Pharmacy and Therapeutics, Formulary Committees, and Clinical Pathways: Has Anything Changed Since 2004?

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Within the last 20 years of observing the health care industry marketplace, stakeholders have offered the same solutions to address new issues with similar applications and processes. As a result, fundamental problems still need to be solved. Health care applications and processes have evolved since 2004, but almost all the fundamentals for these systems are the same or similar. In part, this is reflected in a previously published Editor's page in the *Journal of Clinical Pathways*,[1] which highlighted the disjointedness seen from employer plan sponsors who continue to seek solutions for emerging risks, remove barriers to effective care, and move away from the traditional management path offered to employer or insurer plans by established vendors.

Understanding the beginnings of managed care formulary and hospital-based pharmacy and therapeutics (P&T) committees to assist in managing care costs was discussed, along with issues affecting them in 2004.[2] Example responsibilities, structures, and functions that have remained the same when observing the same in 2024 were reviewed. However, the processes vary along with the number of clinical experience diversity of committee members today. In general, literature from 2004-2024 provides a mixed consensus on which programs or management approaches may be the most effective. Like in the past, the proliferation of new and increasingly expensive therapies in the market continues to cause providers, patients, and payers financial burden while failing to achieve value-based outcomes.

DETERMINING VALUE FOR DELIVERING OPTIMAL CARE

Understanding the appropriate use for higher acquisition cost therapies remains a vexing issue in making specific formulary recommendations. An integrated management program for hospitals, known in thrombosis literature as the Clinical Effectiveness Initiative (CEI), employed a robust multidisciplinary makeup required for making decisions in a process around more sophisticated biotechnology therapies.[3,4]

Researchers incorporated care quality strategies, pathways, and economic considerations into the CEI. Specific outcomes resulted in emptying hospital beds more efficiently, more patients being treated through better resource utilization, and effective work appropriately using different generation therapies, which yielded significant clinical efficiency. Collaboratively balancing multiple needs of the organization with effective patient outcomes could be and was accomplished within existing committee structures.[4]

In addition to clinical professional organizations such as the Centers for Medicare and Medicaid Services (CMS) or the National Institute of Health (NIH), third-party administrators and insurers today have access to standardized care pathway services like MCG Health by Milliman and InterQual by Change Healthcare that assist in outlining options for determining appropriate coverage criteria. Additional sources for determining scientific merit, use patterns, or US Food and Drug Administration (FDA) approval status by indication have also increased. As tools for committee members, they allow for more accessible research, policy development, and coverage policy drafting. However, monitoring, updating, and analyses are still required to ensure plan performance for the plan sponsor.

Using data to provide insight into multiple therapies and integrate overall costs remains a central theme under the rubric of whole-person health. However, as care has moved out of the acute care hospital walls, alternate care sites have emerged within insurance networks, offering patients a more community-based experience of care that is generally different than a hospital and is at a lower cost of care. Having disparate and nonconnected data around patient care or cost now has greater complexity.

CARE PATHWAYS TO PREDICT RISK

Some primary or specialty care centers are owned or operated under contract with health care systems, but all sites and insurers typically follow the traditional committee approaches. By not evolving nor addressing variation in care issues in any setting, health insurers increasingly face a dilemma around coverage. In an article published in *Forbes*, several aspects of anticipating claims costs mentioned by the author included the broader variation in clinical care costs and ever-increasing direct therapy costs not in line with expected risk.[5] This

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DISCLOSURE: F.R.V. reported serving as an advisory board member for the *Journal of Clinical Pathways*.
CITATION: *J Clin Pathways.* 2024;10(4):37-38.

lack of known risk is a key fundamental for fully funded or self-funded insurance programs.

Precision medicine itself introduces variation in anticipated patient population costs of insurance coverage. As transformative health reform efforts attempted to solve such gaps, implementation remains challenging with the increasing care costs. An ability to promulgate a pathway with adequate data to remain up to date with therapy technologies remains out of reach for most. For hospitals, health care providers, and health plan sponsors, this is another challenge in provider and/or benefit management.[6]

Value assessments for therapies and return-on-investment (ROI) models need to address the real value basis of advanced therapies. If barriers can be broken down, simplified, and kept current for pathways, that creates a real opportunity for an integrated program.

SUMMARY AND ACTION REQUIRED

Fundamentals regarding therapy policy and decision-making have remained mostly the same since 2004. Over the past two decades, plan sponsors have increasingly outsourced tasks and reduced internal staff. The result has been traditional benefit management and solutions that try to deal with advanced therapies with outdated strategies.

While many traditional therapies (eg, chemical or "generation zero biologics") can be managed similarly to management strategies from 20 years ago, care costs associated with old or new generation therapies still require new strategies. For plan sponsors, determining a value for delivering optimal care has reemerged as a core issue for business owners and plan members. Self-funding care cost risk also carries a fiduciary responsibility exposure for a lawsuit that has now been realized in 2024.

One component to enhance the effective management of advanced therapies requires robust care pathways. Providers can utilize such pathways to determine various risks around the use of those novel products, thereby providing predictability for use by stakeholders insuring health cost risk. Cost predictability provides more certainty in pricing premiums, benefit structures, and program needs in managing advanced therapies. Ultimately, the goal is to allow appropriate care for patients who are members of a health benefit plan, resulting in optimal care outcomes. The growing research and development (R&D) pipeline and the current small number of advanced therapies in the US market offer an opportunity for change in how key stakeholders could collaborate to achieve the common goal of enhanced patient outcomes effectively. ◆

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