# Changing the Way We Pay for Health Care: Is Value the New Plastic?

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Congress enacted the Health Maintenance Organization Act of 1973—informally known as the HMO Act—to "stimulate interest by consumers and providers in the health maintenance organization (HMO) concept, and to make health care delivery . . . available and accessible."[1] Dr. Paul Elwood proposed the concept (and the term) of a "health maintenance organization" as a model for comprehensive, coordinated, and affordable group health care insurance. In 1973, health care consumed an unsustainable 7.5% of the gross domestic product (GDP), and HMOs were offered as a solution to improve patient care outcomes (utility) at the same or lower costs (a simple equation of value). The word "value" appears once in the HMO Act (and out of context).[2]

Forty-four years later, all U.S. public and private health insurance programs follow "managed care" principles in health program structure, delivery, and risk sharing, and health care now exceeds 18% of the GDP. Is value the answer to our unmet need to provide more care to more people *and* manage costs, while all components of health care grow in unit cost and utilization rate?

The theme of the Academy of Managed Care (AMCP) Nexus 2017 meeting is "Changing the Way We Pay for Health Care," further described as "the emergence of value as the defining factor and goal." We have witnessed a parade of health care services research, Centers for Medicare & Medicaid Services (CMS) programs, shared-risk payment approaches, and health care legislation that have failed to achieve the Sisyphean quest to manage costs and quality of care in a value-based approach. Value promises to guide rational coverage decisions or, at least, to justify paying for high-cost products and services. Value is the hottest topic of publications and discussions: Value may be the new plastic.[3]

The alignment of 2 emerging value-oriented trends—value-based drug pricing and provider payment evolution—may support our value quest from the prescription drug program perspective.

## Value-Based Drug Pricing: Payer and Manufacturer Approaches

Formulary decision makers are moving from cost minimization to cost-effectiveness, and some perform formal cost-effectiveness analyses (CEAs). Premera Blue Cross reported its ongoing success of a value-based formulary based on CEAs.[4] Regardless of methodologies and decision processes, pharmacy & therapeutics, health technology assessment, and medical policy committees are increasingly considering value in coverage decisions, often without formal CEAs. We must conduct comparative value assessment before we identify, prefer, and pay for higher value drugs. Many formulary decision makers monitor external value framework organization reports, including those of the Institute for Clinical and Economic Review (ICER), National Comprehensive Cancer Network (NCCN), and American Society of Clinical Oncology (ASCO), each with unique and criticized methodologies and conflicting conclusions.[5,6] NCCN Guidelines strongly influence oncology drug coverage decisions and care pathways.[7] ICER reports are becoming widely consulted by decision makers and manufacturers and rated as "influential" by about one third of payers.[8] Value framework assessments are advisory but not enforceable and often ignored by manufacturers in pricing decisions, at least for now.

Pharmaceutical manufacturers often include CEAs and budget impact models in AMCP Format drug dossiers that are often not applicable because of improper assumptions and do not reflect actual and confidential net costs of individual payers.[9] Plans and pharmacy benefit managers (PBMs) make drug assessments and value decisions using myriad U.S. Food and Drug Administration (FDA) clinical data, published clinical and economic evidence, manufacturer dossiers and contracts, and internal economic and plan benefit designs and membership analyses, which result in different formulary decisions for the same drugs.[10] Value framework assessments may provide guidance for plans and PBMs, but an ICER-reported cost per quality-adjusted life-year (QALY) may not be applicable because of different cost inputs or decipherable for some payers or providers. We understand and may use CEAs, but utility analyses are not yet widely embraced by U.S. payers. However, payers may use an ICER-reported cost-effectiveness price as leverage in manufacturer contract negotiations.

Drug prices and increases, driven by the growth in specialty drugs, have drawn drug cost comparisons with the United Kingdom and the European Medicines Agency (EMA) and threats of congressional price controls. CMS forecasts a 6.4% annual growth in prescription drug spending through 2025, down from the 2015 growth of 9.0% associated with medication use for the hepatitis C virus, but higher than the 5.4% overall national health spending trend.[11-13] Perhaps for the appearance of self-policing, a few pharmaceutical companies have pledged to limit annual price increases to no more than 10%, no more than 20% higher than a competitor, or to a percentage tied to the Consumer Price Index.[14,15] However, while all price controls are appreciated, the overall effect on pharmacy program costs will be slight until more or all

companies pledge to reduce prices and price increases. We have come to expect annual brand drug price increases of 10% or more. Blue Cross Blue Shield reports that brand drug price increases are now 25% and higher.[16-18] Some pharmaceutical companies are engaging in 2 value-based approaches to achieve formulary access and reimbursement beyond traditional contracting and demonstrate drug cost responsibility.

### Performance-Based Risk-Sharing Arrangements

Performance-based risk-sharing arrangements (PBRSAs) are common in the United Kingdom and European Union but less so in the United States. These contracts allow manufacturers to share in the financial risk and usually provide a financial payment, often tied to drug clinical failure, back to the payers. The first reports of U.S. PBRSAs began to emerge in 2009,[19] and others have followed, but administrative, data, and cost barriers have prevented broad growth. Recently, more PBRSAs have been implemented in such disease areas as multiple sclerosis, heart failure, and hyperlipidemia.[20-22] Some contracts are with new drugs without real-world clinical or cost experiences, which help mitigate unknown financial risk and support formulary coverage. The annual cost of PBRSA-contracted drugs *may* result in a more favorable value-based net cost experience, although cost-effectiveness may not be realized (based on ICER cost-per-QALY thresholds). Nevertheless, PBRSAs are at least a positive public relations posture showing that pharmaceutical manufacturers support shared risk and value-based approaches.

### Value-Based Prices

Value-based prices may replace market-driven new drug prices. ICER conducts a variety of independent, value-based assessments on drugs, as well as on devices and procedures. After the ICER report on multiple sclerosis,[23] Genentech launched ocrelizumab in March 2017 at an annual wholesale acquisition cost of $65,000, just above the ICER cost-effectiveness upper cost-per-QALY threshold of $58,608 and less than many competitors. Time will tell if payers respond to value-based price, and if other manufacturers follow Genentech's example.

## Provider Payment Evolution

CMS and the CMS Innovation Center have launched a panoply of provider reimbursement acronyms (e.g., APM, QPPs, MACRA, BHP, OCM, SSP, and MIPS) to "provide high quality and cost-efficient care."[24,25] Value-based reimbursement incentives align with accountable care organization shared-risk models and payer-provider reimbursement initiatives and are supported by Cancer Clinical Care Pathways,[26-28] which provide outcomes-based provider reimbursement and encourage the use of cost-effective drugs. Provider incentives to pursue better outcomes through cost-effective drugs and treatments are consistent with payer and pharmaceutical manufacturer value-based strategies.[29]

## Communicating Value to Plan Sponsors and Patients

Over 150 million insured individuals are in employer-sponsored programs, and approximately 10 million individuals are in Health Insurance Marketplace (Exchange) plans.[30,31] Employers purchase insurance based on benefit richness and affordability. Most rely on plan and PBM recommendations based on the benefits (utility) desired, cost, and willingness to pay (the concept, not the utility methodology). The pharmaceutical industry has been generally unsuccessful in convincing employers to accept higher drug costs in exchange for reduced medical costs or increased productivity, since it is difficult to show causation, especially when their plans and PBMs remain skeptical of these direct and indirect economic outcomes.

Patients are engaged in risk sharing through deductibles and cost shares, selection of health care benefit options (e.g., HMO vs. preferred provider organization), understanding of their medical conditions and treatments, and ability and willingness to pay. Many patients rely on a health care professional to recommend drug options, to which they will often not adhere,[32] and only health-motivated patients actively engage in health education and shared decision making and may make subjective value-based decisions.[33] Plans and providers should translate drug value options so patient willingness *and* ability to pay are factored into shared decisions.

## Challenges and Hazards of Value-Based Health Care

The best designed and most egalitarian policies and programs may cause unintended consequences. CMS requires coverage of FDA-approved oncology drugs, and most plan and PBM programs provide liberal coverage, with prior authorizations, of most oncology drugs. By contrast, the UK's National Institute for Health and Care Excellence (NICE) recommends coverage of fewer oncology drugs based upon cost-effectiveness and may remove oncology drug coverage to meet budget shortfalls.[34-37] Is NICE and the EMA "condemning cancer victims to early death,"[35] or is NICE acting in the best interest of society and patients by avoiding use of less effective and expensive cancer drugs?[36,37] Is the FDA an "enlightened organisation (sic)" to provide for cancer patients' needs?[38] Oncology presents unique real-world and emotional challenges because of the treatment unpredictability and the high cost of possibly brief survival extensions. The AMCP Partnership Forum has addressed these and other issues such as designing value-based oncology care programs.[39] In addition to not having single-payer health care as in other countries, Americans have a unique perspective on, and an unwillingness to accept, death. Patients or families often demand continued, expensive therapy, despite marginal survival expectations, options that are not always available in other countries.

## Does Cost-Effectiveness Equal Affordability?

Just when the outrage and cost bubble from hepatitis C drugs are passing,[12] on August 30, 2017, the FDA approved Kymriah (tisagenlecleucel) from Novartis, the first chimeric antigen receptor T-cell therapy (CAR-T) in the United States,[40] with an estimated cost of $475,000,[41] which is lower than the $649,000 cost expected by biotech investors.[42] This new drug may be cost-effective despite the high cost,[43-47] which illustrates that cost-effectiveness does not guarantee affordability. Novartis may offer a PBRSA to Medicaid and possibly other payers, requiring payment only for patients who respond to the drug.[44,48] The EMA has already approved 2 gene therapy drugs, Strimvellis ($648,000 USD) and Glybera $1.4 million USD), for ultra-orphan diseases; each has had 1 patient approved for use so far.[49] Glybera was found to be cost-effective compared with no treatment.[50]

The ICER released a draft background and scope document describing novel methods to assess the effectiveness and value of 2 CAR-T treatments, since traditional value methodologies must be adapted to very high-cost drugs with possible lifelong benefits,[51] which may reset our perspective on CEAs. However, if the FDA does not consider value, and if the Patient Protection and Affordable Care Act essential health benefits require coverage of at least 1 drug from each category, CAR-T therapy and other unique and expensive drugs will be available in the United States, albeit with management. Value-based pricing, PBRSAs, and CEAs may mitigate the psychological impact of $1 million drug costs and may demonstrate drug value. However, value cannot guarantee societal affordability, although patient assistance programs may improve patient access and affordability.[41,52,53]

## Future Considerations

Proponents of a single-payer system point to drug cost disparities in the United States compared with European countries.[54] However, this is a far more complicated argument that must consider drug development, drug availability, health care systems, and coverage restrictions. If the United States selects UK-style price controls and forces value-based drug coverage restrictions, then like the United Kingdom, we must accept drug coverage limitations, and the fact that noncovered drugs are of "low value" may not be comforting to a patient with the disease who needs the banned drug.

In the United States, we, as a society, must determine the type of health care we desire and how much we are willing to pay for it, while realizing there will be unintended consequences of our decisions. We seem to have 2 paths: (1) continue to liberally cover more treatments, although some may be of dubious value or (2) force value-based decisions UK style and accept that we are being "responsible" by managing societal costs and that many people will be denied care. If the latter occurs, to what country will citizens of the United Kingdom travel to pay out of pocket for cancer care?

Perhaps value assessment will provide a middle ground, through which we can measure and identify value, apply clinical and humanistic filters, allow cost management to drive some drug coverage decisions for which we have ample therapeutic alternatives, and accept that we will pay for some lower value drugs for other medical conditions without effective therapeutic options. Of course, this third value-based option presents another challenge: Who or what agency gets to make that decision?

It is important to remember that value assessment depends on perspective. UK patients denied cancer drugs do not consider value-based coverage denial by NICE as acceptable. Paying for value may not resolve all issues, since cost-effectiveness does not guarantee affordability, although knowing the value of treatment options allows decision choices. Perhaps value-based coverage decisions may at least provide justification and solace when the health care component of the GDP achieves 25%.

The value bell cannot be unrung. The United States is broadly and boldly experimenting with value-based assessment and reimbursement approaches. Articles in this and other issues of *JMCP* and on the AMCP website, as well as the presentations at the AMCP Nexus meeting, provide fresh insights and useful guidance and challenges to thoughtfully expand our appreciation of drug value through clinical, economic, and humanistic outcomes, as we meet the challenge of delivering the highest quality of care to our patients through a value-based health care delivery approach.

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### DISCLOSURES

Navarro is a clinical professor in the College of Pharmacy at the University of Florida, Gainesville, and is an assistant editor with the *Journal of Managed Care and Specialty Pharmacy*. Navarro reports consulting fees from Analysis Group, Amgen, Novartis, and Allergan.

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