2024 ANNUAL PROVIDER NOTICE

As part of our commitment to our partners and to honor our core value of Commitment to Regulatory Compliance from the "top down," Navis Clinical Laboratories® is providing this annual notice to support our mutual goals of compliant business practices and adherence to the guidelines issued by the Office of Inspector General (OIG). This notice serves to educate, update, and inform our partners on issues related to compliance with federal laws and regulations, as well as updates to billing and coding practices of Navis.

DRUG TESTING CODING AND REIMBURSEMENT CHANGE

The Centers for Medicare and Medicaid Services (CMS) uses a bundled system. CMS reimburses testing through four Healthcare Common Procedure Coding System (HCPCS) procedure codes for presumptive screening tests and four HCPCS procedure codes for definitive confirmation testing in tiers based on the number of drug classes tested. Navis's requisition forms are aligned with the coding and classification of testing based on drug classes.

Test Panels, Testing Custom Profiles and Standing Orders

The OIG has stated that testing panels and profiles should be precise because referred tests are supposed to be patient specific. Additionally, nearly all Medicare Administrative Contractors (MACs) also require that each test ordered is individualized. Every drug test ordered and submitted to Navis for laboratory testing services MUST be based on the individual patient treatment plan, or otherwise be deemed medically necessary when ordered, and the testing must be clearly explained and documented in that patient's medical records for every date of service. The provider's prompt review and use of the testing result in the treatment of the patient's medical condition should also be captured in the medical records.

Navis CORE

The American Medical Association (AMA) has assigned a discreet Current Procedural Terminology (CPT®) code to facilitate the reimbursement of CORE, Navis's proprietary quantitative oral fluid test. CORE uses a noninvasive, readily observable collection method, a unique algorithm, and patient-specific criteria to help determine whether patients' oral fluid drug levels are consistent with what has been prescribed. The CORE CPT code, 0011U, is defined by the AMA as "prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites."

MEDICAL NECESSITY

Medicare policy guidelines state that Medicare will only pay for laboratory testing that is reasonable and medically necessary for use in the treatment of the patient's medical condition and is not primarily for the convenience of the patient or ordering provider. The medical necessity determination by providers should be based on the individual patient's history, clinical indications, risk rating and treatment protocols. Drug testing for routine or job -related screening or monitoring purposes, unrelated to treatment of an individual patient's condition, is not covered by Medicare and Medicaid programs. Navis requires a supporting diagnosis code (ICD-10 codes) for all outpatient test requisitions. Even if a service is determined to be reasonable and medically necessary, individual patient coverage may be limited if the service is provided more frequently than allowed under Medicare, Medicaid, or other private insurance coverage policies. All lab tests can only be ordered by a licensed medical provider authorized under applicable state law to order clinical tests. If ordering lab tests for Medicare/Medicaid patients, the provider must be eligible to order such testing by their provider type.

Medicare Local Coverage Determinations

Numerous MACs have issued local coverage determinations (LCDs) governing reimbursement standards and procedures for controlled substance monitoring and drugs of abuse testing. These LCDs, among other things, set

forth criteria establishing medical necessity for drug testing within the MAC's region of jurisdiction. These LCDs apply to both presumptive drug screens and definitive confirmation drug tests. These LCDs are available upon request or found on CMS's webpage at https://www.cms.gov/medicare-coverage-database/indexes/national-and-local- indexes.aspx.

Payer Coverage Policies

Many payers issue payer coverage policies limiting the number of both presumptive screens and definitive confirmation drug testing and defining when definitive confirmation drug testing is appropriate. Payers have also in some instances instituted a prior authorization requirement for certain types of testing or testing after certain per-patient-per-year limits have been reached. If you have questions about payer coverage policies seen within your practice's payer mix, please reach out to your Navis representative.

DRUG TESTING ORDERS

All authorized providers who order clinical toxicology laboratory services for Medicare, Medicaid, Tricare, or other government program payment must follow all applicable laws, regulations, and rules for coverage. A clinical laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or other individuals authorized by law to order laboratory tests, who is enrolled in Medicare/Medicaid and who has not been excluded or disbarred.

Provider Signature

Medicare does not require that the ordering provider sign the submitted laboratory requisition forms. However, providers who do not sign laboratory requisitions are required by CMS to maintain medical record documentation for the patient which clearly demonstrates the provider's intent to order the performed testing. There are a number of payer policies which do require the authorized ordering provider's signature on each laboratory requisition form. We strongly recommend that ordering providers sign each laboratory requisition form to avoid the potential additional burden of having to provide supplemental progress notes or medical records, which must themselves be signed to document the provider's intent to order the referenced laboratory test.

Verbal Test Orders

Medicare regulations require that all orders for laboratory tests ultimately be reduced to a verifiable writing. If a physician or his/her authorized representative orders a test by telephone or wishes to add a test to an existing order, he or she must document the verbal order in the patient's medical records. Further, a follow-up written order is required to support the verbal order. In cases where an authorized provider calls in a test order or verbally modifies a previously submitted written order, Navis will send a written confirmation of the verbal request to the ordering physician, which must be signed by an authorized person and sent back to the laboratory for its records. Testing will not be performed until the confirmation or a properly completed Navis requisition form is returned to the laboratory.

Ambiguous or Unclear Test Orders

Navis only submits claims for reimbursement for tests that have been both ordered and performed. If the laboratory receives a requisition without a clear test order, we will be required to put the test on hold. We will contact the provider to clarify what testing is to be performed before any tests are conducted or billed.

Definitive Testing

Reflex definitive testing occurs when initial test results are positive or outside normal parameters. This is when a second, related test is medically appropriate for confirmation of specific drugs within a class. They should be ordered in accordance with medical necessity guidelines and coverage limitations. Navis will bill reflex quantitative tests as well as the initial screen test when reflex definitive tests are ordered.

Financial Assistance Programs

Navis 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. Navis 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 Navis's services. Patients with special financial needs may be eligible for support to help defray some of Navis's testing costs. Navis encourages those patients who may not be able to pay fully for Navis's services to contact us for an assessment of eligibility for financial support in accordance with federal guidelines.

Patient Billing

The amount billed by Navis is based on the patient's insurance plan as set forth in the explanations of benefits (EOBs) or similar statements furnished by the health insurance plan. Navis makes reasonable attempts to collect patient balances for each date of service consistent with any state and federal limitations on and requirements relating to balance billing. In addition to sending patient bills, Navis's efforts may include phone calls and other correspondence. If a provider receives a complaint from a patient about any of Navis's bills, we ask the provider to notify us promptly of the complaint and to refer the patient to Navis for resolution of his or her concerns.

Advance Beneficiary Notice

An advance beneficiary notice (ABN) should be completed by the patient for all ordered tests not likely to be covered by Medicare. It should provide the estimated cost of the tests. This notice allows us to bill the patient. The ABN is provided on the back of the first page of the laboratory requisition form and the patient's signature is required at the time of specimen collection.

MEDICAL RECORD DOCUMENTATION FOR DRUG TESTING

As an indirect healthcare service provider, Navis does not initially obtain all the documentation to support each order. Thus, Navis must reach out to the treating provider to obtain documentation that supports the medical necessity of the test when necessary for a payer claim review.

The patient's record should include all required documentation to support the test order, medical necessity and specific diagnostic information of each drug class tested. It is recommended that each patient's medical records contain the drug testing results and documentation on the review and use of the results in the treatment of the patient's medical condition. The MACs have historically provided the following recommendations around proper documentation:

- Written or electronic documentation of the order for the date of service billed
- Signed and dated physician order for each ordered drug test
- Current treatment plan
- List of patient's prescribed medications
- List of illicit medications
- Risk assessment plan
- Sufficient information to identify the ordering physician or non-physician practitioner
- Diagnostic or other medical information by the ordering physician or non-physician practitioner, including any ICD-10 code or narrative description supplied
- Medical record documentation (e.g., history and physical, progress notes) indicating the medical necessity for performing each drug test
- Test requisition order forms and testing result reports

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 administrative simplification rules require a covered entity, such as a physician, to retain required documentation for six (6) years from the date of its creation or the date, many states have even longer retention requirements.

NAVIS' COMMITMENT TO COMPLIANCE

Navis is committed to compliance with all aspects of applicable state and federal laws and regulations, including but not limited to the physician self-referral law (Stark Law), Anti-Kickback Statute, Eliminating Kickbacks in Recovery Act ("EKRA"), the False Claims Act, Civil Monetary Penalties Law and HIPAA.

Anti-Kickback Statute and EKRA

Navis complies with federal law prohibiting our lab from offering or paying anything of value to induce the referral of tests that are covered by Medicare, Medicaid, or any other federal health care program. Any form of payment or kickback that is intended to secure business for federal health care testing referrals is strictly prohibited.

Stark Law

Navis tracks its non-compensation benefits to actual and potential referral sources and strictly adheres to its business courtesy to healthcare professionals policy. Navis does not accept referrals from a physician where the referral would violate the Stark Law.

False Claims

The OIG states that any individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal, and administrative law. Navis will not knowingly bill Medicare, Medicaid, or any other federal healthcare program, for testing that is non-covered, unreasonable, and/or unnecessary.

HIPAA – Patient Privacy

Navis is a HIPAA-covered entity and protects the confidential nature of protected health information (PHI) and other confidential information we receive, whether in verbal, written or electronic form. Navis complies with applicable laws and regulations governing the privacy and security of PHI, including HIPAA and the Health Information Technology for Economic and Clinical Health Act (HITECH).

Any reports of potential or actual misconduct can be reported 24/7 through the Navis Compliance line (253) 328-8007.

Urine, Oral Fluid, Hair and Blood Drug Testing				
CMS HCPCS Code	**Code Description**	**2022 Medicare Rate**	**2023 Medicare Rate**	**2024 Medicare Rate**
G0479 (2016) – 80307 (2018-Current)	**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 Drug tests(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service.	$62.14	$62.14	$62.14
G0480	**Definitive drug test(s)** –Drug test(s), definitive, utilizing (1) 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)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug- specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day;1-7 drug class(es), including metabolite(s) if performed*	$114.43	$114.43	$114.43
G0481	**Definitive drug tests –** 8-14 drug classes*	$156.59	$156.59	$156.59
G0482	**Definitive drug tests –** 15-21 drug classes*	$198.74	$198.74	$198.74
G0483	**Definitive drug tests –** 22+ drug classes*	$246.92	$246.92	$246.92

***Drug class, including metabolites, listed below and include specimen validity testing, per patient encounter per day, for reference purposes.**

Drug Classes	
Alcohol	Alcohol(s)
Ethyl Glucuronide	Alcohol Biomarkers
Kratom	Alkaloids, not otherwise specified
Amphetamines, Methamphetamines, Phentermine	Amphetamines
Citalopram, Duloxetine, Fluoxetine, Paroxetine	Antidepressants, serotonergic class
Amitriptyline	Antidepressants, Tricyclic and other cyclicals
Desipramine	Antidepressants, Tricyclic and other cyclicals
Imipramine	Antidepressants, Tricyclic and other cyclicals
Nortriptyline	Antidepressants, Tricyclic and other cyclicals
Bupropion, Venlafaxine	Antidepressants, not otherwise specified
Clozapine, Olanzapine, Quetiapine, Risperidone, Aripiprazole, Haloperidol	Antipsychotics, not otherwise specified
Secobarbital, Phenobarbital, Butalbital	Barbiturates
Benzodiazepines	Benzodiazepines
Buprenorphine	Buprenorphine
THC	Cannabinoids, natural
Spice	Cannabinoids, synthetic
Cocaine	Cocaine
Fentanyl	Fentanyls
Gabapentin	Gabapentin, non-blood
Heroin	Heroin Metabolite
Ketamine	Ketamine and Norketamine
Methadone	Methadone
MDMA	Methylenedioxyamphetamines
Methylphenidate	Methylphenidate
Codeine/Morphine	Opiates
Hydrocodone	Opiates
Hydromorphone	Opiates
Meperidine, Naloxone, Naltrexone, Dextromethorphan	Opioids and opiate analogs
Oxycodone	Oxycodone
Phencyclidine	Phencyclidine
Pregabalin	Pregabalin
Zolpidem	Sedative Hypnotics (nonbenzodiazepines)
Carisoprodol	Skeletal muscle relaxants
Cyclobenzaprine	Skeletal muscle relaxants
Tapentadol	Tapentadol
Tramadol	Tramadol
Bath Salts (Cathinones)	Drugs - stimulants, synthetic or substances, definitive, qualitative or quantitative, not otherwise specified