THE HENRY J. KAISER FAMILY FOUNDATION

MEDICARE PART D 2010 DATA SPOTLIGHT

COVERAGE OF TOP BRAND-NAME AND SPECIALTY DRUGS

Prepared by Elizabeth Hargrave[i]; Jack Hoadley and Laura Summer[ii]; and Juliette Cubanski and Tricia Neuman[iii]

SEPTEMBER 2010

Medicare Part D drug plans use formularies (lists of covered drugs), cost sharing, and utilization management techniques to manage enrollees' use of drugs. As a result, beneficiary access to and out-of-pocket costs for a particular drug can vary widely from one Part D plan to another. This Part D Data Spotlight examines coverage of top brand-name and specialty drugs. The analysis is based on the authors' analysis of data from all national and near-national stand-alone prescription drug plans (PDPs) offered by Part D sponsors in 2010, representing 91 percent of all PDPs nationwide and about 87 percent of PDP enrollment.[1]

The analysis documents wide variation across PDPs with respect to coverage, tier placement, cost sharing, and the use of utilization management tools. These variations have potentially significant implications for beneficiaries' access to medications and out-of-pocket costs. This research is part of a series of data spotlights analyzing Medicare Part D plans in 2010 and key trends since 2006.[2]

TOP DRUGS

The lists of top drugs used in this analysis are based on prescriptions filled by Medicare beneficiaries in Part D plans in 2006.[3] The top brand-name drugs are the ten most common drugs that lack generic equivalents in February 2010, by number of prescriptions filled (Exhibit 1). These drugs include several cholesterol-lowering and cardiovascular drugs, as well as a proton pump inhibitor (PPI) used to treat gastrointestinal reflux and ulcers; medications used to treat dementia, depression, and bipolar disorder; a drug for treating osteoporosis; and an inhaled drug that treats asthma, emphysema, and other respiratory disorders. The median price listed by national plans on the Medicare Prescription Drug Plan Finder for each of these drugs is $200 or less for a month's supply in 2010.

Exhibit 1: Top Brand-Name Drugs in Medicare Part D Plans, 2010

Rank	Drug Name	Type of Drug	Median Listed Monthly Price
1	Lipitor	Cholesterol	$86
2	Plavix	Cardiovascular	$152
3	Nexium	PPI	$164
4	Lexapro	Depression	$86
5	Diovan	Cardiovascular	$68
6	Aricept	Dementia	$198
7	Seroquel	Atypical Anti-psychotic	$155
8	Actonel	Osteoporosis	$98
9	Advair Diskus	Respiratory	$200
10	Vytorin	Cholesterol	$104

SOURCE: Georgetown/NORC analysis of data from CMS for the Kaiser Family Foundation.
NOTE: Ranked by number of prescriptions filled by Part D enrollees in 2006, among drugs that remain on patent. Medians rounded to nearest dollar.

Exhibit 2: Top Specialty Drugs in Medicare Part D Plans, 2010

Rank	Drug Name	Type of Drug	Median Listed Monthly Price
1	Procrit	Anemia (with ESRD, cancer, HIV)	$2,409
2	Enbrel	Rheumatoid Arthritis	$1,622
3	Humira	Rheumatoid Arthritis	$1,595
4	Truvada	HIV	$975
5	Gleevec	Cancer	$3,955
6	Thalomid	Cancer	$6,576
7	Copaxone	Multiple Sclerosis	$2,611
8	Tracleer	Pulmonary arterial hypertension	$5,315
9	Reyataz	HIV	$895
10	Kaletra	HIV	$734

SOURCE: Georgetown/NORC analysis of data from CMS for the Kaiser Family Foundation.
NOTE: Ranked by total spending by Part D enrollees in 2006, among specialty drugs. Medians rounded to nearest dollar.

The top ten specialty drugs in this analysis are the drugs with the highest total spending in 2006, among those ever placed on a specialty tier (Exhibit 2).[4] These drugs include three used to treat HIV; two for rheumatoid arthritis; two for cancer; one for anemia in patients with kidney failure, HIV, and cancer; one for multiple sclerosis; and one for pulmonary arterial hypertension. None of these ten drugs are among the 100 drugs with the most Part D prescriptions in 2006, but because of their high prices, all were among the 100 drugs accounting for the most Part D costs in 2006. CMS allows plans to place drugs on a specialty tier only if their monthly cost is $600 or more; half of the ten drugs in this analysis have a median monthly price of more than $2,400.

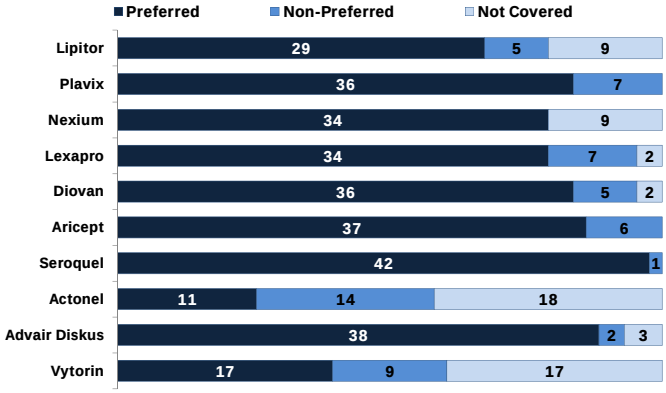
Author affiliations: [i] NORC at the University of Chicago [ii] Georgetown University [iii] Kaiser Family Foundation

As new brand and generic drugs have entered the market, we expect that the relative utilization and spending on some of these drugs may have shifted since 2006.[5] Yet these drugs all remain commonly prescribed brand and specialty drugs. They provide a snapshot of the variation in coverage among Medicare Part D plans, with implications for enrollees' medication access and out-of-pocket spending.

COVERAGE AND TIER PLACEMENT OF TOP DRUGS

Coverage. Of the top ten brand-name drugs in this analysis, three are listed on formulary by all national PDPs in 2010: Aricept, an Alzheimer's treatment; Plavix, to prevent blood clotting; and Seroquel, an anti-psychotic (which must be covered by all plans under CMS guidance for protected drug classes) (Exhibit 3). Listed by the smallest number of national plans are Actonel, an osteoporosis drug, and Vytorin, a cholesterol drug. Actonel has several alternatives within its class, including generic Fosamax (alendronate), and some PDPs apparently prefer to direct use to these other drugs. Vytorin is a combination of two cholesterol drugs, and recent studies have questioned whether it is more effective than a generic statin taken alone. The other top brands are widely covered; over two-thirds of the national plans list each on a preferred tier.

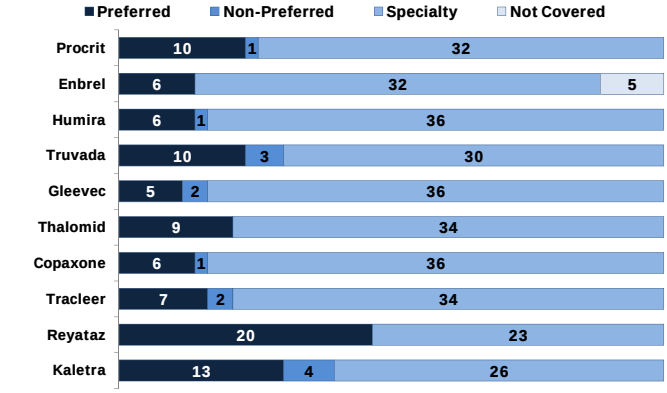
Exhibit 3
Coverage and Tier Placement of Top Brand-Name Drugs in National PDPs, 2010



SOURCE: Georgetown/NORC analysis of data from CMS for the Kaiser Family Foundation.
NOTES: "Preferred" coverage includes seven plans that do not distinguish between preferred and non-preferred brands. Five plans use the non-tiered standard benefit design and two use a single brand tier.

Of the ten specialty drugs, nine are listed on formulary by all national plans (Exhibit 4). The exception, Enbrel, is used for treating rheumatoid arthritis and other conditions. Its omission may reflect plan sponsor decisions in negotiating prices among competing drugs in the class. Humira, in the same class, is covered by all of the national plans. Similarly, Procrit, used to treat certain cases of anemia, is always covered by national plans, but closely related drugs Epogen and Aranesp are sometimes left off formularies (not shown).[6] Many top specialty drugs do not have close substitutes; half are required to be covered because they are in protected classes (HIV and cancer drugs).

Exhibit 4
Coverage and Tier Placement of Top Specialty Drugs in National PDPs, 2010



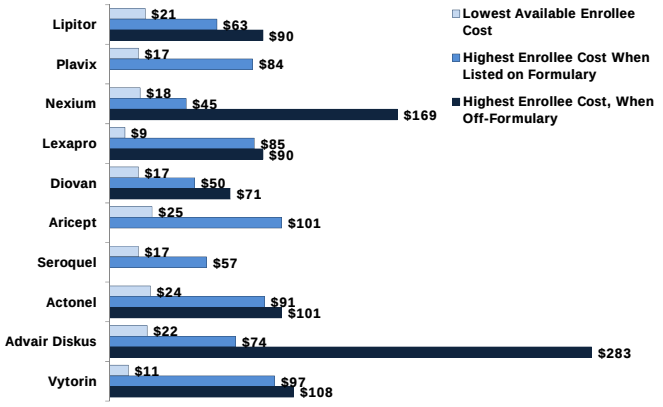
SOURCE: Georgetown/NORC analysis of data from CMS for the Kaiser Family Foundation.
NOTES: "Preferred" coverage includes seven plans that do not distinguish between preferred and non-preferred brands. Five plans use the non-tiered standard benefit design and two use a single brand tier.

Tier placement. The majority of national and near national plans (36 of 43) use a specialty tier; five others use the untiered standard benefit design with 25 percent coinsurance for all drugs, and the remaining two plans have non-specialty brand tiers with coinsurance of at least 25 percent.[7] Most plans place the top specialty drugs on a specialty tier or another tier with coinsurance most of the time. However, half of the top specialty drugs are placed on a non-specialty tier with flat coinsurance by at least some national plans – creating dramatic differences in cost sharing, as discussed in the next section.

COST SHARING FOR TOP DRUGS

Cost sharing for top drugs varies widely across plans (Exhibits 5 and 6). For all of the top brand drugs, there is at least a two-fold difference between the lowest and highest amount that an enrollee might pay, even when the drug is included on a plan's formulary. The absolute difference is highest for Vytorin, with a difference of $86 between the lowest and highest cost sharing for a month's supply of that drug. The cost differential if a drug is not covered by a plan can be even greater. The most extreme case among the top brands is Advair Diskus, which costs up to $283 for a month's supply when not covered – nearly four times as much as even the highest on-formulary cost sharing for that drug ($74).

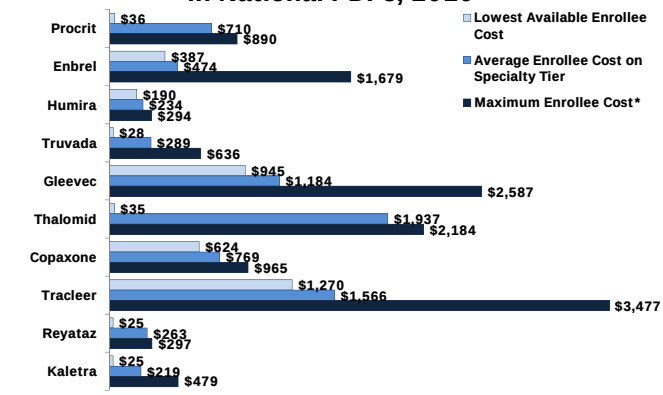
Exhibit 5
Monthly Cost Sharing for Top Brand-Name Drugs in National PDPs, 2010



SOURCE: Georgetown/NORC analysis of data from CMS for the Kaiser Family Foundation.
NOTES: Amounts shown are for top brand-name drugs based on prices found on the Medicare Drug Plan Finder.

Plans typically charge 25 percent to 33 percent cost sharing for drugs on specialty tiers, with no opportunity to appeal for a lower amount (as beneficiaries can do with drugs on other non-preferred tiers). Because these drugs are expensive, a drug's placement on the specialty tier has dramatic cost implications for enrollees (Exhibit 6). For example, the HIV drugs Kaletra and Reyataz have list prices of $734 and $895 per month, respectively. When these drugs are covered on a preferred tier, the cost sharing can be as low as $25 per month during the initial coverage period. But when they are on a specialty tier, monthly cost sharing for these drugs is typically $219 and $263, respectively – about ten times as much.

Exhibit 6
Monthly Cost Sharing for Top Specialty Drugs in National PDPs, 2010



SOURCE: Georgetown/NORC analysis of data from CMS for the Kaiser Family Foundation.
NOTES: Amounts shown are for top brand-name drugs based on prices found on the Medicare Drug Plan Finder. *For maximum enrollee cost, all of the top specialty drugs but Enbrel are on formulary.

Half of the top ten specialty drugs – Enbrel, Humira, Gleevec, Copaxone, and Tracleer – are never placed on a tier with less than 25 percent cost sharing. One plan places several of these specialty drugs on a non-preferred tier with 65 percent cost sharing, resulting in even higher expenses for enrollees taking these drugs. For example, a month's supply of Gleevec with 65 percent cost sharing costs $2,587, and a month's supply of Tracleer costs $3,477.

Part D enrollees who take expensive specialty drugs are likely to reach the coverage gap early in the year, since the gap is reached after total drug spending exceeds $2,830 in 2010.[8] For three of the top specialty drugs, beneficiaries would reach the coverage gap filling their first prescription; with any of the drugs, beneficiaries would reach the gap within four months, even in the unlikely event they took no other drugs.

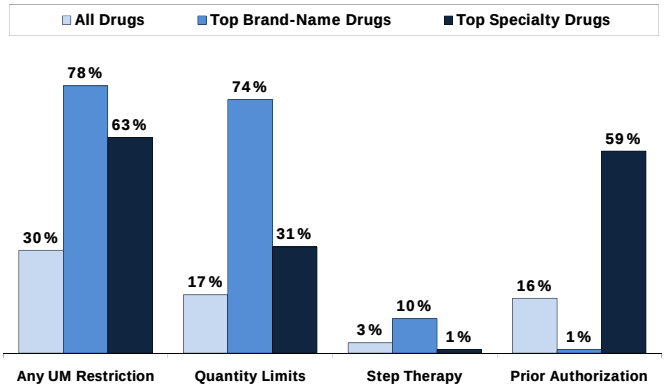
Enrollees who can afford to pay the full cost of their drugs during the gap are also likely to reach catastrophic coverage quickly, after spending $4,550 out of pocket in 2010 (less the new $250 rebate, as discussed below). Beneficiaries using Gleevec alone would reach the catastrophic coverage level in two months. Those using HIV drugs would also reach catastrophic coverage well before the year is over, based on use of any one such drug; enrollees are likely to take more than one.

COVERAGE RESTRICTIONS

Plans may use techniques such as prior authorization, quantity limits, and step therapy requirements to manage the utilization of drugs. While PDPs apply utilization management (UM) criteria to only about 30 percent of all drugs listed on their formularies,[9] most of the top drugs are generally subject to UM (Exhibit 7). In some cases, these utilization management practices may limit a beneficiary's access to a drug, even if it is listed on a plan's formulary.

Exhibit 7

Share of Formulary Drugs with Utilization Management Restrictions Across National PDPs, 2010



SOURCE: Georgetown/NORC analysis of data from CMS for the Kaiser Family Foundation; Medicare Payment Advisory Commission .
NOTES: UM is utilization management.

Quantity limits restrict how long a beneficiary can use a particular drug, the dosage that can be taken during a month, or the day's supply. This is the most commonly used UM tool for the top brands, but less common for specialty drugs. On average, plans impose quantity limits on the top brand drugs about three quarters of the time when they cover them – far more often than for all drugs (17 percent). In many cases, the quantity limits for these drugs restrict beneficiaries to purchasing a 30-day supply, whereas they might be able to buy a 90-day supply for generics. This tool is also used for all of the specialty drugs except Truvada, but never by more than half of the plans covering a drug.

Step therapy generally requires individuals to try a less aggressive or less expensive drug before the restricted drug will be covered. For both top brands and top specialty drugs, step therapy is less frequently used than quantity limits. Among the top brands, plans require step therapy about 10 percent of the time. Actonel is the most likely to have a step therapy requirement, with nearly half of the national plans covering the drug requiring step therapy. One plan, for example, requires the beneficiary to have tried using either generic Fosamax (alendronate) or the brand drug Boniva before getting approval for coverage of Actonel. Plavix and Seroquel are the only top brands that never have a step therapy requirement in any of the national plans. Among the specialty drugs, the only one with a step therapy requirement is Tracleer, in five national plans.

Prior authorization requires a doctor to communicate with the drug plan and to obtain authorization before the restricted drug will be covered. This is uncommon among the top brands, but far more common among the top specialty drugs. Only two of the top brands (Seroquel and Advair Diskus) have a prior authorization requirement, each in just one of the national plans. In contrast, four of the top specialty drugs (Procrit, Enbrel, Humira, and Copaxone) have prior authorization requirements in at least 95 percent of the national plans covering them. These requirements may specify that the drug is being prescribed for an FDA-approved (non-experimental) use and may include documentation of both specific diagnosis and clinical indicators. The three specialty drugs that never have a prior authorization requirement are all used to treat HIV. CMS notes in its guidance to plans that prior authorization and step therapy are generally not considered a best practice for these drugs.[10]

DISCUSSION

This analysis reveals wide variation across Part D plans in the coverage of commonly used drugs, in terms of formulary and tier placement, cost sharing, and utilization management. Plans may be using these tools not only to manage beneficiaries' drug use, but also as leverage for price negotiations with drug manufacturers, particularly in cases where multiple brands are available in a class. These variations also have important implications for beneficiaries' access to specific medications and out-of-pocket spending, underscoring the importance of medication-specific Part D plan comparisons. As more Part D claims analysis is completed, it will become clearer whether beneficiaries are in fact choosing the plans that offer the best coverage of drugs they are taking.

In reviewing plan bids, CMS looks at plan cost sharing in an effort to prevent discrimination against certain types of beneficiaries. For 2010, plans with cost sharing of over $45 for preferred brands or over $95 for non-preferred brands were flagged for additional scrutiny.[11] This type of review was codified by CMS in recent Part D regulations.[12] Furthermore, CMS has indicated its willingness to use authority clarified in the 2010 health care reform law (P.L. 111-148 and P.L. 111-152) to reject bids if a plan sponsor proposes a significant increase in cost sharing.[13]

The wide variation in cost-sharing amounts in 2010, particularly for specialty drugs, suggests that some selection issues for expensive drugs may remain. Plans that place expensive drugs on a tier with flat cost sharing are likely to attract a disproportionate number of beneficiaries using those drugs. A plan placing the same expensive drugs on a tier with 65 percent coinsurance is much less likely to attract users of those drugs if those beneficiaries are shopping carefully. CMS intends to give additional scrutiny in 2010 to plans that use coinsurance rather than flat dollar cost-sharing amounts.[14] This review could result in a reduction in certain plans of some of the extremely high costs faced by enrollees who use expensive drugs.

As our analysis reveals, even the best available coverage can still result in very high cost sharing for certain drugs. Half of the top specialty drugs are never placed on a tier with less than 25 percent cost sharing. The minimum beneficiary out-of-pocket cost for these drugs ranges from $190 to $1,270 per month. Even if beneficiaries have no other treatment options for their condition, they cannot appeal a drug's placement on a specialty tier in the same way that they could appeal if the drug were on a preferred or non-preferred tier.

Many beneficiaries taking these expensive drugs quickly reach the Part D benefit's coverage gap, where out-of-pocket costs rise to 100 percent of the total cost of the drug. However, changes to Part D enacted as part of the health care reform law will reduce beneficiary costs for brand-name drugs in the coverage gap from 100 percent in 2010 to 50 percent in 2011, phasing down to 25 percent by 2020. Also in 2010, beneficiaries who reach the coverage gap will receive a $250 rebate, regardless of their level of spending in the gap. These changes should be a significant help to Part D enrollees who use expensive drugs.

---

[1] The analysis is based on data for the 43 unique, national and near-national stand-alone prescription drug plans (PDPs) offered by 16 organizations in 2010. Data were collected from the Medicare Drug Plan Finder in January 2010 for zip code 21201 (Baltimore, MD). In some cases, cost-sharing amounts for a given national plan vary modestly from one region to another; drug prices also fluctuate over time and across different pharmacies and locations. These small differences would not change the overall findings of this analysis.
[2] Other Medicare Part D 2010 Data Spotlights, based on the authors' analysis of CMS data, are available at http://www.kff.org/medicare/med110909pkg.cfm.
[3] We used data compiled by CMS from 2006 Part D claims data, available in the file "Appendix.pdf" at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartDSymposiumPresentations_2008.zip
[4] We defined a specialty drug as any drug that appears on a specialty tier in at least one plan and meets CMS's cost requirement for being on a specialty tier ($600/month).
[5] Data from 2008 claims recently posted by CMS produce similar lists to those used here. Had these data been available, we would have dropped Vytorin (#11 in 2008) from the brand list in favor of Actos. For the specialty list, we would have dropped Kaletra, Reyataz, and Thalomid in favor of Atripla, Forteo, and Revlimid. It is unlikely that the results would have been significantly different.
[6] We collected data on the 40,000 units/mL version. It is also sold in a less concentrated (10000u/ml) version that is not typically on plans' specialty tiers because of its lower price. But this version often cannot be substituted for patients receiving self-administered subcutaneous injections of Procrit.
[7] For more on plan tier structures, see Hargrave et al., "Medicare Part D 2010 Data Spotlight: Benefit Design and Cost Sharing." http://www.kff.org/medicare/upload/8033.pdf
[8] The 2010 health care reform law (P.L. 111-148) provides a $250 rebate to Part D enrollees with any spending in the coverage gap in 2010.
[9] Jack Hoadley, Elizabeth Hargrave, and Katie Merrell, "Medicare Part D Benefit Designs and Formularies, 2006-2010," presentation to MedPAC, January 15, 2010, http://www.medpac.gov/transcripts/2010%20Formulary%20Analysis%20for%20MedPAC%20-%20Hoadley.pdf
[10] CMS. Medicare Prescription Drug Benefit Manual Section 30.2.5 - Six Classes of Clinical Concern., at http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf
[11] CMS guidance notes that plans may be allowed to use cost sharing amounts above these levels in one tier if they are offset by lower cost sharing in other tiers. CMS, "2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions." Memorandum from Cynthia G. Tudor, Director, Medicare Drug Benefit and C&D Data Group, to All Part D Plan Sponsors. April 16, 2010.
[12] CMS, "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs: Final Rule." Federal Register, April 15, 2010, 19677-19826.
[13] CMS, "2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions." Memorandum from Cynthia G. Tudor, Director, Medicare Drug Benefit and C&D Data Group, to All Part D Plan Sponsors. April 16, 2010.
[14] CMS, "2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions." Memorandum from Cynthia G. Tudor, Director, Medicare Drug Benefit and C&D Data Group, to All Part D Plan Sponsors. April 16, 2010.