

2022 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 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 Health. *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 Health'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.

PRIOR AUTHORIZATION

Certain payers may require pre-authorization for Millennium Health's services. Any required pre-authorization paperwork should be completed by the ordering provider's office before the lab test order is submitted. Please include the pre-authorization paperwork with the test order.

MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS

For certain tests, Millennium Health is subject to Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) of the Part B Medicare Administrative Contractor (MAC) for Jurisdiction E, Noridian Healthcare Solutions. 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. These documents can be accessed on the [Medicare website](#).

Urine Drug Testing

On June 28, 2016 and updated on April 8, 2021, 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](#).

TEST ORDERING

All tests are available for order by paper test requisition forms and Intellium®, a web-based platform. A standard Millennium Health requisition form (whether via web-based platform or in paper form) must always be used when ordering tests. The Millennium Health requisition forms are designed to emphasize patient specific ordering of only medically necessary tests. If Millennium Health receives a test order on a non-Millennium Health requisition form or an incomplete Millennium Health requisition form, processing of your test order may be delayed. As necessary, Millennium Health will contact physicians to have them resubmit the test order on a Millennium Health test requisition form or otherwise clarify each specific test being ordered. Only tests that are ordered will be reported.

PATIENT SPECIFIC ORDERING

Policy changes and guidance from Medicare Administrative Contractors, other government regulatory authorities and commercial insurers 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 Health supports these efforts to help ensure testing is medically necessary based on individual patient specific elements identified during the clinical assessment. Therefore, Millennium Health does not accept non patient specific panels, including "custom profiles" or preset panels.

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 Health 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 Health requisition form is returned to the laboratory.

PATIENT PRIVACY (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), Millennium Health 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 Health compliance hotline by calling 866-677-3847.

CLINICAL CONSULTANTS

Physicians and other clinicians authorized to order tests have the services of clinical consultations with Millennium Health toxicologists, where they can review results and answer questions. Toxicologists 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 Health's test list with CPT and HCPCS G-Codes and Calendar Year 2021 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 Health 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 Health 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 Health's services.

Patients with special financial needs may be eligible for support to help defray some of Millennium Health's testing costs. Millennium Health encourages those patients who may not be able to pay fully for Millennium Health'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 Health 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 Health 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 Health 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 Health will bill the patient's insurance in order to secure reimbursement. If the patient is found to have no insurance, Millennium Health 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: <https://www.millenniumhealth.com/for-clinicians/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 Health services for a hospital patient or a SNF resident, please notify Millennium Health to ensure that the services are appropriately billed.

LABORATORY SERVICES PROVIDED TO OPIOID TREATMENT PROGRAMS

Effective January 1, 2020, Section 2005 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (“SUPPORT”) Act established a Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by Opioid Treatment Programs (“OTPs”) as defined by Medicare in 42 CFR 410.67(c). Toxicology testing by an OTP is bundled for OUD treatment services in an episode of care provided to people with Medicare Part B medical insurance and can only be billed by the OTP.

Exhibit 1

Oral Fluid and Urine Drug Testing

2021 CMS HCPCS Code	Code Description	2021 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
Benzoyllecgonine (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	Methylenedioxyamphetamines	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