PGx Common Questions and Overview

Pharmacogenetic testing, also called DNA Drug Sensitivity Testing, is the testing of certain genes to determine how individuals might react to specific medications. With insight derived from pharmacogenetic testing, healthcare providers may decrease the need for "trial-and-error" dosing and might substantially reduce the adverse drug effect risk (ADEs).

Unique software allows the analysis of more than 4,000 compounds including prescription drugs, over-the-counter medications, herbal supplements, vitamins, nutraceuticals and recreational drugs. The FDA has updated the label of more than 250 drugs to include pharmacogenetic information and the breadth of coverage continues to grow.

You need a healthcare provider who is licensed and able to write a prescription (e.g. MD, DO, NP, PA) to complete the test order.

Both you and your provider will receive a genetic profile report and a personalized prescribing report prepared by a pharmacist that provides information on drug-drug and FDA approved drug-gene interactions. Most testing reports and processes include a consultation with one of our pharmacists. A pharmacist will review the software recommendations for improvements to a patient's medication regimen. Recommendations will be made to your authorizing healthcare provider via the physician report.

The process is protected within HIPAA compliance standards.

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If a patient takes four or more medications regularly or has had an adverse reaction that resulted in a doctor or emergency room visit, then they may benefit from DNA sensitivity testing. Additionally, a combination of the following conditions indicates an increased risk of adverse reactions to medications. Pharmacogenetic testing can provide insight to help reduce the risk

Conditions that may put a patient at risk:

- Over 65 years of age
- Experiencing unwanted side effects from medication(s)
- Feels their medications aren't working
- Currently taking or considering any of the medications on this list

Or, has one or more of the following medical conditions:

- acid reflux
- mental health condition
- arthritis
- cancer
- asthma/COPD
- thyroid disorder
- organ transplant
- diabetes
- osteoporosis
- blood pressure (high)
- cholesterol (high)
- migraines
- peptic ulcer
- depression
- prostate (enlarged)
- pregnancy
- post-Myocardial Infarction (MI) surgery

Target Genes for testing:

- **CYP2D6** is the best-studied drug-metabolizing enzyme and affects 25% of all prescription drugs.
- **CYP2C9** acts on 15% of drugs in clinical use.
- **CYP2C19** acts on 15% of drugs in clinical use

- Commercial insurance coverage is very limited but varies by plan and provider. They may cover PGx testing in some diagnostic situations including adverse drug reactions or lack of response to medication, pain management, cancer management, and management of many co-morbid conditions.
- Medicare coverage is limited to CYP2D6 only for patients initiating amitriptyline or Pamelor® (nortriptyline) for treatment of depressive disorders or for patients taking Xenazine® (tetrabenazine) doses greater than 50mg/day and to CYP2C19 patients with Acute Coronary Syndrome (ACS) undergoing Percutaneous Coronary Intervention (PCI) that are initiating or reinitiating Plavix® (clopidogrel) therapy. Submissions are reviewed on a case by case platform by Medicare or Medicaid at this time. Medicare Advantage may cover in some instances. Call your insurer to check what is covered on your policy.
- Pharmaceutical companies regularly use PGx tests in clinical trials to exclude people for whom the drug will be dangerous or ineffective or to better understand the efficacy of their offerings.
- Medical centers around the country are using PGx tests on patients in order to avoid serious drug side effects, reduce trial-and-error, and achieve more accurate prescribing.
- PGx testing is a key part of precision medicine, and with our patient-friendly report, you are able to have a more informed discussion with their healthcare providers.

Two million, two hundred thousand (2.2 million) serious adverse reactions occur per year, according to a report published by the Journal of the American Medical Association report. These ADEs lead to approximately 1.3 million emergency room (ER) visits per year, and $3.5 billion excess spend of medical costs.