Precision Medicines Need Precision Patient Assistance Programs

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Consumer cost sharing for medical care in general, and specialty medications specifically, is high and getting higher. The average deductible for employer-sponsored single coverage increased by more than 250% between 2006 and 2016 and is now nearly $1500.[1] Even after meeting their plan deductible, patients are often liable for high co-payments and coinsurance.

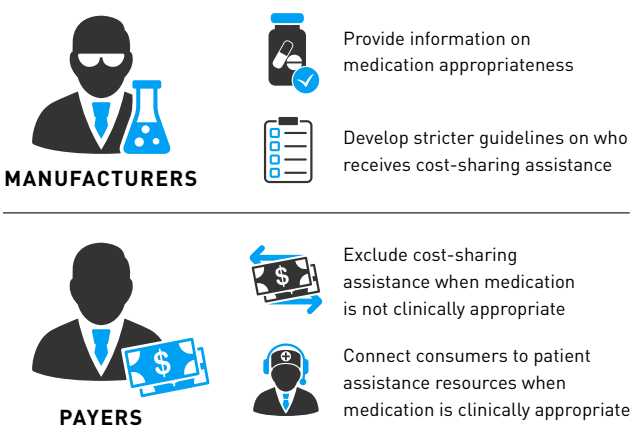
Cost sharing has potential to be a useful tool for purchasers to encourage prudent spending of healthcare dollars and reduce wasteful expenditures. However, cost sharing has historically been implemented as a blunt instrument, usually failing to distinguish between high- and low-value clinical services. There is a robust evidence base showing that individuals who are subject to high levels of cost sharing use less of both high- and low-value care in similar proportions. The higher the cost sharing, the greater the corresponding reduction in service use.[2,3] Not surprisingly, cost-related underuse of evidence-based services disproportionally impacts poorer Americans and those with chronic conditions.[4]

Patient Assistance Programs

In response to the growing financial burden resulting from consumer cost sharing, patient assistance programs (PAPs) have been established to help patients pay for their medical care. PAPs may be delivered in several forms, including co-payment assistance cards (commonly referred to as "co-pay cards"), manufacturer assistance programs, and grants from charitable patient assistance foundations. Co-pay cards are typically targeted to individuals with commercial insurance coverage; individuals enrolled in Medicare, Medicaid, or other federal healthcare programs cannot use these programs.

Although PAPs may serve to increase access to otherwise costly prescription medications, some payers, purchasers, and researchers have expressed concerns that co-pay cards undermine incentives for clinicians and patients to respect plan formularies, thereby unnecessarily increasing expenditures. Use of co-pay cards for branded medications when generic equivalents are available has drawn particularly harsh attention.

FIGURE. Elements of Precision Patient Assistance Programs



Co-pay Accumulator Adjustment Programs

Until recently, co-pay assistance funds counted toward meeting the patient's deductible, allowing some individuals to reach their plan deductible after only nominal out-of-pocket (OOP) expenditure. To mitigate this strategy that potentially would result in more patients reaching their deductible, pharmacy benefit managers (PBMs) have started to implement co-pay accumulator adjustment programs (CAAPs) that ensure that any pharmaceutical manufacturer subsidy toward patients' OOP medication cost is *not* credited toward their deductible. It has been estimated that nearly 60% of covered lives in commercial health plans are covered by payers that have implemented a CAAP.[5]

Because most co-pay cards have an annual limit on the amount of assistance that an individual patient may receive, many patients under a CAAP are at risk of experiencing "co-pay surprise" midway through the plan year when the co-pay card's maximum assistance amount has been reached but the plan deductible has not been satisfied. In this issue of *The American Journal of Managed Care®*, Sherman and colleagues report that the use of a CAAP for specialty medications treating autoimmune diseases was associated with significant reductions in medication adherence, a measure that often predicts adverse clinical events leading to downstream costs.[6]

The competing strategies of PAPs and CAAPs create confusion and administrative burden for clinicians and patients, potentially reducing adherence to clinically indicated services and worsening patient outcomes.

Adding Precision to PAPs

Recognizing that blunt cost-sharing programs and opposing interventions to reduce OOP costs for high-cost medications are likely to persist, plans, PBMs, and manufacturers could minimize potential harm through new partnerships (**Figure**). These patient-centered collaborations could facilitate the use of patient co-pay assistance only when high-cost medications are indicated in high-value clinical scenarios. A "truce" might include the following provisions, each of which could serve to enhance access to clinically indicated therapies and decrease the financial and logistical burden on patients/families and their clinicians in these scenarios where higher-cost, high-value medications are warranted:

- Payers would accept the use of external financial patient assistance to reduce consumer cost sharing when a particular medication is clinically indicated. This would mean forgoing utilization management (eg, step therapy, prior authorization, formulary exclusions) in these situations. Use of CAAPs would be limited to circumstances in which the medication is clearly a low-value option (eg, use of a branded drug when a generic alternative is available). This might reduce the risk of decreased medication adherence to an essential medication resulting from unexpected cost sharing a member may face if/when a PAP reaches an annual or monthly limit. Payers might also encourage their contracted providers and care managers to connect financially insecure individuals to patient assistance resources when clinically appropriate.
- Manufacturers would ensure that information on clinical appropriateness—including scenarios in which a medication is not clinically appropriate—is well communicated in PAP materials. For manufacturer-administered programs serving those with commercial coverage who are underinsured, applications might inquire as to whether lower-cost first-line treatments had been appropriately tried.

Such collaborative arrangements would benefit from consensus on clinically indicated uses of a specific medication. Designation of high value could be based on alignment with clinical guidelines issued by professional societies, the National Comprehensive Cancer Network pathways, or other trusted third-party sources. In many instances, this designation of high value could include use of recommended first-line therapy prior to more expensive biologic or specialty medications (eg, use of methotrexate in rheumatoid arthritis prior to use of a tumor necrosis factor inhibitor or Janus kinase inhibitor). In other instances, it might include the presence of certain patient-specific characteristics (eg, biomarkers) that make a targeted therapy appropriate (eg, use of trastuzumab [Herceptin] for patients with early-stage breast cancer that is human epidermal growth factor receptor 2–positive).

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Precision Medicine Needs Precision PAPs

Advances in precision medicine call for greater use of precision benefit design that encourages and enables patients to receive the right care, at the right time, in the right place, at an OOP price they can afford.[7] Purchasers, PBMs, and pharmaceutical manufacturers have critical roles to play in enabling more seamless access to the right medication at the right time to improve the experiences of patients, families, and providers, and they could find common ground by piloting precision PAPs that complement these efforts. Through collaboration, stakeholders can steward limited healthcare resources while ensuring that OOP costs rarely prevent patients from accessing high-value therapies. ■

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