

Pharmacogenomics

A Word to Remember

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Pharmacogenomics uses our genetic makeup to determine the best drug, dosage and frequency to maximize its effectiveness and minimize side effects – and it's within our reach today.

Pharmacogenomics is the study of how your genetic makeup can affect your response to drugs. It involves identifying genetic variations that influences your ability to metabolize, absorb, and respond to a medication. This information is then used to tailor drug therapy to your unique genetic



profile, to optimize treatment outcomes and to reduce the risk of side effects. For example, you may have a specific genetic variation that metabolizes a certain medication more quickly or slowly than someone without that variation, which could affect the dosage or frequency of the drug needed giving you enhanced results.

Pharmacogenomics is an emerging field in medicine and is gaining acceptance as a best practice in many areas of drug therapy including pain management, where genetic variations can have a significant impact on treatment response. However, the use of pharmacogenomics in pain management is not yet widely accepted as a best practice. This is primarily due to lack of standardization, lack of a robust evidence base, and the cost of genetic testing and limited accessibility to genetic testing.

Nonetheless, pharmacogenomics testing in pain management is increasingly considered to be an important tool in individualizing patient care and improving drug safety, but more research and implementation is needed to gain full adoption in the medical community and payment by insurers.

As a result, the use of pharmacogenomics in pain management is an area of active research and development. An increasing cohort of studies agree that genetic variations influence a person's response to certain pain medications, such as opioids. For example, certain genetic variations may affect how quickly a person metabolizes opioids, which could affect their risk of side effects or the effectiveness of the medication including indicating paradoxical reactions where side effects may outweigh benefits or risk of dependency or addiction may be substantially reduced.

Individualized pain management for CRPS lags other fields such as cancer

As research in the field continues to develop and more data is available, it is certain that pharmacogenomics will play an increasingly important role in the individualized management of pain, particularly in patients with chronic pain, where the risk of side effects and addiction are perceived to be high among political and regulatory bodies despite a compelling body of evidence to the contrary.

Pharmacogenomics has the potential to play a role in the individualized management of pain, called [precision medicine](#), particularly for patients with chronic pain or those who have not responded well to traditional treatment options. By identifying genetic variations that may affect a person's response to pain medications, healthcare providers can tailor treatment to an individual's unique genetic profile, which could lead to better treatment outcomes and reduced risk of side effects.

For example, research has shown that certain genetic variations in the genes that encode for enzymes involved in the metabolism of opioids such as CYP2D6, CYP2C19, CYP3A4, and UGT2B7 can affect a person's response to these medications. This information can help healthcare providers select the most effective opioid medication and dosage for a patient to optimize pain control while minimizing side effects.

Pharmacogenomic testing can also help to identify which patients are at the greatest risk of adverse reactions to non-opioid pain medication such as non-steroidal anti-inflammatory drugs (NSAIDs) and anti-seizure medications and those who may not receive a pain management benefit equal to the risk.

While pharmacogenomics has the potential to improve pain management, it is not a standalone solution. Using these tests in conjunction with other clinical information such as patient history and physical examination, comorbidities and other health status indications will deliver the best results. The scarcity of specific skill and experience sets in rare diseases like CRPS/RSD combined with the cost of genetic testing, limited accessibility and insurance coverage are still major challenges that need to be addressed before it can be widely adopted in the field of pain management.

Nonetheless, health insurers are increasingly approving payment for pharmacogenomic studies

Whether or not health insurers will pay for pharmacogenomic studies varies not just on the insurer but the specific circumstances of the test. Often the coverage for pharmacogenomic testing may depend on whether the test is considered medically necessary. The first step is to check with your insurance provider to see if they will cover the cost of the test. You can do this by calling the customer service number on the back of your insurance card or by visiting the insurance provider's website.

When you contact your insurance provider, you should have your policy number and any other relevant information available, such as the specific test you are interested in having done. You should also ask if the test is considered medically necessary and if there are any specific criteria that must be met for the test to be covered.

Even if your insurance does not cover pharmacogenomic testing, they stand to benefit the most. Here is the best way to make your case:

1. **Gather information:** Research the specific test you are interested in having done and the benefits it can provide. Your doctor can help with this task and may be the best person to make this call or provide you with a letter of medical necessity. This may include information on how the test can improve treatment outcomes, reduce the risk of adverse reactions, and lower healthcare costs.
2. **Contact your insurance provider:** Explain the specific test you are interested in having done and the benefits it can provide. Provide any relevant information, such as a letter of medical necessity from your doctor if they are not calling directly.

3. **If your request is denied, make an appeal:** If your insurance provider denies coverage for the test, you have the right to appeal the decision. Your insurance provider is required to provide information on the appeals process and any necessary documentation.
4. **Be persistent:** If at first, you don't succeed in getting coverage, don't give up. Keep in touch with your insurance provider and healthcare provider. Keep providing them with new information and studies about the clinical and economic benefits of pharmacogenomic testing. Enlist your doctors to help.

Please keep in mind that even if your health insurer covers the cost of a pharmacogenomic test, there may still be out-of-pocket costs for the patient, such as co-pays or deductibles. In cases where the insurance coverage is not clear, it is always best to check with the insurance provider to get a better understanding of the specific cost of the test.

If you are paying out of pocket, what is the cost for pharmacogenomic testing?

The cost can vary widely depending on the specific test being done and the laboratory that is conducting the test. Some pharmacogenomic tests can cost a few hundred dollars, while others can cost over a thousand dollars. Additionally, the cost of pharmacogenomic testing may depend on whether the test is being done as part of a research study or as a commercial test.

There are some pharmacogenomic testing companies that offer testing services at a lower cost using saliva sample or a cheek swab and provide the results online.

Is there federal legislation to support or compel insurance coverage for pharmacogenomics?

Currently, there is no federal legislation that specifically supports or compels insurance coverage for pharmacogenomic testing. However, there are a few laws and regulations that may impact coverage for pharmacogenomic testing:

1. The Affordable Care Act (ACA) requires that insurance plans cover certain preventive services, including some genetic tests, without any cost-sharing.
2. The Genetic Information Nondiscrimination Act (GINA) prohibits discrimination based on genetic information in employment and health insurance.
3. The 21st Century Cures Act requires the U.S. Food and Drug Administration (FDA) to establish a program to encourage the development of pharmacogenomic tests and to work with the Centers for Medicare & Medicaid Services (CMS) to ensure that these tests are covered by Medicare.

It's important to note that while these laws and regulations may impact coverage for pharmacogenomic testing, they do not specifically require insurance providers to cover pharmacogenomic tests.

Additionally, some states have legislation that affects pharmacogenomic testing, such as laws that require health insurers to cover certain types of genetic testing, but it's also important to check with the state's laws and regulations regarding pharmacogenomic testing.

To test or not to test?

There is an adage in medicine not to let perfection stand in the way of progress. Waiting for absolute proof that pharmacogenomic testing is effective when studies to date, including those for pain

management, strongly indicate that it can be beneficial both clinically and economically, is a personal call between you and your doctor.

Even if your insurer does not cover the testing, the monetary savings can be substantial in the form of reduced medication, procedure, hospitalization and physician visit costs if your health status improves as a result. The quality of life benefits in the form of reduced pain and suffering, increased mobility and activity, of course, are priceless.

This is a conversation I urge you to have, and the purpose of this article – to provide sufficient information to have that conversation.

Want to know more about the science of pharmacogenomic testing? Here are some resources:

[Practical Pain Management](#) – The science of Pharmacogenomic Testing

[Pharmacogenomics and Precision Medicine – Mayo Clinic - YouTube](#)

[Pharmacogenomic Testing Labs](#) – Where to Find Them

Since medically retiring after 35 years in CEO roles in hospitals, medical device companies and value-based care providers, James Doulgeris stays active by advising healthcare companies and systems in the AI and analytics spaces. He also works to improve care and treatments for the rare disease community including the first initiative to use clinical and claims analytics to identify, diagnose and treat rare disease beginning with CRPS/RSD. As award winning novelists for "The Dyodyne Experiment," Doulgeris is hard at work with his writing partner, V. Michael Santoro, on its sequel, "Sentience." He is also a contributor writing articles and providing background and interviews on healthcare for national publications and news outlets.