

2017 Annual Physician Notice

(As amended September 20, 2017 to include information on the CogenDx branded DxWound product)

The Office of Inspector General (OIG) recommends clinical laboratories send notices to physicians and other providers who use their services, at least once a year, to inform the recipients of the laboratory's policies for test ordering and billing and provide certain other information regarding the laws and regulations that govern laboratory services. This Annual Notice is provided pursuant to that recommendation.

The following information is intended to promote awareness of federal regulations and to explain the requirement for physicians to furnish appropriate documentation when ordering testing services. If you have questions about the contents in this notice, we encourage you to contact us for more information.

MEDICAL NECESSITY:

Medicare will only pay for tests that meet the Medicare coverage criteria and are medically necessary for the diagnosis or treatment of the individual patient. The medical need for drug testing must be based on patient-specific elements identified during the clinical assessment and documented by the clinician in the patient's medical record. Tests used for routine screening of patients without regard to their individual need are not usually covered by the Medicare Program, and therefore are not reimbursed. As a participating provider in the Medicare Program, Millennium Health (Millennium) has a responsibility to educate physicians and to implement test ordering procedures to help ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations. As the physician, you are responsible for ordering tests only when they are medically necessary, for documenting medical necessity in the patient's permanent medical record, and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to Millennium. *The Office of Inspector General takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.*

Millennium Health has developed a documentation tool to assist you with assessing and documenting medical necessity and implementing definitive testing into patient-specific test orders and treatment plans. It should supplement, rather than replace, other forms of documentation and notes you currently utilize. The documentation tool can be provided upon request.

MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS:

The Medicare Program publishes National Coverage Determinations (NCDs) and local Medicare contractors publish Local Coverage Determinations (LCDs) for certain tests. These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare, typically by reference to specific ICD-10 codes that are deemed to support coverage. LCD policies referenced in this document can be accessed on the Medicare website via the links provided at the last page of this document prior to Exhibit 1.

Urine Drug Testing:

On June 28, 2016, our Medicare Administrative Contractor Noridian Healthcare Solutions, LLC (Noridian), implemented an LCD entitled "**Controlled Substance Monitoring and Drugs of Abuse Testing (L36668)**". This policy, among other things, provides guidance regarding covered indications, ICD-10 codes that support medical necessity and expected

frequency for Urine Drug Testing (UDT). This policy can be accessed on the Medicare website via the link on page 6 of this document.

Genetic Testing

Effective October 1, 2015, Noridian issued an LCD for certain genotyping tests (i.e., pharmacogenetic tests) offered by Millennium entitled “**CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L36310)**”. Coverage and reimbursement for genotyping services for CYP2D6 and CYP2C19 is limited to defined therapeutic indications, and genotyping services for CYP2C9 and VKORC1 are only covered in the context of a clinical study.

- *CYP2D6 Genotyping (CPT 81226)*: The LCD considers CYP2D6 genotyping to be medically necessary for patients who have a depressive disorder and for whom initial therapy is being planned with amitriptyline or nortriptyline therapy. The LCD also considers CYP2D6 genotyping to be medically necessary for patients being considered for tetrabenazine therapy at doses greater than 50 mg/day. The LCD does not consider CYP2D6 genotyping to be medically necessary for any other therapeutic or diagnostic indications.
- *CYP2C19 Genotyping (CPT 81225)*: The LCD considers CYP2C19 genotyping to be medically necessary for patients with acute coronary syndrome (ACS) who are undergoing percutaneous coronary intervention (PCI) and are initiating or reinitiating clopidogrel (Plavix®) therapy. The LCD does not consider CYP2C19 genotyping to be medically necessary for any other therapeutic or diagnostic indications.
- *CYP2C9 & VKORC1 Genotyping (CPT 81227 & CPT 81355)*: The LCD provides coverage for CYP2C9 & VKORC1 genotyping to predict warfarin responsiveness only when Medicare beneficiaries have not been previously tested for CYP2C9 and VKORC1, have received fewer than five days of warfarin, and are enrolled in a prospective, randomized, controlled clinical study that has been approved by the Centers of Medicare & Medicaid Services (CMS). All other instances of genetic testing for CYP2C9 and/or VKORC1 are considered investigational and are not covered by the LCD.

Effective April 1, 2016, Noridian issued an LCD for HLA-B*15:02 genotype testing entitled “**HLA-B*15:02 Genetic Testing (L36145)**”. Coverage and reimbursement for HLA-B*15:02 is limited to defined therapeutic indications.

- *HLA-B*15:02 Genotyping (CPT 81381)*: The LCD provides coverage for HLA-B*15:02 genotype testing for patients of Asian and Oceanian ancestry who are being considered for initial treatment with carbamazepine, phenytoin or fosphenytoin. All other instances of genotyping are not considered medically necessary.

Effective June 16, 2016, Noridian issued an LCD for certain genetic tests offered by Millennium for thrombophilia testing entitled **Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36155)**. 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.

- *F5/F2 Genotyping (CPT 81240/ 81241/)*: The LCD considers genotyping for FVL in the F5 gene and the G20210 G>A variant in the F2 gene to be medically necessary for pregnant women with a previous history of VTE associated with a transient risk factor (e.g., surgery, trauma) who are not otherwise receiving anticoagulant prophylaxis and for pregnant women with a family history of known thrombophilia who exhibit signs and symptoms of disease. Medicare does not otherwise cover F5/F2 genetic testing for pregnant women. The LCD advises that denied claims can be appealed for coverage with submission of medical records supporting the necessity for testing, specifically how testing modified anticoagulant prophylaxis management for the patient.

- *MTHFR Genotyping* (CPT 81291): The LCD considers MTHFR genotyping to be investigational and not a covered Medicare benefit in ANY clinical scenario.

Currently there are no active or draft LCDs issued by Millennium’s Medicare Administrative Contractor Noridian for genetic testing services offered by Millennium for infectious disease testing (DxWound testing). There is an active LCD policy issued by Palmetto GBA Medicare entitled “**Infectious Disease Molecular Diagnostic Testing (L33433)**”. This policy provides guidance regarding diagnoses for which the identified CPT/HCPCS procedures are covered. Testing performed for patients that do not meet the covered diagnosis criteria will be denied automatically as not medically necessary.

Presently, this policy is applicable only to laboratories located in Palmetto GBA’s jurisdiction, which encompasses North Carolina, South Carolina, Virginia and West Virginia, and thus is NOT applicable to testing ordered from Millennium, regardless of the location of the ordering clinician (although the policy does apply to testing performed by physician office labs located in Palmetto’s jurisdiction). Nevertheless, we believe many of the requirements included in this LCD eventually will be adopted by the individual CMS contractors nationwide, and thus are preparing to ensure both our and your compliance with the Palmetto standards, including through revised test requisition forms and the documentation tool mentioned above.

For the most current information regarding Medicare coverage, please use this link: <https://www.cms.gov/medicare-coverage-database>.

TEST ORDERING:

Millennium has two web-based platforms that may be used to order tests from Millennium. CONNECT is available for drug testing and VIRA is used to order genetic testing. These platforms help health care providers track and view specimens as they progress through transit, testing and delivery of results. A standard Millennium test requisition form (whether via web-based platforms or in paper form) should always be used when ordering tests. The Millennium requisition forms are designed to emphasize physician choice and encourage physicians to order only those tests which the physician believes are appropriate and medically necessary for the diagnosis or treatment of each patient. If Millennium receives a test order on a non-Millennium requisition form or an incomplete Millennium requisition form, processing of your test order may be delayed. As necessary, Millennium will contact physicians to have them resubmit the test order on a Millennium test requisition form or otherwise clarify each specific test being ordered.

ELIMINATION OF CUSTOM PROFILES:

Policy changes and guidance from Medicare Administrative Contractors, other government regulatory authorities and commercial insurers now discourage, if not outright prohibit, clinicians’ use of non-patient-specific panels, including “custom profiles,” when ordering laboratory drug testing . As the industry leader in definitive drug testing for medication monitoring, Millennium supports these efforts and has devoted substantial resources to developing processes that will seamlessly encourage the ordering of only medically necessary tests for each patient. Accordingly, in 2015 Millennium eliminated its use of physician-directed custom profiles. Eliminating custom profiles, along with not creating our own pre-set panels, helps ensure that testing is medically necessary based on individual patient specific elements identified during the clinical assessment and documented by the clinician in the patient’s medical record. Elimination of custom profiles and adoption of patient specific ordering without panels is also important for physicians. Health plans and regulatory authorities are increasingly expecting physicians to strictly comply with new medical policies related to drug test ordering or risk network termination for non-compliance. We support these efforts to help better ensure that only medically

necessary tests are ordered for each patient and we are taking steps to further the interests of both our clinician and health plan customers.

VERBAL TEST ORDERS:

Medicare regulations require that all orders for laboratory tests be in writing. If a physician or his/her authorized representative orders a test by telephone or wishes to add a test to an existing order, a written order is required to support the verbal order. In these cases, Millennium will send a confirmation of the verbal order request to the ordering physician, requesting it to be signed and sent back to the laboratory for its records. Testing will not be performed until the signed confirmation or a properly completed Millennium requisition form is returned to the laboratory.

PATIENT PRIVACY (HIPAA):

Under the Health Insurance Portability and Accountability Act (HIPAA), Millennium is a health care provider and a covered entity. It is our policy to fully comply with the HIPAA privacy and security standards. Our privacy policy is available at <http://millenniumhealth.com/privacy-policy/>.

INDUCEMENTS:

Federal law prohibits offering or paying any remuneration – meaning anything of value – to induce the referral of tests that are covered by Medicare, Medicaid or other federal health care programs. Any form of kickback, payment or other remuneration that is intended to secure the referral of federal health care program testing business is strictly prohibited and should be reported to the Millennium compliance hotline by calling 866-677-3847.

CLINICAL CONSULTANTS:

Physicians and other clinicians authorized to order tests have the services of clinical consultants and toxicologists available to ensure proper test ordering and answer questions. They may be reached at (866) 866-0605.

PROHIBITED REFERRALS:

It is the policy of Millennium Health to comply with all aspects of the laws and regulations governing physician self-referral, most notably including the federal Stark law. The Stark law's self-referral ban states that if a financial relationship exists between a physician (or an immediate family member) and a laboratory (or certain other kinds of healthcare providers), and the relationship does not fit into one of the law's exceptions, then (a) the physician may not refer Medicare patients to the laboratory, and (b) the laboratory may not bill Medicare for services referred by the physician. The kinds of relationships between laboratories and physicians that may be affected by these laws include the lease or rental of space or equipment and the purchase of medical or other services by a laboratory from a referring physician.

MEDICARE RATES:

Millennium's test list with CPT and HCPCS G-Codes and Calendar Year 2017 Medicare maximum reimbursement rates for each test is attached hereto as Exhibit 1.

FINANCIAL ASSISTANCE PROGRAMS:

Millennium understands that providing quality patient care has a related cost, which in some situations may be burdensome for patients and result in some patients avoiding certain necessary services because they are concerned about

the expense. Millennium is committed to delivering the best patient care to all, and to meet this objective has established a financial support program. This financial support program helps ensure affordable access to Millennium's services. Patients with special financial needs may be eligible for support to help defray some of Millennium's testing costs. Millennium encourages those patients who may not be able to pay fully for Millennium's services to contact us for an assessment of eligibility for financial support in accordance with federal guidelines.

PATIENT BILLING POLICY:

Insured patients are billed Deductibles, Co-Insurance and Co-Payments as required by their Insurance Provider. Millennium reserves the right to use resources available to search for active insurance if information is not provided or if the order is marked "Uninsured" or "Patient Does Not Have Insurance Coverage."

Under HIPAA, patients may opt out of using their insurance benefits in order to prevent reporting this service to their insurance carrier. Millennium must be informed at the time of ordering if the patient is choosing this option and the patient's insurance information **must** be provided. The patient will be billed at Medicare rates for the services performed. If payment is not received within 60 days, Millennium will bill the patient's insurance in order to secure reimbursement.

Millennium offers a patient self-pay option for patients who wish to waive insurance benefits and pay a flat, out-of-pocket rate for testing services. Coverage of testing services will vary according to type of test ordered, insurance type and patient benefits. Certain tests may not be a covered benefit for some patients due to active LCDs or other insurer coverage policies that limit benefits to narrow clinical indications. Patients seeking testing services who do not wish to use their insurance coverage must sign a Patient Self Payment Agreement or Advanced Beneficiary Notice (Medicare patients only) at the time of ordering. The patient will be billed a flat fee irrespective of the number of tests ordered. Millennium will invoice the patient and payment must be received within 120 days. If the patient is found to have no insurance, Millennium may offer an uninsured rate. Patients are encouraged to contact us if they believe there is a billing error, need to establish payment arrangements or have questions about their bill.

Links to LCD policy's referenced in this document:

1. Noridian Healthcare Solutions, LLC. "Controlled Substance Monitoring and Drugs of Abuse Testing (L36668)."
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36668&ContrId=365&ver=3&ContrVer=1&CtrctrSelected=365*1&Ctrctr=365&s=67&DocType=Active&bc=AggAAAIAAAAAAAAA%3d%3d
2. Noridian Healthcare Solutions, LLC. "CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L36310)"
<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36310&ContrId=365>
3. Noridian Healthcare Solutions, LLC. "HLA-B*15:02 Genetic Testing (L36145)"
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36145&ContrId=360&ver=4&ContrVer=1&CtrctrSelected=360*1&Ctrctr=360&s=6&DocType=Active%7cFuture%7cAllProposed&bc=AggAAAIAAAAAAAAA%3d%3d
4. Noridian Healthcare Solutions, LLC. "Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36155)"
<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36155&ContrId=364>
5. Palmetto GBA. "Infectious Disease Molecular Diagnostic Testing (L33433)"
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33433&ContrId=381&ver=41&ContrVer=1&CtrctrSelected=381*1&Ctrctr=381&name=&DocType=Active&s=34%7c48%7c53%7c58&bc=AggAAAQAAAAAAAA%3d%3d

Exhibit 1

Oral Fluid and Urine Drug Testing

2017 CMS HCPCS Code	Code Description	2017 Medicare Allowable
80307	Presumptive drug test - any number of drug classes, any number of devices or procedures by instrumented chemistry analyzers, includes sample validation when performed, per date of service	\$79.81
G0480	Definitive drug tests, 1-7 drug classes*	\$117.65
G0481	Definitive drug tests, 8-14 drug classes*	\$160.99
G0482	Definitive drug tests, 15-21 drug classes*	\$204.34
G0483	Definitive drug tests, 22+ drug classes*	\$253.87

*** Drug class includes any of the classes listed below. The list below matches the drugs included in those drug classes, for reference. Includes specimen validity testing, per day, including metabolites if tested.**

List of Drug Classes that may be included in Definitive Drug Testing Codes listed above

Drug	Drug Class	2017 AMA Code
Alcohol	Alcohol(s)	80320
Ethyl Glucuronide	Alcohol Biomarkers	80321
Kratom	Alkaloids, not otherwise specified	80323
Amphetamines, Methamphetamines, Phentermine	Amphetamines	80324-80326
Citalopram, Duloxetine, Fluoxetine, Paroxetine	Antidepressants, serotonergic class	80332-80334
Amitriptyline	Antidepressants, Tricyclic and other cyclicals	80335-80337
Desipramine	Antidepressants, Tricyclic and other cyclicals	80335-80337
Imipramine	Antidepressants, Tricyclic and other cyclicals	80335-80337
Nortriptyline	Antidepressants, Tricyclic and other cyclicals	80335-80337
Bupropion, Venlafaxine	Antidepressants, not otherwise specified	80338
Clozapine, Olanzapine, Quetiapine, Risperidone, Aripiprazole, Haloperidol	Antipsychotics, not otherwise specified	80342-80344
Secobarbital, Phenobarbital, Butalbital	Barbiturates	80345
Benzodiazepines	Benzodiazepines	80346
Buprenorphine	Buprenorphine	80348
THC	Cannabinoids, natural	80349
Spice	Cannabinoids, synthetic	80352
Cocaine	Cocaine	80353

Drug	Drug Class	2017 AMA Code
Fentanyl	Fentanyls	80354
Gabapentin	Gabapentin, non-blood	80355
Heroin	Heroin Metabolite	80356
Ketamine	Ketamine and Norketamine	80357
Methadone	Methadone	80358
MDMA	Methylenedioxyamphetamines	80359
Methylphenidate	Methylphenidate	80360
Codeine/Morphine	Opiates	80361
Hydrocodone	Opiates	80361
Hydromorphone	Opiates	80361
Meperidine, Naloxone, Naltrexone, Dextromethorphan, Levorphanol	Opioids and opiate analogs	80362-80364
Oxycodone	Oxycodone	80365
Phencyclidine	Phencyclidine	83992
Pregabalin	Pregabalin	80366
Zolpidem	Sedative Hypnotics (nonbenzodiazepines)	80368
Carisoprodol	Skeletal muscle relaxants	80369
Cyclobenzaprine	Skeletal muscle relaxants	80369
Tapentadol	Tapentadol	80372
Tramadol	Tramadol	80373
Bath Salts (Cathinones)	Stimulants, synthetic	80371

Pharmacogenetic Testing

Drug or Drug Class	Drugs Targeted	Genes Evaluated	CPT Codes	2017 Medicare Allowable	Test Method
Addiction	Methadone	CYP2B6	81479	TBD	qPCR
	Naltrexone	OPRM1	81479	TBD	qPCR
Anticoagulants	Warfarin	CYP2C9, VKORC1	81227 81355	\$176.03 TBD	qPCR
Anticonvulsants	Carbamazepine, Eslicarbazepine, Forphenytoin, Lamotrigine, Oxcarbazepine, Phenytoin	HLA-B*15:02	81381	\$129.74	qPCR
Antidepressants, SSRIs/SNRI	Citalopram, Escitalopram, Sertraline,	CYP2C19,	81225	\$293.40	qPCR
	Fluoxetine, Paroxetine, Venlafaxine, Vortioxetine	CYP2D6	81226	\$454.07	qPCR
	L-methylfolate	MTHFR	81291	\$59.88	qPCR
Antidepressants, Tricyclic (TCA)	Amitriptyline, Clomipramine, Doxepin, Imipramine,	CYP2C19, CYP2D6	81225 81226	\$293.40 \$454.07	qPCR
	Desipramine, Nortriptyline	CYP2D6	81226	\$454.07	qPCR
Antipsychotics	Aripiprazole, Haloperidol, Risperidone	CYP2D6	81226	\$454.07	qPCR
	Clozapine, Olanzapine, Risperidone	DRD2	81479	TBD	qPCR
	Clozapine, Olanzapine	HTR2C	81479	TBD	qPCR
ADHD Therapy	Atomoxetine	CYP2D6	81226	\$454.07	qPCR
Benzodiazepines	Diazepam	UGT2B15	81479	TBD	qPCR
	Lorazepam, Oxazepam	CYP2C19	81225	\$293.40	qPCR
Muscle Relaxants	Carisoprodol	CYP2C19	81225	\$293.40	qPCR
NSAIDs	Celecoxib	CYP2C9	81227	\$176.03	qPCR
Opioids	Codeine	COMT, CYP2D6, OPRM1	81479	TBD	qPCR
			81226	\$454.07	
			81479	TBD	
	Fentanyl	CYP3A4, CYP3A5, OPRM1	81401	TBD	qPCR
			81401 81479	TBD TBD	
Hydrocodone, Oxycodone, Tramadol	CYP2D6	81226	\$454.07	qPCR	
Methadone	CYP2B6	81479	TBD	qPCR	
Morphine	OPRM1, COMT	81479 81479	TBD	qPCR	
Platelet Inhibitors	Clopidogrel	CYP2C19	81225	\$293.40	qPCR
Neuromuscular blockers	Succinylcholine	BCHE	81479	TBD	qPCR
N/A	N/A	F2/F5	81241 81240	TBD	qPCR

DxWound Genetic Testing

Test Category	Test Name	CPT Code	2017 Medicare Allowable	Test Method
Aerobic Bacteria, Gram-Positive	Enterococcus faecalis	87798	\$48.14	qPCR
Aerobic Bacteria, Gram-Positive	Enterococcus faecium	87798	\$48.14	qPCR
Aerobic Bacteria, Gram-Positive	Mycobacterium abscessus	87551	\$48.14	qPCR
Aerobic Bacteria, Gram-Positive	Mycobacterium chelonae	87551	\$48.14	qPCR
Aerobic Bacteria, Gram-Positive	Staphylococcus aureus	87640	\$48.14	qPCR
Aerobic Bacteria, Gram-Positive	Staphylococcus lugdunensis (Coagulase-Negative)	87798	\$48.14	qPCR
Aerobic Bacteria, Gram-Positive	Streptococcus agalactiae (Group B)	87653	\$48.14	qPCR
Aerobic Bacteria, Gram-Positive	Streptococcus pyogenes (Group A)	87651	\$48.14	qPCR
Aerobic Bacteria, Gram-Negative	Acinetobacter baumannii	87798	\$48.14	qPCR
Aerobic Bacteria, Gram-Negative	Citrobacter freundii	87798	\$48.14	qPCR
Aerobic Bacteria, Gram-Negative	Enterobacter aerogenes	87798	\$48.14	qPCR
Aerobic Bacteria, Gram-Negative	Enterobacter cloacae	87798	\$48.14	qPCR
Aerobic Bacteria, Gram-Negative	Escherichia coli	87798	\$48.14	qPCR
Aerobic Bacteria, Gram-Negative	Proteus mirabilis/vulgaris	87798	\$48.14	qPCR
Aerobic Bacteria, Gram-Negative	Pseudomonas aeruginosa	87798	\$48.14	qPCR
Virulence Gene	PVL	87999	N/A	qPCR
Anaerobic Bacteria, Gram-Positive	Clostridium perfringens	87798	\$48.14	qPCR
Anaerobic Bacteria, Gram-Positive	Clostridium septicum	87798	\$48.14	qPCR
Anaerobic Bacteria, Gram-Negative	Bacteroides fragilis	87798	\$48.14	qPCR
Anaerobic Bacteria, Gram-Negative	Prevotella intermedia	87798	\$48.14	qPCR
Anaerobic Bacteria, Gram-Negative	Prevotella oralis	87798	\$48.14	qPCR
Fungi	Aspergillus flavus	87798	\$48.14	qPCR
Fungi	Aspergillus fumigatus	87798	\$48.14	qPCR
Fungi	Aspergillus niger	87798	\$48.14	qPCR
Fungi	Candida albicans	87481	\$48.14	qPCR
Fungi	Candida glabrata	87481	\$48.14	qPCR
Fungi	Candida parapsilosis	87481	\$48.14	qPCR
Fungi	Candida tropicalis	87481	\$48.14	qPCR
Antibiotic Resistance Genes	Carbapenemase	87798	\$48.14	qPCR
Antibiotic Resistance Genes	Extended-Spectrum β -Lactamase	87798	\$48.14	qPCR
Antibiotic Resistance Genes	Macrolide-Lincosamide-Streptogramin B Resistance	87798	\$48.14	qPCR
Antibiotic Resistance Genes	Oxacillin/Methicillin Resistance	87798	\$48.14	qPCR
Antibiotic Resistance Genes	Vancomycin Resistance	87798	\$48.14	qPCR