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PRESCRIPTION DRUG PRICING

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FORMULARIES

Formularies are tools used by purchasers to limit drug coverage based on favorable clinical performance and relative cost.

Formularies are lists of drug products covered by payers that distinguish between preferred or discouraged products by dividing outpatient therapies into three to five "tiers," each with a different level of patient cost sharing. The application of formularies to drug selection is similar to the application of medical treatment guidelines (used by medical specialty groups, health care providers, and insurers) to decisions about treatment regimens. Formulary selection involves an assessment of products' clinical performance and relative cost. Formularies convey substantial leverage to purchasers in negotiations with manufacturers. That leverage is the primary cost-control mechanism in Medicare Part D (the drug benefit portion of Medicare) and in most private insurance plans. Formularies limit coverage for drugs that the payer has determined do not show adequate clinical differentiation or benefit to justify the cost.

Background

Formularies have grown in importance as both drug-selection and cost-control tools over the past three decades. The emergence of formularies in the late 1980s was driven by a structural change in the drug industry—the development of several multibrand categories in which up to a half-dozen related, but not interchangeable, brands existed, with each commanding a similar price. Formularies gained prominence as a tool for purchasers to use in selecting among these treatment options, with purchasers often obtaining rebates from drug manufacturers in exchange for preferred formulary placement. The cost benefits for patients from choosing a preferred product create incentives for them to ask for specific brands and for plans to attempt to influence doctors to prescribe them.

Congress recognized the importance of formularies in the Medicare Modernization Act of 2003, which created the Part D retail prescription drug benefit (implemented in 2005). Part D's reliance on stand-alone private prescription drug plans was based on an assumption that these plans, representing large groups of beneficiaries, would be able to negotiate low prices from pharmaceutical companies in return for preferred placement on formularies. Experts also anticipated that the formulary system would increase the uptake of generic drugs by assigning generic drugs the lowest cost to patients.

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The Centers for Medicare and Medicaid Services (CMS) developed rules in 2006 to control how private plans under Part D create and manage formularies. These included rules on the composition and process for plans' Pharmacy and Therapeutics (P&T) Committees, which recommend formulary placement for individual drugs. These committees generally comprise clinicians (primary care and specialists), pharmacists, nurses, legal experts, and administrators. CMS also required annual review of Part D plan formularies to assure adequate coverage: Each formulary must include at least two products in each of fifty-seven designated major therapeutic categories.

"The original Part D legislation established six protected classes of drugs."

The original Part D legislation also established six protected classes of drugs (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants) for which plans must cover all, or substantially all, medications. This was an effort to ensure that Part D plans would provide patients with broad access to different drugs in these categories. In 2014 CMS suggested removing protections for three of the six categories but was blocked by opposition in Congress.

The endorsement of the formulary approach as a key element of Part D confirmed trends in other government programs (primarily the Department of Veterans Affairs) and the private sector and established formularies as a well-accepted component of drug selection and cost control.

Formulary Terms

PATIENT COST SHARING

Cost sharing refers to the amount the insured patient pays out of pocket at the point of sale. It can take the form of coinsurance or copays. Coinsurance is usually a percentage of the full cost of a drug; copays are a fixed amount per prescription. Coinsurance is designed to control costs by putting more of the direct cost of expensive products onto the patients who use them. In most cases, formulary drugs are organized into tiers, based on clinical assessments and negotiated prices obtained by the plans. A typical four-tier formulary might include generic, preferred brand, nonpreferred brand, and specialty tiers. Higher-price products appear on the higher tiers and carry the highest coinsurance rates.

Increasing rates of coinsurance and growth in the number of products subject to coinsurance in top formulary tiers have created potential alignment between patient advocates and drug manufacturers around the establishment of limits on the amount of drug costs that fall on patients. Such limits would shift drug expenses from the relatively small percentage of patients taking specialty drugs onto the entire insured population, through increases in other areas such as drug deductibles or full plan deductibles.

A limit on either the percentage size of coinsurance or a patient's total out-of-pocket drug spending would reduce individual patients' financial liability but would confer more upward pricing flexibility for manufacturers and would shift costs to insurers and their subscribers.

UTILIZATION MANAGEMENT

Health and drug plans employ three cost-control tools in conjunction with formularies: prior authorization, step therapy, and quantity limits. These tools restrict the stage at which a drug can be used (for example, after several precursor attempts at treatment with other therapies or non-drug approaches) or limit how much drug can be purchased on one prescription. There is recent evidence that plans use these tools more frequently in the ACA-established exchanges

than in the employer insurance sector. Part D plans are also slowly incorporating the tools, which have grown to affect 5 percent of the drugs covered by Part D plans, up one percentage point in 2016.

Trends Affecting The Future Of Formularies

RAPID CHANGES TO SPECIALTY DRUG TIERS

The standard lower formulary tiers encourage use of generics and help with selection between therapeutically similar but not interchangeable brands; the top tiers deal with specialty products. The lower tiers are well established with good operating rules and understandable, and generally well accepted, cost-sharing arrangements. The specialty area is in a more difficult and unsettled situation. The high cost-sharing formulas in the specialty tiers are a burden to patients. Some insurers' recent moves to subdivide the specialty tier into separate preferred and non preferred categories suggest that the effort to make the top tier work as a restraint on high specialty prices is still an ongoing project. Exhibit 1 shows such a five-tier formulary structure, in use in 2017 by the BlueCross BlueShield Federal Employee Program.

There is no single common definition of a "specialty" drug. Most definitions are based on five features in which high cost is primary, and there are four other corollaries: The drug must either treat a rare condition, require special handling, use a limited distribution network, or require ongoing clinical assessment. The Medicare Part D drug cost threshold generally sets a floor ($670 per month in 2017) for defining a drug as specialty.

The top tier is becoming more important as more specialty drugs enter the market and become an increasingly significant part of overall drug expenditures. In particular, a surge in orphan drug approvals has contributed to the expansion of specialty tiers; the Food and Drug Administration approved forty-six new molecular entity orphan drugs over the past thirty months.

America's Health Insurance Plans (AHIP)—the health insurance trade association—forecast in 2016 that over 250 new specialty products would reach the market between 2016 and 2020. Further, AHIP found that almost half of the 150 existing specialty drugs studied "cost in excess of $100,000 per year, with expenditures for 3 percent of the drugs studied exceeding half-a-million dollars per patient per year." MedPAC has pointed to the impact on Part D spending

EXHIBIT 1

Five-Tier Formulary Design

Tier 1	**Generic drugs:** Typically the most affordable and are equal to their brand-name counterparts in quality, performance characteristics, and intended use.
Tier 2	**Preferred brand-name drugs:** Proven to be safe, effective, and favorably priced compared to nonpreferred brands.
Tier 3	**Nonpreferred brand-name drugs:** These drugs have either a generic or preferred brand available; therefore, patients' cost share will be higher.
Tier 4	**Preferred specialty drugs:** Proven to be safe, effective, and favorably priced compared to nonpreferred specialty drugs.
Tier 5	**Nonpreferred specialty drugs:** These drugs typically have a preferred brand available; therefore, patients' cost share will be higher.

SOURCE BlueCross BlueShield Federal Employee Program (adapted).

from the recent entry of new biologics: "Between 2011 and 2014, Part D spending on biologics grew by 31 percent per year, on average. During the same period, specialty-tier drugs, some of which are biologics, grew by 37 percent per year, on average."

Insurers try to defray their rapidly escalating drug costs by increasing drug deductibles, copays, and coinsurance levels, especially on nonpreferred brand and specialty drug tiers. A recent analysis of changes in cost sharing by patients taking drugs in the nonpreferred brand tiers found a one-year increase of over 13 percent in 2016, across health exchange plans. The higher cost-sharing rates (up to 33 percent on the top specialty tiers of some formularies) create a substantial financial burden for patients receiving treatments with specialty drugs, which often address rare diseases.

COST-SHARING LIMITS

Some states have begun to address high levels of patient cost sharing for drugs through legislative or regulatory action on drug benefits in Medicaid or health exchange plans. This is a fertile area of government interest, supported by both patient advocates and drug manufacturers.

In 2015 seven states took legislative action to limit patients' out-of-pocket payments. In 2016 California adjusted rules for Covered California (the state's health exchange) to cap monthly specialty drug cost sharing at $250, create a separate pharmacy deductible, and require at least one specialty drug in each category to be included on a lower cost-sharing tier.

A NEW MODEL FOR VALUE ASSESSMENTS

The evolution and acceptance of formularies over the past three decades has been accompanied by a parallel growth and acceptance of P&T committees. This trend may lead to a new model for broader drug value assessment work. There are early efforts to create nongovernmental, independent value assessment groups. The Institute for Clinical and Economic Review, which began full public review operations in 2015, convenes meetings of appraisal committees to review the comparative effectiveness of new products and create baseline assessments of long-term societal benefits and value to short-term drug budgets. Such efforts to create neutral value-assessment groups draw heavily on the experience of P&T committees.

TARGETED THERAPEUTICS AND FORMULARIES

The trend toward very specific, targeted therapeutics for well-defined subsets of patients may change the effectiveness of formularies as a product selection tool in the future. It is a different exercise for plans to try to make substitutions among highly selective tumor-specific oncology products, for example, than to make old-style choices among a group of similar statins or even among tumor necrosis factor inhibitors.

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