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Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients

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ABSTRACT The continuing launch of innovative but high-price drugs has intensified efforts by payers to manage use and spending and by pharmaceutical manufacturers to support patient access and sales. Payers are restricting drug formularies, requiring more stringent prior authorizations, and raising patient cost-sharing requirements. Manufacturers are investing in programs that help patients and physician practices navigate administrative controls and help patients meet cost-sharing obligations. Based on a compilation and analysis of the existing peer-reviewed and professional literature, this article estimates that payers, manufacturers, physicians, and patients together incur approximately $93.3 billion in costs annually on implementing, contesting, and navigating utilization management. Payers spend approximately $6.0 billion annually administering drug utilization management, and manufacturers spend approximately $24.8 billion supporting patient access in response. Physicians devote approximately $26.7 billion in time spent navigating utilization management, whereas patients spend approximately $35.8 billion annually in drug cost sharing, even after taking advantage of manufacturer and philanthropic sources of financial support. All stakeholders in the US pharmaceutical system would benefit from a deescalation of utilization management, combining lower drug prices with lower barriers to patient access.

The US is experiencing a rise in prescription drug prices and spending, fueled primarily by a wave of innovative but high-price drugs such as those for hepatitis C.[1] As a consequence, payers have intensified the use of administrative utilization management mechanisms such as formulary restrictions, prior authorization, and step edits, as well as the use of financial utilization management mechanisms such as deductibles, copayments, and coinsurance.[2,3] For instance, in 2020 the three largest pharmacy benefit managers excluded 846 drugs from their formularies, compared with 109 in 2014,[4] and one-third of large commercial payers now impose access restrictions on specialty drugs that are more stringent than those on the Food and Drug Administration (FDA) label.[5] Similarly, drug insurance benefits have increased cost-sharing requirements for less preferred agents, evolving into four- and five-tier formularies with percentage coinsurance and deductibles linked to the nondiscounted list price of the drug.[6]

As payers have intensified utilization management, pharmaceutical manufacturers have responded with programs that support patient access and sales. Many provide financial aid to eligible patients in the form of "copay cards" and drug donations through manufacturer-sponsored patient assistance programs. Manufac-

turers have also developed administrative support programs to help patients and physician practices navigate prior authorization requirements. These initiatives have induced payers to further tighten utilization management, in turn leading manufacturers to further expand their access support programs. This escalating cycle of utilization management and patient support creates significant burdens for physicians and patients. Physicians must devote extensive time seeking payers' approval for prescriptions, and patients must pay the required cost sharing or abandon their medications, resulting in adverse health impacts.

Utilization management by payers and access support by manufacturers can play positive roles in the health care system, discouraging the use of inappropriate and overpriced medications on one hand and promoting the use of effective and cost-effective medications on the other. However, the US health system is experiencing a vicious cycle of ever-higher list prices leading to ever-greater access restrictions, which in turn is prompting further price increases and even more burdensome restrictions. All stakeholders would benefit from a thoughtful moderation of this marketplace war of "all against all."

To date, there has been no comprehensive overview of the breadth and depth of payer drug utilization management initiatives, manufacturer responses, and the implications for physicians and patients. As a first step toward filling this gap, we examined the available peer-reviewed literature, industry reports, journalistic articles, and other documents to quantify and aggregate spending on utilization management and its impacts on the principal stakeholders in the pharmaceutical care system: payers, manufacturers, physicians, and patients.

Study Data And Methods

STUDY FOCUS For the purposes of this study, we use the term "drug utilization management" broadly to include both administrative mechanisms such as prior authorization and financial mechanisms such as patient cost sharing.

This study focused on the costs of implementing (payers), countering (manufacturers), navigating (physicians), and enduring (patients) drug utilization management. The available literature is incomplete and of variable quality, and a formal meta-analysis was not conducted. Importantly, key expenditure categories could not be quantified, such as those related to the clinical assessment of each new drug (payers), forgone sales (manufacturers), uncollectible copays (physicians), and treatment delays and medication abandonment (patients).

DATA SOURCES AND SEARCH METHODS A database search was conducted in Ovid for peer-reviewed articles published between 2009 and 2020. This search was performed using terms related to formulary management, utilization management, cost sharing, manufacturers' market-access strategies, copay cards, patient assistance programs, hub services, and physician and patient time related to utilization management, returning 2,239 unique citations. Articles were selected that focused on the costs, prevalence, and trends associated with utilization management and countermeasures, as well as the impact of these initiatives on physicians and patients. From this screening, forty-eight publications were identified for full-text review.

A manual search was also performed of reports, news articles, and blog posts published by think tanks, foundations, academic centers, government agencies, advocacy groups, and conferences. Additional sources were identified through this search (for example, for potentially relevant journals not included in Ovid) and through a review of the citations included in peer-reviewed and non-peer-reviewed publications (for example, using the snowball search method). As a result, 116 new citations were identified, leading to the review of 164 full-text publications. The online appendix describes our sources, search terms, selection criteria, and methods in greater detail.[7]

We compiled estimates of spending related to drug utilization management based on the twenty-two publications that had what we considered to be the most reliable data and methods. Our professional judgment was used in assessing the quality of particular estimates, especially those derived from journalistic articles or industry white papers. If we found more than one estimate for the same component of spending, we used the average value of all relevant estimates. The appendix describes in detail how we derived point estimates in cases where multiple possible values were available from the literature.[7] If no quantitative estimate was available for a component, it was excluded from the analysis. All costs were annualized and then normalized to 2019 values, using the Consumer Price Index for All Urban Consumers all items index from the Bureau of Labor Statistics.

LIMITATIONS Our study had several limitations. First, although we conducted an extensive compilation and analysis of peer-reviewed papers, industry reports, journalistic articles, and other documents, this was not a systematic review, and some publications may have been missed. Second, many of the relevant materials came from journalistic, consultant, and industry sources that gave no details on where they ob-

tained their numbers. Third, as individual components of spending come from different sources that may use very different methods, there is the potential for overlap. Finally, numerous expenditures could not be quantified; thus, we believe that our findings represent an underestimation, and perhaps a major underestimation, of the full cost of drug utilization management.

Study Results

Exhibit 1 depicts the utilization management process in a simplified form. The process begins when the patient seeks the clinical advice and support of a physician. The physician must then submit the prescription for approval to the insurer or pharmacy benefit manager, often with documentation from electronic medical records, treatment history including prior use of other drugs, and laboratory test results. If the prior authorization criteria are not met, the prescription is rejected. The physician can appeal the rejection on behalf of the patient, providing more documentation or discussing the case with the payer's medical director, or they can abandon the prescription. If the prescription meets the payer's criteria and is accepted, the patient must decide whether the required cost sharing is affordable. If it is not affordable, the patient can seek financial support from the drug manufacturer or, in some cases, an independent charitable foundation, or they can abandon the prescription. The outcome of the process is that either a drug is dispensed or it is abandoned, entailing extensive time and administrative expense in either case.

Exhibit 2 summarizes the components of utilization management that could be quantified in this study, as well as those for which no reliable estimates could be found. The appendix describes the process of utilization management and manufacturer access support programs, plus the assumptions and methodology of this study, in greater detail.[7]

OVERVIEW OF SPENDING RELATED TO UTILIZATION MANAGEMENT Payers, manufacturers, physicians, and patients annually incur costs of approximately $93.3 billion in administering, countering, navigating, and enduring drug utilization management. This estimate constitutes a lower bound to total spending, as many components of the utilization management cycle could not be quantified. To place this figure in context, in 2019 the US spent approximately $409 billion on branded drugs, including retail and nonretail (for example, physician-administered) prescriptions.[6] The US spent another $102 billion on generic drugs, but these typically are not the target of payer utilization management.[6]

Exhibit 3 summarizes our estimates of the costs incurred by each of the four stakeholder groups in implementation, counterinitiatives, navigation, and compliance with drug utilization management. Further details are in the appendix.[7]

SPENDING BY PAYERS We estimate that payers spend $6.0 billion each year on the administration of drug prior authorization.[8–13] This is based on the volume of rejected prior authorization requests per year and the average of the cost

EXHIBIT 1

The process and outcomes of drug utilization management, by stakeholder

Stakeholders	Prescription process initiation	Prior authorization process	Cost-sharing assessment	Prescription process outcomes
Patients	Meet with doctor to obtain diagnosis and prescription	Provide necessary information and await approval to begin drug treatment	Seek copay support or use personal funds	If prior authorization approved and copay affordable, fill prescription. Otherwise, prescription is abandoned
Physicians	Prescribe drug based on diagnosis	Initiate prior authorization process electronically or manually	Help patient identify copay support, seek to collect copay	If prior authorization denied or copay not affordable, discuss alternatives with patient
Payers	Apply formulary, prior authorization, and cost-sharing policies	Assess physician documentation and authorize or deny request	Require physician or pharmacy to collect copay	If prior authorization approved and patient can afford copay, pay claim; otherwise, claim is not paid
Manufacturers	Promote drugs and educate physician practices about payer utilization management policies	Work with physicians to navigate prior authorization process	Provide copay support to eligible patients	If prior authorization approved and patient can afford copay, drug dispensed; otherwise, drug is not dispensed

SOURCE Authors' analysis.

EXHIBIT 2

Components of drug utilization management, by stakeholder

Stakeholders	Components quantified	Components that could not be quantified
Payers	Cost of administering prior authorization (notes 8–13)	Administration of other drug utilization management components, such as step edits Administration of patient cost-sharing programs Administrative activities required to set utilization management policies
Manufacturers	Cost to provide or maintain administrative support services (for example, hub services) to help navigate utilization management (notes 15–17) Cost of providing direct financial assistance (for example, copay cards) to commercially insured patients (notes 18 and 19) Cost of donating drugs to insured patients via manufacturer-sponsored patient assistance programs (notes 21–24)	Reduced sales on prescriptions that failed prior authorization or to which patients did not adhere because of cost sharing
Physicians	Cost of time spent interacting with payers on drug utilization management, including both physician and staff time (notes 25–29)	Cost of time spent with patients to explain benefits and identify alternative drugs Cost of time spent interacting with payers and pharmacies over step edits and other aspects of utilization management
Patients	Out-of-pocket expenses, including payments made for deductible, copay, and coinsurance provisions but not including copay for common nonspecialty drugs (tier 1 copays) (notes 6 and 30)	Time spent collaborating with physicians to obtain prior authorization from payers Adverse health outcomes due to potential delays in treatment, use of suboptimal medicine, or medication abandonment

SOURCE Authors' review of data from the sources indicated (numbers refer to endnotes in the text).

per rejected claim for manually and electronically submitted requests. Manual requests are substantially more expensive to process than their electronic counterparts. We did not include spending by payers on prior authorization requests that were accepted on the first pass, as this could not be measured and was assumed to be small. Our estimate does not include the cost of administering other utilization management policies aside from prior authorization, such as step edits and quantity limits, because of a lack of relevant studies. It also does not include the cost of administering patient cost-sharing programs or the cost of initially establishing utilization management policies, such as the time devoted by pharmacy and therapeutics committees and internal payer finance and contracting teams. As a result, the $6.0 billion figure represents a conservative estimate of the total spending by payers. For context, according to data from the Centers for Medicare and Medicaid Services' National Health Expenditure Accounts, govern-

EXHIBIT 3

Annual spending related to drug utilization management by each stakeholder group

Stakeholders and descriptions	Cost ($ billions)
Payers	
Cost of administering prior authorizations	6.0
Manufacturers	
Cost of administrative support programs that help physician practices and patients navigate utilization management	5.0
Cost of direct financial payments to assist commercially insured patients in meeting copay or coinsurance requirements	13.6
Cost to provide insured patients with free medications through manufacturer-sponsored patient assistance programs	6.2
Physicians	
Cost of physician practices' time interacting with payers over prior authorization	26.7
Patients	
Patient spending on branded drug cost sharing after taking advantage of manufacturer-financed copay support	35.8
Total	93.3

SOURCE Authors' review of data from the sources indicated in exhibit 2. **NOTE** All spending was inflated to 2019 US dollars, using the Consumer Price Index for All Urban Consumers all items index from the Bureau of Labor Statistics.

ment and private insurers spent a total of $306 billion in 2018 for all administrative purposes.[14]

SPENDING BY MANUFACTURERS We estimate that pharmaceutical manufacturers spend $24.8 billion annually on administrative support programs, direct financial support, and drug donations related to drug utilization management. This figure does not include the loss to manufacturers from reduced sales on prescriptions that were rejected by payers or that patients did not fill because of cost sharing.

Manufacturers have developed administrative support programs, often termed "hub services," that help patients and physicians navigate utilization management and, in some cases, support patient education and adherence. Spending on these programs was $5.0–$6.7 billion in 2016.[15,16] Approximately 80 percent of this is spent in direct response to utilization management, including prior authorization support, benefit verification, and appeals assistance.[17] We estimate that pharmaceutical manufacturers spent $4.3–$5.7 billion in 2019, with a midpoint estimate of $5.0 billion, on administrative support programs that counter utilization management.

Manufacturers spent an estimated $13–$15 billion on direct patient financial support in 2018 through the redemption of copay cards to help patients offset copays, coinsurance, and deductibles—a 117 percent increase since 2014.[18,19] This includes support for patients receiving generic drugs, which would not be the target of utilization management. On the basis of interviews with industry experts as well as the existing literature,[20] we estimate that 90–100 percent of the total, or $11.9–$15.3 billion in 2019, is attributable to supporting patients using innovative, high-price drugs that face utilization management, with a midpoint estimate of $13.6 billion. Payers and manufacturers devote very little effort to managing the use of low-price generic drugs.

Manufacturers also donate prescribed drugs to uninsured and underinsured patients through manufacturer-sponsored nonprofit foundations, which are known as patient assistance programs. Underinsured patients are defined as those who have health insurance but face insurmountable cost-sharing requirements. For example, some patients have health insurance that excludes coverage for prescription drugs altogether, whereas others face annual prescription drug deductibles that are very large relative to their household income. The value of drug donations provided by manufacturer-sponsored patient assistance programs totaled $14.3 billion in 2018,[21] a 119 percent increase since 2014. We estimate that 48 percent of this spending goes to insured patients, with the remainder going to uninsured patients.[22–24] Of the amount directed to insured patients, 89 percent, or $6.2 billion in 2019, is allocated to patients who face utilization management such as formulary exclusions, high copays, and coverage limits, with the remainder being distributed to patients who face no payer access restrictions.[24]

The US drug pricing and access system is economically and politically unsustainable.

In summary, manufacturers spend $13.6 billion on direct patient financial support and $6.2 billion on drug donations supporting patients who face utilization management, for a total of $19.8 billion per year. The amounts paid by patients themselves to satisfy cost-sharing requirements, discussed below, is over and above these sums spent by manufacturers on their behalf.

Total manufacturer spending related to utilization management, including administrative support programs, direct financial support, and drug donations, is estimated at $24.8 billion per year. Manufacturers' charitable contributions to independent charitable foundations were outside the scope of this study and are not included in this estimate. Direct financial support and drug donations for uninsured patients are also not included, nor is spending by manufacturers to develop and implement patient support initiatives. The estimate does include the value of drugs donated to insured patients, which is measured by manufacturers using list rather than net prices.

SPENDING BY PHYSICIANS We estimate that physician practices spend $26.7 billion per year interacting with payers on behalf of their patients, especially in navigating prior authorization requirements. This estimate is based on the weekly time spent per physician practice combined with information on physician and staff hourly earnings.[25–28] Weekly time spent per physician practice on drug prior authorizations and formularies was calculated by personnel type (for example, physicians, nurses, clerical staff, and administrators), as reported in physician surveys.[25–27] This time was then multiplied by

Clinical rather than financial criteria should be foundational when setting utilization management policy.

hourly earnings by personnel type, based on information from the Census Bureau.[28] Summing these values resulted in a total spending of $44,829 per physician practice in 2017. This was scaled to a national estimate by using the number of practicing physicians who work in specialties that frequently encounter prescription drug utilization management.[29]

Physicians and their staff also spend time discussing with patients their health plan's drug formulary and utilization management. For every interaction that a physician has with a payer over prior authorization, there is often a corresponding conversation with the patient whose prescription is in question. It was not possible to quantify these time costs. It also was not possible to quantify the loss of physician practice revenue because of an inability to collect required copays from patients for visits devoted to discussing prescription rejections and cost sharing. The $26.7 billion figure hence represents a conservative estimate of the total cost to physicians of drug utilization management.

SPENDING BY PATIENTS In this study "drug utilization management" includes administrative mechanisms such as prior authorization and financial mechanisms such as patient cost sharing. These mechanisms affect patients both financially and through their health outcomes.

Total patient out-of-pocket spending for prescription drugs, including copays, deductibles, and coinsurance, has trended upward, going from $74 billion in 2015 to $82 billion in 2019. These costs are based on IQVIA's claims data[6] and represent what patients actually spend after taking advantage of manufacturer copay cards and other sources of financial support. However, not all prescription drug cost sharing is aimed at controlling access to innovative and specialty drugs. For example, most patients receive generic drugs, which carry only a modest copay (often in tier 1 of their formulary) that is not designed to influence a patient to choose a different, cheaper drug. In contrast, copays and coinsurance in higher formulary tiers apply to branded agents and specialty drugs and are intended to influence their use. Therefore, in our estimate of utilization management, we include only patient spending that is above and beyond the level of the average generic copay, which is normally designated as tier 1 cost-sharing in drug formularies.

A study conducted by the Kaiser Family Foundation indicated that the average tier 1 copay was $11 in 2018.[6,30] Applying this to the 4.2 billion prescriptions annually filled for all generic and branded drugs results in $46.2 billion in annual patient spending that is at the level of the average tier 1 copay and should not be attributed to utilization management.[6] We subtracted this $46.2 billion from the total patient out-of-pocket spending for prescription drugs (estimated at $82 billion for 2019 by IQVIA) to arrive at an estimate of $35.8 billion in annual patient cost sharing that can be attributed to utilization management. Taken in context, estimates from IQVIA indicate that coinsurance alone, which is commonly used to influence drug selection, makes up 34.3 percent of all out-of-pocket expenses, accounting for $28.1 billion in cost to patients.[6]

The administrative and financial mechanisms of drug utilization management can also lead to prescription abandonment and treatment delays for patients, potentially affecting health outcomes. Approximately 20 percent of prescriptions in the US are never filled. This proportion varies depending on patient population and therapeutic area (from 2 percent to 75 percent),[31–33] leading to approximately 125,000 annual deaths and 10 percent of all hospitalizations.[31] It has been estimated that the social costs for these outcomes range from $68 billion to $289 billion annually.[31,34] Delays in treatment and medication abandonment can impose significant adverse health and economic costs on patients and health systems. The delay in adopting evidence-based pharmaceutical treatment for hepatitis C, coronary heart disease, diabetes, and atrial fibrillation has been estimated to have cost the health care system $39 billion in 2013.[34] However, given that there are no comparable data across indications, we do not include these health effects in our estimates of the cost of utilization management. Our $35.8 billion figure hence represents a conservative estimate of the total cost to patients.

Policy Implications

The US pharmaceutical system exhibits high prices and onerous utilization management, in-

cluding administrative mechanisms such as prior authorization and financial mechanisms such as cost sharing. Utilization management burdens the payers that must administer it, the manufacturers that must respond to it, the physicians who must comply with it, and the patients who must endure it. The data summarized in this study suggest that costs related to drug utilization management total at least $93.3 billion per year. This likely represents a significant underestimate because we were not able to quantify numerous components.

An alternative approach to managing drug price and access is emerging—one in which a manufacturer's use of value-based pricing is linked to value-based patient access criteria from a payer.[35] In this framework, individual manufacturers voluntarily set prices with reference to benchmarks proposed by independent health technology assessment organizations. These prices are then linked to value-based access, where individual payers limit utilization management to criteria based on clinical evidence and social values, again as developed by independent organizations. An example of one such independent organization is the private, nonprofit Institute for Clinical and Economic Review. The institute regularly proposes value-based drug price benchmarks and recently published criteria for value-based access.[36]

Drug manufacturers will more likely adopt prices in line with independent benchmarks if payers also establish patient access criteria in line with independent benchmarks. In this framework, price benchmarks do not dictate, in a mechanical sense, the final price to a manufacturer but rather serve as anchor points for price negotiations. By extension, value-based criteria for utilization management are not imposed in a mechanical fashion on the payer but rather serve as benchmarks for negotiating the actual terms of prior authorization and cost sharing.

The proposed exchange of value-based price for value-based access does not imply that utilization management will disappear, as it will continue to have an important role in minimizing the use of inappropriate and overpriced medications. Similarly, pharmaceutical manufacturers will need to continue charging prices sufficient to offset their research expenditures as well as the marginal costs of manufacturing and distribution. However, neither payers nor manufacturers need to continue spending the enormous sums documented in this study.

Versions of this exchange have been observed in recent years. In 2018 Regeneron, Sanofi, and Express Scripts reached an agreement around the cholesterol-lowering PCSK9 drug Praluent (alirocumab), whereby the manufacturer agreed to charge a net price close to the Institute for Clinical and Economic Review benchmark. In exchange, Praluent was subjected to simpler prior authorization criteria and had meaningful reductions in cost-sharing requirements compared with the period before this deal was reached.[37,38] Another example can be found in the agreement between Amgen and CVS Caremark for Amgen's PCSK9 drug, Repatha (evolocumab).[39]

Value-based price for value-based access would permit a reduction in spending on the creation and countering of utilization management.

Scaling up these examples to the larger pharmaceutical price and access system will be complex and challenging, but the high potential rewards may stimulate market and policy innovations. Payers and manufacturers, in parallel with scientific and professional organizations, have already begun developing frameworks for value-based pricing, with significant efforts by private entities such as the Institute for Clinical and Economic Review and the International Society for Pharmacoeconomics and Outcomes Research and by public or quasi-public entities such as those in major European nations.[40,41] In contrast, comparable US frameworks for value-based patient access are still largely lacking.

Recently, there have been multiple stakeholder-driven efforts to address this need. For example, the American Medical Association has released prior authorization and utilization management reform principles, the Institute for Clinical and Economic Review has released principles for fair patient access, and the National Pharmaceutical Council has published stakeholder views on step therapy criteria.[42–44] Similarly, efforts to address patient access through policy change have begun to surface, such as H.R. 2279, the Safe Step Act, introduced in the House of Representatives in 2019. The common

theme across these efforts is that clinical rather than financial criteria should be foundational when setting utilization management policy.

The US drug pricing and access system is economically and politically unsustainable. It is reliant on high list prices and onerous barriers to patient access. The $93.3 billion of costs incurred annually for drug utilization management is one of the most counterproductive uses of resources in the US health care system and should be targeted by all stakeholders. A broader exchange of value-based price for value-based access would permit a reduction in spending on the creation and countering of utilization management. It would reduce administrative burdens and frustrations for physicians while improving access and health outcomes for patients. Additional studies are needed to help support movement in this direction. First, a systematic review and analysis should be conducted to quantify and break down the economic burden of drug utilization in greater detail. Second, there is a need to thoroughly analyze the impact that value-based price for value-based access could have on the US health care system. Last, further discussions around existing challenges and potential paths to scale up the adoption of value-based price for value-based access are required. ■

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