Specialty Tiers: Unequal Treatment

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August 2011

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This National Minority Quality Forum Issue Brief examines specialty tiering—a management tool that a health-care insurer or payer uses to limit its liability and increase the beneficiary’s share of the costs of certain prescription drugs, assigning them to a specialty reimbursement tier. In 2003, in its seminal study on health-care disparities, the Institute of Medicine cautioned: “Aspects of health systems—such as the ways in which systems are organized and financed, and the availability of services—may exert different effects on patient care, particularly for racial and ethnic minorities.”1 Specialty tiering exerts different effects by design. Public and private insurers, payers, and pharmacy benefit managers should discontinue the practice, which compromises access to quality care and increases the potential for disparate and poor health-care outcomes among minority populations, the financially less able, beneficiaries with cancer or other complex diseases that require expensive medical therapies, and those whose biologies may cause them to metabolize drugs differently.

Defining Specialty Drugs

In the 1990s health insurers began placing medications with higher-than-average prices on a specialty tier to control their financial risk by limiting beneficiaries’ access to these more expensive medications. The specialty tier was added to the standard tiers (in most cases, three: generic, branded, and preferred drugs) that health-benefit managers had previously created as devices to encourage use of less-expensive medications (Table 1). Unlike the standard tiers, which have fixed copayments, the specialty tier requires that beneficiaries pay coinsurance—a percentage of the drug price. Coinsurance means that the consumer may pay substantially more for medication; it is a cost-shifting agent whose discriminatory effect varies with the price of the drug and the economic capacity of the beneficiary.

Insurers and payers vary in how they define specialty drugs. Specialty tiers commonly include drugs that are injected, infused, taken orally, or inhaled or that require special handling, close supervision, or monitoring. Most significant, they are dis-

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<th>Tier</th>
<th>Beneficiary Payment</th>
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<tr>
<td>1</td>
<td>Lowest copayment</td>
<td>Most generic prescription drugs</td>
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<tr>
<td>2</td>
<td>Medium copayment</td>
<td>Preferred brand-name prescription drugs</td>
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<td>3</td>
<td>Higher copayment</td>
<td>Nonpreferred brand-name prescription drugs</td>
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<td>Specialty</td>
<td>Highest copayment or coinsurance</td>
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t languished from medicines on other tiers by cost. Each individual insurer or payer determines whether a drug is placed on a specialty tier. The insurer or payer does not consider beneficiary variability (ability to pay coinsurance, nature or severity of illness, or dosing requirements), which could influence the cost of treatment. This one-size-fits-all pricing strategy introduces inequalities into the plan that become more severe as the amount of the coinsurance rises.

Insurance: Risk Pooling and Sharing

In most developed countries, medical care (including drugs, devices, and professional services) is purchased primarily through insurance (either through a private insurer or through government-mandated social insurance), because the average consumer does not have the financial capacity to purchase health care in the marketplace. Group health-insurance plans have evolved in response to this incapacity, as mechanisms that benefit both the consumers and the providers of health services. The principal feature and benefit of group insurance (private or public) is the pooling and sharing of beneficiary risk. This feature allows the members—the consumers—to purchase essential and efficacious medical therapies whose costs might otherwise be prohibitive.

While the analogy is not perfect, it might be helpful to think of private health insurance as a community bank in which premiums (funds) are deposited by members or on their behalf. When the need for care arises, members can purchase health care (make a withdrawal). If the cost of care exceeds the premiums paid, the beneficiary is borrowing from the other members of the plan who at that moment may need little or no medical care. Continued deposits of premiums by all members replenish the benefit fund.

There are two types of private health plans: (1) for-profit entities, whose principal obligations are to their shareholders, and (2) nonprofit insurers, which by their charters must operate in the public interest. Both types of health plans must employ sound business practices to remain solvent. The price (the premium) of a plan’s product is informed by reimbursements for the products and services that its members use, maintenance of adequate financial reserves, administrative costs, and, for commercial plans, shareholder profits. To be successful, private plans must manage these variables.

Throughout the twentieth century, private plans used either community rating or experience rating to determine the premiums that individuals were required to pay. Under community rating, each member, regardless of health status or risk for illness, paid the same premium. This form of risk pooling enabled the insurers to balance the costs for those who needed more medical care against the costs, if any, for those who needed less. The premium reflected equal sharing of the risk. Conversely, experience-rated plans employed actuarial estimations to charge higher premiums to members who were anticipated to need more health care and lower premiums to those whose health-care needs were anticipated to be less. Plans also had the option to restrict membership, excluding people with prior conditions that could translate into costly patterns of medical utilization. Whether by a community- or an experience-rating system, the payment of the premium demanded by the insurer conferred membership in a group of beneficiaries who were distinct from the uninsured.

To revisit the banking analogy, when the need for health care arises, the member applies to the bank (the insurer) to make payment for medical products and services.
In an ideal situation, from the consumer’s point of view, all applications should be treated the same. The premium embodies the fully loaded risk, allowing each member’s request to be handled without a copayment or additional out-of-pocket expenses. Unfortunately, ideal circumstances do not prevail. More typically, at the time of service a beneficiary is faced with additional out-of-pocket expenses (deductibles, copayments, and/or coinsurance) that moderate the risk-pooling effect of insurance and introduce inequalities that can produce the Institute of Medicine’s predicted “different effects on patient care.”

**Discriminatory Effects of Cost Shifting**

Unfortunately, over the past thirty years, rather than have the full risk expressed in the premium, insurers and payers have tended to shift costs, pushing more of the costs of health care to the insured at the moment of care, in the forms of copayments, deductibles, and coverage limitations. This trend has undermined the primary benefit of health insurance to many beneficiaries: sharing of collective risk to afford what would otherwise be unaffordable.

Out-of-pocket expenses are less consequential for the more affluent, but it is well documented that those with fewer resources, with lower levels of disposable income, are more likely to forgo needed therapy as financial demands increase.³

insurance that restricts access to critical care may directly trigger acute events.

Cost-shifting agents influence the quantity and quality of health care that plan members may obtain to improve the quality and length of their lives. Some health economists contend that if these fees are set too low, they encourage consumer demand, which triggers unnecessary utilization by health-care providers, resulting in higher health-care expenditures; others argue that if the same fees are set too high, they become barriers to appropriate and essential care. Just as the absence of health insurance contributes to health disparities, cost shifting (which modifies the risk pooling of insurance) has different effects on patient care, particularly for racial and ethnic minorities. Subject to the regulating force of cost shifting, which is insensitive to beneficiaries’ circumstances, those who are insured may find at a time of need that, even though they have paid the required premium, their situation is little different from that of someone who is uninsured.

**Cost Shifting and Prescription Drugs**

In the past fifteen years, national spending on prescription drugs has grown dramatically. In response, many health-insurance plans have limited their prescription-drug benefits by aggressively using formularies, preferred-drug systems, generic-pricing systems, pharmacy networks, mail-order pharmacies (when they are less costly), disease management, and physician and patient education. These tools restrain the numbers and kinds of drugs used and lower the prices at which they are acquired from manufacturers and pharmacies. All of these tools, to some degree, work by influencing the physician’s or the consumer’s choices about what drugs are prescribed and where prescriptions are filled.⁴ Where these initiatives responsibly
influence the provider or the patient to make choices that are beneficial to the consumer and keep the premium low, they are to be applauded, but frequently these efforts deliberately shift costs to consumers, undermining the essential risk-pooling value of health insurance.

Specialty tiering is a case in point. Except where government mandates have intervened, each plan determines its own policy for specialty tiering. The most expensive medications, costing hundreds or thousands of dollars per month, are commonly tiered as specialty drugs. Specialty tiering works by shifting costs to consumers whose illnesses require them to consume products that a plan has decided should require a coinsurance rate. The member pays a percentage of the drug cost, as opposed to the typical copayment that other drugs on the plan’s formulary are assigned. From the consumer perspective, the difference between a copayment and a coinsurance rate for a medication may be significant.

Specialty tiers are problematic because they chip away at the risk-pooling effects of insurance by shifting a significant percentage of the cost of expensive medical treatments to beneficiaries, possibly forcing the less affluent to choose between paying for basic living expenses and taking their medications. The central principle of insurance is a sharing of risk among the community of beneficiaries. Insurers (public or private) violate that principle when they establish conditions that require some members at a critical time of need to pay proportionately more for medical care.

**Specialty Tiering and Unequal Treatment**

Specialty tiering promotes inequalities. Consider the example of African Americans on dialysis. African Americans are disproportionately represented among patients who have end-stage renal disease. These patients need renal replacement therapy—either a kidney transplant or dialysis. Anemia afflicts virtually all dialysis patients and is a major cause of morbidity among patients with end-stage renal disease. The treatment for their anemia is erythropoietin alpha (EPO), which increases oxygen levels in the blood. Many African Americans require a higher dosage of EPO to achieve the level recommended by clinical guidelines. EPO is an expensive medication that is frequently placed on the specialty tier, where it is subject to coinsurance. An African American beneficiary may have paid the same premium as others in the plan, but be required to pay coinsurance, rather than the standard copayment, for EPO. Because many African Americans need larger doses of EPO, they will be required to pay more coinsurance than beneficiaries who achieve the same clinical effect with less EPO. This increased burden compounds financial exposure and may compromise quality of care, safety, and longevity. Instead of spreading the risk evenly across the community of beneficiaries, in this instance specialty tiering shifts a greater burden to the African American beneficiary.

Multiple sclerosis is another example. Drugs to manage the disease may cost $3,000 or more a month. A patient with health insurance might pay a typical $55 copayment for each medication, but if the drug has been specialty tiered with a typical coinsurance rate of 25% to 33%, it would cost the patient at least $750 a month. A low-income worker may have the same benefits in a plan as a better-paid coworker, but a coinsurance cost of $750 a month could have vastly different implications for the low-income employee. Specialty tiering thus may exert different effects on patient care.
Government as Regulator

Because of the importance of health insurance to the general welfare, states have regulated private health-insurance companies and their products since the late nineteenth century. Although the federal government has historically respected the states’ role in regulating insurance, in more recent years it has begun to dominate. In regulating health insurance, states have had certain policy objectives, such as ensuring the financial solvency of insurance companies, promoting risk spreading, protecting consumers against fraud, and ensuring that consumers receive promised benefits. To achieve these ends, states have imposed mandates on health plans, requiring that they cover certain health-care providers, benefits, and patient populations. These mandates vary from one state to another. A number of states have prohibited specialty tiering, recognizing that it does not promote risk sharing.

Government as Insurer

The federal government is the single largest purchaser of health care in the United States. Between Medicare and Medicaid, it buys nearly a trillion dollars in health care annually. While government’s mission is quite different from that of a private insurer, there is a dominant school of thought that suggests that government should use its purchasing power to reduce overall consumer demand for health care by instituting price controls, shifting costs to beneficiaries in government health-care programs, and reducing the availability of new therapies. One of the major insurance programs that government manages is Medicare. It was created as a response to a serious problem: The private market did not and could not work for a large proportion of the nation’s elderly and disabled population. Given the health risks of the elderly, the premiums that plans quoted for seniors were well beyond the ability of most to pay. Medicare provided a means of
insuring tens of millions of elderly consumers who otherwise could not afford health insurance.

Medicare was designed as a social-insurance program, rather than as a social-welfare program: The program is funded, at least in part, by mandatory contributions from wage earners and employers, benefits are paid from a fund earmarked for that purpose, and Medicare pays out its benefits under the same set of rules for all qualified individuals participating in the program, regardless of health or economic circumstances. One factor that distinguishes Medicare from private insurance is that the former is mandatory. By statute, wage earners and employers must contribute. A cost-shifting agent that discriminates among beneficiaries—such as a specialty tier, which can impact those least able to pay the most—has no place in a social-insurance program. Government has a fiduciary responsibility to manage Medicare equitably. The benefit is not means tested, those with higher incomes do not pay more into the system, and certainly the distribution of the benefit should not be subject to coinsurance, which has the potential to discriminate against the financially less able, people living with diseases that require expensive medical therapy, and those whose biology causes them to metabolize drugs differently.

Medicare did not have a prescription-drug benefit until 2003. When the prescription-drug benefit was made available to Medicare beneficiaries, specialty tiering was included as cost-controlling agent. Medicare’s drug benefit was to be administered by private plans (“Medicare Part D Plans”), with oversight from the Centers for Medicare and Medicaid Services (CMS).

CMS has promulgated its formulary-review guidelines in Medicare Modernization Act Final Guidelines—Formularies, which envisions “bringing drug benefit strategies that are already providing effective coverage to millions of seniors and people with a disability to the Medicare population.” The guidelines include two key, but contradictory, objectives: “to assure that drug plans provide access to medically necessary treatments for all and do not discriminate against any particular types of beneficiaries and to encourage and support the use of approaches to drug benefit management that are proven and in widespread use in prescription drug plans today.” In the latter regard, the expectation is that utilization management will include “access to non-formulary drugs, prior authorization, step therapy, quantity limitations, generic substitution, and therapeutic interchange protocols,” as well as specialty tiers, to direct consumer demand and to share costs.

“In order to ensure that a Part D sponsor does not substantially discourage enrollment by specific patient populations reliant upon these medications,” CMS’s Medicare Prescription Drug Benefit Manual lists the following requirements for specialty-tier approval:

• Only one tier is designated a specialty tier exempted from cost-sharing exceptions.
• Cost-sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit (or an actuarially equivalent for sponsors with decreased or no deductible under alternative prescription drug coverage designs).
• Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month amount established by CMS in the annual Call Letter may be placed in the specialty tier. CMS will apply an upfront evaluation across all plans for drugs that exceed the dollar-per-month threshold and are intended for inclusion in the specialty tier.
• If not all drugs (including all strengths) within a category or class meet the criteria for inclusion in the specialty tier, the sponsor must ensure that placement of the remaining drugs among the other tiers of the formulary does not substantially discourage enrollment.”
Medicare Part D Plans are not required to grant exception requests for drugs on the specialty tier, so beneficiaries must pay the full cost-sharing amount for these expensive drugs, even if no other drug is available. The central problem with specialty tiering is not that it discourages enrollment by certain beneficiaries, but that cost sharing in insurance programs discriminates and promotes inequalities among beneficiaries. A beneficiary who succumbs to a disease that requires treatment with a drug on a specialty tier would have had a greater out-of-pocket burden than a beneficiary whose ailment could be treated with a non-specialty-tier drug. The pooling-and-sharing effect of insurance is effectively replaced with the luck of the draw. Any Medicare beneficiary who cannot pay or qualify for a program that covers the cost sharing would be denied the medication. Another group of beneficiaries would feel the financial strain, possibly having to make difficult choices among food, shelter, and paying for a medication. In the private sector, specialty tiering violates the risk-spreading principle of health insurance, but it is voluntary, and presumably consumers can shop for better a product. When government uses cost shifting to dampen consumer demand in social insurance, it is institutionalizing systemic inequalities in a mandatory program—essentially, valuing the lives and well-being of one group of citizens over another. The basic tenet of insurance is confounded by a stratification based on financial ability.

Reforming Health Care for the Twenty-First Century

The recently passed Patient Protection and Affordable Care Act has, for all intents and purposes, created a peculiarly American system of national social insurance that is mediated through private insurers. Its character will unfold in the coming years, but health insurance is now mandated. Cost shifting, which may exert different effects on patient care, particularly for racial and ethnic minorities, must be avoided. Government must not compel every citizen to contribute to a system that discriminates based on ability to pay, deploying the force of law to enforce injustice, punishing those who do not comply.

For nearly eighty years, the risk-pooling power of insurance has driven consumer demand and financed innovations in medical products and services that have brought us to the doorway of a biomedical revolution. Rather than slow down consumer demand, we must step through that doorway by finding creative ways to finance this biomedical revolution, which promises not only to conquer the diseases that have plagued us but also to drive down health-care costs in the long run. Our newly designed social insurance provides opportunities to improve health care and its delivery. We must not squander them by shifting costs and dampening consumer demand by discriminating against the disadvantaged. We must find more effective ways to contain the growth of health-care expenditures without compromising the availability and affordability of care for the patient. Specialty tiering is not a solution; it will simply exacerbate the problem in the short and the long terms.
Endnotes


