LETTER OF MEDICAL NECESSITY

PHARMACOGENOMIC (PGx) TESTING

Patient Name:_____ Patient Date of Birth:_____/_____/_____

Date of Service:_____/_____/_____ ICD-10 Diagnosis Codes: _____

DEAR CLAIMS SPECIALIST:

Please consider this Letter of Medical Necessity as a formal request for full coverage of **PGxOne™ Plus** panel, a multi- gene pharmacogenomic testing service that I prescribed for the above-mentioned patient. Pharmacogenomic laboratory testing services will be performed by Admera Health LLC, a CLIA-certified laboratory under CLIA #31D2038676 and NPI #1124438528. Along with the patient's clinical information and history, the results will assist me in making patient- specific clinical decisions regarding the medical management of your subscriber to avoid harmful and costly adverse drug events, optimize drug dose and increase chances of treatment success.

This testing will lead to a change in the management of the patient and will eliminate the need for further testing by:

- Reducing trial-and-error in prescribing medications.
- Selecting the right medication that's effective with less side effects.
- Increase patient medication compliance.
- Reducing associated costs such as revisits, hospitalization, changes of medications, as well as avoiding secondary new medications.
- No need for retesting as it is a lifetime test. Patient's DNA doesn't change.
- Selecting the correct medication for the patient, may reduce the need or frequency of tests associated with the patient's condition.

PGxOne™ Plus panel includes comprehensive analysis of ABCB1, ACE, ADRA2A, AGTR1, ANKK1, APOB, APOE, ATM, CDA, CES1, CNR1, COMT, CYP1A2, CYP2B6, CYP2C19, CYP2C8, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, DPYD, DRD1, DRD2, ERCC1, F2, F5, FAAH, G6PD, GRIK4, GSTP1, HFE, HLA-B, HTR1A, HTR2A, HTR2C, IFNL3, ITPA, KIF6, LDLR, MTHFR, NAT2, NOS1AP, NQO1, OPRM1, SCN2A, SLC6A4, SLCO1B1, TPMT, UGT1A1, UGT2B15, VKORC1, and XRCC1; including single nucleotide polymorphisms, copy number variations, and deletions/insertion.

This lifetime useful test will provide the safest, most effective and affordable medical care possible in several therapeutic areas including but not limited to cardiovascular drugs, anticoagulants, anti-hypertensives, sulfonylureas, antibiotics, Statins, antineoplastic agents, NSAIDS, Opiates, enzymes, hormones, antidepressants, and anxiolytics among others.

INFORMED CONSENT:

The patient has provided informed consent after being counseled about the drug response implications associated with the genes on the **PGxOne™ Plus** test, and the meaning of possible test results. Counseling will be made available to the healthcare provider and/or patient by a PharmD or Genetic Counselor trained in pharmacogenomics by a third-party provider.

SEE ATTACHED CLINICAL NOTES FROM THE DATE OF SERVICE

Progress notes for date of service may include clinical reason for ordering PGX test, medication list, and documentation of counseling (PharmD and/or GC with pharmacogenomics training).

The FDA recommendations for genetic testing are currently listed on the labels of over 150 prescription medications. Please visit (http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm) for more information. Recommendations typically include pharmacologic treatment contraindications and dose-selection strategies based on patient genetic status. In addition, medical professional organizations such as CPIC, ACMGG, and PharmGKB provide and update therapeutic guidelines for many areas of medicine based on pharmacogenomic results. As a health-care prescriber, I am obligated to provide the best medical care possible for my patients. Medical management based on patient-specific pharmacogenomic testing can improve clinical outcomes and PREVENT unnecessary suffering and costs.

Billing for genetic testing services will be initiated upon completion of services. As completion of genetic testing can take several months, **I am requesting your authorization be valid for 6 months.**

LABORATORY INFORMATION:

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. Please contact **ADMERA HEALTH LLC** at 1-908-222-0533 with any questions.

The requested genetic testing is medically necessary for my patient for several reasons. The primary reason(s) for my request apply specifically to the patient listed above:

___ Determine Drug-Gene interactions, better predicting how the patient will metabolize medications
___ Determine Drug-Drug interactions based on the patient's genetic-determined phenotype
___ Reduce the number of medications that my patient is currently taking
___ Aid to determine the potential effectiveness of medications prescribed to my patient
___ Aid to determine the best course of therapy for my patient
___ Avoid toxicity and adverse drug reactions (ADR's)
___ Patient is not responding to the drugs he/she has been prescribed
___ Patient has suffered recent or previous Severe Adverse Drug Reactions (SADR)
___ Other (please specify): _____

ADDITIONAL CLINICAL INFORMATION:

Previously failed medication(s): _____

Currently failing medication(s): _____

Proposed new medication(s): _____

SADR symptoms/presumed associated medication: _____

PHYSICIAN INFORMATION:

Ordering Clinician Name (Printed):_____

Ordering Clinician Signature:_____Date:____/____/____