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Management of Newer Medications for Attention-Deficit Hyperactivity Disorder In Commercial Health Plans

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Abstract

Purpose—In the US, many individuals with attention deficit hyperactivity disorder (ADHD) pay for their medications using private health insurance coverage. As in other drug classes, private insurers are actively seeking to influence utilization and costs, particularly for newer and costlier medications. The approaches that insurers use may have important effects on patients' access to medications. This paper examines approaches (e.g., copayments, prior authorization, and step therapy) that commercial health plans are employing to manage newer medications used to treat ADHD and changes in approaches since 2003.

Methods—Data are from a nationally representative survey of commercial health plans in 60 market areas regarding alcohol, drug abuse and mental health services in 2010. Responses were obtained from 389 plans (89% response rate), reporting on 925 insurance products. For each of six branded ADHD medications, respondents were asked whether the plan covered the medication and if so, on what copayment tier each medication was placed, and whether it was subject to prior authorization or step therapy. Measures of management approach were constructed for each medication and for the group of medications. Bivariate and multivariate analyses were used to test for association of the management approach with various health plan characteristics.

Findings—There was considerable variation across these 6 medications in how tightly they were managed by health plans, with newer medications being subject to more stringent management. The proportion of insurance products relying solely on copay tiering to manage novel ADHD medications appears to have decreased since 2003. Less than half of insurance products (43%) managed these 6 medications solely by use of Tier 3/4 placement, and most of the remainder (48%) used other restrictions (with or without Tier 3/4 placement). The average insurance product restricted access to at least 3 of the 6 brand-only medications examined, whether through copayment tier placement or other approaches. More ADHD medications were left unrestricted in HMO products than in PPO ones; products with internal or hybrid-internal contracts for behavioral

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health; those not contracting with pharmacy benefits managers; and those with for-profit ownership.

Implications—Many plans have supplemented copayment tiering with other approaches such as prior authorization and step therapy to influence utilization and decrease costs. It may be that plans have found copayments to be less effective in redirecting utilization in this medication class. The impact on clinical outcomes was not examined in this study but should be prioritized using other data sources.

Keywords

Attention deficit hyperactivity disorder; formularies; prior authorization; copayments; step therapy; ADHD medications

Introduction

Attention-deficit hyperactivity disorder (ADHD) is a burdensome and increasingly prevalent condition, estimated to affect 9% of children¹ and 4.4% of adults in the United States.² In a majority of cases, treatment of ADHD involves medications (with or without behavior therapy). For example among US children with ADHD in 2011, an estimated 69% were taking medication for it, according to one study.³ In the US, many individuals with ADHD pay for their medications using private health insurance coverage. Private insurers are actively seeking to influence utilization and spending for most classes of medications, particularly newer and costlier ones. The approaches that insurers use can have important effects on patients' access to medications. This paper examines the approaches that private health plans are employing to manage newer medications used to treat ADHD, using nationally representative survey data from 2010.

As in other medication classes, there has been rapid innovation in the medications used to treat ADHD in the last two decades. Innovations have included the development of new formulations of existing medications, such as sustained release or patch delivery versions of methylphenidate and amphetamine salts and sustained release versions of the alpha agonist medications, clonidine and guanfacine. Another type of innovation has been the development of new molecular entities such as atomoxetine (launched in 2002 in the US) and lisdexamfetamine (launched in 2007).⁴ The alpha agonists and atomoxetine differ from the earlier ADHD medications in that they are not stimulants and are therefore viewed by some as posing less risk of addiction.⁵ Lisdexamfetamine requires cleavage by stomach acids of the protein, lysine, in order to be active in the blood stream, with purported benefits of decreased abuse through inhalation or injection as well as potentially fewer side effects. Both types of innovation (different formulations of existing medications and novel moieties) have rapidly gained substantial shares of prescribing. In one state Medicaid program (Florida), by 2005, long-acting, brand-name ADHD drugs accounted for 82% of ADHD drug prescribing and 94% of ADHD drug spending.⁶ One reason for the appeal of sustained-release formulations is that many ADHD patients are school-aged children, and the use of once-daily dosing can remove the need for visits to the school nurse, which could complicate medication adherence.

At the same time, rapid adoption of new medications raises costs to insurers, as the manufacturers of those medications are able to charge considerably higher prices due to patent protection. One recent study of multiple private insurers reported that spending on stimulants grew by an average of 21% per year during 2001-08. (The study did not address non-stimulant ADHD medications.) Although growth in utilization because of increased diagnosis and treatment was a contributing factor, the fastest growing component of spending (12% per year) was the cost per day supplied, which could reflect a shift toward costlier medications.⁷

In the US, many insurers seek to redirect patients and physicians toward generic medications or less expensive branded ones, often with the help of external contractors known as pharmacy benefits managers (PBMs). Plans and/or their PBMs use a variety of tools to control spending. First, plans may exclude certain drugs from coverage altogether. Second, plans may require physicians or patients to obtain prior authorization before using certain medications, or to document that treatment with a less costly medication has already been tried unsuccessfully (known as 'fail first', or step therapy). Third, plans may define certain branded medications as 'preferred', and charge patients a higher copayment for other branded medications within that class.⁸ The medications which a plan typically prefers are those for which it (or its PBM) has negotiated price rebates from drug manufacturers. This third approach, known as the 'tiered' or 'incentive' formulary, has become almost universal among commercial health plans.⁹ For any given medication, plans may use these three management tools individually or in combination. Prior research has found health plans' pharmacy management approaches to be influenced by various factors including direct-to-consumer advertising¹⁰ and internal organization of the health plan.¹¹

Insurers' policies toward newer medications are superimposed on a medication selection process that is already complicated. One issue is that different medications may work for different patients, but physicians have little basis for predicting this beforehand.¹² For most children and adolescents with ADHD, established guidelines recommend prescribing an FDA-approved medication, with a stronger recommendation for stimulants than for nonstimulants, potentially accompanied by behavioral therapy.^{13,14} Another issue is that medications may differ in their impact on medication adherence, which is a major concern for ADHD, where adherence may require action by both the patient and his/her parents. Mean adherence rates for ADHD medications vary across studies from 36% to 85%.¹⁵ Lack of adherence may reflect a number of familial factors as well as factors related to the medication itself, such as intolerable side effects or the frequency with which medications may need to be taken each day. For example, children taking longer-acting stimulants have been found to adhere for longer periods than those taking shorter-acting ones.¹⁶ However, the longer-acting medications are newer and costlier until patent expiration and the introduction of generic versions. These examples suggest that insurers' policies toward newer medications must have important implications for patient access and for treatment adherence.

There has been little research on the effect of these policies specifically for ADHD treatment. In one such study, Huskamp and colleagues found that the introduction of a three-tier formulary by one insurer did not cause most existing patients to substantially change

their use of ADHD medications, although it may have lowered rates of medication initiation.¹⁷ As a result, the three-tier formulary shifted costs from the insurer to patients. A review of step therapy studies in 2011 found no studies of the effect of step therapy for ADHD.¹⁸

Little is known about the way health plans are currently managing the medications used to treat ADHD. In 2003, a national survey of health plans found that plans were placing more restrictions on novel ADHD medications than on novel antidepressants and antipsychotics.¹⁹ However, since that time important changes in medication options have occurred, including the approval and diffusion of multiple brand-only long-acting agents. One recent report on coverage at six New England health plans in 2012 found considerable variation in policies, with one of the plans using tiered copayments while the others used step therapy for some or all brand-only ADHD medications.²⁰

In deciding how to manage ADHD medications (as with other classes), a health plan must consider a variety of other goals beside cost containment. These include the medications' effectiveness (on average and for subgroups), side effect profiles, substitutability, diversion potential and their effect on use and cost of nonpharmacy medical care. A related question is whether plans' choice of pharmacy management approaches might relate to other plan characteristics. For example, for-profit plans might be expected to choose more restrictive approaches than other plans, as a way to increase their profits. Similarly, health maintenance organizations (HMOs) are viewed as generally managing medical care more stringently than point-of-service (POS) and preferred provider organization (PPO) products. Also, plans that manage their enrollees' mental health care internally (rather than contracting with an external vendor) may be more attuned to psychiatric medication issues and therefore may try to manage their costs more actively.

A related question is which medications within the ADHD class are managed more stringently. Other things equal, one would expect tighter management of medications that are newer, and those that are costlier. In practice, plans (or their PBMs) will negotiate different prices for the same medication, depending on their bargaining power and priorities. However, this bargaining must be influenced by the manufacturer's 'list price', even if cash customers are the only ones who pay close to list price. Newness of a drug matters because plans often want time to review a new drug's likely impact before approving it.

Given the importance of health plans' management approaches for patient access and adherence, this study sets out to address the following questions:

- How many of the newer ADHD medications are available without restriction, on average?
- Which medications are plans more likely to restrict? (Ones that are newer? Costlier?)
- Which management approaches are plans using most frequently?
- What plan characteristics are associated with greater use of restrictions?

For the third question, we also examine what has changed since 2003. Between 2003 and 2010, several new long-acting ADHD medications were launched (e.g. Focalin XR (dexamethylphenidate) and Intuniv (guanfacine)), and several older ones lost patent protection (e.g. Adderall XR (extended release mixed salts of amphetamine)).

Methods

Data source and population

Data were collected for the 2010 benefit year through the third round of a nationally representative survey of commercial health plans regarding alcohol, drug abuse and mental health services. Previous rounds of the survey were conducted in 1999 and 2003. In 1999, 434 health plans were surveyed in 60 market areas (92% response rate); in 2003, 368 plans in the same market areas were surveyed (83% response rate); in 2010, 389 plans again in the same market areas were surveyed (89% response rate).

The study used the same market areas as the Community Tracking Study (CTS), a longitudinal study of health system change funded by the Robert Wood Johnson Foundation.²¹ The primary sampling units were the 60 market areas that CTS had selected to be nationally representative. The second stage consisted of sampling plans within market areas. Plans serving multiple market areas were defined as separate plans for the study and data were collected with respect to a specific market area.

The 2010 survey used a panel design with replacement. For the 2010 survey, the 2003 national sample of 814 plans was augmented with a sample of plans not previously operating in the market areas. Of the 106 new plans identified, 82 were selected, maintaining the sample rates from previous rounds. Thus the 2010 sample consisted of 896 plans. Of the 814 health plans from Rounds 1 and 2, only 463 health plans were initially determined to be operational in the 60 sites in 2010. These 463 health plans plus health plans newly identified and selected during Round 3 resulted in a fielded sample of 545 health plans. Of these 545 plans, 39 plans had merged with another plan in the same site, and only the parent company was interviewed. After screening for eligibility, 107 were ineligible due to the plan closing (N=35), low enrollment and/or not offering comprehensive health care products (N=69), or offering Medicaid/Medicare products only (N=4). There were 438 eligible plans, of which 389 responded (89%) and reported on 939 products. For the clinical portion of the survey, 385 plans (88%) responded, reporting on 925 products. Non-respondents tended to be located in larger metropolitan areas in the South and West.

Data Collection

The survey was administered by telephone to senior health plan executives. Typically, there were 2 respondents per health plan (1 each for the administrative and clinical components). For some national or regional health plans, we interviewed respondents at the corporate headquarters level regarding multiple sites. In some cases the health plans referred us to their specialty contractor, the managed behavioral health organization (MBHO), for more detailed information. Health plans typically offer multiple products such as a health maintenance organization (HMO), a preferred provider organization (PPO) or a point of

service plan (POS). Each plan was asked about its top three commercial products, defined by size of enrollment. All items were asked at the product level within each market-area-specific health plan. Respondents were asked to treat as one product “any packages, plans or contracts that are similar in terms of out-of-network coverage, referrals, and primary care physicians”.

Medications

ADHD medication questions were part of a pharmacy module that also asked about two other medication classes. To maintain a manageable burden on respondents, it was necessary to ask only about a subset of the large number of ADHD medications and formulations available. We chose to focus on newer medications for which generic versions were not available in 2010, or at least not in the same formulation. The rationale was that when a medication is available in both brand and generic versions for the same formulation, it is not of policy interest to know how health plans restrict the brand version. The specific medications included are:

- Two formulations of methylphenidate: Concerta and Daytrana. Concerta is a long-acting formulation and Daytrana is a transdermal patch.
- One formulation of dexamethylphenidate: Focalin XR, a long-acting formulation.
- One amphetamine salt: Vyvanse (lisdexamfetamine dimesylate), which is long-acting.
- Two nonstimulants: Strattera (atomoxetine) and Intuniv (guanfacine). Strattera is an intermediate- to long-acting SNRI; Intuniv is long-acting.

For descriptive purposes, two characteristics are reported for each of the six drugs studied. First, the year the drug was approved in the U.S. was obtained from a website maintained by the U.S. Food and Drug Administration (FDA).²² Second, we identified the dosage most commonly used in 2010 in a state Medicaid program. The monthly cost for that dose was obtained from a Consumer Reports publication which reported the national average cash price for sales in retail outlets in January 2012.²³ This cost reflects what health plans might pay if they could not negotiate rebates (and is thus independent of plan characteristics). Insured customers would typically only pay a portion of this amount, as a copayment or coinsurance to the health plan.

Pharmacy approaches

This study drew primarily on responses to questions about how plans cover prescription medications. Respondents to the administrative module were asked about the overall tiering structure. Respondents to the clinical module were read a list of medications, and were asked for each one: whether it was covered, and if so, on what cost-sharing tier each medication was placed; whether it was subject to prior authorization; and whether it was only available to patients who had failed treatment on another medication (step therapy). Various of these restrictions could be applied in combination, so for drug-level analyses we developed a simpler classification which is exhaustive and mutually exclusive. The four categories are: exclusion, placement on Tier 3 or 4 (with no other restriction), other management approach, or unrestricted. ‘Other restriction’ could therefore include the use of prior authorization or step therapy, with or without placement on Tier 3 or 4.

In addition, for some analyses our focus was on plans' overall management of the group of medications studied. From the drug-level items, aggregate measures were constructed to identify which combinations of restrictions each plan was using for the class as a whole, e.g. placement on Tier 3 or 4 only, prior authorization only, both (with no other restrictions), etc. Again, the classification was constructed to be exhaustive and mutually exclusive. For one analysis, the classification was simplified to three categories.

Other variables

In addition, various health plan characteristics were available in the survey data and used in some analyses.

- Product type. Respondents classified their health plan products as one of: health maintenance organization (HMO), point-of-service (POS), preferred provider organization (PPO), and consumer-directed plan (CDP). CDPs have emerged more recently as a product that gives plan members more choice but also more financial risk, often involving high deductibles.
- Contracting arrangement for mental health. Based on plans' responses, arrangements were initially classified into four categories: *external specialty* (contracted with a MBHO for delivery and management of specialty behavioral health services); *hybrid-internal* (behavioral health services managed by a separate, behavioral health specialty division of the same company that manages general medical care); *internal* (all behavioral health services provided by plan employees or through a network of providers directly administered by the plan); and *external comprehensive* (contracted with a single vendor for both general medical and behavioral health provider networks). Comprehensive contracts were reported by only four products in 2010, so for this paper we combined the specialty and comprehensive approaches into a single category, labeled external contracts.
- Whether the plan had a contract with a pharmacy benefits manager (PBM).
- Profit status (for-profit or nonprofit).
- Region (location of the plan's market area – by census region).

2003 data

To address our longitudinal question, one analysis compares class-level management approaches in this survey to results from the previous survey round in 2003. That survey asked about three ADHD medications: Concerta, Metadate CD (both including methylphenidate), and Strattera (a selective norepinephrine inhibitor).

Statistical approach

The data presented were weighted to present national estimates for health plans' commercial-managed care products in the continental U.S. After simplifying the class-level management variable into 3 values as described above, χ^2 tests were used to evaluate the association of the management approach with each of the five health plan characteristics listed above. In addition, multivariate regression analyses were conducted for two specific

dependent variables. First, logistic regression models were used to predict plans' use of a three- or four-tier approach for ADHD medications. Not all the available plan characteristics could be used in this regression due to some overly strong correlations. Second, count data models were used to predict the number of ADHD medications that a plan left unrestricted (among the 6 studied). All statistical analyses were implemented using SUDAAN software (version 11), for accurate estimation of the sampling variance given our complex sampling design.²⁴ All tests were 2-tailed, and results with $p < .05$ were considered statistically significant. Our sample included too few CDP products to analyze them separately, so they were combined with the PPO category for bivariate and multivariate analyses. The rationale is that CDPs' reliance on cost-sharing rather than gatekeeping makes them more similar to PPOs than to HMO or POS products.

Results

Study sample

Most of the health plan products in our sample belonged to one of three predominant types: health maintenance organizations (HMOs), preferred provider organizations (PPOs), or point-of-service (POS) plans (Table 1). In addition, a few products were consumer directed plans, a more recent innovation. Only 15.2% of products managed behavioral health care internally, with the rest either using external contractors who were independent from the plan (14.8%) or using a vendor owned by their parent corporation (70%: 'hybrid internal'). Three-quarters of products had a contract with a pharmacy benefits manager, and 88% were offered by a for-profit health plan.

Among plans reporting their copayment levels, the mean copayment amounts were \$16 for Tier 1, \$22 for Tier 2 and \$27 for Tier 3. Very few plans had a fourth copayment tier, or fewer than three tiers. (Data not shown; nonresponse on copayment levels was 38%, higher than for other variables.)

Management of individual ADHD medications

The six medications considered were all approved by the U.S. FDA in the preceding ten years (Table 2). In 2010, the monthly cost of a typical dose varied from \$201 to \$238. By contrast, the monthly cost of generic short-acting methylphenidate was only \$90. (Data not shown).

There was considerable variation across these 6 medications in how tightly they were managed by health plans. Intuniv, the newest of these medications, was excluded from coverage by 26% of health plan products, whereas none of the other medications was excluded by more than 1% of products. In addition, 56.8% of products made Concerta available on an unrestricted basis, whereas only 32.9% did so for Intuniv. Concerta and Daytrana were rarely subject to prior authorization or step therapy approaches (3% of products), whereas Vyvanse was often subject to such approaches (29% of products). It is apparent that the medications subject to more stringent management tended to be newer, in terms of years since their introduction. The table does not exhibit such a clear relationship between the monthly cost of the drug and the management approach. We tested the

importance of these two factors by estimating a regression to predict whether a drug was unrestricted, using a dataset with one observation per drug per plan (and controlling for clustering by plan). In this model, medication age was a significant positive predictor of a drug being unrestricted and medication cost was a significant negative predictor ($p < .0001$ for each, data not shown). These results correspond to what one would expect.

Management of the medications as a group

In addition to examining plans' management of each individual medication, it is helpful to characterize their approach to these newer ADHD medications as a group. This analysis indicates that in 2010, 43% of insurance products managed these 6 medications solely by use of Tier 3/4 placement, and most of the remainder (48%) used other restrictions (with or without Tier 3/4 placement) (Table 3, right panel). The other restrictions could include exclusion, prior authorization or step therapy for at least one medication. Only 8% of products left all 6 of these medications unrestricted. Across all products in our data, the mean number of medications left unrestricted was 2.66 (out of the 6).

This pattern is somewhat different from the situation in 2003 (Table 3, left panel), when 69.5% of products only used Tier 3 placement to manage novel ADHD medications, and 15.9% left all three of them unrestricted. Over time the data suggest a migration to tighter management of novel ADHD medications, even as there have been changes in which specific medications are novel.

Correlates of the class-level management approach

All the product characteristics we considered were associated with the product's management approach, at $p < .05$ or less (Table 4). HMO and POS products appeared less likely to rely solely on Tier 3/4 placement, but this was not because they were less restrictive. Rather, HMO and POS products were more likely than PPO products to use other approaches as well or instead of Tier 3/4 placement. Products that managed behavioral health care internally, rather than contracting externally, were more likely to leave all 6 medications unrestricted. In fact, the products that managed behavioral health care internally were the only ones that took this no-restrictions approach.

Products without PBM contracts were more likely to rely solely on Tier 3/4 placement, as were for-profit plans and plans in the West region. Products with PBM contracts were less likely than other products to leave all six of these medications unrestricted.

Multivariate logistic analysis of the decision to rely solely on Tier 3/4 placement confirmed that this approach was more common in PPO products, products that managed behavioral health care with a hybrid-internal approach, and products in the West census region (Table 5). Not all the available product characteristics could be used in this regression due to overly strong correlations. The negative binomial regression model indicated that more ADHD medications were left unrestricted in HMO products than in PPO ones. Also, more ADHD medications were left unrestricted in products with internal or hybrid-internal arrangements; those without PBM contracts; and those with for-profit ownership. These associations do not necessarily have causal interpretations, given potential endogeneity of some of the explanatory variables (see Limitations, below).

Discussion

The results of this study indicate that commercial health plans continue to actively manage newer ADHD medications through tiered formularies and other tools. The average insurance product restricts access to at least 3 of the 6 brand-only medications we studied, whether through copayment tier placement or other approaches. Among these 6 medications, the ones subject to more stringent management tend to be newer and costlier.

The comparison of our 2010 results to the 2003 survey suggests a migration over time from reliance on tiering as the sole cost management approach, toward use of other approaches, with or without tiering. The proportion of plan products relying solely on tiering for ADHD medications decreased from 69.5% to 43.4%. One possible explanation could be that plans found that copayments were less effective in redirecting utilization in this medication class. Huskamp and colleagues' earlier ADHD study noted that the response to copay changes appeared to be lower for ADHD medications than for other classes. They suggested that this could reflect parents' reluctance to seek or agree to cost-driven medication changes for a child when the current regimen has proven effective.¹⁷ This could have led plans to turn instead to other cost management tools such as step therapy, in their quest to address the rapid spending growth for the ADHD medication class. Another possible reason for stricter management over time might be growing concern about possible overuse of ADHD medications, including diversion and abuse of stimulants. Finally, this pattern may reflect the fact that at the time of survey, the 3 drugs we asked about in 2003 were 'newer' on average (mean: 2 years on market) compared to the 6 drugs included in 2010 (mean: 5.2 years on market). If plans regulate newer drugs more stringently, this could skew the cross-year comparison.

Plans' use of these approaches has implications for patient access and medication adherence, by steering patients toward certain medications that the plan prefers. For some patients, the plan-preferred medication may not work or may have unwanted effects; it is estimated that 20% of patients do not respond to the first stimulant selected, but most of these will respond to another stimulant.²⁵ For those patients, the question is how easily the health plan's policies allow them to switch medications, and at how large an additional cost to the family. Step therapy allows switching after documentation of 'failure' on the first medication; a tiered copayment approach does not require documentation, but charges patients more if the new medication is one that the plan considers nonpreferred. In our sample, the mean copayment for nonpreferred drugs was \$27, compared to \$22 for preferred drugs (in plans that charged copayments). This range is smaller than is often reported. Some authors have recommended that for ADHD medications, step therapy should be accompanied by patient (and/or parent) education in order to maximize medication adherence.⁴²⁶

At the same time, many health plans are concerned about their performance on the Health Plan Employer Healthcare Effectiveness Data and Information Set (HEDIS) quality measures. The HEDIS measure for ADHD tracks plans' rates of follow-up care for children prescribed ADHD medications, separately for the initiation and continuation/maintenance phases of treatment. The continuation/maintenance part of the measure asks how many patients stayed on medication for at least 210 days.²⁷ In 2012 the national average

performance on this measure was 46% for HMO plans and 45% for PPOs.²⁸ To the extent that restrictive formulary practices complicate patient adherence, this could eventually worsen plans' performance on the continuation/maintenance part of the HEDIS ADHD measure. Provider prescribing and patient adherence face other challenges including recent shortages of generic ADHD medications, both short and long-acting.

Limitations

Several limitations of this study should be noted. First, we do not know how administrative restrictions such as step therapy were applied in practice, only whether the plan reported applying them. Second, we were only able to ask about six medications, and plans may apply more or fewer restrictions to other ADHD medications that we did not ask about. It could be that inclusion of different ADHD medications would have given somewhat different results. Third, there is some potential for endogeneity bias in the regression analyses. For example, plans' decisions about management of ADHD medications and their contracting choices may both be driven by some third factor, such as health plan officials' perceptions about how serious a cost problem they face. More generally, the impact on clinical outcomes was not examined in this study but should be prioritized using other data sources.

Conclusion

The results in this paper are a snapshot of a historical moment when most long-acting agents were still on patent, and were therefore costly to plans and patients. More recently, Concerta lost exclusivity in 2012, and long-acting Focalin is expected to do so in 2016. With the entry of generic versions, plans will presumably shift their efforts toward promoting generic substitution to drive down the price, perhaps by widening the gap between brand and generic copays. The result should be improved patient access to long-acting agents, compared to what we document here. Plans' step therapy and prior authorization activities may shift to the next set of brand-only drugs - except that these appear likely to be fewer in number, in the next few years. The 2012 PhRMA report identified 20 medications in development for ADHD, as of June 2012,²⁹ but few of these have reached the later stages of the approval pipeline. Industry experts have suggested that for the foreseeable future, new medications in this and other psychotropic classes are unlikely to be 'game-changers', in the way that the long-acting agents have proved to be for the ADHD medication class.³⁰

Use of these pharmacy management strategies may also be affected by ongoing public policy changes, such as the implementation of the federal mental health parity (2008) and health reform (2010) laws. The final rules implementing the 2008 federal insurance parity law specified that criteria for formulary inclusion could not be more stringent for psychiatric medications than for other classes, opening the door to challenges to plans' formulary decision-making. However, it is not yet clear how stringency of formularies will be evaluated. In the case of the Affordable Care Act, private insurance coverage will expand in many states with the creation of the new health insurance marketplaces. Presumably the new marketplace plans will face some of the same pharmacy cost issues, and turn to some of the same management techniques as traditional commercial plans. Should this happen, the

pharmacy cost management techniques described here may soon be applied to new, previously uninsured populations.

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Table 1

Characteristics of study sample

	N of products (weighted)	% of products (weighted)	SE (weighted)
Product type			
HMO	2,420	28.7	0.67
PPO	3,004	35.6	0.58
POS	2,613	31.0	0.38
CDP	390	4.6	0.64
Contracting arrangement for behavioral health			
External	1,250	14.8	2.33
Hybrid Internal	5,899	70.0	3.26
Internal	1,278	15.2	2.19
PBM Contract			
Yes	6,150	73.0	1.89
No	2,277	27.0	1.89
Profit status			
For-profit	7,390	87.7	1.98
Non-profit	1,037	12.3	1.98
Region			
Midwest	1,884	22.4	7.12
Northeast	777	9.2	2.92
South	3,917	46.5	8.04
West	1,849	21.9	7.56

Note: HMO=health maintenance organization. PPO=preferred provider organization. POS=point-of-service plan. CDP=consumer-directed plan.

Table 2

Health plans' management of selected individual ADHD medications

Brand name	Generic name	Monthly cost of medication ¹	Year launched in US	Percent (SE) of products applying policy:				Total
				Exclude	Tier 3/4 placement only	Other ²	Unrestricted	
Concerta	methylphenidate extended release	\$217	2000	0.2% (0.24)	39.5% (1.75)	3.4% (0.71)	56.8% (1.45)	100%
Strattera	atomoxetine	\$233	2002	0.0% (0)	42.7% (2.91)	10.5% (1.88)	46.7% (1.83)	100%
Focalin XR	dexmethylphenidate	\$225	2005	0.2% (0.24)	39.8% (1.57)	12.0% (1.76)	48.0% (1.79)	100%
Daytrana	methylphenidate transdermal	\$238	2006	0.8% (0.27)	60.2% (2.08)	3.7% (0.71)	35.3% (1.68)	100%
Vyvanse	lisdexamfetamine dimesylate	\$201	2007	0.2% (0.24)	20.9% (1.28)	29.0% (1.8)	49.8% (1.92)	100%
Intuniv	guanfacine	\$218	2009	26.0% (1.51)	26.0% (1.93)	15.2% (1.45)	32.9% (1.82)	100%

Notes:

¹ Monthly cost is the average retail price of the typical daily dose for each drug; see text for details.

² 'Other' approaches include prior authorization and step therapy, with or without Tier 3/4 placement.

Table 3

Health plans' management of the ADHD medication class

	2003		2010	
Management approach	% of products (weighted)	Standard error	% of products (weighted)	Standard error
Exclusions only	5.9%	2.1	0.0%	0
Tier 3/4 placement only	69.5%	3.2	43.4%	3.13
Prior authorization requirement only	1.0%	0.2	0.1%	0.03
Prior authorization and Tier 3/4 placement (but no other restrictions)	5.9%	1.6	1.2%	0.46
Step therapy- only			1.0%	0.51
Step therapy plus other			19.2%	2.29
Other combination of restrictions	1.7%	0.9	26.9%	1.64
None of the above (unrestricted)	15.9%	1.9	8.3%	1.62
Total	99.9%		100.0%	
Mean number of medications left unrestricted	N/A	N/A	2.66	0.07

Note: N/A=Not available.

Table 4

Management of the ADHD medication class, by plan characteristics

	Percent of products using:			Total
	Tier 3/4 only	Other restrictions, with or without Tier 3/4	No restrictions	
Product type ^a				
HMO	36.1%	55.5%	8.4%	100%
PPO/CDP	48.5%	42.1%	9.4%	100%
POS	43.4%	50.0%	6.7%	100%
Contracting Arrangement for Behavioral Health ^a				
External	30.1%	69.9%	0.0%	100%
Hybrid internal	50.1%	49.9%	0.0%	100%
Internal	22.8%	18.0%	59.2%	100%
Contract with PBM ^a				
Yes	31.3%	66.4%	2.3%	100%
No	75.2%	0.8%	24.0%	100%
Ownership ^b				
For-profit	40.5%	50.6%	8.9%	100%
Not-for-profit	66.9%	30.1%	3.1%	100%
Region ^a				
Central	16.3%	66.2%	17.5%	100%
Northeast	50.4%	39.0%	10.6%	100%
South	47.4%	49.7%	2.9%	100%
West	58.7%	31.8%	9.5%	100%
All plans	43.4%	48.4%	8.3%	100%

Note:

HMO=health maintenance organization. PPO=preferred provider organization. POS=point-of-service plan. CDP=consumer-directed plan. PBM=pharmacy benefits manager.

^a denotes association between row and column variable at $p < .01$

^b at $p < .05$.

Table 5

Multivariate predictors of class-level management approach

	Predictors of using Tier 3/4 as the only restriction (logistic)				Predictors of the number of ADHD medications left unrestricted (Count model)			
	Odds ratio	Lower bound	Upper bound		Incidence rate ratio	Lower bound	Upper bound	
Intercept	0.610	0.380	0.980	*	0.941	0.594	1.489	
Product type (ref=PPO)								
HMO	0.610	0.490	0.770	**	1.052	1.001	1.107	*
POS	0.760	0.670	0.850	**	1.007	0.964	1.053	
Contract type (ref=external)								
Hybrid internal	2.350	1.420	3.880	**	1.198	1.027	1.397	*
Internal	0.610	0.150	2.560		2.326	1.908	2.835	**
PBM contract (1=yes)	-	-	-		0.818	0.765	0.875	**
For-profit (1=yes)	-	-	-		2.599	1.728	3.909	**
Region (ref=South)								
Central	0.220	0.130	0.370	**	1.017	0.956	1.082	
Northeast	1.300	0.860	1.960		1.133	0.967	1.327	
West	1.780	1.360	2.320	**	0.967	0.902	1.037	
Sample size (unweighted)	898				906			

Note: 'a' denotes statistical significance at $p < .01$; 'b' at $p < .05$. Lower and upper bounds are reported for a 95% confidence interval. HMO=health maintenance organization. PPO=preferred provider organization. POS=point-of-service plan. CDP=consumer-directed plan. PBM=pharmacy benefits manager.