ON TARGET:

Best Practices for Offering Pharmacogenomic Testing Benefits

by | **Jeffrey A. Shaman, Ph.D.**

Pharmacogenomic (PGx) testing has emerged as an effective strategy to help organizations reduce health care spending in addition to helping health and wellness plan participants avoid potentially adverse reactions to medications. What should plan sponsors look for in a PGx program?

benefits
MAGAZINE

Research shows that 99% of people have gene variants that can affect their response to medication.[1] That means nearly everyone has some level of risk of experiencing adverse drug events and, in some cases, potentially life-threatening consequences if their doctor prescribes a medication that's not right for them. However, gene-drug interactions are not routinely factored into health care decisions, which can be a missed opportunity for benefit plan sponsors and plan participants. Pharmacogenomic (PGx) testing has emerged as a way to avoid these adverse drug events as well as to help plan participants find the most appropriate drug in a more timely and efficient manner.

PGx is the study of how genes affect a person's response to medication, combining *pharmacology* (the study of drugs) and *genomics* (the study of genes and their functions). By understanding how genetic makeup affects drug response, health care providers can prescribe the right medication and dosage with less trial and error, improving treatment effectiveness and reducing side effects. PGx is used clinically to improve prescribing in various medical fields such as mental health, oncology, cardiology, pain management, endocrinology and neurology.

An example of its application includes the prescribing of blood thinners. Approximately 30% of people do not properly metabolize one of the most commonly prescribed blood thinners on the market. If someone needs to be treated for a medical emergency like a heart attack or stroke, they could have a poor clinical outcome (e.g., a secondary cardiovascular event) if placed on the wrong drug.[2]

PGx testing—and more broadly, medication safety programs—has become more widely available as an employee benefit. This article will describe one employer's experience with offering a voluntary PGx benefit and discuss considerations for offering a PGx program.

A Case Study on PGx Testing

In 2021, a U.S. employer initiated a voluntary PGx-enriched medication safety program. The organization identified a group of individuals as being at high risk for medication safety issues based on a confidential review of pharmacy and medical claims that revealed the likelihood of potential drug-drug interactions, gene-drug interactions, contraindications and other health care risks. Starting in February 2021, the organization offered PGx testing at no additional cost to this cohort, their spouses and eligible adult dependents who were enrolled in its employer-sponsored health plan. To date, more than 1,000 employees have had their DNA analyzed for medication safety risks through the program.

Each participant opted into the benefit through a secure online portal where they provided a brief medical history, had the ability to submit their current medication list and requested an at-home test kit. After providing a saliva sample, they returned their kit through the mail. At the laboratory, the DNA sample was analyzed to specifically identify genetic information that influences medication risks.

Using a clinical decision support system (CDSS) to evaluate genetic and nongenetic risk factors—such as U.S. Food and Drug Administration (FDA) black box warnings and age-specific considerations—pharmacists met with each participant over the phone to talk through recommended adjustments to their current medications and/or dosage. These recommendations were documented in a written report and, with the individual's consent, the pharmacist communicated these recommendations directly to the individual's health care provider. Participants also received guidance on medications they should avoid in the future based on their DNA, which doesn't change through an individual's lifetime.

More than 85% of participating employees received actionable recommendations about their current medications to discuss with their doctors, according to study results submitted by researchers from two PGx providers.[3]

Data from participants across the program reveal that PGx testing:

- **Reduced employee health care resource utilization.** When employees began taking the correct medications, both hospitalizations and emergency department visits decreased measurably. This reduction indicates both individual health improvements and a shift away from more costly acute care services.
- **Drove downward trends in health care costs.** Stemming from the reduction in health care resource utilization, total health care costs (per member per month) also decreased. In contrast, health care costs for nonparticipants in this employee population continued to rise.

These trends are consistent with outcomes of other real-world PGx-enabled precision medicine programs. For example, the Teachers' Retirement System of the State of Kentucky (TRS) saw participants' inpatient visits decrease by 14.9%, emergency department visits decrease by 6.8% and outpatient visits decrease by 1.9%, as well as charged-to-plan health care savings of $218.34 per member per month, resulting in more than $37 million in savings in less than three years.[4]

Offering a PGx Benefit

Following are considerations for employers and self-insured health plans that may be interested in offering a PGx benefit.

Genetic Testing Benefits Take Many Forms

PGx programs are different from other genetic testing benefits that focus on evaluating predilection for hereditary diseases like cancer but not medication safety. A PGx employee benefit program should specifically test the genes and variants known to impact medication safety and efficacy.

Some services provide genetic testing for medication safety in response to specific medical concerns or focus on specific therapeutic areas like mental health. However, the most broadly applicable PGx programs analyze and report on each part of the genome that affects medication response for all therapeutic areas. This form of testing sometimes costs less than focused testing. It allows individuals to take only one DNA test, even if they're not currently taking medication, and receive the benefit of knowing which drugs they should avoid at any point in their lives—similar to an allergy test that informs people what to avoid in the future.

Employers have a number of design options:

- **Funding:** The benefit can be offered as an employee-pay-all voluntary benefit or can be partially or fully

subsidized by the employer. If the employer is covering the cost of the program, the vendor may charge a fee per member per month or by the individual services performed.

- **Who is covered:** Employers may choose to allow all employees to participate or engage only a high-risk subset of employees.

No matter the implementation and payment model, employers should seek a provider with a lengthy track record and a scientifically proven program.

PGx Integration With a Comprehensive Medication Management (CMM) Program

Comprehensive medication management (CMM) focuses on taking a whole-person approach to identifying the best medications for an individual, taking into account drug-drug interactions, diet, smoking status, age and other factors. What it doesn't consider is how a person responds to a medication due to their genetics. That's where PGx testing comes into play. On its own, neither CMM nor PGx is a complete approach to optimizing health care treatment plans. CMM may give a "green light" to one medication for a particular person, but genetic information could raise a red flag. The converse is also true. When PGx and CMM are integrated, the greatest benefit is realized in terms of clinical outcomes and conserving health care dollars. It is beneficial to find a partner with experience implementing, managing and operating a complete PGx+CMM program.

The Role of Pharmacists

Pharmacists, leveraging powerful risk assessment technologies, are a key piece of the puzzle for ensuring that PGx benefits are delivered and communicated to participants and their prescribing physicians. Unlike other health care providers, pharmacists have years of training and experience specifically dedicated to medication safety and management and should play a central role in providing actionable guidance and educating individuals and their doctors. Studies show that clinical and economic improvements increase when pharmacists deliver the information on medication changes.

Ongoing Access to PGx Information

A person's DNA does not change over time, but other key factors like age, their medical conditions, which medications they take and even lifestyle choices like what they eat and drink will change. Plus, dozens of new drug therapies are approved by the FDA each year and new scientific research is being published daily.[5] Naturally, these shifting variables and new developments can affect medication safety. Ensuring that employees' genetic information is accessible over time allows employers to provide a benefit that yields ongoing value rather than a static, moment-in-time analysis.

Importance of Employee Education

While the Genetic Information Nondiscrimination Act (GINA) protects individuals against discrimination based on their genetic information, privacy and information security should be top priorities when considering a genetic testing program. Beyond thinking about the confidentiality of health care information, employees will likely have questions about what happens to their genetic data. It's a topic that, if not vetted and explained properly, has the potential to be a roadblock for adoption. Plan sponsors should ensure that their program provider follows Health Insurance Portability and Accountability Act (HIPAA) regulations and is HITECH-certified, that employees retain ownership of their

takeaways

- *Pharmacogenomics (PGx)* is the study of how genes affect a person's response to medication, combining *pharmacology* (the study of drugs) and *genomics* (the study of genes and their functions).
- PGx is used clinically to improve prescribing in various medical fields such as mental health, oncology, cardiology, pain management, endocrinology and neurology.
- One employer that implemented a voluntary PGx testing program for its employees found that the program reduced employee health care resource utilization among employees who participated in the program. Total health care costs also declined for participants.
- Employers and plan sponsors that are considering implementing a PGx program should look for programs that specifically test the genes and variants known to impact medication safety and efficacy. Design options include employee-pay-all or fully or partially employer-subsidized programs.
- Plan sponsors should ensure that their program provider follows Health Insurance Portability and Accountability Act (HIPAA) regulations and is HITECH-certified, that employees retain ownership of their genetic information and personal information is not shared with anyone without their consent.

genetic information and that personal information is not shared with anyone without their consent. Addressing patient data privacy concerns early in an implementation can allay employee concerns proactively.

The Future of PGx

Advances in PGx will likely focus on new medications, data portability, reimbursement and education. As more medications are developed and tested, there will be a growing need to integrate PGx information into treatment plans to ensure personalized and effective care. To achieve this, there is a need for improved data portability and interoperability between different health care systems and databases to enable the sharing and analysis of PGx data. In addition, reimbursement policies may need to be reevaluated to incentivize the adoption of PGx testing and implementation. Education and awareness also play a critical role in the successful integration of PGx into clinical practice. Health care professionals and patients alike need to be informed about the benefits and limitations of PGx.

Conclusion

Overall, incorporating a PGx-enriched CMM program as a wellness benefit—taking into account both genetic and nongenetic risks—is a strategy that may lead to improved health outcomes, significant cost savings and increased employee satisfaction.

bio

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Endnotes

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