Placement of Selected New FDA-Approved Drugs in Medicare Part D Formularies, 2009-2013

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ABSTRACT

OBJECTIVES: To assess formulary decisions by Part D plans for selected newly approved drugs.

STUDY DESIGN: Retrospective cohort study.

METHODS: Formulary placement and restrictions were identified for 33 drugs in 8 therapeutic classes (antihyperglycemics, anticoagulants, antiplatelets, disease-modifying agents for multiple sclerosis [MS] and rheumatoid arthritis [RA], chronic obstructive pulmonary disease [COPD] drugs, antiepileptics, and antipsychotics) in 863 Part D plans with continuous CMS contracts between 2009 and 2013. Multivariable models estimated the impact of drug characteristics and Part D plan characteristics on probability of drug adoption and, for adopters, evaluated factors associated with months to adoption and requirements for prior authorization (PA) or step therapy (ST).

RESULTS: First Part D formulary placements varied from 2 to 14 months post FDA approval. On average, 56.7% of plans placed each drug within 6 months and 64.1% placed within 1 year of the National Drug Code assignment date. The most rapid adoption was for antipsychotics and antiepileptics. The slowest was for COPD drugs. More than 90% of disease-modifying agents for MS and RA were subject to PA. ST was uncommon except for antihyperglycemic agents. In adjusted analyses, enhanced benefit plans had a 4% higher probability of formulary placement (P <.01), and each additional star in the CMS star rating system increased the probability of adoption by 4% (P <.01). Overall, Medicare Advantage prescription drug plans had higher placement rates due to greater reliance on enhanced plan offerings and higher star ratings.

CONCLUSIONS: We found significant heterogeneity in formulary placement and restrictions for 33 new drugs in the Part D marketplace between 2009 and 2013. Further research is necessary to determine whether this pattern applies to other drug classes.

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The Medicare Part D program provides drug benefits to more than 37 million Medicare beneficiaries enrolled in about 2700 plans operated by more than 150 sponsors.[1] Plan coverage is guided by CMS formulary provisions that generally require plans to offer at least 2 products in each therapeutic class. Exceptions are made for innovator classes with just a single product and the so-called "protected classes" (immunosuppressants used for organ transplant rejection prophylaxis, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics) in which essentially all drugs must be covered. These exceptions notwithstanding, CMS-mandated therapeutic classes are broadly defined, giving plan sponsors considerable latitude in selecting products for formulary placement. Moreover, plans can influence utilization for covered products through cost-sharing tier assignment and utilization management tools, including step therapy (ST) and prior authorization (PA). As a result, there is a high degree of heterogeneity in benefit designs across the Part D market,[2,3] which makes it extremely difficult to assess whether (and which) plans consistently offer coverage for high-value medications.

The objective of this paper was to improve policy makers' understanding of how quickly Part D sponsors add newly FDA-approved drugs to their formularies. We had 3 specific aims. The first was to track rates of formulary placement by Part D plans for each new drug selected for analysis for a minimum of 12 months following FDA approval. Our second aim was to identify policies that plans adopted upon formulary placement, including ST and PA. Our final aim was to assess how formulary adoption decisions were influenced by characteristics of the drugs, number of competing products, and Part D plan characteristics.

Our approach exploits a unique characteristic of the Part D market in which stand-alone prescription drug plans (PDPs) are at risk only for drug spending, while managed care Medicare Advantage prescription drug plans (MAPDs) are also at financial risk for Part A and B services. We expected these differences in risk exposure to influence the timing of formulary adoption and the application

TAKEAWAY POINTS

Findings from recent studies suggest that stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MAPDs) respond to different incentives in constructing their drug formularies, but no published studies have examined formulary adoption of newly approved drugs in the Part D marketplace. This study extends the literature by (1) comparing take-up rates for selected new FDA-approved drugs by Part D plans from 2009 to 2013 and (2) examining characteristics of plans and drugs associated with timing to formulary placement, and utilization management restrictions (ie, prior authorization and step therapy) upon placement. Our main findings include:

- First Part D formulary placements varied between 2 and 14 months after FDA drug approvals for 33 drugs under investigation, with 56.7% of drugs placed within 6 months and 64.1% within 12 months.
- The most rapid adoption was for antiepileptics and antipsychotics, which are both CMS protected classes. The slowest adoption rates were for chronic obstructive pulmonary disease drugs.
- Overall, MAPDs had higher formulary placement rates compared with PDPs due to greater proportions of enhanced benefit plans and higher star ratings, but were also more likely to impose prior authorization on newly approved drugs.

of PA and ST and, ultimately, to lead to reduced beneficiary access to newly approved therapies in PDPs relative to MAPDs. Moreover, because MAPD plans are permitted to use savings generated in the provision of Part A and B services to subsidize Part D coverage, we expected to observe higher formulary placements among MAPDs. Findings of 2 studies suggest that MAPDs and PDPs respond to different incentives when constructing their drug formularies,[4,5] but no published studies have examined formulary adoption of newly approved drugs in the Part D marketplace.

METHODS

Selection of Drugs for Review

We selected all new drugs approved by the FDA between January 2009 and December 2013 in 8 therapeutic classes and then tracked Part D formulary coverage for these drugs through December 2014. We included 2 classes with relatively few competing products—anticoagulants and antiplatelets—as well as 2 classes with many competing products—antihyperglycemics and medications used in treating chronic obstructive pulmonary disease (COPD). We also selected 2 classes dominated by new, expensive biologic agents—disease-modifying agents used in treating multiple sclerosis (MS) and rheumatoid arthritis (RA)—and 2 CMS protected classes—antiepileptic drugs and antipsychotics. In all, we evaluated 33 drugs among the 438 products approved by the FDA during this time period.[6] Although the drug selection criteria were qualitative rather than quantitative, we believe this study will help spur additional research on the diffusion of new drug products within the Medicare marketplace.

Data Sources, Sample Selection, and Study Variables

Primary data for the study were obtained from CMS monthly formulary files for all Part D plans from 2009 through 2014. The formulary files were supplemented with annual Part D plan characteristics from CMS Part D landscape files. Data on drug approvals and National Drug Code (NDC) assignments were obtained from the FDA.[7]

To ensure consistent tracking of all time-related variables, we restricted the sample to 863 Part D plans with continuous CMS contracts over the study period (from 3728 plans in 2009 decreasing to 2660 in 2013). Continuity of contracts was determined based on unique identification (ID) numbers assigned to each Part D plan. Some plans had such short CMS contracts that we could not assess duration of formulary placement for most drugs of interest. Other contracts had gaps in coverage or changed sponsor-level names, making it impossible to accurately align formulary coverage and plan characteristics over time. The selected plans had a total Part D enrollment of 10 million in December 2009. By December 2013, enrollment in these plans reached 16.6 million, representing approximately 50% of total Medicare Part D enrollment that year.

The CMS monthly formulary files assign other unique ID numbers to each formulary. These numbers change every time there is a modification in formulary coverage, such as placing a newly approved drug. This means that, over time, all Part D plans have many formulary IDs. It was for this reason that we used the plan rather than the formulary as our unit of observation, recognizing that multiple plans may use the same formulary at any given time.

Study variables relating to timing of formulary placement included the FDA approval date, NDC assignment date, and calendar month in which each drug of interest first appeared on formulary among the 863 plans. In most cases, NDC assignment dates followed FDA approval dates by a few days, but in a few cases, the delay was 6 months or more. Because plans cannot place a drug on formulary without an NDC, we tracked Part D plan placement trends from the NDC assignment month. We measured the difference in months between the month the first Part D plan was observed to place the drug ("first adopter") and the adoption month by each subsequent plan. We used first adopter date as the baseline, rather than FDA approval or NDC assignment date, because time prior to first adoption by any Part D plan was—by definition—the same for every adopting plan. The time horizon for measuring months to formulary adoption varied from a minimum of 12 months for drugs approved at the end of 2013 up to 5 years for drugs approved in early 2009.

Drug characteristics included drug type—new chemical entity (NCE), line extension (LE), or combination product (CP)—and timing of drug approval relative to other agents in the same pharmacologic class—first in class, second in class, or third or later in class. To determine place in class, we first identified the FDA Established

Pharmacologic Class (EPC) for each drug of interest. We then searched Micromedex to identify all drugs within each EPC. Next, we identified FDA approval dates from the Drugs@FDA database.[6] For plans that did place each drug on formulary, we captured ST and PA restrictions in the initial placement month from the monthly CMS formulary files.

Finally, we captured essential characteristics of plan structure and performance. On the structural side, we classified plans as either PDPs or MAPDs and determined whether each plan provided basic or enhanced benefits at time of NDC assignment. We also classified PDPs according to whether they offered premiums at or below regional benchmarks. We assessed each plan's performance using CMS star ratings, with 5 stars representing the highest quality. We hypothesized that plans with enhanced benefits and higher star ratings would have earlier and higher formulary placement rates than basic benefit plans, benchmark plans, and those with lower star ratings. Unfortunately, we did not have information on manufacturer rebate offers and so could not model net cost as a variable in formulary placement decisions.

Statistical Analysis

Our descriptive analyses consisted of drug-by-drug tabulations of FDA approval and NDC assignment dates, months to first Part D plan formulary placement, proportion of plans adopting each drug 6 months and 12 months following first placement, and ST and PA restrictions at time of initial formulary adoption.

We employed 2-part regression models to estimate the impact of drug and plan characteristics on formulary placement (part 1) and we identified factors expected to be associated with placement (months to formulary adoption and ST and PA restrictions) for plans that added the drugs to their formularies (part 2).

To assess factors associated with formulary placement (part 1), we created a dataset of 28,479 observations (863 plans × 33 drugs), with values of 1 for plans that placed a given drug on their formularies during the study period and 0 for plans that did not. We employed a similar model structure to estimate the part 2 models. Here, plan/drug observations were restricted to plans whose formularies adopted the drugs of interest. The same strategy was used to estimate the effects of drug and plan characteristics on ST and PA restrictions. All models were estimated using ordinary least squares regression so that the magnitude of the estimated effects could be readily compared across the various models.

We note 2 reasons why the effective sample sizes for these regression models are actually smaller than the nominal samples. First, multiple plans used the same formulary in any given month. The minimum number of unique formularies among the 863 plans was 91 in March 2011; the maximum was 133 in November 2012. Second is the potential for coordinated behavior in formulary adoptions within the same Part D plan. We corrected for the effect of clustering on standard errors using the Robust command in Stata (StataCorp; College Station, Texas).

TABLE 1. Characteristics of Part D Plans Included in Study Sample

Plan Characteristics	All Plans (N = 863)	PDPs (n = 427)	MAPDs (n = 436)
Plan sponsors, n	102[a]	27	87
Sponsor contracts, n	241	31	210
Benefit type, n			
Basic benefits	262	215	47
Enhanced benefits	601	212	389
Benchmark status, n			
Benchmark plan	132	132	0
Nonbenchmark plan	731	295	436
Star rating, mean (SD)	3.36 (0.86)	2.91 (0.70)	3.81 (0.77)

MAPD indicates Medicare Advantage prescription drug plan; PDP, prescription drug plan.
[a]Note that PDP and MAPD sponsors add to more than 102 because some sponsors participated in both markets.
Source: CMS Part D landscape files for 2009-2013.

RESULTS

Table 1 presents characteristics of the 863 Part D plans included in the study sample. The plans were divided almost evenly between PDPs (427) and MAPDs (436). Together they represented 241 contracts among 102 different sponsors. The PDPs were just about evenly split between basic plans (215) and enhanced plans (212), but among MAPDs, enhanced plans predominated (389 vs 47). Benchmark plans were offered exclusively by PDPs. Plan quality measured by star ratings was substantially higher among MAPDs (a mean ranking of 3.81 stars vs 2.91 stars among PDPs).

Table 2 provides descriptive information on all drugs of interest. Most of the products were NCEs (26), with CPs (5) and LEs (2) limited to antihyperglycemic agents and drugs used in treating COPD. Among NCEs, there was a wide mix of agents that were first in class (12), second in class (5), or third or later in class (16).

NDC codes were assigned within a median of 6 days of FDA approval across all drugs reviewed. NDC assignments for every anticoagulant, antiplatelet, disease-modifying agent for MS and RA, and antihyperglycemic agent occurred within 9 days of FDA approval. However, for most COPD drugs, antiepileptics, and antipsychotics, NDC approval dates were delayed by several months (10 months in the case of ezogabine [Potiga], an antiepileptic medication). From the NDC assignment date onward, there were further delays of between 2 months (golimumab [Simponi], lacosamide [Vimpat], and asenapine [Saphris]) and 9 months (rivaroxaban [Xarelto], ticagrelor [Brilinta], indacaterol [Arcapta Neohaler], and fluticasone/vilanterol [Breo Ellipta]) before first observed formulary placement. Both the mean and median times between NDC assignment and first formulary placement was 4.6 months. Within 6 months of first placement, 56.7% of the 33 drugs had been placed on the formularies of the 863 plans under review (47.5% if drugs in protected classes are excluded). Uptake ranged from 17.7% for linagliptin (Tradjenta) to

TABLE 2. Characteristics of Drugs and Formulary Placement by 863 Part D Plans for Selected Products Newly Approved by the FDA Between 2009 and 2013[a]

Therapeutic Class and Generic (brand) Name	FDA Approval Date	NDC Assignment Date	Drug Type	Position in Class[b]	Months Between NDC Assignment and First Formulary Placement	% of Plans With Placement 6 Months Post First Formulary Placement	% of Plans With Placement 12 Months Post First Formulary Placement	% of Plans With ST Upon Placement	% of Plans With PA Required Upon Placement
Anticoagulants									
Dabigatran etexilate mesylate (Pradaxa)	10/19/2010	10/21/2010	NCE	1	5	83.2%	84.2%	1.4%	24.9%
Rivaroxaban (Xarelto)	7/1/2011	7/5/2011	NCE	1	9	79.6%	94.3%	1.3%	18.6%
Apixabam (Eliquis)	12/28/2012	1/2/2013	NCE	2	4	66.7%	76.0%	0.7%	17.7%
Antiplatelets									
Prasugrel (Effient)	7/10/2009	7/16/2009	NCE	2	4	76.8%	82.8%	0.0%	6.4%
Ticagrelor (Brilinta)	7/20/2011	7/25/2011	NCE	3	9	57.6%	64.8%	1.0%	12.4%
Disease-modifying agents for multiple sclerosis									
Fingolimod (Gilenya)	9/21/2010	9/23/2010	NCE	1	6	77.0%	80.8%	0.6%	93.8%
Teriflunomide (Aubagio)	9/12/2012	9/21/2012	NCE	1	7	54.1%	57.3%	0.0%	91.5%
Dimethyl fumarate (Tecfidera)	3/27/2013	3/29/2013	NCE	1	5	36.8%	72.7%	0.0%	89.5%
Disease-modifying agents for rheumatoid arthritis									
Golimumab (Simponi)	4/24/2009	5/1/2009	NCE	3	2	36.3%	42.3%	0.0%	93.4%
Tocilizumab (Actemra)	1/8/2010	1/15/2010	NCE	1	3	63.3%	62.5%	0.2%	93.3%
Tofacitinib (Xeljanz)	11/6/2012	11/8/2012	NCE	1	5	45.1%	46.8%	0.0%	94.5%
Antihyperglycemics									
Saxagliptin (Onglyza)	7/31/2009	8/3/2009	NCE	2	3	70.5%	86.2%	25.9%	2.7%
Liraglutide (Victoza)	1/25/2010	1/28/2010	NCE	2	3	35.0%	35.7%	18.8%	27.4%
Saxagliptin/metformin (Kombiglyze XR)	11/5/2010	11/9/2010	CP	3	4	70.8%	80.8%	24.9%	1.4%
Linagliptin (Tradjenta)	5/2/2011	5/3/2011	NCE	3	3	17.7%	39.2%	21.3%	1.7%
Exanatide ER (Bydureon)	1/1/2012	1/30/2012	LE	3	5	50.0%	66.9%	22.2%	34.0%
Linagliptin/metformin (Jentadueto)	1/30/2012	2/2/2012	CP	3	4	50.8%	65.4%	21.2%	1.9%
Alogliptin (Nesina)	1/25/2013	1/31/2013	NCE	3	4	20.8%	29.6%	34.2%	0.0%
Alogliptin/pioglitazone (Oseni)	1/25/2013	1/31/2013	CP	3	4	19.2%	29.6%	34.9%	0.0%
Alogliptin/metformin (Kazano)	1/25/2013	1/31/2013	CP	3	4	19.2%	29.6%	34.2%	0.0%
Canaglifozin (Invokana)	3/29/2013	4/1/2013	NCE	1	4	24.8%	49.6%	24.3%	9.2%
Respiratory/pulmonary agents for COPD									
Roflumilast (Daliresp)	2/28/2011	5/2/2011	NCE	1	3	33.6%	65.0%	4.2%	23.9%
Indacaterol (Arcapta Neohaler)	7/1/2011	7/21/2011	NCE	3	9	39.4%	54.9%	1.2%	8.0%
Tudorza Pressair (aclidinium)	7/23/2012	8/28/2012	NCE	2	8	45.9%	58.1%	6.8%	1.4%
Prednisone DR (Rayos)	7/26/2012	9/4/2012	LE	3	7	25.4%	26.6%	0.0%	38.0%
Fluticasone/vilanterol Breo Ellipta)	5/10/2013	7/11/2013	CP	3	9	74.0%	[c]	1.1%	0.0%
Umeclidinium/vilanterol (Anoro Ellipta)	12/18/2013	2/24/2014	NCE	1	3	56.1%	[c]	0.8%	0.8%

(continued)

TABLE 2. *(Continued)* Characteristics of Drugs and Formulary Placement by 863 Part D Plans for Selected Products Newly Approved by the FDA Between 2009 and 2013[a]

Therapeutic Class and Generic (brand) Name	FDA Approval Date	NDC Assignment Date	Drug Type	Position in Class[b]	Months Between NDC Assignment and First Formulary Placement	% of Plans With Placement 6 Months Post First Formulary Placement	% of Plans With Placement 12 Months Post First Formulary Placement	% of Plans With ST Upon Placement	% of Plans With PA Required Upon Placement
Antiepileptics									
Lacosamide (Vimpat)	10/28/2008	3/9/2009	NCE	3	2	100%	100%	6.0%	24.4%
Ezogabine (Potiga)	6/10/2011	4/17/2012	NCE	1	4	100%	100%	5.6%	20.2%
Perampanel (Fycompa)	10/22/2012	12/20/2013	NCE	1	4	100%	[c]	3.6%	36.7%
Antipsychotics									
Iloperidone (Fanapt)	5/6/2009	12/15/2009	NCE	3	3	100%	100%	30.5%	19.6%
Asenapine (Saphris)	8/13/2009	9/2/2009	NCE	3	2	95.5%	98.3%	21.9%	15.3%
Lurasidone hcl (Latuda)	10/28/2010	12/21/2010	NCE	3	3	100%	100%	21.0%	16.6%
Mean values	–	–	–	–	4.6	56.7%	64.1%	10.9%	29.8%

COPD indicates chronic obstructive pulmonary disease; CP, combination product; DR, delayed release; ER, extended release; LE, line extension; NCE, new chemical entity; NDC, National Drug Code; PA, prior authorization; ST, step therapy; XR, extended release.
[a]Restricted to plans with continuous Part D contracts over observation period.
[b]1 indicates first; 2, second; 3, third or later.
[c]Fewer than 12 months observed since first formulary placement.

100% placement for the antiepileptics and 2 of the 4 antipsychotics. The adoption rate at 12 months post NDC assignment was 64.1% (57.2% if drugs in protected classes are excluded). For 3 drugs, our observation period (January 2006-December 2014) was too short to observe formulary coverage 12 months post first formulary placement.

The final 2 columns in Table 2 present summary statistics regarding new formulary placements. The application of ST and PA restrictions differed widely by therapeutic class. Across all classes, 10.8% of plans required ST upon formulary placement versus 29.5% for PA. ST was rarely applied to anticoagulants (1.1%), antiplatelets (0.5%), MS drugs (0.2%), RA drugs (0.1%), COPD drugs (2.4%), and antiepileptics (5.1%), but was required for between 19% and 35% of all antihyperglycemic drugs and antipsychotics. PA was required by 89% or more of plans for all MS and RA drugs. Overall, antiplatelet drugs were the least restricted.

Table 3 provides a breakdown of differences in formulary adoption rates between PDP and MAPD plans. Overall, MAPDs had higher adoption rates for 28 of the 33 drugs at 6 months (59.0% vs 52.3%) and 25 drugs at 12 months (65.5% vs 60.0%). For 3 drugs, MAPDs formulary placement rates were more than double those of PDPs at 12 months. Teriflunomide (Aubagio) was placed by 66.3% of MAPDs but only 31.6% of PDPs, liraglutide (Victoza) was placed by 44.0% of MAPDs and 20.0% of PDPs, and prednisone DR (Rayos) was placed by 31.6% of MAPDs versus 13.2% of PDPs. MAPDs had higher rates of adoption for expensive biologic agents used to treat MS and RA. Drugs with significantly higher placement rates among PDPs included prasugrel (Effient) (91.4% of PDPs at 1 year versus 78.4% of MAPDs), saxagliptin/metformin (Kombiglyze XR) (88.6% vs 76.9%), and linagliptin/metformin (Jentadueto) (84.8% vs 61.1%).

Table 4 summarizes results from the regression analysis. As hypothesized, enhanced benefit plans were significantly more likely to place new drugs on formulary (model 1) compared with basic benefit plans by 4 percentage points (P <.01). At the same time, enhanced benefit plans were 2% more likely to impose ST (P <.05) and 5% more likely to impose PA (P <.01) restrictions (models 3 and 4, respectively). Benchmark plans were less likely to add newly approved drugs (–4%; P <.01), and when they did, they delayed adoption (model 2) by nearly a month (0.89 months; P <.01) compared with nonbenchmark plans. Plans with higher star ratings were also significantly more likely to place new drug products per additional star (4%; P <.01). After controlling for other plan characteristics, MAPDs were more likely to impose PA (4%; P <.01) compared with PDPs. However, the fact that MAPDs were much more likely to offer enhanced benefits and earn higher star ratings (Table 1) meant that, overall, MAPD plans had higher and earlier formulary placement rates across the 33 drugs under investigation.

Drug characteristics played a bigger role in formulary placement decisions than did plan characteristics. Compared with NCEs, LEs and CPs were much less likely to be placed on formulary (–36%; P <.01; and –22%; P <.01, respectively). However, plans placing these products did so more quickly than with NCEs (–1.04 months; P <.01; and –0.93 months; P <.01, respectively). The timing of drug approval

TABLE 3. Characteristics of Drugs and Formulary Placement by PDP and MAPD Plans[a]

Therapeutic Class and Generic (brand) name PDPs	% Plans With Placement 6 Months Post First Formulary Placement		% Plans With Placement 12 Months Post First Formulary Placement	
	MAPDs	PDPs	MAPDs	PDPs
Anticoagulants				
Dabigatran etexilate (Pradaxa)	82.9%	84.7%	88.6%	83.5%
Rivaroxaban (Xarelto)	75.0%	81.3%	97.2%	93.3%
Apixaban (Eliquis)	56.8%	70.7%	60.5%	81.3%
Antiplatelets				
Prasugrel (Effient)	90.6%	70.8%	91.4%	78.4%
Ticagrelor (Brilinta)	50.0%	60.4%	55.6%	67.8%
Disease-modifying agents for multiple sclerosis				
Fingolimod (Gilenya)	65.7%	80.0%	74.3%	82.4%
Teriflunomide (Aubagio)	29.7%	61.7%	31.6%	66.3%
Dimethyl fumarate (Tecfidera)	28.9%	37.5%	66.7%	74.5%
Disease-modifying agents for rheumatoid arthritis				
Golimumab (Simponi)	37.5%	37.8%	43.8%	43.2%
Tocilizumab (Actemra)	57.1%	65.2%	57.1%	64.3%
Tofacitinib (Xeljanz)	29.7%	50.0%	28.9%	52.6%
Antihyperglycemics				
Saxagliptin (Onglyza)	75.0%	67.4%	88.6%	84.1%
Liraglutide (Victoza)	20.0%	42.7%	20.0%	44.0%
Saxagliptin/metformin (Kombiglyze XR)	68.6%	69.4%	88.6%	76.9%
Linagliptin (Tradjenta)	5.7%	23.3%	48.6%	37.4%
Exenatide ER (Bydureon)	40.0%	56.3%	56.4%	72.6%
Linagliptin/metformin (Jentadueto)	57.5%	47.9%	84.8%	61.1%
Alogliptin (Nesina)	18.9%	21.7%	23.7%	31.3%
Alogliptin/pioglitazone (Oseni)	18.9%	19.6%	23.7%	31.3%
Alogliptin/metformin (Kazano)	18.9%	19.6%	23.7%	31.3%
Canagliflozin (Invokana)	18.4%	25.0%	38.9%	52.1%
Respiratory/pulmonary agents (COPD)				
Roflumilast (Daliresp)	22.9%	37.8%	60.0%	64.8%
Indacaterol (Arcapta Neohaler)	30.0%	43.8%	44.4%	58.9%
Aclidinium (Tudorza Pressair)	29.7%	51.1%	42.1%	63.2%
Prednisone DR (Rayos)	13.5%	29.8%	13.2%	31.6%
Fluticasone/vilanterol (Breo Ellipta)	81.6%	69.6%	[b]	[b]
Umeclidinium/vilanterol (Anoro Ellipta)	57.9%	55.4%	[b]	[b]
Antiepileptics				
Lacosamide (Vimpat)	100%	100%	100%	100%
Ezogabine (Potiga)	100%	100%	100%	100%
Perampanel (Fycompa)	100%	100%	[b]	[b]
Antipsychotics				
Iloperidone (Fanapt)	100%	100%	100%	100%
Asenapine (Saphris)	96.9%	94.4%	100%	97.7%
Lurasidone hcl (Latuda)	100%	100%	100%	100%
Mean values	54.2%	59.8%	61.9%	67.3%

COPD indicates chronic obstructive pulmonary disease; DR, delayed release; ER, extended release; MAPD, Medicare Advantage prescription drug plan; PDP, prescription drug plan; XR, extended release.

[a]Restricted to plans with continuous Part D contracts over observation period.

[b]Fewer than 12 months observed since first formulary placement.

TABLE 4. Regression Results for 4 Models Estimating the Impact of Plan Characteristics and Drug Characteristics on Study Outcomes

Variables	Models			
	(1) Formulary Placement (OLS coefficient [95% CI])	(2) Months to Formulary Placement (OLS coefficient [95% CI])	(3) ST on Placement (OLS coefficient [95% CI])	(4) PA on Placement (OLS coefficient [95% CI])
Plan characteristics				
Basic benefits (ref)	–	–	–	–
Enhanced	0.03** (0.01-0.05)	−0.28 (−0.73 to 0.17)	0.02* (0.00-0.05)	0.05** (0.02-0.08)
PDP (ref)	–	–	–	–
MAPD	−0.01 (−0.03 to 0.01)	−0.23 (−0.62 to 0.16)	0.00 (−0.02 to 0.02)	0.04** (0.02-0.07)
Nonbenchmark plan (ref)	–	–	–	–
Benchmark plan	−0.04** (−0.07 to −0.01)	0.89** (0.30-1.48)	−0.01 (−0.04 to 0.02)	0.02 (−0.02 to 0.06)
Star rating	0.04** (0.03-0.05)	−0.21 (−0.43 to 0.00)	−0.00 (−0.01 to 0.01)	−0.01 (−0.02 to 0.01)
Drug characteristics				
New chemical entity (ref)	–	–	–	–
Line extension	−0.36** (−0.38 to −0.34)	−1.04** (−1.65 to −0.43)	[a]	0.03 (−0.00 to 0.05)
Combination product	−0.22** (−0.23 to −0.21)	−0.93** (−1.28 to −0.58)	[a]	−0.36** (−0.38 to −0.35)
First in class (ref)	–	–	–	–
Second in class	0.05** (0.07-0.07)	4.53** (4.19-4.87)	0.04** (0.02-0.05)	−0.43** (−0.45 to −0.42)
Third or later in class	0.07** (0.06-0.08)	1.77** (1.50-2.05)	0.13** (0.12-0.14)	−0.23** (−0.24 to −0.21)

MAPD indicates Medicare Advantage prescription drug plan; OLS, ordinary least squares; PA, prior authorization; PDP, prescription drug plan; ref, reference; ST, step therapy.
*P <.05; **P <.01.
[a]Variable excluded from model as original version failed to converge.

relative to other drugs in class had consistently significant effects on all outcome measures. Being second and third in class increased the likelihood of placement by 5% and 7%, respectively (P <.1), but delayed placement by 4.53 months (second in class) and 1.77 months (third or later in class) (P <.01). Later entrants were also significantly more likely to be subject to ST but less likely to require PA.

DISCUSSION

Our analysis of 33 new FDA drug approvals in 8 therapeutic classes between 2009 and 2013 identified 3 sources of delay in the diffusion of new products within the Medicare marketplace. First were potential delays in assigning NDC codes to each new product. Second was the delay before the first Part D formulary places the drug. Third was the time it takes for formulary placement to diffuse within the Part D marketplace following first placement.

Normally, delays caused by failure to promptly assign NDCs are minimal, ranging from a few days to a month. Under certain circumstances, however, it can be months before NDCs are assigned. Across all of the drugs in our study sample, the mean delay between FDA approval date and NDC assignment date was 35.6 days, but this was heavily weighted by long delays for the 3 antiepileptic drugs, due in part to contention about if and where these medications were to be scheduled as controlled substances. Perampanel (Fycompa) was eventually placed into Schedule III and both exogabine (Potiga) and lacosamide (Vimpat) into Schedule V.

Delays between NDC assignment date and first Part D plan formulary placement averaged 4.6 months across the entire sample, with wide variation by therapeutic class: 2 to 4 months for antiepileptics and antipsychotics and up to 9 months for other products. The early placement of antiepileptics and antipsychotics was likely due to their protected class status. Variation in timing of first placement for drugs in nonprotected classes is more difficult to explain. One might surmise that products considered either highly efficacious or having some unique clinical advantage would be quickly adopted by plan formularies, but if that were the case, one would also expect to see a strong correlation between first placement and subsequent rapid diffusion. There was no such correlation in our data. Overall, 56.7% of all drugs had been placed on plan formularies within 6 months after first placement and 64.1% within 12 months following first placement. These adoption rates were heavily influenced by drugs in protected classes. Removing these from the averages dropped the mean adoption rate to 47.5% at 6 months and 57.2% at 12 months. As expected, the rate of adoption was fastest for LEs and CPs, as plans typically place these products on formulary without formal pharmacy and therapeutic (P&T) committee review or a waiting period.

The role that Part D plan characteristics play in formulary adoption decisions largely met our expectations. Nonbenchmark plans and those offering enhanced benefits had higher uptake rates for new drugs, as did plans with higher star ratings. After controlling for differences in plan characteristics, we found similar formulary adoption rates and time to placement among PDPs and MAPDs. However, the fact that MAPDs were predominantly enhanced benefit plans with high star ratings—both significant predictors of higher formulary placement rates—meant that MAPDs placed more new drugs on their formularies than did PDPs: 58.0% versus 52.3% at 6 months and 65.5% versus 60.0% at 12 months. Higher adoption rates for MAPDs are consistent with observations made in prior literature.[2-5] However, these earlier studies did not correlate placement rates with application of utilization management tools. The fact that MAPDs were more likely than PDPs to impose ST and PA restrictions means that patient access to some newer medications could be more limited in MAPDs.

Limitations

These results should be interpreted in light of several caveats. Most important is the fact that we evaluated a relatively small nonrandom sample of all FDA drug approvals between 2009 and 2013. Although our sample included a few LEs and CPs, it was weighted toward NCEs. Samples with different proportions of NCEs, LEs, and CPs would produce different estimates of delays in formulary placements by Part D plans.

Second, we restricted the analysis to all new approvals in just 8 therapeutic classes, albeit representative of a diverse set of classes used in treating common chronic conditions. Nonetheless, we make no claim that our results apply to therapeutic classes we did not investigate. Further research is necessary to determine whether the patterns observed in our analysis apply to other drug classes.

Third, we lacked data on final manufacturer prices (transaction prices minus rebates) faced by plans making formulary decisions for new drug products. Health plans have relatively little bargaining power when considering agents that are first in class. Subsequent approvals increase competition and generally lower acquisition prices.

Fourth, we restricted the study sample of Part D plans to those with continuous contracts from 2008 through 2013. This restriction was necessary in order to compute delays in plans' formulary adoption behavior, but it also meant that our results are not universally generalizable to all Part D plans over the study period.

Fifth, limitations in the CMS formulary files precluded any formal evaluation of generosity of coverage of newly approved drugs. The files contained tier assignment numbers. However, the interpretability of tier numbers was hampered by the fact that cost-sharing tier levels varied both across plans and within plans over time (ie, a tier number of 3 could represent either a nonpreferred brand in a 4-tier plan with a single generic tier or a preferred brand in a 5-tier plan with 2 generic tiers).

Finally, we did not consider the clinical effectiveness of new drugs for Medicare beneficiaries in plan decision making regarding formulary placements. CMS rules and conventional practice by P&T committees place clinical effectiveness at the forefront of formulary considerations,[8-10] but even when following standardized protocols for new drug evaluations, individual P&T committees may come to very different conclusions. Moreover, under CMS regulations, P&T committee decisions are recommendations that may be overruled by plan sponsors. The result is a very heterogeneous pattern of formulary adoptions of newly approved drug products across the Part D marketplace.

CONCLUSIONS

We found significant heterogeneity in formulary placement and restrictions for 33 newly FDA-approved drugs in the Part D marketplace between 2009 and 2013. Further research is necessary to determine whether this pattern applies to other drug classes. ■

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