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Commentary

Prior authorization policies in Medicaid programs: The importance of study design and analysis on findings and outcomes from research

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Summary

U.S. State Medicaid programs for the medically indigent strive to deliver quality health care services with limited budgets. An often used cost management strategy is prior authorization of services or prescription medications. The goal of this strategy is to shape the pharmaceutical market share in the most efficient manner for the particular state Medicaid program, much like commercial managed care organizations. These policies are often scrutinized due to the population Medicaid serves, which in the past was largely composed of individuals with vulnerable health status. Unintended consequences can occur if these policies are not carried out in an appropriate manner or if they greatly restrict services. The data used for policy implementation research is prone to certain problems such as skewness and multimodality. Previous guidelines have been published regarding the best practices when analyzing these data. These guidelines were used to review the current body of literature regarding prior authorization in Medicaid. Further discussed are additional characteristics such as therapeutic areas researched and the outcomes identified. Finally, the importance of considering state-specific characteristics when reviewing individual policies and the usefulness of these results for other programs are also considered.

Keywords: Medicaid; Prior authorization; Methodology; Statistics; Outcomes; Unintended consequences

Background

U.S. State Medicaid programs continuously struggle to balance limited budgets with increasing demand for services. Cost management strategies for state Medicaid programs typically center around three "short-term" control measures: provider reimbursement, enrollment limitations, and benefit reductions and/or restrictions.[1] The majority of Medicaid cost management efforts center on benefit reductions strategies. The pharmacy benefit component of expenditure control strategies is focused on the cost of the products and the utilization of the products.[2] Strategies to control product cost or utilization include: generic mandates, pricing restrictions, step-therapy, prior authorizations, formulary

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restrictions, manufacturer rebates, reduced professional fees (provider reimbursement), and increased patient cost share.

For Medicaid programs, the mainstay cost-containment measure for non-generic medications has become some form of prior authorization (PA) program, such as step-therapy or preferred drug lists (PDLs). Most programs rely on an approval process or prior authorization strategies to encourage use of preferred prescription products. For various reasons, Medicaid programs have not utilized significant copay differentials to discourage the use of non-preferred products. Prior authorizations can be manual or automated system processes. Step therapy programs utilize an evidence-based tiering of available products and typically place the most cost-effective therapies on the lowest tier, or step. Higher tiers or steps require at least one trial of a lower tier medication or an approval process. As of 2004, all but 7 of the contiguous states had or planned to have a preferred drug list.[3] However, there is significant controversy over the ability of these programs to provide quality care while controlling costs; nevertheless, these programs have become a permanent component of Medicaid pharmacy benefits.[4]

The goal of prior authorization policies within Medicaid programs is to actively shape the market share or utilization of drug products in the most efficient manner for that particular state Medicaid program. Each state brings its unique population demographics, reimbursement strategies, regional prescribing influences, and political climate to the table when determining pharmacy benefit policies. Thus, each state's prior authorization policies are uniquely their own and may not be comparable to other state programs. Furthermore, because Medicaid programs often serve individuals in vulnerable physical and mental states of health, it is important to formally review these policies to ensure the intended results were achieved while limiting unintended consequences.[5] In the majority of cases, the intended result of a Medicaid prior authorization policy is to decrease spending on pharmaceutical products while maintaining quality of care. Unintended consequences occur when other aspects of an individual's health care is negatively impacted due to suboptimal therapeutic outcomes and may be seen as increased emergency room visits, physician office visits, adverse events, or utilization of other health care services. It may also be important to consider the therapeutic category which has been included in the policy and the sensitivity of the population to changes in therapies for the applicable disease states.

Hazards in health care data analysis

When analyzing health care resources and costs, there are inherent characteristics of the data that must be considered. Health care data are rarely normally distributed. The data typically are non-negative and skewed positively to the right. The data can also be multimodal with many peaks and troughs; or have an excess of zeros.[6,7] Most data used for policy analysis are from paid administrative claims that were designed for payment, not for research purposes. Most studies are observational and historical. Lack of randomization allows for potential biases and confounding.[7] Many evaluations of prior authorization policies in state Medicaid programs have been performed; however, as statistical methods become more sophisticated and the results of these assessments garner greater scrutiny, it is important to review the current body of literature regarding the implementation of prior authorization in Medicaid programs and to discuss whether the literature meets currently published guidance for analyses of these data.

Published guidelines for handling data

Two published papers provide guidelines for analysis of health care utilization and resources, Diehr (1999)[6] and Mihaylova (2011).[7] Diehr and colleagues outlined methods for working with these types of data.[6] Adjustments for patient characteristics such as age and gender are often only done with a simple linear method and do not account for potential interactions. Additionally, adjustments made using an individual's past utilization (which is a strong predictor of utilization to come) could mask differences. While one-part models are appealing due to their ease of use, these can be less informative when dealing with multi-nodal data, particularly those with a zero intensity, in which case a two-part model is preferred. Transformation of data is often required to overcome the normality issues, unless the data set is large enough to overcome these problems. Diehr offers recommendations on which model to use: for understanding systems, a two-part model is most appealing and preferred; or for analyzing individual effects on costs, a one-part model may be more appropriate.[6] Besides discussion regarding the distributions of these data, Diehr also discusses often neglected issues related to costs such as whether the billed charges are representative of the true costs.