, and $5 for a 90-day equivalent supply. 30-day equivalents were calculated by dividing the number of days supplied by 30, allowing for partial 30-day equivalents. An exception to this calculation were drugs in the antibiotics class; for these drugs, so-called "short fills" (such as those for seven days) were considered a single 30-day equivalent as well. Lastly, if OOP costs were lower under existing benefit structures, they were left unchanged.

Because changes in OOP for M2DL Model drugs can affect the Part D phase in which non-model drugs are paid for (leading to differences in OOP and manufacturer discounts, for instance), the model simulates changes in spending on both model and non-model drugs. No enrollee demand response is assumed with respect to price changes for the drugs. While CMS is developing the M2DL Model as a voluntary model where not all plans may choose to participate, for the purposes of this analysis, all eligible Part D plans are assumed to participate in the M2DL Model. Eligible plans include standalone Prescription Drug Plans (PDPs) and Medicare Advantage

[‡] This restriction would not apply to safety edits, as defined in Section 30.2.2.2 of Chapter 6 of the Prescription Drug Benefit Manual.
[§] LIS enrollees tend to have very low or zero copayments for most drugs, and thus would largely be unaffected by this model.
[**] This analysis relies on the 2024 Medicare Trustees Report.
[††] Note that while the M2DL Model would not take effect until 2027, our analysis uses 2025 as the implementation year.

Prescription Drug Plans (MA-PDs), but do not include private fee-for-service (PFFS) plans, Employer Sponsored Group Waiver (EGWP) plans, section 1876 cost contract plans, section 1833 health care prepayment plans, Program of All-Inclusive Care for the Elderly (PACE) organizations, Medicare-Medicaid plans, and religious fraternal benefit plans.

Projections were generated for each individual drug. Not all PDEs could be linked to an RxCUI. Thus, projections for these drugs were calculated as if they were a single missing RxCUI. Demographic information for Part D enrollees was obtained from the Common Medicare Environment (CME), the authoritative source on enrollment and demographics.

Enrollee rurality was identified based on the enrollee's zip code and county of residence. This was mapped to a core-based statistical area (CBSA), which is in turn classified as Rural-Micropolitan or Urban-Metropolitan. Valid zip code and county combinations without a categorization were categorized as Rural-Other. Zip code and county combinations which cannot be located in zip code data (e.g. they are located outside of the U.S. or are populated with invalid values) were marked as "Unclassified."

Because we do not make assumptions about how plans might respond to the M2DL Model, we did not estimate the effects on the value of plans' basic benefits. We did not account for plan choices to meet actuarial equivalence requirements.

FINDINGS

In 2025, the prescription drugs included in the sample $2 drug list for the M2DL Model are expected to account for a projected 1.02 billion 30-day equivalents among non-LIS enrollees, more than 60 percent of the 1.69 billion 30-day equivalents expected to be filled by non-LIS Medicare Part D enrollees in the same year. Under the current Part D benefit design, these enrollees are projected to spend $3.31 billion in OOP on these drugs, out of $16.02 billion in OOP on all Part D drugs under current projections.

If all plan sponsors were to participate in the M2DL Model, we estimate that in 2025, non-LIS Medicare Part D enrollees see OOP spending fall to $1.2 billion on these drugs, a reduction of over $2 billion in OOP spending. After accounting for increases in OOP spending for non-model drugs (because of changes in the phase that drugs are paid for),[‡‡] total OOP spending would decline by $1.95 billion. This corresponds to an average reduction of $4.91 per-member-per-month (PMPM) or $55.72 per enrollee per year. As noted previously, this does not account for how plans will respond to meet actuarial equivalence requirements.

$2 billion

in reduced out-of-pocket spending on model drugs if the M2DL Model were in effect in 2025

Changes in OOP Spending by Prescription Drug

In our modeling, OOP reductions are driven by a number of commonly used drugs by non-LIS enrollees, as indicated in Table 1. The ten most-commonly filled drugs on the sample $2 drug list account for over $944 million (nearly 45 percent) of the total OOP reduction expected under the M2DL Model. Projected OOP reductions range from $11.95 million for hydrochlorothiazide (a hypertension drug) to $177.45 million for atorvastatin (a high-cholesterol drug). These drugs are among the most-commonly prescribed generics in Part D,[2] and treat conditions that are common among Medicare enrollees, including high cholesterol, hypothyroidism, hypertension, and diabetes.[24]

[‡‡] While we do not assume any formulary or cost-sharing changes to non-model drugs, a change in the phase of a PDE due to model drug copayments being lower may lead to higher cost-sharing for the given PDE than in the baseline.

Table 1. Top 10 Drugs on Sample $2 Drug List, by 30-Day Equivalents, Non-LIS

Active Ingredient	Total Fills	Total 30-Day Equivalents	Total OOP (millions), Baseline	Total OOP (millions), Projected	Total OOP Reduction (millions)	Average OOP Reduction per 30-Day equivalent	Examples of Condition(s) Treated
Atorvastatin	39,113,590	105,109,761	$304.16	$126.71	$177.45	$1.69	High-cholesterol
Amlodipine	27,106,186	70,302,928	$131.21	$71.69	$59.52	$0.85	Hypertension
Levothyroxine	24,994,900	63,983,214	$206.10	$76.43	$129.67	$2.03	Hypothyroidism
Lisinopril	20,473,813	54,327,816	$114.02	$59.78	$54.24	$1.00	Hypertension, heart failure, chronic kidney disease
Losartan	20,399,086	53,842,366	$165.20	$65.65	$99.55	$1.85	Hypertension, heart failure, chronic kidney disease
Metformin	18,258,313	48,142,772	$102.33	$50.61	$51.72	$1.07	Diabetes
Metoprolol Succinate	17,980,134	45,790,483	$189.07	$57.76	$131.31	$2.87	Atrial fibrillation, heart failure
Rosuvastatin	16,663,332	44,952,587	$193.21	$56.17	$137.04	$3.05	High cholesterol
Hydrochlorothiazide	11,494,004	30,444,212	$38.98	$27.03	$11.95	$0.39	Hypertension
Tamsulosin	11,686,767	28,520,112	$128.46	$36.60	$91.86	$3.22	Benign prostatic hyperplasia

Notes: Estimates based on applying OACT projections from the 2024 Medicare Trustees Report to 2023 Part D event data. OOP includes patient pay amounts and does not include additional payments that may count towards TrOOP. Model drugs are aggregated to their unique active ingredient for the purpose of reporting. Baseline: projections under current OACT assumptions. Projected: projections under current OACT assumptions, with application of M2DL Model. OOP: out-of-pocket.

While the prescription drugs responsible for the largest OOP reduction in total are generally commonly used medications among the Medicare Part D population, a different set of prescription drugs have disproportionately large reductions in OOP costs per 30-day equivalent. Table 2 illustrates this variation. The two drugs with the largest reduction are buprenorphine/naloxone ($29.22) and naltrexone ($16.49). The former is used to treat opioid use disorder, and the latter is used to treat alcohol use disorder and opioid use disorder. Other drugs with the largest OOP per 30-day equivalent reduction include treatments for Parkinson's disease, asthma, and certain cancers.

Table 2. Top Drugs on Sample $2 Drug List by Reduction in OOP per 30-Day Equivalent, non-LIS

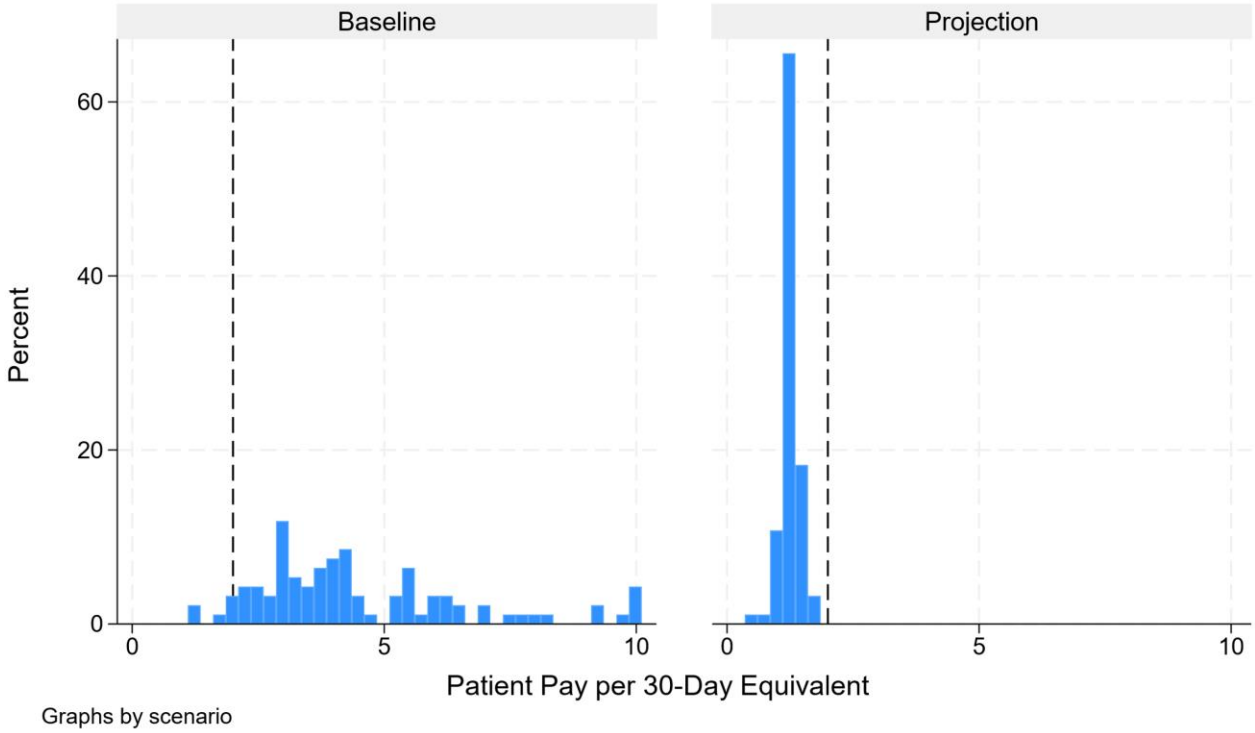
Active Ingredient	Average Reduction in OOP per 30-Day Equivalent	Examples of Condition(s) Treated
Buprenorphine/Naloxone	$29.22	Opioid use disorder
Naltrexone	$16.49	Alcohol use disorder, opioid use disorder
Carbidopa/Levodopa	$10.27	Parkinson's disease
Albuterol	$9.73	Asthma, chronic obstructive pulmonary disease
Hydroxyurea	$8.24	Sickle cell disease, certain blood cancers
Methotrexate	$7.93	Rheumatoid arthritis, certain autoimmune conditions, certain cancers
Levetiracetam	$7.79	Seizure disorder
Tamoxifen	$6.88	Breast cancer
Nystatin	$6.85	Skin infections
Divalproex	$6.25	Bipolar disorder, migraines, seizure disorder

Notes: Estimates based on applying OACT projections from the 2024 Medicare Trustees Report to 2023 Part D event data. OOP includes patient pay amounts and does not include additional payments that may count towards TrOOP. Model drugs are aggregated to their unique active ingredient for the purpose of reporting. Baseline: projections under current OACT assumptions. Projected: projections under current OACT assumptions, with application of M2DL Model. OOP: out-of-pocket.

For drugs on the sample $2 drug list, a potential benefit of the M2DL Model is improving predictability of OOP costs for patients, reducing the risk of unexpected OOP burden. In Figure 1, we present distributions of OOP spending per 30-day equivalent for prescription drugs on the sample $2 drug list under the baseline assumptions and under the model. In the baseline, average OOP per 30-day equivalent ranges from $1.28 to $30.71. Under the model, however, there is more compression of OOP costs, with average OOP at the active ingredient level ranging from $1.25 to $1.73 per 30-day equivalent. Further underscoring the degree to which variation in OOP spending is reduced under the M2DL Model, the standard deviation of OOP spending per 30-day equivalent is 3.69 in the baseline, and it is 0.18 in the projection. Similarly, the coefficient of variation[§§] is 0.75 in the baseline and 0.14 in the projection. Taken together, this means that variation in OOP costs for model drugs would fall substantially and be more predictable under the M2DL Model.

[§§] Coefficient of variation is defined as the ratio of the standard deviation to the mean.

Figure 2. Distribution of Average Out-of-Pocket ($) Per 30-Day Equivalent by Active Ingredient, non-LIS



Notes: Estimates based on applying OACT projections from the 2024 Medicare Trustees Report to 2023 Part D event data. Patient Pay includes patient pay amounts and does not include additional payments that may count towards TrOOP. X-axis is truncated to $10 for readability. Baseline: projections under current OACT assumptions. Projected: projections under current OACT assumptions, with application of M2DL Model. Dotted line indicates $2.

Changes in OOP Spending by Enrollee Demographics

Because utilization of the drugs on the sample $2 drug list varies by demographics, we evaluated potential changes in OOP across a number of enrollee characteristics. As indicated in Table 3, among different age groups, enrollees who are 85 and older and those who are ages 70 to 74 would see the largest relative reduction in OOP spending under the M2DL Model (12.8 percent). On a per enrollee basis, however, those who are 85 and older would see the largest reduction in OOP ($70.31, on average). Compared to other racial and ethnic groups, enrollees who are American Indian/Alaska Natives (AI/AN) would be expected see the largest reduction in OOP spending per enrollee, while Asian enrollees would see the largest relative reduction in OOP spending (15 percent). There were few differences in expected OOP spending reductions by rurality of the enrollee's residence.

Table 3. Changes in OOP by Enrollee Demographics, non-LIS

Demographic	No. Enrollees (%)	OOP $ (millions), Baseline	OOP $ (millions), Projection	OOP $ Change (millions)	% Change in OOP	Average OOP $ Change per Enrollee
Part D Overall	35,012,052 (100%)	$15,839	$13,888	$1,951	12.3%	$55.72
Age						
< 65	3,039,914 (8.7%)	$1,175	$1,057	$119	10.1%	$39.05
65-69	9,758,144 (27.9%)	$3,785	$3,316	$469	12.4%	$48.04
70-74	8,813,723 (25.2%)	$3,945	$3,439	$506	12.8%	$57.38
75-79	6,311,094 (18.0%)	$3,165	$2,775	$390	12.3%	$61.79
80-84	3,791,878 (10.8%)	$2,047	$1,799	$248	12.1%	$65.53
85+	3,004,729 (8.6%)	$1,654	$1,443	$211	12.8%	$70.31
Unknown	292,569 (0.8%)	$69	$61	$8	11.5%	$26.96
Sex						
Female	19,127,872 (54.6%)	$8,570	$7,517	$1,053	12.3%	$55.06
Not Female	15,884,180 (45.4%)	$7,269	$6,371	$898	12.4%	$56.52
Unknown						
Race/Ethnicity						
White	27,886,719 (79.6%)	$13,143	$11,544	$1,600	12.2%	$57.36
Black	2,256,498 (6.4%)	$937	$822	$115	12.3%	$51.08
Hispanic	2,284,903 (6.5%)	$800	$693	$107	13.4%	$46.90
Asian	1,041,186 (3.0%)	$373	$317	$56	15.0%	$53.79
American Indian/Alaska Native	58,145 (0.2%)	$38	$34	$4	10.7%	$69.95
Other	1,484,601 (4.2%)	$547	$479	$69	12.6%	$46.34
Rurality						
Urban	27,651,621 (79.0%)	$12,642	$11,094	$1,549	12.2%	$56.00
Rural-Micropolitan	3,401,042 (9.7%)	$1,568	$1,372	$196	12.5%	$57.69
Rural-Other	2,320,353 (6.6%)	$1,080	$941	$139	12.9%	$59.85
Unclassified	1,639,036 (4.7%)	$549	$482	$67	12.2%	$41.01

Notes: Estimates based on applying OACT projections from the 2024 Medicare Trustees Report to 2023 Part D event data. OOP includes patient pay amounts and does not include additional payments that may count towards TrOOP. Baseline: projections under current OACT assumptions. Projected: projections under current OACT assumptions, with application of M2DL Model. OOP: out-of-pocket.

CONCLUSION

The M2DL Model would allow Part D plan sponsors to offer a fixed price for a set of commonly used generic prescription drugs among the Medicare Part D population. Based on the current sample $2 drug list, which accounts for over 60 percent of 30-day equivalents filled by Part D enrollees, our analysis suggests that this model would reduce aggregate OOP spending among non-LIS enrollees by $2 billion for these drugs. Additionally, by reducing variation in cost-sharing for these drugs, it would make OOP costs more predictable for enrollees and providers. This could lead to improved adherence to these drugs, simplified prescribing, and less confusion at the pharmacy counter.

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