PGx Insight for Employers

Moving from Precise to Personalized Medication Management with PGx and CMM

There are many ways to apply genetic testing results to health care. It can be used to identify risks for inherited diseases such as heart irregularities, elevated cholesterol and cancer. It can also help providers select the medications most likely to be effective for a specific patient to treat or prevent illness.

Pharmacogenomics (PGx), the study of how patients' genetic makeup determines their body's metabolic responses to specific medications, is an integral part of CMM and precision medicine. It is recognized by the FDA for helping health care providers choose a drug that is more likely to work for an individual, avoid drugs that might have serious side effects, adjust the dose of a drug or determine that close monitoring of the individual is needed. The FDA also recognizes the important role of PGx in the drug development process, opening new opportunities in drug discovery.[1]

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However, these emerging diagnostics, aided by an explosion of scientific discovery, have yet to be fully integrated at the point of care. CMM enables the interprofessional team—including a clinical pharmacist—to ensure appropriate use of medications and gene therapies.

Without PGx, many physicians base their medication prescribing on the outdated method of trial and error in finding the right medicine and the right dose. This assumes that most patients are normal metabolizers of specific medications, which is far from accurate. PGx can be used to determine which medication or combination of medications will work best for an individual, as well as the dosage that should be used (based on their body's rate of metabolizing the medication). PGx can be particularly useful in identifying medications that should be stopped because they may not be effective for the patient given their genetic profile or because of their potential for causing adverse drug events such as overdose or toxicity.

PGx is a major win for patients and employers as it eliminates long periods of wasteful, costly and often harmful

About the GTMRx Institute

The **Get the Medications Right Institute** brings critical stakeholders together, bound by the urgent need to optimize outcomes and reduce costs by getting the medications right. We are physicians, pharmacists, nurses, patients, health IT innovators, drug and diagnostics companies, consumer groups, employers, payers—aligned to save lives and save money through comprehensive medication management. Our goal is to ensure appropriate and personalized use of medication and gene therapies by advancing a scientific, evidence-based and cost-effective decision-making process and a team-based, systematic approach to medication use. We believe this will offer consumers a personalized approach to medication use. For those who pay for care, it will create a reduction in total cost of care—saving lives and saving money.

Questions? See our *GTMRx Belief Statements*

1 Center for Drug Evaluation and Research. (n.d.). Table of Pharmacogenomic Biomarkers. Retrieved January 09, 2021, from https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling

trial-and-error medication use, preserves a patient's quality of life and quickly delivers the clinical outcomes needed to get employees back to work—all goals of CMM. Evidence supports integration of PGx as part of the CMM process.

Employers and physicians often associate the use of PGx with costly biologic or specialty medications and the emerging field of biosimilars, but it is rapidly advancing beyond its early use in cancer treatment. PGx can pinpoint the right medications and doses for more frequently used medications, such as drugs for depression and to prevent blood clots from reoccurring. In fact, there are currently 431 prescription medications with FDA designated PGx labeling;[2] 30 of them are commonly utilized.[3] For many, labeling designates specific medical actions to be taken based on PGx results.

Integrating PGx within the CMM process

As PGx testing is more broadly adopted at the practice level, the clinical pharmacist on the CMM team's role in the interpretation and use of pharmacogenomic testing should not be understated. Like a tailored suit, precision medicine is precisely fitted and delivered medical care based on the characteristics of a patient's unique genetic profile, lifestyle and environment. As part of the CMM process members of the care team assess all these factors to design a personalized plan to achieve the best possible treatment outcomes.

A Mayo Clinic study revealed that PGx testing for patients using a blood thinner resulted in a 43% lower risk of hospitalization for bleeding or blood clots and a 31% reduction in hospitalizations overall when compared to a control group without PGx testing..

Much of PGx testing today is either gene-drug specific to identify effectiveness, safety and dosing of a specific medication, or it is used to identify drugs in the same class most likely to be effective for the patient. These approaches are proven to achieve desired treatment outcomes and cost savings. For example, a Mayo Clinic study revealed that PGx testing for patients using a blood thinner resulted in a 43% lower risk of hospitalization for bleeding or blood clots and a 31% reduction in hospitalizations overall when compared to a control group without PGx testing.[4]

Vanderbilt University's PREDICT study examining the cost efficiency of pre-emptive testing found that 60% of singular drug-gene tests deemed necessary for treatment were avoided through pre-emptive testing.

Another method preemptively tests a variety of gene-medication panels (especially medications commonly used) so results are ready at the initial point of care, thus reducing time to treatment, multiple provider encounters, the need for multiple gene-drug specific tests and associated costs.

Many vendors offer multi-panel testing and other types of gene testing. They are promoted as health care cost savers and important additions to preventive wellness programs. Some gene testing can identify hereditary predisposition for illnesses, thus encouraging patients to proactively act to reduce risk. Once multi-panel testing has been performed, the results are always available for use in identifying risks for adverse drug events associated with medication therapy—whether it is one prescription, a combination or the overall picture of a patient's regimen that includes over-the-counter medications and supplements.

Vanderbilt University's PREDICT study examining the cost efficiency of pre-emptive testing found that 60% of singular drug-gene tests deemed necessary for treatment were avoided through pre-emptive testing.[5] Another study concerning depression treatment attributed $3,962 per patient in annual savings because of pre-emptive PGx testing.[6]

2 Table of Pharmacogenomic Biomarkers in Drug Labeling. U.S. Food and Drug Administration. Accessed Sept. 6, 2020. https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling

3 Krebs, K., Milani, L. Translating pharmacogenomics into clinical decisions: do not let the perfect be the enemy of the good. *Hum Genomics* 13, 39 (2019). https://doi.org/10.1186/s40246-019-0229-z

4 Epstein RS, et al. Warfarin genotyping reduces hospitalization rates. Results from the MM-WES (Medco-Mayo Warfarin Effectiveness Study). J Am Coll Cardiol. 2010;55(25):2804–12.

5 Van Driest SL, et al. Clinically actionable genotypes among 10,000 patients with preemptive pharmacogenomic testing. Clin Pharmacol Ther. 2014;95(4):423–31.

6 Maciel A, Cullors A, Lukowiak AA, Garces J. Estimating cost savings of pharmacogenetic testing for depression in real-world clinical settings. Neuropsychiatr Dis Treat. 2018;14:225–30.

Barriers to employer-provided PGX testing

While there are many reasons employers consider coverage of pre-emptive PGx testing as an employee health care benefit, there are also plan design considerations that must first be addressed, such as

- procuring a testing vendor;
- determining which testing panels are most clinically useful for stratified groups of employees and retirees;
- deciding whether testing should be provided to all covered members or only those in specified high risk groups;
- establishing payment methodologies and clear ROI analysis;
- ensuring that there is a process of care, like CMM, applied to interpret and use results effectively, making sure that patients and their prescribing physicians are given understandable and actionable data and
- ensuring this added benefit is legally compliant with regulations such as the Health Insurance Portability and Accountability Act, the Genetic Information Nondiscrimination Act, the Americans with Disabilities Act and Equal Employment Opportunity Commission dictates.

Physician and patient resistance

Physician and patient resistance to PGx is a common barrier. This can, in part, be attributed to lack of physician familiarity with PGx testing and the interpretation and application of results. PGx is fairly new, with rapid knowledge gain over just the past decade—well after many practicing physicians and pharmacists graduated from degree programs and entered the field. Even physicians who received genetics education may feel unprepared to work with patients at high risk for genetic conditions and could lack confidence in interpreting PGx test results or are reluctant due to lack of awareness of local availability and reliability of testing resources.[7] Patient fears about privacy and how their test results might be used by outside parties must also be addressed through education.

Cost of diagnostics

Cost for PGx testing is the second major barrier. Although condition-specific studies demonstrate global cost-savings for PGx testing because it offers the care team important information to improve efficiency and accuracy in prescribing the right medications.[8,9,10,11] For conditions like depression and heart disease—often among the most costly chronic conditions for employer populations—the cost-saving evidence for PGx testing is well established. In recent years, market competition has also resulted in a significant decline in PGx testing costs, especially when employing a competitive request for proposal.

These barriers can be mitigated through engagement of medication experts in the CMM process. Today, clinical pharmacists are focusing on PGx education (and often certification) to enable collaboration with physicians and patients to eliminate these knowledge gaps. Clinical pharmacists are well-equipped to partner with physicians to cost-effectively utilize PGx testing and interpretation in a way the patient can understand.

Employers and other self-funded plans play a critical role in facilitating improved treatment outcomes and financial savings through a more personalized approach to medication use.

Steps employers can take now include:

1. **Learn more** about precision medicine and PGx testing to enable discussions with employees/retirees, executive leadership, health plan administrators and health care providers. Participating regularly in meetings with clinical pharmacists associated with your medical carriers and PBMs can be useful, providing insight into market changes pertinent to treatment of your covered members. Perform an RFP or RFI to get the current strategies and competitive pricing.

continued

7 Krebs, K., Milani, L. Translating pharmacogenomics into clinical decisions: do not let the perfect be the enemy of the good. *Hum Genomics* 13, 39 (2019). https://doi.org/10.1186/s40246-019-0229-z

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9 Zhu, Y., Swanson, K. M., Rojas, R. L., Wang, Z., Sauver, J. L., Visscher, S. L., . . . Borah, B. J. (2019). Systematic review of the evidence on the cost-effectiveness of pharmacogenomics-guided treatment for cardiovascular diseases. Genetics in Medicine, 22(3), 475-486. doi:10.1038/s41436-019-0667-y

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11 Zhu, Y., Moriarty, J.P., Swanson, K.M. et al. A model-based cost-effectiveness analysis of pharmacogenomic panel testing in cardiovascular disease management: preemptive, reactive, or none?. *Genet Med* (2020). https://doi.org/10.1038/s41436-020-00995-w

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2. **Lower barriers** by assuring that your health plan summary plan description states that evidence-based pharmacogenomic testing as a diagnostic tool is a covered benefit and informing your medical carriers, PBMs and plan members about coverage. Invite high risk members and those with polypharmacy to participate, and be clear that this information is for the sake of getting the right medicine and dose the first time.

3. **Require use of PGx testing** as part of prior authorization processes when medications with FDA indicators are prescribed for new use, in collaboration with the physician and a clinical pharmacist if appropriate. Advocate that Medicare plans are allowed to do the same.

4. **Educate plan members** about opportunities created by precision medicine to avoid wasteful and potentially harmful medications, explaining that some medications are not as effective as others based on their personal genetic profile. Encourage them to ask physicians if PGx testing is indicated when new medications are prescribed or when medications being used are not producing desired treatment outcomes.

5. **Incorporate clinical pharmacist-enabled CMM** into your employee health plan to facilitate use of PGx to assure high-quality care delivery for your members and elimination of waste caused by non-optimized medication use. This allows you to move from a precise to a more personalized approach to medication use. Do this in combination with your PBM and your medical carrier. If that is not possible, carve this process independently.

Employer Resources from GTMRx

Outcomes of Implementing and Integrating PGx within CMM in Team-Based Care
6-MINUTE READ

Teacher's Retirement System of Kentucky: Pharmacogenomics: Improving outcomes, lowering costs by making precision medicine personal
6-MINUTE READ

Comprehensive Medication Management in Benefits Design: A Toolkit for Employers
13-MINUTE READ

"Mike's Journey: A Patient and His Physician Talk about PGx and Getting His Medications Right"
LISTEN TO PODCAST

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Get the medications right

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