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Mental Health and Pharmacogenomic (PGx) Testing

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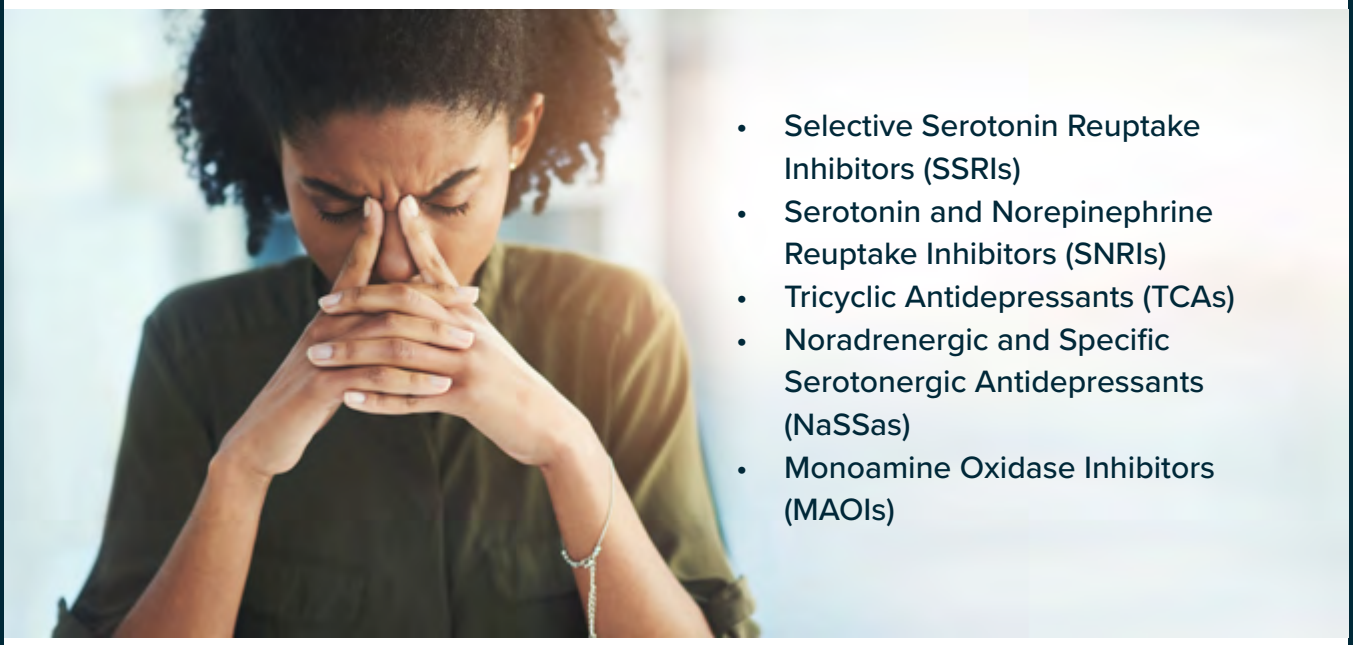
‘Mental Health’ is a broad topic that may mean different things to different people. The Centers for Disease Control and Prevention (CDC) defines mental health as:

> *“Emotional, psychological, and social well-being. It affects how we think, feel, and act. It also helps determine how we handle stress, relate to others, and make healthy choices.”*

Mental health is critical to everyone, regardless of their age or stage of life. Mental illness, which is a specific diagnosis that affects thoughts and behaviors, is not the same as mental health. People can be impacted by mental illness, mental health, or both simultaneously.

The statistics of mental health and mental illness are staggering. Over half of the population will be diagnosed with mental illness or a mental health disorder at least once in a lifetime. Over 20% of people in the United States will experience mental illness in any given year. Similarly, 20% of children have a mental illness that adversely impacts quality of life. About 4% of people in the United States have a major mental illness such as bipolar disorder, major depression, or schizophrenia, among other conditions.

Healthcare providers may prescribe medication to treat mental illness and mental health conditions. There are five classes of medications commonly used for treatment:



- Selective Serotonin Reuptake Inhibitors (SSRIs)
- Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)
- Tricyclic Antidepressants (TCAs)
- Noradrenergic and Specific Serotonergic Antidepressants (NaSSas)
- Monoamine Oxidase Inhibitors (MAOIs)

Medications to treat mental health conditions may also be known as antidepressants, anti-anxiety medications, stimulants, antipsychotics, and mood stabilizers. There are many choices patients and providers have for medical management. Each medication has its own strengths and risks for side effects. Traditionally, healthcare providers have used a “trial and error” approach when prescribing these medications to patients. It can take weeks for a medication to show the desired effect, and it is estimated that less than half of patients with major depressive disorder are satisfied with the first medication prescribed. Therefore, most patients may be on a “medical odyssey” to find the right medication and dose to manage mental health and mental illness.

This process can take months or even years before their medication is optimized.

The aim of precision medicine is to tailor a patient's treatment based on their unique clinical scenario (biology, genetics, environment, etc.). There are multiple genes that impact how different medications are metabolized. Pharmacogenomic (PGx) testing allows the clinician to prescribe a specific medication using the patient's genetic profile as a guide and provides a targeted (rather than random) approach to medical management of mental health issues and mental illness. There are numerous peer-reviewed journal articles citing the benefits of PGx for major depressive disorder, bipolar disorder, psychiatric disorders, and others.

However, PGx is not a "silver bullet" since medication response is multifactorial, having both genetic and environmental influences.

Even with the demonstrated clinical utility and the availability of PGx testing, there are still barriers in place in the United States preventing it from being standard of care. In 2018, the FDA issued a safety communication warning the public about direct to consumer (DTC) PGx testing. The FDA conceded that there is scientific evidence for PGx testing, however, some DTC companies were marketing tests to customers without robust scientific data. This warning from the FDA impacted DTC and clinical laboratories in the PGx space. In 2020, the FDA issued a collaborative review of scientific evidence for PGx and published a table of pharmacogenetic associations.

Health plan coverage for PGx in the United States is inconsistent, presenting another barrier regarding cost. A study published in 2020 reviewed over 220 medical policies for PGx from 41 different health insurance companies.

They reported insurance overage was available for about 40% of PGx tests mentioned in payor policies reviewed.

Finally, studies have shown that some medical specialties are lacking in PGx knowledge, and further education is needed. Even with the demonstrated clinical utility and the availability of PGx testing, there are still barriers in place in the United States preventing it from being standard of care. In 2018, the FDA issued a safety communication warning the public about direct to consumer (DTC) PGx testing. The FDA conceded that there is scientific evidence for PGx testing, however, some DTC companies were marketing tests to customers without robust scientific data. This warning from the FDA impacted DTC and clinical laboratories in the PGx space. In 2020, the FDA issued a collaborative review of scientific evidence for PGx and published a table of pharmacogenetic associations.

Mental health and mental illness are quite common globally and have been exacerbated by the COVID-19 pandemic. Healthcare providers will continue to treat and manage these health conditions. Additionally, some clinicians may experience their own mental health issues and be diagnosed with mental illness. When properly implemented, PGx has the potential to be a tool to increase efficiency in mental health medical management. Although there are barriers within certain health systems preventing access to PGx, there are resources available to providers that may assist in medication management.

About careviso

careviso offers combined expertise in laboratory, technology solutions, and HUB services to help both patients and physicians. We are the market leader in molecular diagnostic patient access, offering prior authorizations, benefits investigation, notifications, genetic counseling, and more. **Learn more** about our products and how we can help your business today!

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