WHITE PAPER

REVISING SPECIALTY TIERS

PROTECTING MEDICARE PART D BENEFICIARIES FROM BURDENSOME COST SHIFTING

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MAPRx
Medicare Access for Patients Rx

Navigating the Prescription Drug Program

Gary G., Michigan

Gary thought he had his financial assistance grant set up to cover his out-of-pocket costs for the product he relies on to treat his psoriasis, but then he received a $3,000 bill from his pharmacy. His grant ran out at the same time he entered the Medicare Part D coverage gap, and now he is searching for help to cover the costs of his medication. He ended up putting the $3,000 on his credit card but he says that paying it off will "wipe out" the savings he and his wife have left. He makes just over too much money from Social Security to qualify for financial assistance with his Medicare costs.

Ann B., Wisconsin

Ann was diagnosed with MS at age 40 and was forced to retire due to the physical effects of the disease. Faced with the reality of living solely on her husband's income, Ann and her husband stocked up on food and household essentials while creating a stringent budget. Ann eventually was granted benefits through Social Security Disability Insurance (SSDI), but she still struggles to pay for her MS medication because her cost sharing ranges from $350 to $1,740 per month due to her insurance plan's "tier system".

The Medicare Part D program has helped a large number of beneficiaries manage their drug expenses; nevertheless, there is a subset of Part D enrollees who have debilitating and life threatening chronic conditions—conditions like arthritis, cancer, multiple sclerosis (MS), psoriasis and hundreds of rare diseases—who continue to pay extremely high drug prices because their prescribed medication is placed on a "specialty tier" by their insurance plan. Patients with other diseases, such as lupus and Sjögren's syndrome, are waiting for new biologic drugs to be approved and also will potentially be affected by this policy.

The current specialty tier policy is flawed because it allows Part D plans to impose high coinsurance for expensive drugs, resulting in high out-of-pocket spending for beneficiaries who need drugs included on this tier. Furthermore, current policy does not allow beneficiaries to appeal a plan's cost-sharing requirements. This policy has a negative impact on all beneficiaries needing high-cost products but disproportionately impacts beneficiaries with certain chronic conditions, including some conditions that the Medicare program has identified as requiring special protections to ensure beneficiary access.

As the benefit matures, more beneficiaries are being exposed to specialty tier policies; more plans are adopting specialty tiers and are including a greater number of prescription drugs on these tiers. In 2006, only about half of all Part D plans used specialty tiers as a mechanism to manage costs and reserved them for a small group of prescription drugs. Now, nearly all Medicare Advantage Prescription Drug Plans (MA-PDs) and most Prescription Drug Plans (PDPs) employ specialty tiers. In addition, the number of drugs being placed on this tier of plans' formularies has increased over 90 percent since 2006.[1]

The specialty tier policy creates an undue burden on one of the most vulnerable populations--seniors and people affected by life-threatening diseases. In order to ensure all Part D beneficiaries are receiving needed care, the Centers for Medicare & Medicaid Services (CMS) and Congress must reconsider this policy.

PLANS USE SPECIALTY TIERS TO SHIFT COSTS TO ENROLLEES

Current Part D rules allow plans to structure their formularies with tiered cost sharing for covered drugs. The most popular benefit design for a PDP in 2013 is a five-tiered formulary, which typically includes different cost-sharing tiers for preferred generics, non-preferred generics, preferred brands, and non-preferred brands, as well as an additional "specialty" tier for high-cost drugs.[2]

Plans use specialty tiers as a mechanism to shift the expense of biologics and other high-cost drugs to beneficiaries. In order to be eligible for specialty tier placement, a drug's negotiated price must exceed $600 per month. Cost sharing for drugs on this tier is limited to 25 percent coinsurance (or up to 33 percent, if the plan lowers the deductible),[3] and plans can deny beneficiaries' requests for cost-sharing exemptions for drugs on this tier. Drugs on the specialty tier are typically biologics or highly-specialized drugs with few generic or therapeutic equivalents. Thus, beneficiaries who need specialty drugs must always pay the full cost-sharing amount.

USE OF SPECIALTY TIER GROWING IN PART D; EXPANDING IN OTHER MARKETS

Since the beginning of the Part D program, the number of plans that have adopted a specialty tier has increased dramatically. In 2006, only 50 percent of plans had a specialty tier, but by 2012 this number grew to nearly 87 percent of all Part D plans.[4] Because such a high proportion of plans have a specialty tier, most Part D beneficiaries are enrolled in a plan that has a specialty tier. Of those enrollees in plans with tiered cost sharing in 2012, approximately 90 percent of enrollees in PDPs and 99 percent of enrollees in an MA-PD were in a plan with a specialty tier.[5] Further, there has been a 94 percent increase in the number of prescription drugs included on a

EXHIBIT 1:
Plan Use of Specialty Tiers, 2010-2013

	2010	2011	2012	2013
Percentage of Plans with a Specialty Tier	84%	85%	87%	90%
Average Number of Drugs on a Designated Specialty Tier	158	171	179	194
Average Percent of Drugs on a Designated Specialty Tier	4.8% of all Part D drugs	6.4%	7.8%	8.6%

Source: Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features.

specialty tier on a plan's formulary, with the average number of drugs being 100 in 2006 and 194 in 2013.[6] Similarly, the percentage of covered drugs on specialty tier is growing—4.8 percent of Part D drugs in 2010, rising to 8.6 percent in 2013).

Cost sharing on this tier also has increased since the inception of the Part D program. According to the Kaiser Family Foundation, over 40 percent of PDP enrollees and 87 percent of MA-PD enrollees in plans with specialty tiers faced the maximum 33 percent coinsurance rate in 2012.[7] This is a significant increase from 2006, when only 4 of the 35 national or near-national PDPs charged 33 percent for specialty tier drugs.[8]

While plans operating in the commercial market do not utilize the specialty tier as frequently as in Medicare Part D, their prevalence is expected to grow. Historically, the commercial market follows trends in Medicare Part D; since 2005, the percentage of workers in an employer-based plan with 4+ tiers has more than tripled, from 4 percent to 14 percent.[9]

SPECIALTY TIER AFFECTS A SUBSET OF ENROLLEES DISPROPORTIONATELY AND IS DISCRIMINATORY

When Part D was implemented, Congress established rules to try to ensure fair access for all enrollees. The Medicare Modernization Act (MMA) required that Part D formularies include a range of drugs so that the formulary does not "substantially discourage" enrollment by any group of beneficiaries.[10] In addition, CMS created requirements that a plan's cost sharing or deductible cannot "discriminate based on health status."[11] Research has shown, however, that specialty tiers tend to impact certain groups more than others.

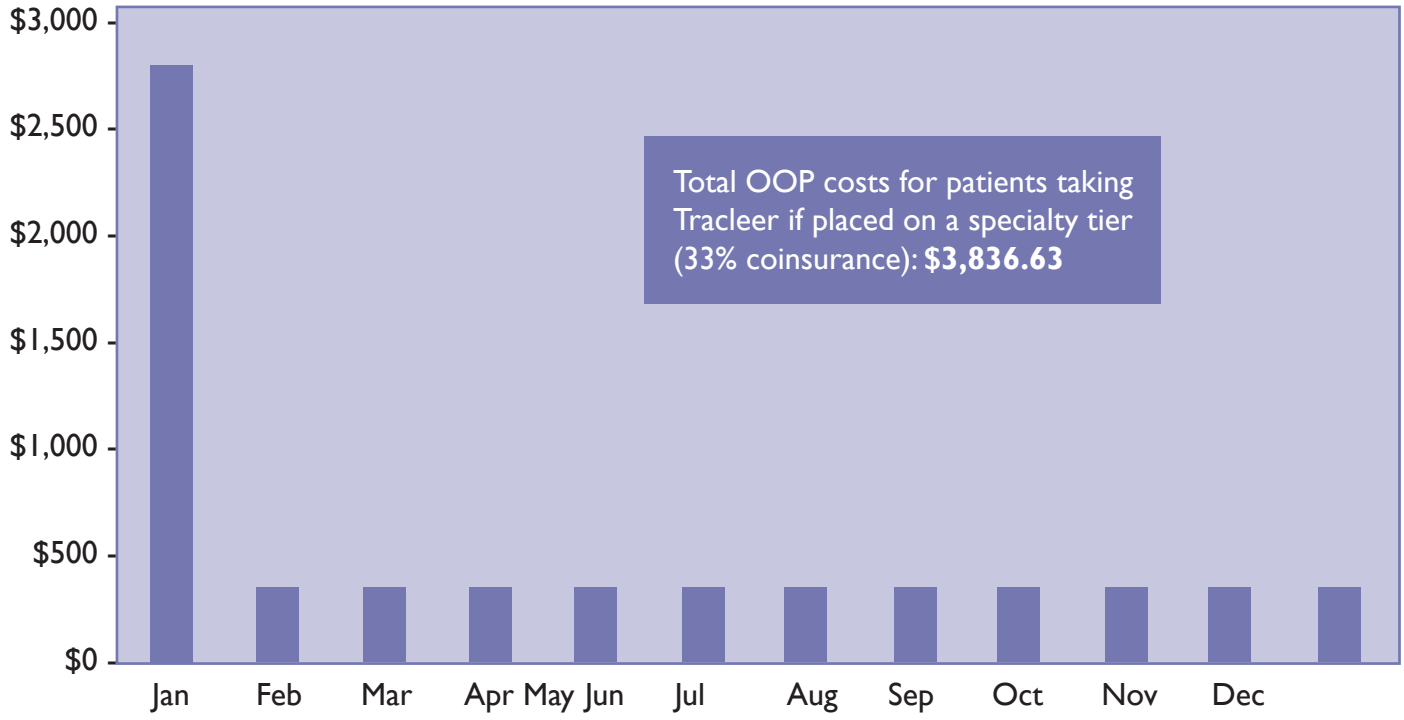
Specialty tiers do not affect all beneficiaries equally because these tiers are more heavily weighted with drugs that treat specific chronic conditions.[12] Typical classes of drugs found on specialty tiers tend to be for severe conditions, such as cancer, HIV/AIDS, rheumatoid arthritis and multiple sclerosis.[13] In fact, drugs in just four classes made up two-thirds of specialty tier drugs, including: antineoplastics, antivirals, antibacterials and immunological drugs for transplant patients.[14] Three of those classes (antineoplastics, antivirals, and immunological drugs for transplant patients) are considered protected classes, meaning that CMS requires plans to cover "all or substantially all" of the drugs in each class on formulary. CMS created additional protection for these drugs to ensure access for beneficiaries; however, the high cost sharing required for these drugs prevents many beneficiaries from accessing their prescriptions.

ENROLLEES TAKING SPECIALTY TIER DRUGS HAVE HIGH OUT-OF-POCKET (OOP) COSTS

Annual treatment costs for drugs on the specialty tier can cause financial hardship for Medicare beneficiaries. For example, Tracleer (used to treat pulmonary hypertension) costs approximately $6,826.47 a month. Even with prescription drug coverage from Part D, this beneficiary would pay $3,836.63 out of their own pocket every year for a single medication needed to treat their condition.[15] For the two-thirds of people with chronic diseases who take two or more drugs, the costs rise even higher, making needed prescriptions even more difficult to afford.[16] For many individuals, this is cost prohibitive and their only option is to stop taking these medications that are vital to their health and quality of life.

Unlike other tiers that are subject to a copayment (a flat dollar amount), beneficiaries' cost sharing for specialty tier prescriptions can range greatly depending on the negotiated drug price and coinsurance amount. Thus, two beneficiaries enrolled in different national plans could face extremely

EXHIBIT 3:
Monthly OOP Costs for a Patient Taking Tracleer



Example given uses benefit design of AARP's Medicare Rx Preferred PDP, the largest Part D plan by enrollment, which imposed 33% coinsurance for specialty tier drugs. Cost sharing is based on negotiated price for Traceleer of $6,826.47 which is the negotiated price listed on Plan Finder for this plan.

Cost-sharing amounts do not include Part D premiums.

different costs for the same drug. For example, the average monthly out-of-pocket cost for Gleevec (used to treat cancer) in 2010 was $1,184; however, some plans charged up to $2,587 for the same drug.[17] Therefore, one beneficiary may be paying almost double the amount depending on their choice of plan and the coinsurance assigned to the drug.

EXHIBIT 4:

Samples of Monthly Cost Sharing for Top Specialty Drugs in National PDPs, 2010

Indication	Drug	Median Full Cost/Month	Minimum Cost Sharing/Month	Average Cost Sharing on Specialty Tier/ Month	Maximum Cost Sharing/Month
Anemia (with ESRD, cancer, HIV)	Procrit	$2,409	$36	$710	$890
Cancer	Gleevec	$3,955	$945	$1,184	$2,587
Cancer	Thalomid	$6,576	$35	$1,937	$2,184
HIV	Kaletra	$734	$25	$219	$479
HIV	Reyataz	$895	$25	$263	$297
HIV	Truvada	$975	$28	$289	$636
Multiple Sclerosis	Copaxone	$2,611	$624	$769	$965
Pulmonary Arterial Hypertension	Tracleer	$5,315	$1,270	$1,566	$3,477
Rheumatoid Arthritis	Enbrel	$1,622	$387	$474	$1,679
Rheumatoid Arthritis	Humira	$1,595	$190	$234	$294

Select specialty tier drugs and cost sharing, based on Georgetown, NORC analysis of data from CMS for the Kaiser Family Foundation. For a list of the top 50 specialty tier drugs, see Appendix.

STATE AND FEDERAL LEGISLATORS ARE CONSIDERING LEGISLATION TO LIMIT USE OF SPECIALTY TIERS

Legislation to address the use of specialty tiers in commercial formularies was passed in the State of New York in 2010 and in Vermont in 2011.[18,19] In addition, a number of other states have introduced legislation to eliminate or restrict the use of specialty tiers, including: Arizona, California, Maine, Maryland, Mississippi, Nebraska, and Rhode Island. At the federal level, Rep. Bill Cassidy (R-LA) introduced H.R. 1239, the Accessing Medicare Therapies Act of 2013, which amends cost-sharing under a Medicare prescription drug plan to require incurred costs to include the negotiated price of a covered part D drug if the drug is: 1) classified in the highest copayment tier; 2) furnished to the individual free or at nominal charge under a compassionate treatment program; and 3) covered under the formulary of the plan, if the drug is furnished other than through such a program, or is available through exception or appeal.[20]

[1]Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. 2006 data from February 2007; 2008 data from November 2007; 2009 data from February 2009 with the incorporation of the specialty tier indicator data from April 2009; 2010 data from November 2009; 2011 data from November 2010; 2012 data from November 2011; and 2013 data from October 2012.

[2]Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. 2006 data from July 2006. 2007 data from May 2007. 2008 data from July 2008. 2009 data from November 2008. 2010 data from November 2009. 2012 data from November 2011. 2013 data from October 2012.

[3]CMS, Contract Year 2008 Call Letter, April 19, 2007.

[4]Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. 2006 data from February 2007; 2007 data from November 2006; 2008 data from November 2007; 2009 data from February 2009 with the incorporation of the specialty tier indicator data from April 2009; 2010 data from November 2009; 2011 data from November 2010; 2012 data from November 2011; and 2013 data from October 2012.

[5]Hoadley, Jack et al. *Analysis of Medicare Prescription Drug Plans in 2012 and Key Trends Since 2006.* Kaiser Family Foundation. September 2012.

[6]Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. 2006 data are from February 2007; 2008 data are from November 2007; 2009 data are from February 2009 with the incorporation of the specialty tier indicator data from April 2009; 2010 data are from November 2009; 2011 data are from November 2010; 2012 data are from November 2011; and 2013 data are from October 2012.

[7]Hoadley, Jack et al. *Analysis of Medicare Prescription Drug Plans in 2012 and Key Trends Since 2006*. Kaiser Family Foundation. September 2012.

[8]Ibid.

[9]Kaiser Family Foundation & Health Research and Educational Trust. *Employer Health Benefits: 2012 Annual Survey*. September 2012.

[10]Social Security Act, Section 1860D-11(e)(2)(D)(i).

[11]CMS. Contract Year 2009 Call Letter, March17, 2008. Available at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf.

[12]CMS. Medicare Prescription Drug Benefit Symposium: Specialty Tier Overview and Analayses. October 30, 2008.

[13]Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. Data from October 2012.

[14]Hargrave, Elizabeth et al. Drugs on Specialty Tier. Presented to the Medicare Paryment Advisory Commission on February 23, 2009.

[15]Medicare PlanFinder data for AARP Medicare Rx Preferred in ZIP Code 20036, Washington, DC. Accessed on April 24, 2013.

[16]Medco Health Solutions, Drug Trend Research Center, "Chronic Medication Nation." May 14, 2008. Available at: http://medco.mediaroom.com/index.php?s=64&cat=23.

[17]Hoadley, Jack et al. Medicare Part D 2010 Data Spotlight: Coverage of Top Brand-Name and Specialty Drugs. Kaiser Family Foundation. September 2010.

[18]New York S.5000-B/A.8278-B signed on October 2, 2010.

[19]Vermont S. 104 signed on May 26, 2011.

[20]H.R. 1239, Accessing Medicare Therapies Act of 2013. http://thomas.loc.gov/cgi-bin/thomas

REVISION OF THE SPECIALTY TIER POLICY IS NECESSARY

It is imperative that Congress consider legislation that will protect Medicare's most vulnerable, chronically ill beneficiaries. MAPRx is supportive of The Part D Beneficiary Appeals Fairness Act (H.R. 2827, introduced in the 113th Congress), which would create an appeals process for Medicare Part D beneficiaries who rely on costly prescription drugs in the specialty tiers. Specifically, the bill sponsored by Representative Hank Johnson, would allow beneficiaries to seek tiering exceptions for specialty tier drugs and prohibit any Medicare Part D Prescription Drug Plan sponsor to make any element of the tiered-cost sharing structure ineligible for an exception. MAPRx would also like Congress to examine and address issues regarding Medicare Part D cost sharing.

Revising this portion of the Part D program is will ensure that each beneficiary is receiving equitable treatment and is able to receive the proper medical care she needs.

Please consider helping to make drug access fair for everyone.

APPENDIX:

Top 50 Specialty Tier Drugs

#	Drug Name	% of Specialty Tiers
1	Revlimid	99.93%
2	Xalkori	99.90%
3	Zelboraf	99.86%
4	Tarceva	99.69%
5	Zytiga	99.69%
6	Promacta	99.59%
7	Thalomid	99.55%
8	Tracleer	99.55%
9	Enbrel	99.52%
10	Humira	99.48%
11	Avonex	99.45%
12	Kuvan	99.45%
13	Tasigna	99.41%
14	Sutent	99.31%
15	Copaxone	99.21%
16	Votrient	99.14%
17	Zolinza	99.07%
18	Sprycel	99.03%
19	Afinitor	98.97%
20	Nexavar	98.83%
21	Gleevec	98.83%
22	Actimmune	98.76%
23	Arcalyst	98.69%
24	Incivek	98.66%
25	Tykerb	98.24%

#	Drug Name	% of Specialty Tiers
26	Cerezyme	98.17%
27	Xenazine	97.86%
28	Xolair	97.31%
29	Fuzeon	97.04%
30	Valcyte	96.90%
31	Sylatron	96.86%
32	Humira Pen	96.73%
33	Pegasys	96.66%
34	Exjade	96.55%
35	Erivedge	96.52%
36	Inlyta	96.48%
37	Caprelsa	96.24%
38	Isentress	95.93%
39	Letairis	95.86%
40	Selzentry	95.59%
41	Pegasys ProClick	95.14%
42	Orfadin	94.28%
43	Adagen	94.07%
44	Intelence	93.04%
45	Atripla	92.73%
46	Truvada	91.07%
47	Somatuline Depot	90.97%
48	Somavert	90.76%
49	Leukine	90.69%
50	Complera	90.66%