Date: April 14, 2017

Paradigm Laboratories, LLC
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Tucson, Arizona 85712

RE: Annual Notice to Providers

Dear Healthcare Provider:

The Office of Inspector General ("OIG") of the Department of Health and Human Services recommends in its Compliance Program Guidance that laboratories send an annual notice to providers. This document serves as the annual notice for Paradigm Laboratories ("Paradigm"), and provides helpful information regarding the ordering and processing of laboratory tests. Paradigm has adopted and continues to enforce a comprehensive compliance program in order to adhere to applicable federal and state laws, as well as all program requirements for federal, state, and private health plans. We remind all providers requesting services from our laboratory that they are also responsible for abiding by all applicable federal and state laws, rules, and regulations concerning the provision of health care services.

Medical Necessity and Diagnostic Information Requirements

- Federally funded healthcare programs only pay for tests that meet the respective program's definition of "medical necessity." These programs may deny payment for a test that the provider believes is appropriate but which does not meet the federally funded healthcare program's definition of medical necessity. It is the responsibility of the ordering provider to ensure that claims being submitted for payment to federally funded programs (and third party payers) only occur when services are covered, reasonable, and medically necessary. Therefore, you should only order those tests that you believe are covered, reasonable, and medically necessary for the diagnosis and treatment of your patients.
- The Centers for Medicare and Medicaid Services ("CMS") has developed national and local coverage determinations that identify those tests that CMS determined will be covered under the Medicare program. CMS's National Coverage Determinations ("NCDs") may be found at http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd.
- CMS also has authorized its Medicare Administrative Contractors ("MACs") to develop Local Coverage Determinations ("LCDs"), which may be found at https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. These guidelines may supplement or be in addition to the National Coverage Determinations and give direction for medical necessity on selected tests. LCDs applicable to Paradigm may be found under Noridian Healthcare Solutions which is the Part B MAC for Jurisdiction F (https://med.noridianmedicare.com/web/jfb/policies).
- Medicare generally does not pay for screening tests unless certain medical necessity criteria are met or other exceptions apply. You are encouraged to review applicable guidance (including NCD and LCD guidelines) to determine if the drug tests you order from Paradigm are medically necessary.
- Paradigm will bill a patient's insurance and, when applicable, is obligated to collect any co-pays, deductibles, and amounts not covered by insurance from the patient. Paradigm undertakes reasonable collection efforts in accordance with applicable requirements.

Ordering of Tests

To simplify the processing of tests, we request and encourage the use and completion of Paradigm's Laboratory Requisition. However, our laboratory will accept requisitions and orders that contain the following information, which is required by applicable regulations and/or is necessary to process the ordered tests:

1. Date
2. Patient Name
3. Patient's Date of Birth
4. Test(s) to be performed
5. Diagnosis code(s) identifying the need for each test
6. Additional information relevant and necessary to a specific test to ensure accurate and timely testing and reporting of results as determined by the laboratory.

In the event that we receive an incomplete or ambiguous order, we will make every attempt to contact your office for the necessary information. If, however, we are unable to obtain the missing information, we will be required to postpone the requested service until the necessary information is provided. To help us provide the best possible service to your patients, we appreciate your cooperation in submitting complete, valid orders.

Ordering Particular Tests

Testing profiles should only be ordered when all profile components are medically necessary, as only medically necessary components will be paid. Individual tests or a less inclusive profile should be ordered for a patient when all of the tests are not medically necessary.

To the extent that you order a customized profile, you should note the following:

- The Medicare program provides to the testing laboratory tiered reimbursement based on the number of drugs/analytes tested and/or separate reimbursement for individual components contained in a customized profile;
- Ordering profiles may result in tests which are found not to be covered, reasonable, or medically necessary, and only those tests that are medically necessary should be ordered for each patient; and
- The OIG takes the position that a provider who orders medically unnecessary tests and who knowingly causes a false claim to be submitted may be subject to sanctions or remedies under federal civil, criminal, and administrative law.

Medicare Fee Schedule/Paradigm Laboratories Standard Charges

Code	Code Description	Standard Charges	2017 Medicare Fee Schedule (Jurisdiction F)
Respiratory Panel			
87486	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, amplified probe technique	$120.00	$47.18
87581	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma pneumoniae, amplified probe technique	$120.00	$47.18
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism	$120.00	$47.18
87633	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets	$1,419.00	$560.29

	Total Respiratory Panel	**$1,779.00**	**$701.83**
BioFire GI Panel			
87999	Unlisted Microbiology Procedure detection and identification of nucleic acids from mulitple bacteria, viruses, parasites, directly from stool samples. Includes sample preparation, reverse transcription, PCR and detection for 22 targets in a freeze-dried format.	$1,419.00	$230.30
87507	Infections agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex erverse transcription, when performed, and mulitplex amplified probe technique, multiple types or subtypes, 12-25 targets	$1,419.00	$560.29
Toxicology			
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (eg, immunoassay); capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges) includes sample validation when performed, per date of service	$800.00	$79.81
G0483	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem) and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed	$634.68	$253.87
G0480	Drug test(s), definitive, ... 1-7 drug class(es), including metabolite(s) if performed	$294.13	$117.65
G0481	Drug test(s), definitive, ... 8-14 drug class(es), including metabolite(s) if performed	$402.48	$160.99
G0482	Drug test(s), definitive, ... 15-21 drug class(es), including metabolite(s) if performed	$510.85	$204.34

List of Drug Classes that may be included in the Definitive Drug Testing Codes	
Classes	**Drugs**
Alkaloids, not otherwise specified	Cotinine
Amphetamines	Amphetamine, Methamphetamine
Antidepressants, serotonergic class	Venlafaxine
Antidepressants, tricyclic and other cyclicals	Amitriptyline, Desipramine, Doxepin, Imipramine, mirtazapine, nortriptyline
Antidepressants, not otherwise specified	Trazodone
Antipsychotics, not otherwise specified	Aripiprazole, olanzapine, quetiapine, risperidone

Benzodiazepines	Alprazolam, chlordiazepoxide, clonazepam, diazepam, flurazepam, loreazepam, nordazepam, oxazepam, temazepam, 2-hydroxy-fluraz- epam, 7-aminoclona-zepam, a-htdroxyalprazolam, a-hydroxymidazolam, a-hydroxytriazolam
Buprenorphine	Buprenorphine
Cannabinoids, natural	THC-COOH
Cocaine	Benzoylecgonine
Fentanyl	Fentanyl
Heroin metabolite	6-acetylmorphine
Ketamine and norketamine	Norketamine
Methadone	Methadone, EDDP
Methylenedioxyamphetamines (MDA, MDEA, MDMA)	MDEA, MDMA(ecstasy)
Methylphenidate	Methylphenidate (Ritalin)
Opiates	Codeine, Hydrocodone, Hydromorphone, Morphine
Opioids and opiate analogs	Dextromethorphan, dextrorphan, normeperidine, norbuprenorphine
Oxycodone	Oxycodone, oxymorphone
Phencyclidine (PCP)	Phencyclidine (PCP)
Skeletal muscle relaxants	Cyclobenzaprine
Stimulants, synthetic	Adderal
Tapentadol	Tapentadol
Tramadol	Tramadol

Document Requirements

The information you provide on the test requisition should accurately reflect the medical reasons for requesting the specified tests. The patient's record should include all required documentation to support the test order and the medical necessity of such tests. At the time of the test request, specific diagnostic information demonstrating the reason why the test was ordered should be documented in the patient's record. ICD-10 coding is required. In the event of a federally funded program or contractor, third party payer, or compliance audit or request for medical necessity documentation, Paradigm may request a copy of your medical record documentation to support the medical necessity of the test that was ordered.

Provider Signatures

CMS does not require ordering providers to sign paper or electronic laboratory requisitions. However, in the absence of a signed laboratory requisition, CMS requires documentation within the beneficiary's medical record maintained by the ordering provider to show such provider's clear intent to order the performed testing. Paradigm requests and encourages all ordering providers to sign laboratory requisitions to ensure there is no question as to each provider's intent to order the performed testing.

Last updated: April 14, 2017