PHARMACOGENETICS TESTING

Noridian issued an LCD for pharmacogenetic tests offered by MD Labs entitled *MolDx: Pharmacogenomics Testing (L38335)* and released *Article A57384 Billing and Coding: MolDX: Pharmacogenomics Testing*, both of which became **effective August 17, 2020**. The LCD Coverage identifies reimbursement for genotyping services that are limited to specific genes when medications with established gene-drug interactions are being considered.

1. The LCD provides coverage for pharmacogenomics testing when medications are being considered for use or are already being administered that are medically necessary, appropriate, and approved for use in the patient's condition and are known to have a gene(s)-drug interaction that has been demonstrated to be clinically actionable as defined by the FDA[1] or Clinical Pharmacogenetic Implementation Consortium[2] (CPIC) guidelines (category A and B).
2. The LCD requires that the ordering physician provide documentation of current medications that are in use or under consideration that necessitate the pharmacogenomics testing. The LCD does **not** consider pharmacogenomics testing medically necessary solely because a patient has a particular diagnosis or if the identified gene(s)-drug interaction does not have an actionable use. The below table lists example gene-drug interactions with FDA prescribing information and CPIC category A and B guidelines.

Example of Gene-Drug Interactions with FDA Prescribing Information and CPIC Guidelines			
Gene	**CPT**	**Drug Recommendation**	**Source**
CYP2C19	81225	Clopidogrel	CPIC, FDA
CYP2C19	81225	SSRIs (class)	CPIC
CYP2C19	81225	Tricyclic Antidepressants (class)	CPIC
CYP2C9	81227	NSAIDs (class)	CPIC
CYP2D6	81226	Aripiprazole	FDA
CYP2D6	81226	Atomoxetine	CPIC, FDA
CYP2D6	81226	Brexpiprazole	FDA
CYP2D6	81226	Codeine	CPIC, FDA
CYP2D6	81226	SSRIs (class)	CPIC
CYP2D6	81226	Tramadol	FDA
CYP2D6	81226	Tricyclic Antidepressants (class)	CPIC
CYP2D6	81226	Venlafaxine	FDA
CYP2D6	81226	Vortioxetine	FDA

Should you have any questions or concerns, call MD Labs Billing Department at 775-499-5150.

Warfarin / CYP2C9 & VKORC1 Pharmacogenetic Testing (CPT 81227 & CPT 81355)

Effective August 3, 2009, the Centers for Medicare and Medicaid Services issued an NCD for warfarin response pharmacogenomic testing titled: *Pharmacogenomic Testing for WARFARIN Response (NCD 90.1)*. Noridian also released *Article A55179 Billing and Coding: MolDx: CYP2C9 and/or VKORC1 Gene Testing for Warfarin Response*. This LCD indicates coverage and genotyping services for CYP2C9 and

[1] https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations
[2] https://cpicpgx.org/guidelines/

VKORC1 are **only** covered in the context of a clinical study.

National Coverage Determination 90.1 provides coverage for CYP2C9 & VKORC1 genotyping to predict warfarin responsiveness **only** for beneficiaries who are candidates for anticoagulation therapy with warfarin who have not been previously tested for CYP2C9 or VKORC1 alleles, have received fewer than five days of warfarin in the anticoagulation regimen for which testing is ordered, and are enrolled in a prospective, randomized, controlled clinical study that meets standards set by the Centers for Medicare and Medicaid Services. All other instances of genetic testing for CYP2C9 and/or VKORC1 are considered investigational and are not covered by the NCD.

MTHFR Genotyping (CPT 81291)

Effective June 16, 2016 and updated November 1, 2019, Noridian issued an LCD for certain genetic tests offered by MD Labs for thrombophilia testing entitled *Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36155)* and released *Article A57423 Billing and Coding: MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)*. This LCD indicates that coverage and reimbursement for testing for the Factor V Leiden (FVL) variant in the F5 gene and the G20210G>A variant in the F2 gene is limited to specific therapeutic and diagnostic indications, and genetic testing for MTHFR is not covered. The LCD considers MTHFR genotyping to be investigational and not a covered Medicare benefit in ANY clinical scenario.

Should you have any questions or concerns, call MD Labs Billing Department at 775-499-5150.