



2021 Wisconsin Diagnostic Laboratories Annual Notice to Providers

February 2021

Dear Physician/Client:

Wisconsin Diagnostic Laboratories (WDL) provides this annual notice in accordance with the recommendation made by the Department of Health and Human Services Office of the Inspector General (OIG) as part of our Compliance Program. The purpose of this notice is to provide general information related to federally funded programs that will help physicians, clients and the laboratory ensure that claims meet appropriate program requirements.

This annual notice specifies current payer program requirements. Please review the information contained in this document and contact Ceil Duclon, Executive Director of Laboratory Services, at (414) 805-7692, if you have any questions or concerns.

Authorized Ordering Providers

A clinical laboratory may only bill for testing ordered by a licensed physician or other individuals authorized by law to order laboratory tests. If your license is revoked or suspended, you may not order or refer laboratory testing. You must notify WDL Client Services immediately at (414) 805-7600 if your license has been revoked or suspended.

Requirements for Diagnostic Information

A diagnosis that supports medical necessity must be documented by an ordering provider that accurately describes the patient's condition on the date of service in the patient's medical record, for each test ordered. For example, the government has addressed the obligation of ordering providers to give adequate diagnostic information to laboratories in the form of notes or ICD-10 diagnosis codes specific to the test(s) ordered at the time of the order, prior to services provided. More than one diagnosis may be necessary when there are multiple tests ordered.

Medical Necessity

OIG recognizes that physicians and other authorized individuals must be able to order any tests that they believe are appropriate for the treatment of their patients. Payers will only pay for tests that meet coverage criteria and are reasonable and necessary to treat or diagnose a patient. Tests ordered in the absence of signs, symptoms or complaints are considered "screening," and may be subject to Medicare Preventive Services benefits.

Routine screening tests that have no preventive service coverage are the financial responsibility of the beneficiary; however, payers will pay for some laboratory tests when screening for certain diseases. The Medicare Preventive Services guide lists the services covered along with specific diagnosis codes and frequency limitations at:

<https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html>

OIG False Claims Guidance

Only tests that meet payer coverage policies may be submitted for reimbursement. Individuals who knowingly cause a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law.

Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)

NCDs and LCDs are coverage determination policies issued by Medicare payers that provide coverage information, and outline whether certain services are considered medically reasonable and necessary by defining medical conditions through the inclusion of a list of ICD-10 (diagnosis) codes for which tests are covered or reimbursed. The patient medical record must contain supporting documentation for medical necessity of the services performed.

An NCD for a diagnostic laboratory test is a national policy statement granting, limiting or excluding Medicare coverage for that test. Active Medicare NCDs may be viewed at:

<https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx>

An LCD is a decision made by a Medicare Administrative Contractor (MAC) on whether to cover a particular item or service on a MAC-wide basis. Active LCDs may be viewed at:

<https://www.cms.gov/medicare-coverage-database/indexes/lcd-state-index.aspx>

Panels and Profiles

Organ or disease related panels are groups of individual tests approved by the American Medical Association (AMA). Payers will only pay for panels if each component in the panel is medically necessary. The individual tests may be ordered, and this should be considered, if any of the tests included in a panel are not medically necessary.

Reflex Testing

Reflex testing occurs when initial test results indicate that a second related test is medically necessary to confirm or validate the initial test results. Unless confirmatory reflex testing is required by law, tests may be ordered with or without reflex criteria. When ordering tests that include reflex criteria, it is necessary to document the reflex order in the patient's medical record.

Advance Beneficiary Notice (ABN)

An Advance Beneficiary Notice of Non-coverage (ABN), Form CMS-R-131, should be issued by providers (including independent laboratories, home health agencies and hospices), physicians, practitioners and suppliers to Original Medicare (fee for service or "FFS") beneficiaries in situations in which Medicare payment is expected to be denied. An ABN should be issued when an item or service is not considered reasonable or necessary under Medicare Program standards.

The ABN is issued prior to services being provided in order to inform the Medicare beneficiary of their potential financial liability in circumstances in which there may not be coverage. The beneficiary can then make an informed decision to receive the service and sign the agreement to

pay, or decide not to receive the service and document that option on the ABN form. A separate ABN must be used for each encounter.

Additional information about ABNs may be viewed at:

<https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>

Medicare Fee Schedule

The Medicare Clinical Lab Fee Schedule (CLFS) reimbursement rates were revised and updated effective January 2021. The CLFS rates have been established based on the weighted median private payer rate as required by the Protecting Access to Medicare Act (PAMA) of 2014. Co-payments and deductibles do not apply to services paid under the CLFS. Medicaid reimbursement will be equal to, or lesser than Medicare reimbursement.

The 2021 CLFS may be viewed or downloaded at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files>

Laboratory Test and Website Information

An electronic version of Wisconsin Diagnostic Laboratories Test Directory can be found at:

<https://www.testmenu.com/wisconsindiagnostic>.

The Laboratory Test Menu, which includes all in-house and send-out tests offered by WDL, is a reference tool that includes test ordering information, specimen type and volume, special instructions and delivery information, as well as reference ranges that include units of measure.

Listed CPT codes are intended as general guidelines and should only be used for reference. They should not be used without confirming their appropriateness with applicable payers.

Clinical Consultant

The Medical Director and other pathologists are available to provide technical or consultative services regarding appropriate test use and ordering. Please call the WDL Client Services Department at (414) 805-7600 or toll free at (888) 611-3438 to request assistance.

Please review this information with your staff as appropriate. We thank you for sharing our commitment to complying with all federal, state and local laws, and for the opportunity to serve your laboratory needs.