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Authors

Robinson, James C

Howell, Scott

Pearson, Steven D

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VIEWPOINT

Value-Based Pricing and Patient Access for Specialty Drugs

James C. Robinson, PhD, MPH
University of California, Berkeley.

Scott Howell, MD, MBA
Novartis
Pharmaceuticals Corp,
East Hanover,
New Jersey.

Steven D. Pearson, MD, MSc
Institute for Clinical and
Economic Review,
Boston, Massachusetts.

Insurers, employers, and pharmacy benefit managers (PBMs) bemoan high prices for specialty drugs and respond by closely managing patient access to drugs through prior authorization, step therapy, and consumer cost sharing. Pharmaceutical firms are concerned when the use and sale of specific drugs fall short of projections. High prices and access barriers compound each other. Pharmaceutical firms help physicians to navigate utilization management and patients to cover their financial obligations, but then must consider the costs of these programs in subsequent prices. Payers respond to price increases by intensifying access management. Physicians and patients are caught between payers and manufacturers, facing ever-higher administrative and financial obstacles.

The list prices charged for specialty drugs have been rising rapidly in the past decade, both at the time of initial market launch and through post-launch increases.¹ Between 2005 and 2013, for example, the launch price of new oncology drugs increased 12% per year without commensurate increases in efficacy, implying that the price per life-year gained increased from \$139 000 to \$207 000.² Even after accounting for negotiated discounts and rebates, prices for major specialty drugs in the United States are substantially higher than in other developed nations.³

Insurers and PBMs are imposing intense administrative requirements on physicians prescribing specialty drugs.⁴ In 2016, 82% of 52 082 firms with 200 or more employees required prior authorization and

been interrupted. When poorly designed and implemented, step therapy programs may also make it difficult for physicians and patients to avoid having to start again with therapies that patients have already “tried and failed” before (eg, when enrolled in a different health plan). Some health insurance plans feature annual deductibles and percentage co-insurance instead of dollar co-payments. These have created meaningful financial barriers to specialty drug access. In 2016, 23% of individuals with employment-based insurance had an annual deductible of \$2000 or more⁵ and 48% of Medicare Part D enrollees were subject to percentage co-insurance for specialty drugs.⁶

The concerns of insurers, manufacturers, physicians, and patients highlight the failure of the current model of drug pricing and access in the United States. Innovative purchasers and manufacturers are potentially interested in closer and longer-term relationships that support the need of the purchasers for affordability and the need of the manufacturers for patient access and net revenue. This requires a new framework for linking price negotiations with improved patient access.

Value-Based Prices

Governmental health technology assessment entities in other nations and independent nonprofit entities, such as the Institute for Clinical and Economic Review, in the United States are calculating “value-based” benchmark prices for specialty drugs. These price benchmarks are based on assessments of the clinical and cost-effectiveness of new drugs relative to existing treatments and the prevailing standard of care. The benchmark prices frequently, although not always, are less than the list prices established by drug firms and the net prices negotiated by those firms with insurers and PBMs. Many manufacturers have been unwilling to accept

these benchmark prices because they cannot expect to achieve desired prescription volumes and revenues due to payers’ management of patient access.

It is important simultaneously to address the twin challenges of high prices and high access barriers. Voluntary contractual initiatives between individual manufacturers and payers, in which acceptance of value-based prices is accompanied by acceptance of value-based patient access, might be a way forward.

Manufacturers of specialty drugs might be willing to adopt value-based benchmark prices for their products if they could be sure that physicians and patients would face lowered restrictions on access. For their part, insurers might better facilitate patient access if they were charged value-based benchmark prices.

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68% required step therapy.⁵ Prior authorization, an administrative requirement that a physician prescribing an expensive drug obtain insurer approval to ensure the cost will be reimbursed, may require documentation that the patient has the Food and Drug Administration (FDA)-approved indication, and, in some cases, has a level of disease severity narrower than the FDA-approved indication.

Step therapy is an administrative requirement that a physician first prescribe a lower-priced drug and only move to a higher-priced alternative if the patient does not respond or develops adverse drug effects. Some step therapy programs require physicians to document the patient’s history of treatment, which can be difficult for new patients or those whose treatment has

Corresponding Author: James C. Robinson, PhD, MPH, University of California, Berkeley, 247 University Hall, Berkeley, CA 94720-7360 (James.Robinson@Berkeley.edu).

Value-Based Patient Access

A new model linking price and access would dictate that drugs priced at or below the value-based levels should face streamlined and more modest prior authorization, step therapy, and cost-sharing requirements than those prevalent in the US health care system today. Drugs priced above value-based benchmarks proposed by organizations meeting criteria for rigor and independence can continue to encounter more stringent requirements.

In particular, drugs priced at or below value-based benchmarks should have no prior authorization requirements beyond streamlined physician documentation that the prescription is made according to the FDA label (indicating diagnosis and covered patient subpopulation) and that the prescription is made by an appropriately trained clinician. Drugs priced above the value-based benchmark would continue to have current forms of prior authorization, whereby physicians may be required to supply extensive documentation of disease history and severity, test results, and patient behavioral factors. Drugs priced at or below the value-based benchmark should only be considered for step therapy in limited cases where competing drugs are also priced below the benchmark and insurers seek to reward the manufacturer willing to accept the lowest price.

Drugs priced at or below the value-based benchmark should have no consumer cost-sharing requirements beyond modest dollar

co-payments per prescription, analogous to the payments charged for generic and preferred brand drugs in today's tiered formularies. In the language of contemporary benefit design, drugs charging value-based prices should be placed in the preferred formulary tier without co-insurance. Patients whose physicians prescribe drugs not charging value-based prices, however, could continue to face co-insurance for those prescriptions.

Lower Prices and Better Access

The US pharmaceutical market has 2 major challenges: high prices for payers and high access barriers for patients. Drug manufacturers require sufficient revenues to sustain research, but can accept lower prices if clinically appropriate patients have good access to their products. Insurers require health care cost moderation but can facilitate patient access to prescribed medications if drugs are priced at value-based benchmark levels. While some payers and manufacturers may prefer the unsatisfactory status quo, others may recognize a mutual interest in more collaborative contracts that reduce prices and barriers to access. Indeed, with fewer barriers for prescribing, it is quite possible that as overall use of a drug increases, overall revenue also may increase rather than decrease. Physicians would benefit from reduced administrative burdens and patients would benefit from access to the medications they need to sustain and improve their health.

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