admera health

Admera Health
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CLIA ID 31D2038676

LETTER OF MEDICAL NECESSITY FOR ADMERA HEALTH

We request full out of network benefit coverage for the diagnostic test **PGxOne™ Plus.** Our patient's personal and/or family history (histories) as well as current medication regimen are suggestive of high risk for adverse drug events based on my evaluation and review of available literature. In this patient's case, pharmacogenetics testing is crucial in order to establish/confirm a genetic diagnosis and in guiding appropriate and immediate medical management, predict disease prognosis and eliminate potential adverse drug events. We consider this test medically necessary for the diagnosis and treatment for the following patient:

PATIENT INFORMATION

Patient Name:

Insurance Carrier:

ID:

Date of service:

TEST DESCRIPTION

The PGxOne™ Plus Panel- analyzes fifty (50) genes that impact a patient's response and susceptibility or risks with different medications. The results will help make sure that a patient's prescription drugs will be safe and effective, avoid potentially harmful and costly adverse drug events, correct dose adjustments and obtain better treatment outcomes. The **PGxOne™ Plus** genes are:

ATP Binding Cassette Subfamily B Member 1, Angiotensin Converting Enzyme, Adrenoceptor Alpha 2A, angiotensin II receptor-1, Ankyrin Repeat And Kinase Domain, Apolipoprotein E, ATM Serine Threonine Kinase, Congenital dyserythropoietic anemias, Carboxylesterase 1, Cannabinoid receptor 1 (brain), Catechol Methyltransferase Genotype, Cytochrome P450 1A2, Cytochrome P450, family 2, subfamily B, polypeptide 6, Cytochrome P450 2C19 CYP2C19 Genotyping, Cytochrome P450, family 2, subfamily C, polypeptide 8, Cytochrome P450 2C9 CYP2C9, Cytochrome P450 2D6 CYP2D6, Cytochrome P450 Family 3 subfamily A gene 4, cytochrome P450, family 3 subfamily A allele 5, cytochrome P450, family 4 subfamily A allele 2, Dihydropyrimidine Dehydrogenase, Dopamine receptor D1, Dopamine receptor D2, Excision repair cross-complementation group 1, Coagulation Factor II Thrombin, F5 Gene coagulation factor 5, Fatty acid amide hydrolase, Glucose 6 Phosphate Dehydrogenase, Glutamate receptor, ionotropic, kainate 4, Glutathione S-transferase pi 1, UDP Glucuronosyltransferase 1A1 UGT1A1, 5-hydroxytryptamine -serotonin- receptor 1A, G protein-coupled, 5-hydroxytryptamine- serotonin-receptor 2A, G protein-coupled, 5-hydroxytryptamine -serotonin- receptor 2C, G protein-coupled, Interferon Lambda 3,Inosine Trisphosphatase, Kinesin family member 6, MTHFR Methylenetetrahydrofolate reductase, N-acetyltransferase2, Nitric oxide synthase 1 (neuronal) adaptor protein, NADPH dehydrogenase, quinone 1, Opioid receptor, mu 1, Sodium channel, voltage-gated, type II, alpha subunit, Solute carrier family 6 -neurotransmitter transporter, member 4, Solute Carrier Organic Anion Transporter, TPMT Genotype, Glucoronosyltransferase 1A1, DP glucuronosyltransferase 2 family, polypeptide B15, Vitamin I Epoxide Reductase Complex Subunit VKORC1 and X-ray repair complementing defective repair in Chinese hamster cells 1.Genetics account for much of the variability seen in our patients' responses to drug therapies and the implications of pharmacogenetics have been

Signature Required on Reverse Side

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well documented. Currently there are at least 130 FDA-approved drugs with Pharmacogenomic information in their labeling. The labeling for some of the products includes specific actions to be taken based on the biomarker information. In order to choose the more suitable medication and avoid potentially serious adverse drug events, it is extremely important to perform this test to understand how a patient's genotype influences the metabolism of medications.

This lifetime useful test is geared towards successful treatment outcomes while using cardiovascular drugs, anticoagulants, anti-hypertensives, sulfonylureas, antibiotics, Statins, antineoplastic agents, NSAIDS, Opiates, enzymes, hormones, antidepressants and anxiolytics among others.

The results from the **PGxOne™ Plus** test outlines what medications will get metabolized normally, which ones will need an increase in dose, which will be harmful and which ones will need lowering of the dose. It becomes even more critical on patients treated with multiple medications at a time.

PGxOne™ Plus is performed only at ADMERA HEALTH LLC, a clinical reference laboratory in South Plainfield, New Jersey. ADMERA HEALTH is CLIA certified and CAP-accredited. Clinical tests performed by ADMERA HEALTH have been validated in accordance with the guidelines established by these and other applicable agencies.

NETWORK PROVIDER SERVICES

I chose ADMERA HEALTH LLC to perform **PGxOne™ Plus** instead of alternative in-network laboratory testing because ADMERA HEALTH LLC is the only provider in my area providing this comprehensive testing.

LABORATORY AND PHYSICIAN INFORMATION

For additional information about the **PGxOne™ Plus** test, please contact **ADMERA HEALTH LLC** at 1-908-222-0533.

REFERENCE MATERIALS

Results Report is attached for your consideration

We are requesting that you consider **PGxOne™ Plus** for full payment based on the above explained medical necessity of our patient. If there are no existing Out of Network Benefits, please consider applying an exception of care approving coverage of this test which will reflect in future substantial benefits for his/her medical treatment.

Signature: (Medical Provider) _____

Date: _____

Information Required on Reverse Side