

Strategic Analysis & Intelligence (SAI) Report:

The Tier 4 Phenomenon:

**Shifting the High Cost of Drugs to
Consumers**

Bill Walsh
March 9, 2009

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Preface

AARP has long been concerned that the high prices of certain prescription drugs places them out of the reach of many consumers. That concern has only heightened as specialty drugs enter the market offering remarkable breakthroughs for some of our most persistent diseases – but with price tags well beyond the means of many Americans. AARP has been among those leading the charge for comprehensive health care reform to assure that everyone, regardless of income, has a chance to obtain the best medicines available. Unfortunately, under the current U.S. health care system, coverage alone is no guarantee that consumers will be able to afford high drug or medical costs. Indeed, as specialty drug prices rise at three times the rate of inflation, employers and insurers have ramped up efforts to shift more of the costs onto consumers. One of the fastest-growing cost-shifting strategies – known as “Tier 4” pricing – is the focus of this report.

Consumers are accustomed to paying fixed-dollar co-payments at the pharmacy counter. More and more often, consumers are being asked to pay a percentage of the drug bill. Charging a percentage “coinsurance” is not new and parallels the trend in cost-sharing for all medical services. What is noteworthy and alarming, however, is that the rate has been on the rise and is being applied to some of the highest-cost drugs – breakthrough treatments for cancer, MS, AIDS, arthritis, kidney disease – those that insurers and employers list on the “fourth tier” of their drug plan formularies.

It’s become a double-whammy for consumers: To get their drugs, they are forced to pay a growing share of an ever-growing price. This year, some Medicare plans will charge more than 50 percent of the cost of their Tier 4 drugs. While some Medicare beneficiaries are partially shielded from those high cost-sharing requirements, many are not. And consumers in the commercial market, which lacks the safety-net protections of Medicare, are even more exposed at a time of economic stress.

Concerned that fourth tiers were being used to saddle consumers with an unfairly large share of drug costs, AARP asked AVOS Life Sciences to conduct a study of the Tier 4 phenomenon. AVOS looked at the pervasiveness of the Tier 4 benefit design in both the Medicare and commercial markets and analyzed the impact of high cost-sharing requirements on consumers. AVOS also conducted a survey of large employers in an effort to predict the growth of fourth tiers in the future. This report encapsulates AVOS’ findings and identifies a path forward to relieve consumers of the burden of high-cost specialty drugs.

Executive Summary

- ❖ Specialty drugs generally include prescription medicines that are used to treat complex, chronic conditions and require special administration, handling, and care management. Many specialty drugs are used to treat conditions such as cancer, rheumatoid arthritis, and multiple sclerosis that affect millions of older Americans.
- ❖ Specialty drugs are currently among the most expensive drugs on the market, with prices that can range from \$5,000 to more than \$300,000 per year. These prices are rising: Last year, prices of specialty drugs rose at three times the rate of inflation.¹
- ❖ Some 90 percent of Medicare Part D prescription drug plans² and some 10 percent of commercial health plans – covering more than 20 million Americans – have created a special pricing category for specialty and injectable drugs known as a “specialty tier” or “fourth tier.” On a fourth tier, consumers are charged an enhanced dollar co-payment or a percentage of each prescription’s cost.
- ❖ Fourth tiers often charge consumers 25 percent to 35 percent of the drug price. Already in 2009, some Medicare coinsurance rates grew significantly higher. One of the largest plans will increase coinsurance from 25 percent to 43 percent for Tier 4 drugs.
- ❖ Assuming they qualify for Medicare Part D’s safety net programs, consumers with very low incomes and assets are largely protected from specialty drug costs. But for other Medicare beneficiaries, the impact can be substantial: The annual out-of-pocket expenses for someone with \$25,000 in drug costs would be \$5,012, not including monthly premiums.
- ❖ A beneficiary who makes \$30,000 a year and doesn’t qualify for Medicare’s safety-net protections would have to forego basic living expenses to afford even “low-cost” specialty drugs. At the same time, the extra drug costs would force them even quicker into Medicare’s coverage gap, known as the “doughnut hole.”

¹ Rx Watchdog Report, “Trends in Manufacturer Prices of Specialty Prescription Drugs Used by Medicare Beneficiaries 2004 to 2007,” by Stephen W. Schondelmeyer *PRIME* Institute, University of Minnesota; Leigh Purvis, AARP Public Policy Institute; and David J. Gross, AARP Outreach & Service, September 2008.

² “Drugs on Specialty Tiers,” by Elizabeth Hargrave, Jack Hoadley and Katie Merrell, for MedPAC, February 2009, No. 09-1

- ❖ If Medicare beneficiaries get their drugs administered in a hospital or doctor's office (covered by Medicare Part B), they are subject to 20 percent cost-sharing unless they have supplemental insurance. An estimated 4.8 million Medicare beneficiaries don't carry supplemental coverage.
- ❖ Those in private health plans have no protection against high coinsurance rates at a time when wages are stagnant and average household expenses, energy prices and drug costs are rising.
- ❖ Today, the specialty drugs found on fourth tiers are used to treat conditions that affect less than 5 percent of the population, but that number is expected to grow as new drugs are approved and the drugs that are already on the market are used to treat an expanding array of conditions.

Introduction

Specialty drugs³ have allowed medical science to make enormous strides in the treatment of diseases that often affect older populations, such as cancer, rheumatoid arthritis, and multiple sclerosis. But like many breakthrough treatments, specialty drugs can carry an enormous price tag. And increasingly, that cost is being passed on to consumers.

This report found that the high level of cost sharing associated with specialty drugs on fourth tiers could force some older Americans, many of whom are on fixed incomes, to choose between life-saving drugs and basic living expenses. Consumers in the commercial market are even more exposed to specialty drugs' high costs.

Unlike in Medicare, private plans often do not have safety nets such as stop-loss or catastrophic coverage, so beneficiaries are responsible for an unlimited share of drug costs. Also unlike Medicare, there are no special subsidies for low-income consumers in the commercial marketplace. The estimated 45 million Americans without health insurance coverage are the worst off of all. For them, the prices of specialty drugs put these breakthrough treatments all-but out of reach.

Some countries have taken steps to reduce the cost of specialty drugs by creating a regulatory approval process for "generic" versions of biologic drugs known as biosimilars. The United States has not done so. Unlike traditional pharmaceuticals, which eventually face price competition from less-expensive generic versions, most specialty drugs will not face generic competition in the United States without legislative changes.

Specialty Tiers in Health Plans

Health plans have traditionally been designed using tiers that group drugs by similar cost-sharing requirements, often a three-tier design with an escalating co-payment for each tier. For example, Tier 1 drugs have the lowest copayments and are usually generic drugs. Tier 2 drugs have a higher co-payment and are "preferred" brand name drugs, or drugs that offer better value.

Tier 3 drugs, assigned the highest co-payment, are "non-preferred" brand name drugs, or drugs that are usually more expensive and lack proof of greater effectiveness than the drugs on the "preferred" brand name drug

³ Specialty Drugs generally include prescription medicines that are used to treat complex, chronic conditions and require special administration, handling, and care management.

list. Frequently plans place brand-name drugs with generic equivalents on third tiers to encourage consumers to purchase cheaper, generic versions. Some health plans have added fourth tiers as well, also known as a “specialty” tier and including more expensive specialty and injectable drugs (e.g. Ambien for insomnia, Menopur for infertility and Sotret for acne).

In some cases, plans charge consumers a fixed dollar amount for their Tier 4 drugs. Increasingly, however, they are charging a percentage and that percentage is on the rise.

In June 2008, Avalere Health reported that Medicare Part D beneficiaries pay Tier 4 coinsurance charges ranging from 25 percent to 35 percent.⁴ An analysis published in December by the AARP Bulletin showed that the level of Tier 4 coinsurance appears to be going up. The second-largest Part D plan, Humana’s Standard Option PDP serving some 1.5 million beneficiaries, went from charging 25 percent for Tier 4 coinsurance in 2008 to 43 percent in 2009.⁵

As the AARP Bulletin pointed out, the increase means that enrollees taking the cancer drug Gleevec will go from paying \$854 per month in coinsurance to \$1,366 per month. The extra cost hits seniors hard. Most are on fixed incomes and the higher drug costs forces them quickly into Medicare’s drug coverage gap, the “doughnut hole,” where they must bear 100 percent of the cost of their prescriptions.

In its own follow-up study in December, Avalere Health and the American Cancer Society concluded that the high rate of coinsurance is hitting people with cancer especially hard.⁶ The report said that Medicare stand-alone drug plans have been over the past four years shifting brand-name oral cancer drugs, including Gleevec, Sutent, Tarceva, Thalomid and Tykerb, to specialty tiers where consumers are charged a percentage of the drug cost.

In 2009, 84 percent of Part D beneficiaries are in plans that put Gleevec in a high-cost specialty tier, up from 39 percent in 2006. And, the report said, the coinsurance rates are also increasing. Between 2006 and 2009, the coinsurance charged in Part D plans for Gleevec, Sutent and Tarceva rose from 27 percent to 33 percent, placing an escalating financial load on some of the sickest beneficiaries.

⁴ “Increased Cost-Sharing and the Use of Specialty Tiers in Medicare Part D,” Avalere Health presentation, June 11, 2008.

⁵ “Medicare Part D: How to Avoid Bigger Bills,” by Patricia Barry, AARP Bulletin, Dec. 2, 2008.

⁶ “Cost Sharing for Cancer Patients in Medicare, 2009,” Avalere Health and the American Cancer Society’s Cancer Action Network, Dec. 5, 2008.

The Medicare Payment Advisory Commission, MedPAC, has also taken note of the trend in rising cost-sharing on specialty drug tiers. In a report released last month, it found that between 2006 and 2008, the percentage of Medicare MA-PDP plans with specialty tiers rose from 67 percent to 90 percent.⁷

Given that specialty drugs have prices that can range from \$5,000 to more than \$300,000 per year⁸, the financial burden that coinsurance places on consumers can be substantial. In many cases, it's prohibitive.

Specialty tiers were explicitly allowed by the Medicare Modernization Act of 2003, the legislation that created Medicare Part D. The rationale behind this provision was that catastrophic coverage, which caps beneficiaries' out-of-pocket drug expenses at 5 percent after a certain spending threshold, was seen as some measure of financial protection. But with specialty drug prices soaring,⁹ the power of such financial protections erodes.

Some very low-income Medicare beneficiaries are eligible for a subsidy that shields them from a majority of their prescription drug costs. The Medicare Part D low-income subsidy program charges co-payments of \$1 to \$5 for most prescriptions purchased by beneficiaries who: 1) Meet the asset test and, 2) Have incomes below 150 percent of the federal poverty line.¹⁰ But those beneficiaries who are disqualified by their assets or who make more than one-and-a-half times the federal poverty level remain extremely vulnerable to specialty drug-related costs.

Beneficiaries getting their drugs through Medicare's Part D are not the only ones who are vulnerable to the high cost of Tier 4 drugs. Those getting their drugs through the Part B portion of the Medicare program, which includes certain drugs that are generally administered in a hospital or doctors' office, are subject to 20 percent of the cost.

They include immunosuppressants for transplant patients and the hormone Erythropoietin (commonly known as EPO) for dialysis. Supplemental insurance coverage can help consumers pay part of the 20 percent coinsurance. But according to the Department of Health and Human Services, 11 percent of Medicare beneficiaries, or 4.8 million enrollees, lack supplemental coverage.¹¹

⁷ MedPAC Specialty Tier report, February 2009.

⁸ Rx Watchdog 2008 Specialty Drug Pricing study.

⁹ Rx Watchdog specialty drug report. The report found that in 2007, the prices that manufacturers charged to wholesalers and other direct purchases for 144 brand-name and generic specialty drugs rose 8.7 percent, or three times the rate of inflation.

¹⁰ Asset eligibility limit for 2008 was \$11,900. According to CMS Poverty Guidelines for 2008, 150 percent of the federal poverty line is \$10,400 for an individual and \$21,200 for a family of four.

¹¹ AVOS analysis of 2006 HHS data.

Specialty tiers are not restricted to Medicare plans. As is frequently the case, the commercial market is following Medicare’s lead. An estimated 10 percent of commercial plans have placed drugs on specialty tiers.¹² That level of penetration in the commercial market means that more than 20 million Americans have health insurance coverage which includes a fourth tier. The rate is expected to grow in the future as rising specialty drug prices put increasing financial pressure on employers.¹³

The Impact of Tier 4 Formularies

Biologically derived drugs, which are created from living organisms, make up the bulk of those on specialty tiers.¹⁴ The AVOS analysis found that the average annual price of the most widely used biologic drugs on a fourth tier exceeds \$20,000.

The following chart lists the annual costs of some of the most commonly used biologic drugs on fourth tiers.

The average annual cost of the most widely used biologic drugs on fourth Tiers typically exceeds \$20,000

Drug	Indication	Dosage	Red Book Price	Estimated Annual Cost*
Betaseron	MS	.25 mg/every other day	.3mg, 15s ea: \$2328.72	\$30,000
Rebif	MS	44 mcg, 3 times a week	44 mcg/0.5 ml, 0.5 ml 12s: \$2191.01	\$30,000
Avonex	MS	30 mg/week	33 mcg, 4s: \$2120.40	\$27,500
Epogen	Cancer Anemia	23-45 units per pound (body weight)	2000 u/ml, 1ml: \$29.10	\$6,000
Humira	RA	40 mg/every other wk	40 mg/.8ml, 2s ea: \$1661.92	\$22,500
Remicade	RA	3 mg/kg; wk 2, wk6, and then every 8 weeks	100 mg, ea: \$697.13	\$20,000
Enbrel	RA	50 mg/week	50 mg/ml: \$207.74	\$12,000
Rituxan	RA	375 mg/m2 given as an IV infusion weekly for 4 doses	50 ml: \$3119.38	\$30,000

*Variation can be + or - 15% or more depending on indication, duration of therapy and individual patient situation

Source: Red Book, AVOS Analysis

When these types of drug costs are examined using the standard Medicare Part D benefit, the out-of-pocket share can be substantial.

¹² Avalere Health analysis.

¹³ AVOS Life Sciences.

¹⁴ AVOS analysis of CMS data.

Assuming a level of Tier 4 coinsurance of 25 percent, a Medicare beneficiary with \$25,000 in annual drug costs would have to pay \$5,012 out-of-pocket in 2008, before monthly Medicare premiums.¹⁵

The following table illustrates how high drug costs and coinsurance would add up under the standard Medicare Part D benefit.

For a senior with total drug costs of \$25,000 per year, out-of-pocket expenditures on drugs can total as much as \$5,012 (not including Part D premium)

Part D Standard Benefit Design Parameters	2008
Deductible	\$275
Initial Coverage Limit \$2,510 (assume responsible for 25%)	\$558
Donut Hole (responsible for 100% up to \$5,726)	\$3,216
Catastrophic Coverage (responsible for 5% of remaining costs for the year - \$19,264 in this case)	\$963
Total out of pocket costs incurred by the patient for drugs:	\$5,012

Source: AVOS Analysis of CMS data. Assumes \$20,000 in specialty drug costs, which is average for a Tier 4 biologic, and \$5,000 in addition drugs, a level not uncommon for people with chronic conditions.

For many Medicare beneficiaries, the consequences of such high drug costs can be dire. A drug bill of \$5,012 would force them to choose between cutting thousands of dollars out of their basic living expenses (such as housing, food and clothing) or skimping on their medicines.¹⁶ Most consumers would find it impossible to forego such fundamental living expenses and would opt to give up their prescription drugs instead.

As the MedPAC report in February pointed out, high cost sharing will force Medicare beneficiaries into the coverage gap quicker than they would otherwise reach it. Forced to cover 100 percent of the cost of their drugs while the doughnut hole, the MedPAC report noted that some beneficiaries may simply stop taking their drugs altogether and never get out of the coverage gap.¹⁷

¹⁵ AVOS Analysis of CMS data.

¹⁶ AVOS analysis of Bureau of Labor Statistics, Consumer Expenditure Survey 2006

¹⁷ MedPAC report, p. 8.

The recession has already prompted Americans to cut back on their health care spending. A February 2009 survey by the Kaiser Family Foundation found that 53 percent of those surveyed had cut back on health care spending as the economy has worsened in the previous twelve months.

Twenty-one percent said they opted not to fill a prescription and 15 percent said that they had split pills or skipped a medication.¹⁸ Similarly, a recent study from the Commonwealth Fund found that 54 percent of Americans did not get recommended medical care, fill prescriptions or see a doctor when sick because of costs.¹⁹

A recently released CMS study found that of the Medicare beneficiaries who used specialty-tier drugs in 2007, 39 percent had assets and incomes too high to qualify for special subsidies that might shield them from high coinsurance costs.²⁰ However, most consumers in the commercial insurance market have few reliable options for coping with high drug costs. Drug companies provide free prescriptions through patient assistance programs, but income limits apply and people on Medicare are ineligible.

AVOS' research found that even when their drug costs are \$5,000 per year – on the low end of specialty drug costs for people with chronic illnesses – many older Americans would still be forced to sacrifice basic necessities. For a Medicare beneficiary making \$30,000 per year, that level of drug costs would force them to either forego their drugs or slice \$6,125 out of their basic living expenses.

When the price of the specialty medicines goes up, so does the level of basic expenses they would have to eliminate, as is illustrated by the following chart.

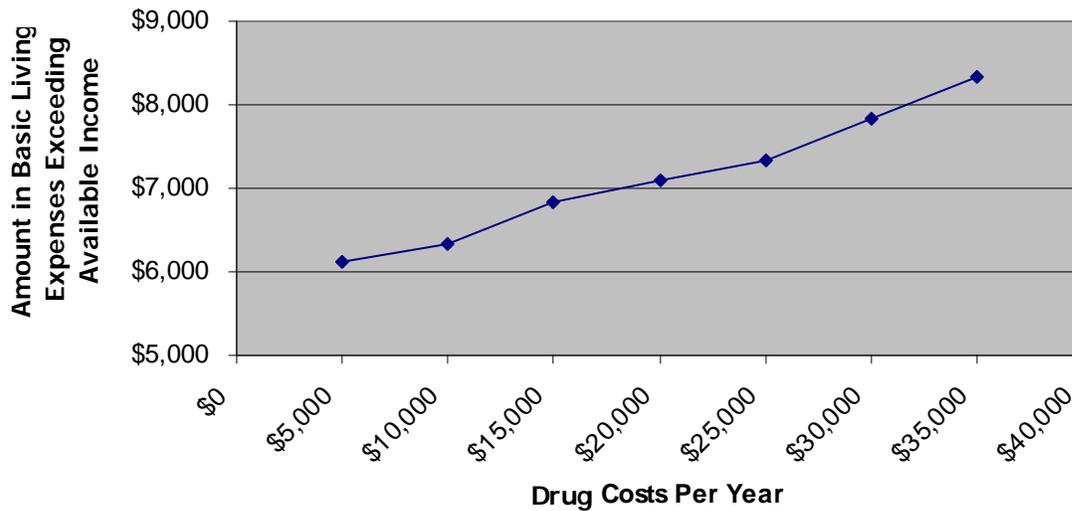
¹⁸ Kaiser Health Tracking Poll, Feb. 3-12, 2009.

¹⁹ "In Chronic Condition: Experiences of Patients with Complex Health Care Needs in Eight Countries, 2008, Health Affairs (web exclusive), Nov. 13, 2008, Cathy Shoen, M.S., et al.

²⁰ CMS, Part D Symposium Fact Sheet, 2008.

http://www.cms.hhs.gov/prescriptiondrugcovgenin/downloads/partDSymposiumFactSheet_2008.pdf

A Rising Burden: The amount a Medicare beneficiary making \$30,000 per year would have to forego in basic living expenses at various levels of drug costs



AARP chart based on AVOS analysis of CMS and BLS data

Employer Survey

In an effort to understand the forces driving the growing Tier 4 phenomenon, AVOS conducted a survey of twenty-eight large (at least 10,000 employees) service-industry and manufacturing employers. All offered health insurance coverage to their employees.

The survey, conducted via email questionnaire, found that the main reason companies wanted fourth tiers in their insurance plans was due to high drug costs. Companies also said the high Tier 4 coinsurance rates were used as a mechanism to encourage employees to consider less-expensive options, if they exist.

AVOS also conducted telephone interviews with eight large employers and employer trade groups. These companies acknowledged they were aware that, in response to high out-of-pocket costs, workers might cut back on their medicines or stop taking them altogether. While most expressed a willingness to fully cover their workers if financially feasible, the rising cost of specialty drugs is making it increasingly difficult for them to do so.

The employer survey found that while the commercial market continues to adopt Tier 4 formularies, the pace is not as fast as was seen with Medicare Part D plans. Employers were sensitive to the negative impact that would surround a coverage denial of a seriously ill employee when there were few other options for assistance in the commercial market.

It was unclear how quickly Tier 4 formularies would grow in the commercial market, but if the price of specialty drugs continues to rise at current rates, employers may have an incentive to place them on fourth tiers.

Conclusions and a Pathway Forward

Medicare beneficiaries who may have thought they were protected from high prescription drug costs may find they may have to go without basic necessities to pay for specialty prescriptions. Those in the commercial market, which lacks the basic safety-net protections offered through Medicare, are even more exposed.

If their employers decide to place specialty drugs that they need on a fourth tier, they must find a way to come up with their share of the cost, or do without. Without lower-cost alternatives, they have little choice.

One way to help consumers with the high cost of specialty drugs is to allow generic biologic drugs to enter the market. Unlike traditional chemically-derived drugs, which typically face competition from less-expensive generic versions after their patents expire, most biologic drugs are regulated by the Public Health Service Act, which currently lacks a statutory pathway to approve generic biologic drugs.

Therefore, biologic drug patent holders do not face generic competition when their patents expire, leaving them free to continue charging prices that are considerably higher than the prices of most non-biologic drugs. Some countries have already allowed biosimilars to enter the market. In the United States, legislation creating a regulatory pathway for biosimilars was introduced in 2007 and is also expected to be filed in 2009.