



Date: January 8, 2025

To: All Tribal Diagnostics Clients
From: Compliance Department
RE: Annual Notice to Physicians

Dear Provider:

In their document “Compliance Program Guidance for Clinical Laboratories” (which can be found at <https://oig.hhs.gov/documents/compliance-guidance/806/cpglab.pdf>), the Office of the Inspector General recommends laboratories provide notice to physicians and other ordering providers on an annual basis. The notice must, at minimum, contain information regarding:

- The Medicare National Policy and the Medical Contractor's local medical review policy for lab tests
- Organ or disease-related panels will only be paid and will only be billed when all components are medically necessary
- The Medicare laboratory fee schedule
- The Medicaid reimbursement amount relative to the Medicare reimbursement amount
- The phone number of the clinical consultant

Tribal Diagnostics, LLC is issuing this notice in accordance with this recommendation. We are committed to conducting business in accordance with all federal, state, and local laws, and in adherence with program requirements for all federal, state, and private health plans. This letter serves as continuing education for ordering providers on our policies and procedures related to these expectations.

Clinical Consultant:

Tribal Diagnostics’ Laboratory Director and Clinical Consultant is Yanzheng Zhang, M.D. Dr. Zhang can be contacted at zhangmd@tribaldiagnosics.com. His phone number is 972-697-8585.

Medicare Medical Necessity Policy:

Tests submitted for Medicare reimbursement must meet program medical necessity requirements, or Medicare may deny payment for a test that the physician believes is appropriate (such as a screening test) but does not meet the Medicare definition of medical necessity. Coverage determination policies define the medical conditions by including a list of ICD (diagnosis) codes for which Medicare covers or reimburses these tests. HIPAA regulations require ICD code(s) to be present on each claim filed. These codes must also be documented in the patient’s medical records.

Please follow the links below for a listing of tests for which CMS and Tribal Diagnostics’ Medicare Administrative Contractor (Novitas Solutions) have developed National Coverage Decisions (NCD) and Local Coverage Decisions (LCD).

Local Coverage Determinations: https://www.novitas-solutions.com/webcenter/portal/MedicalPolicy_JH/

National Coverage Determinations: <https://www.cms.gov/medicare/coverage/determination-process>

Frequency Limitations for Certain Laboratory Tests:

In addition to restrictions on what Medicare will reimburse based on the patient's condition (ICD code), certain laboratory tests have specific frequency limitation requirements. The limitations may apply to tests from the laboratory NCDs and LCDs.

Medicare Preventive Screening Laboratory Tests:

Certain preventive screening laboratory tests are covered services for Medicare beneficiaries. Benefit coverage is specific for each service, covered diagnosis codes(s), coverage requirements, and frequency limitations. Please follow the link below for information regarding preventive screening laboratory tests.

<https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00008244>

American Medical Association (AMA) Organ or Disease-Oriented Panels:

Organ or Disease Oriented Panels (CPT codes 80048 - 80090) should only be ordered when all components in the panel are medically necessary. They were developed for coding purposes only and should not be interpreted as clinical parameters. Medicare will only pay for them when all tests within the panel are deemed medically necessary. See section 90-2, "Organ or Disease-Oriented Panels," at the link below for more information.

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c16.pdf>

Reflex Laboratory Tests:

Based on the results of an initial laboratory test, Tribal Diagnostics may perform additional testing, which can result in an extra charge. An example of a reflex test that may be performed is a urine microscopic based upon values outside of the normal range for the urine chemistry values (dipstick). Relevant practices in laboratory medicine and the avoidance of performing unnecessary testing help dictate which tests are subject to this policy.

Advance Beneficiary Notice of Non-Coverage (ABN):

Medicare will only pay for Part B Laboratory services determined to be reasonable and necessary. We may need to obtain an Advance Beneficiary Notice of Non-Coverage (ABN) from a patient in advance of what is believed to be a non-covered laboratory service, based on:

- Limited Coverage – An ABN is required if the diagnosis is not covered
- Frequency Limit - An ABN is required at each encounter for frequency-limited tests
- Non-Coverage – An ABN is required for experimental or research use tests or tests designated by Medicare as non-covered

Please select Manual 100-04 Medicare Claims Processing Manual Chapter 30 Financial Liability Protections Section 50 Form CMS-R-131 Advance Beneficiary Notice of Non-Coverage (ABN) at the link below for more information.

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>



Medicare Laboratory Fee Schedule:

Medicare reimburses laboratory services based on their published fee schedule. Medicaid reimbursement for laboratory services is equal to or less than the amount Medicare reimburses. Please see the link below for access to the fee schedule and select the most current year and quarter presented (for example, 25CLABQ1) for the first quarter of 2025. Schedules are updated each quarter of each given year.

<https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/files>

If you have any questions about this notice's content, don't hesitate to contact your Tribal Diagnostics sales representative or Tribal Diagnostic's Compliance Officer (jacke@tribaldiagnosics.com).

Sincerely,

John J. Ewart, MBA, MT(ASCP), CHC, CCEP
Tribal Diagnostics Compliance and Privacy Officer