2020 Annual Physician Notice

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 OIG 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 a documentation tool, available in paper form but also as part of Millennium's web-based ordering process, which is designed to assist providers in meeting documentation requirements regarding the medical necessity of definitive laboratory testing. 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, and updated on 10/01/2019, 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, limitations, and/or medical necessity. Article A55001 Billing and Coding: Lab: Controlled Substance Monitoring and Drugs of Abuse Testing contains billing, coding, or other guidelines that complement the Local Coverage Determination (LCD) for Lab: Controlled Substance Monitoring and Drugs of Abuse Testing L36668. These documents can be accessed on the Medicare website.

Genetic Testing

Effective October 1, 2015 and updated November 1, 2019, Noridian issued an LCD for certain genotyping tests (i.e., pharmacogenetic tests) offered by Millennium entitled **"CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L36310)" and released Article A57378 Billing and Coding: MolDX: CYP2C19, CYP2D6, CYP2C9 and VKORC1 Genetic Testing.** 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 CYP2C19 and/or VKORC1 are considered investigational and are not covered by the LCD.

Effective April 1, 2016 and updated November 1, 2019, Noridian issued an LCD for HLA-B*15:02 genotype testing entitled **"HLA-B*15:02 Genetic Testing (L36145)" and released Article A57466 Billing and Coding: MolDX: HLA-B*15:02 Genetic Testing.** 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 and updated November 1, 2019, 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) and released Article A57423 Billing and Coding: MolDX: Genetic Testing for Hypercoagulabilitiy / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) .** 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.

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

TEST ORDERING:

All tests are available for order by paper test requisition forms and Intellium[SM], a web-based platform. A standard Millennium requisition form (whether via web-based platform or in paper form) must always be used when ordering tests. The Millennium requisition forms are designed to emphasize patient specific ordering of only medically necessary tests. 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. Only tests that are ordered will be reported.

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.

INDUCEMENTS:

Federal law prohibits offering or paying any remuneration – meaning anything of value – to induce or reward 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 review results 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 (also known as the physician self-referral 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 2020 Medicare reimbursement rates for each test is attached hereto as Exhibit 1. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

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 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. 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. 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 the out of pocket rate for the services performed. If payment for such service is not received within 60 days, Millennium will bill the patient's insurance in order to secure reimbursement. If the patient is found to have no insurance, Millennium will bill the patient at the out of pocket rate.

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 should contact us if they have questions about their bill or need to establish payment arrangements. To learn more, Please call 877-451-7337 or visit our website: http://www.millenniumhealth.com/health-care-provider-resources/billing-information/

LABORATORY SERVICES PROVIDED TO HOSPITALS AND SKILLED NURSING FACILITIES

When a hospital obtains laboratory tests for hospital outpatients under arrangements with a clinical laboratory, only the hospital can bill for the arranged services that are provided to Medicare beneficiaries. Medicare Claims Processing Manual, CH. 16, Sec. 40.3. Under the Medicare Outpatient Prospective Payment System ("OPPS"), payment for clinical diagnostic laboratory tests provided to hospital outpatients is generally packaged into the payment for the outpatient procedure performed. Similarly, under the Medicare Inpatient Prospective Payment System ("IPPS"), payment for clinical diagnostic laboratory tests provided to hospital inpatients is packaged into the DRG payment for the admission. Similar payment packaging policies may apply during a Medicare patient's stay in a Skilled Nursing Facility ("SNF"). If you are ordering Millennium services for a hospital patient or a SNF resident, please notify Millennium to ensure that the services are appropriately billed.

Links to LCD policies referenced in this document:

1. Noridian Healthcare Solutions, LLC. "Controlled Substance Monitoring and Drugs of Abuse Testing (L36668)." https://go.cms.gov/2H4bQVi
2. Noridian Healthcare Solutions, LLC. "CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L36310)" https://go.cms.gov/2DSbQXQ
3. Noridian Healthcare Solutions, LLC. "HLA-B*15:02 Genetic Testing (L36145)" - https://go.cms.gov/2VL8TT3
4. Noridian Healthcare Solutions, LLC. "Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36155)" https://go.cms.gov/2V3Fjnw

Exhibit 1

Oral Fluid and Urine Drug Testing

2019 CMS HCPCS Code	Code Description	2020 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	$62.14
G0480	Definitive drug tests, 1-7 drug classes*	$114.43
G0481	Definitive drug tests, 8-14 drug classes*	$156.59
G0482	Definitive drug tests, 15-21 drug classes*	$198.74
G0483	Definitive drug tests, 22+ drug classes*	$246.92

*** 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/Analyte	Billing Drug Class	2020 AMA Code
Ethyl Glucuronide/Ethyl Sulfate	Alcohol Biomarkers	80321
Kratom	Alkaloids, NOS	80323
Amphetamines, Methamphetamines, Phentermine	Amphetamines	80324-80326
Methamphetamine - d/l Isomers	Stereoisomer	80374
Citalopram/escitalopram, Duloxetine, Fluoxetine, Paroxetine	Antidepressants, serotonergic class	80332-80334
Amitriptyline, Desipramine, Imipramine, Nortriptyline	Antidepressants, Tricyclic and other cyclicals	80335-80337
Bupropion, Venlafaxine	Antidepressants, NOS	80338
Aripiprazole, Clozapine, Haloperidol, Olanzapine, Quetiapine, Risperidone	Antipsychotics, NOS	80342-80344
Butalbital, Phenobarbital, Secobarbital	Barbiturates	80345
Alprazolam, Clonazepam, Diazepam, Lorazepam, Oxazepam, Temazepam	Benzodiazepines	80346-80347
Buprenorphine	Buprenorphine	80348
Marijuana, THC	Cannabinoids, natural	80349
Spice compound metabolites	Cannabinoids, synthetic	80350-80352
Benzoylecgonine (cocaine metabolite)	Cocaine	80353
Fentanyl and analogues	Fentanyl	80354
Gabapentin	Gabapentin	80355
6-MAM (Heroin metabolite)	Heroin Metabolite	80356
Ketamine	Ketamine	80357
Methadone / EDDP (methadone metabolite)	Methadone	80358
MDMA	Methylenediozyamphetamines	80359
Methylphenidate, ritalinic acid	Methylphenidate	80360
Atomoxetine	NOS	80375-80377
Codeine, Hydrocodone, Hydromorphone. Morphine	Opiates	80361
Dextromethorphan, Meperidine, Naloxone, Naltrexone	Opioids and opiate analogs	80362-80364
Oxycodone, Oxymorphone	Oxycodone	80365
Phencyclidine	Phencyclidine	83992
Pregabalin	Pregabalin	80366
Zolpidem	Sedative Hypnotics (nonbenzodiazepines)	80368
Carisoprodol, Cyclobenzaprine	Skeletal muscle relaxants	80369-80370
Bath Salts (Cathinones), Phenylethylamines	Stimulants, synthetic	80371
Tapentadol	Tapentadol	80372
Tramadol	Tramadol	80373

Pharmacogenetic Testing

Drug or Drug Class	Drugs Targeted	Genes Evaluated	CPT Codes	2020 Medicare Allowable	Test Method
Addiction	Buprenorphine	CYP3A4, CYP3A5	81230, 81231	N/A	
	Methadone	CYP2B6	81479	N/A	qPCR
	Naltrexone	OPRM1	81479	N/A	qPCR
Anticoagulants	Warfarin	CYP2C9, VKORC1	81227 81355	$174.81 $88.20	qPCR
Anticonvulsants	Carbamazepine, Eslicarbazepine, Fosphenytoin, Lamotrigine, Oxcarbazepine, Phenytoin	HLA-B*15:02	81381	$169.90	qPCR
Antidepressants, SSRIs/SNRI	Citalopram, Escitalopram Sertraline	CYP2C19	81225	$291.36	qPCR
	Fluoxetine, Fluvoxamine, Paroxetine, Venlafaxine, Vortioxetine	CYP2D6	81226	$450.91	qPCR
	L-methylfolate	MTHFR	81291	$65.34	qPCR
Antidepressants, Tricyclic (TCA)	Amitriptyline, Clomipramine, Doxepin, Imipramine	CYP2C19, CYP2D6	81225 81226	$291.36 $450.91	qPCR
	Desipramine, Nortriptyline	CYP2D6	81226	$450.91	qPCR
Antipsychotics	Aripiprazole, Brexpiprazole, Haloperidol, Risperidone	CYP2D6	81226	$450.91	qPCR
	Clozapine, Olanzapine, Risperidone	DRD2	81479	N/A	qPCR
	Clozapine, Olanzapine	HTR2C	81479	N/A	qPCR
ADHD Therapy	Atomoxetine	CYP2D6	81226	$450.91	qPCR
Benzodiazepines	Diazepam	CYP2C19	81225	N/A	qPCR
	Lorazepam, Oxazepam	UGT2B15	81479	$291.36	qPCR
Muscle Relaxants	Carisoprodol	CYP2C19	81225	$291.36	qPCR
NSAIDs	Celecoxib	CYP2C9	81227	$174.81	qPCR
Opioids	Buprenorphine	CYP3A4, CYP3A5	81230, 81231	N/A	qPCR
	Codeine	COMT, CYP2D6, OPRM1	81479 81226 81479	N/A $450.91 N/A	qPCR
	Fentanyl	CYP3A4, CYP3A5, OPRM1	81230 81231 81479	$174.81 $174.81 N/A	qPCR
	Hydrocodone, Oxycodone, Tramadol	CYP2D6	81226	$450.91	qPCR
	Methadone	CYP2B6	81479	N/A	qPCR
	Morphine	OPRM1, COMT	81479 81479	N/A	qPCR
Platelet Inhibitors	Clopidogrel	CYP2C19	81225	$291.36	qPCR
Neuromuscular	Succinylcholine	BCHE	81479	N/A	qPCR
N/A1	N/A1	F2/F5	81241 81240	$73.37 $65.69	qPCR
Sedatives	Midazolam	CYP3A4, CYP3A5	81230 81231	$174.81 $174.81	qPCR
Antiemetics	Ondansetron	CYP2D6	81227	$174.81	qPCR

1 F2/F5 genotyping is not associated with response to a specific medication or medication class. Instead, testing may provide information about potential risk for certain surgery-related complications such as venous thromboembolism.