AfPA
Alliance for Patient Access

AN AfPA POLICY PROPOSAL

INFORMED DRUG PRICING:

A Patient-Centered Approach to Protecting Access to Advanced Medicines

RISING MEDICATION COSTS HINDER PATIENT ACCESS

Research breakthroughs have led to the development of medications that effectively treat some of the most devastating diseases, including cancer, multiple sclerosis, and hepatitis C. However, the costs of novel prescription medications for these and other serious diseases have skyrocketed over the past two decades.[1,2]

High costs are not limited to new medications. The price of Daraprim, a 63-year-old medication to treat the foodborne illness toxoplasmosis, spiked from $1,700 to $75,000 per bottle in 2015.[3] Some other, more common medications have also experienced hikes, though few as egregious as Daraprim's. The cholesterol drug Crestor rose from $981 in 2005 to $2,169 in 2013, while methotrexate, used to treat rheumatoid arthritis and cancer, rose from $395 to $975 during the same time span.[4]

SUMMARY

- Rising costs have made new and existing medications inaccessible for many patients.
- Insurers use these costs to justify barriers to patient access, such as prior authorizations, fail first policies, non-medical switching, and specialty tiers.
- Because medication costs impact the entire population, medication pricing and insurance coverage decisions should be informed by a broad range of patient-centric opinions.
- Physicians are in a unique position to inform medication pricing and coverage decisions because of their relationship with patients and knowledge of disease states.
- Patient advocates can also contribute substantially to the medication pricing and coverage conversations given their patient-centered perspective.

High prices translate into patient access barriers in at least two ways:

1. **Health plans pass costs on to patients through increased cost-sharing for medications.** In the face of unmanageable co-pays and co-insurance requirements, patients lose access to necessary medicines through their inability to pay.

   Health plans offered through Affordable Care Act exchanges have magnified cost-sharing challenges. Research shows that typical Silver plans, most popular among those purchasing health insurance from an exchange, require 38 percent more cost-sharing than traditional, employer-sponsored plans. They also are four times more likely to have combined deductibles—pharmacy benefit plus medical benefit—which typically require cost sharing that's 130 percent higher than that of employer-sponsored plans.[5]

2. **Health plans use public scrutiny about high drug prices to justify techniques that limit access,** such as prior authorization requirements, fail-first policies, and specialty tiers. Patients may also encounter what's known as non-medical switching, where health plans change their policies to compel patients to switch from a stable medication regimen to a cheaper alternative. As concerns about drug pricing grow, these techniques may proliferate—minimizing insurers' costs by limiting an increasing number of patients from accessing their prescribed medications.

INFORMED MEDICATION PRICING AND COVERAGE DECISIONS

Given the impact of medication pricing and coverage decisions on patient access, these matters should be informed by a variety of stakeholders, including physicians, allied health care professionals and patient advocates. Health care providers understand their patients, the disease states, medications, and the impact of medication prices. They therefore have an important perspective that can inform pricing and coverage decisions. Patient advocates too have a unique perspective given their broad knowledge of patient concerns.

Involving physicians and patient advocates in these decisions may encourage practices that better enable patients to access their medications. It may also help broaden pricing and coverage conversations to more accurately reflect a decision's full impact on patient care.

In determining a new medication's price, for instance, decision makers should consider the immediate benefit and short-term cost as well as the overall treatment effect and the long-term financial impact. A drug may have an immediate benefit to a patient—addressing symptoms—as well as a more holistic benefit—stabilizing the patient to minimize the need for emergency room care, for example. Likewise, a drug will have an upfront cost as well as a long-term financial impact. In the scenario described, reducing a patient's trips to the emergency room would reduce overall costs for the patient, the insurer and the health care system.

The same broad analysis should apply to health plans. For example, as insurers consider substitution policies to lower costs, decision makers should explore the effect on both patient health and overall cost. While a less expensive drug may reduce upfront costs, it could also negatively impact patient health.

DETERMINING MEDICATION PRICES: A CASE STUDY

A 2015 *Wall Street Journal* article sheds light on the medication pricing process used by Pfizer to determine the cost of its recent breast cancer drug.[1]

The Pfizer process involved:

- An analysis of the medication's particular risk and benefit profile
- Competing drugs in the marketplace
- The likely response of health insurance companies to various price levels
- Physician input in its pricing decision.

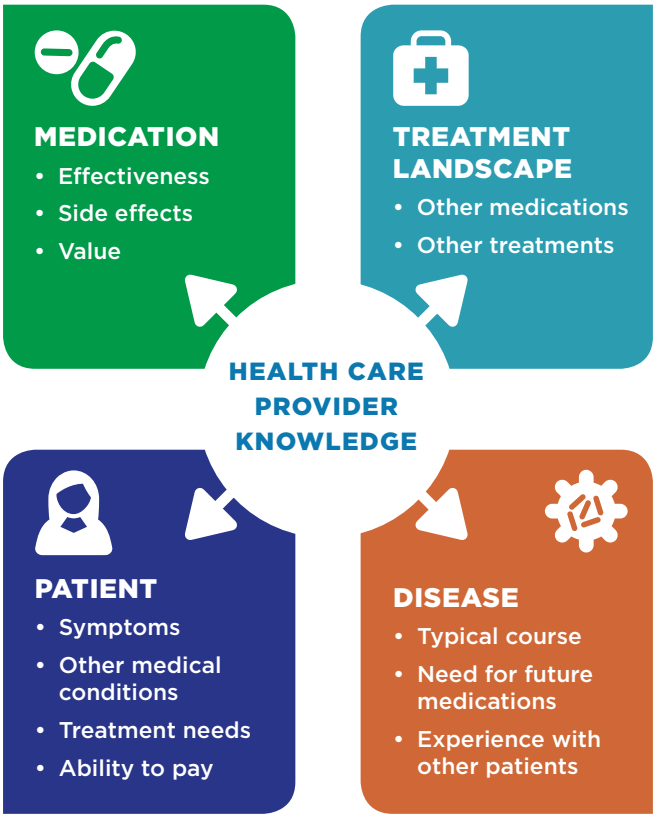
If that leads to more physician's appointments or visits to the emergency room, the policy could also increase overall health plan costs—the opposite of the insurers' intended effect.

Approaching pricing and coverage decisions from a narrow purview may result in shortsighted policies. By broadening the scope of input on these decisions, health care providers and patient advocates can also broaden the conversation so it better reflects system-wide costs and overall patient benefit.

INVOLVING HEALTH CARE PROVIDERS

Involving health care providers in medication pricing decisions makes sense because health care providers understand the disease state, therapeutic landscape, and patient needs.

Health Care Providers' Insight is Multifaceted and Valuable for Pricing Decisions



Physicians, nurse practitioners, physician assistants, respiratory therapists and other health care providers can also evaluate new medications through assessments of clinical benefits and risks, including adverse side effects. As such, physicians are in a strong position to have meaningful input in pricing decisions.

Given physicians' clinical knowledge, it is important that they have channels with which to interact with pharmaceutical companies making pricing decisions.

BARRIERS TO PHYSICIAN INVOLVEMENT

As the Pfizer process demonstrates, some companies do consult physicians within the existing framework. However, several well-intended policies may act as barriers to collaborative discussions:

- **The Physician Payments Sunshine Act** requires the manufacturers of drugs, devices, biologics, and medical supplies covered by federal programs to report physician payments to the Centers for Medicare and Medicaid Services (CMS).[6] Although this requirement was intended to prevent the undue influence of manufacturers on physician treatment practices, it unintentionally deters beneficial interactions between physicians and pharmaceutical companies. In some cases, both physicians and industry fear that the public will misinterpret beneficial interactions regarding research and education.
- **Restrictions on discussing "off-label" uses of prescription medications** can limit health care providers' understanding of a particular drug's value, in terms of both cost and treatment potential.

  Physicians can legally treat patients for "off-label" conditions—conditions other than those for which a drug is FDA approved—based on their medical judgment. Laws prohibiting manufacturers' promotion of off-label uses, however, can have the unintended consequence of curtailing physicians' understanding of a new medications' value and use. This may limit the scope of physician input on pricing decisions.

With a safe harbor provision, manufacturers could discuss off-label uses with a select group of health care providers for the sole purpose of determining pricing. These conversations could give physicians a more comprehensive perspective for evaluating a drug's value and price.

- **Academic medical centers' conflict of interest policies** can further discourage physician-industry relationships. These policies were designed to prevent excessive outside influence on the practice of medicine, and are generally important and reasonable. However, they also make physicians wary of interacting with drug manufacturers even in beneficial ways.

  For example, new medications must undergo clinical trials to be approved by the Food and Drug Administration (FDA). Often, these clinical trials occur at academic medical centers, with physicians participating as investigators and authors on the published articles. Such research and development interactions ultimately benefit patients because they help to bring new medications to the clinic. When it comes to establishing the value and price of those same medicines, physicians should be allowed to engage with the company that will bring the medicine to the clinic.

INVOLVING PATIENTS AND PATIENT ADVOCATES

Patient advocates serve and represent patients in a variety of different ways. They support patients' rights, promote patient-centered research, help patients understand their disease, and assist patients in navigating the health care system. Patient advocates increasingly serve as advisors for:

- International health organizations
- Governmental agencies
- Professional medical societies
- Insurance organizations
- Non-profit research groups
- Policy development organizations.

Often, advocates are current or former patients who have firsthand knowledge of the disease and the challenges that patients face as they undergo treatment. Advocates may also have a broad perspective based on their interactions with numerous patients, physicians, insurers, and other members of the health care system. This broad, patient-centered perspective gives patient advocates an excellent vantage point from which to contribute to the process of setting the price for new or existing therapy. Accordingly, when setting drug prices manufacturers should consult with the advocacy organizations that represent the disease for which the drug has been developed to treat.

INFORMED PRESCRIPTION DRUG COVERAGE POLICIES

The medications covered by health insurance plans are determined by pharmacy and therapeutics committees, also known as formulary committees. These committees include primary care and specialty physicians, pharmacists, and other professionals such as nurses, legal experts, and administrators.[7] These individuals develop medication formularies, or preferred medication lists, based on published evidence and professional judgment.

Members of the formulary committees are required to document potential conflicts of interest to minimize the external influence on formulary decisions.[7] In some cases, the identities of committee members are kept confidential. Although this practice has advantages, it can also appear secretive and subjective. To better develop policies that promote patient access to medications, insurers can make the process of formulary development more transparent and enlist participation from a broader range of stakeholders, including physicians and patient advocates.

INFORMED COVERAGE POLICIES: A CASE STUDY

The Centers for Medicare and Medicaid Services opens its local coverage determinations process to broad input through contractor advisory committees:

- Each state typically has its own committee, which advises the private insurers who provide local Medicare coverage.
- The committees may include a physician from each state medical society, a beneficiary representative and individuals from other affected organizations such as state hospital organizations.
- Committee leadership consists of two co-chairs, one who is the contractor medical director and another of the committee's choice.

The full committee can weigh in on coverage issues that impact health care providers across specialties, though leadership on specialty-specific coverage policies typically falls to the affected specialists. Separate from committee meetings, the group holds an open meeting that welcomes input from other stakeholders. Final coverage decisions lie with the contractor medical director, who tends to be responsive to the input of committee members.

As one physician explained, committee members "keep coverage positions current and relevant to the real world."[8]

DETERMINING COST-SHARING LEVELS IN HEALTH PLANS

Most health care benefit plans use a tier system to categorize the level of patient cost sharing. The highest level of patient co-pay, the specialty tier, is usually reserved for high cost, high value medications used to treat serious or life-threatening diseases. The high co-pays can put patients into substantial debt or even bankruptcy. In the field of cancer treatment, this is known as "financial toxicity," which many argue is on par with the toxic side effects induced by cancer chemotherapies.[9] Alternatively, many patients solve the cost problem by simply failing to fill their prescriptions for high cost medications that could help prevent progression of their disease.[10]

Typical Medication Tiers in Health Care Benefit Plans[11]

Tier	Type of medications	Beneficiary co-pay
Tier 1	Generic drugs	Lowest; typically flat rate
Tier 2	Preferred name brand drugs	Medium; typically flat rate
Tier 3	Non-preferred name brand drugs	Higher; typically flat rate
Specialty Tier	Unique, higher-cost medications, including immuno-oncology therapies	Highest; typically % of medication cost

Patients with health insurance should not have to avoid the best medications or face extreme financial stress if they develop a serious disease. Cost sharing for specialty tier medications must be made more reasonable.

One concern is that the processes health insurers use to determine levels of cost sharing are not widely known and lack transparency. Seeking input from other stakeholders when developing or changing coverage policies may help ensure that co-pays are reasonable for patients. Physicians are logical partners for this input given their knowledge of the therapeutic landscape, disease state, and, most importantly, patient needs. Patient advocates can also provide vital insight into the patient perspective, including the impact that specialty tiers and other coverage policies have on patients' ability to access the medications.

CONCLUSIONS

Patient access to medications is imperative and in the interest of all stakeholders. Given their relationship with patients and knowledge of existing treatments, physicians and other health care providers are well situated to advise pharmaceutical companies and health insurers on setting prices and coverage policies that support patient access.

Similarly, patient advocates have a unique, patient-centered perspective that can help pharmaceutical companies and health insurers understand the ways in which their pricing and coverage decisions affect patients. By involving a broader range of stakeholders, medication pricing and coverage decisions are likely to better reflect levels that patients can afford, enabling them to access medications they need.

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