8901 West Lincoln Avenue, West Allis, WI 53227
5400 Pearl, Rosemont, IL 60018

# 2023 Annual Notice to Providers

September 2023

Dear Physician/Client:

ACL Laboratories maintains an active compliance program that reflects our commitment to conduct business in compliance with all federal, state and local laws. As a participant in federally funded health care programs, ACL Laboratories is required by the Office of Inspector General (OIG) and the US Department of Justice (DOJ) to deliver annual provider education regarding laboratory compliance, billing and coding guidelines, and to inform our provider clients on the responsibilities we share.

This annual notice specifies current Medicare/Medicaid program requirements and ACL policies. Please review the information contained in this notice and contact Heather Coté at 704.512.2587 if you have any questions or concerns.

ACL Laboratories must rely on you, our provider clients, for the following key compliance elements:

## Authorized Ordering Providers

Laboratory testing must be ordered by a licensed physician or other individuals authorized by law. If your license has been revoked or suspended, you may no longer order or refer laboratory testing. Written and electronic orders must identify the ordering provider's National Provider Identifier (NPI). Providers must be enrolled in Medicare and Medicaid programs, and of a provider type that is eligible to order testing, for Medicare and Medicaid patient billing.

## Requirements for Diagnostic Information

Effective October 2, 2015, CMS policy mandates that the physician or practitioner ordering laboratory testing provide diagnostic information specific to the test(s) ordered at the time of the order. Please provide this diagnostic information for a specific condition, disease, sign, symptom or complaint for each test ordered. When testing is ordered to determine or confirm a diagnosis, please provide an ICD-10 code or a text description of the signs, symptoms or chief complaints. It is the responsibility of the authorized ordering provider to document each ordered test and the corresponding diagnosis information in the patient's medical record.

## Requirements for Documentation

Although the signature of the ordering provider is not required on laboratory requisitions, if signed or verified by electronic signature, the requisition will serve as acceptable documentation of a physician order for the testing. In the absence of a signed requisition, documentation of your intent to order each laboratory test billed must be included in your patient's medical record and made available to ACL Billing, as requested. Documentation must accurately describe the individual tests ordered; it is not sufficient to state "labs ordered".

## Prior Authorization

Prior authorization is an administrative process used in healthcare for providers to request approval from payers to provide a medical service, prescription, or supply that support efforts to safeguard patients' access to medically necessary items and services while reducing improper billing and payments to ensure compliance.

This process takes place before a service is rendered and is the responsibility of the physician to obtain prior to the patient presenting for the services.

**Medical Necessity**

Medicare normally covers services deemed medically necessary. Medically necessary is defined as health care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine.

Conversely, tests ordered in the absence of signs, symptoms or complaints are considered screening and are subject to Medicare Preventive Services benefits. Routine screening tests that have no preventive service coverage are the financial responsibility of the beneficiary.

**Medicare Preventive Services**

Medicare will pay for some laboratory tests when screening for disease. The Medicare Preventive Services chart lists the services covered along with applicable ICD-10 codes and frequency limitations. Preventive Services Chart | Medicare Learning Network® | MLN006559 March 2022 (cms.gov)

**Molecular Pathology, Cytogenetics and Genetics Procedures**

Many molecular pathology, cytogenetics and genetics procedures are not considered covered services when ordered to assess disease risk or to screen for carrier status. These tests may be eligible for coverage when results of the testing directly impacts treatment or management of a condition. These tests are usually subject to preauthorization and post payment medical record review. Please adhere to payer guidelines, as indicated.

**Profiles**

Although profiles and test combinations offer convenience in ordering, they may result in the routine ordering of more tests than needed to diagnose and treat patients. Therefore, ACL limits the offering of profiles to those approved by the American Medical Association (AMA) and those that are approved by the laboratory's Pathology Medical Directors.

Please know what tests are in each panel you order and do not order individual tests that might duplicate tests in the panel. Also, please order individual tests rather than a panel when all tests contained in the panel are not required for diagnosis or treatment purposes.

The ACL Directory of Services identifies the individual tests included in a panel under the "Components" heading within a specific test.

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

National and Local Coverage Determinations are two of the most important aspects of Medicare coverage. They are decisions by Medicare and their administrative contractors that provide coverage information and determine whether certain services are considered medically reasonable and necessary.

NCDs are developed by CMS (Medicare) to describe the circumstances for Medicare coverage nationwide for an item or service. NCDs outline conditions for which an item or service is considered to be covered (or not covered). An LCD is a decision by a Medicare Administrative Contractor (MAC) whether to cover a particular item or service on a MAC-wide basis.

The purpose of NCDs & LCDs is to guide health care providers in submitting correct claims for reimbursement by understanding the policy criteria and providing supporting documentation for the services rendered.

Your documentation is a critical piece to support this process. The medical record must contain all components to support medical necessity of the services performed. Please refer to the following link for a listing of Laboratory National Coverage Determinations https://www.cms.gov/medicare-coverage-database/indexes/lab-ncd-index.aspx

## Advance Beneficiary Notices (ABN)

An Advance Beneficiary Notice (ABN) is a notice a provider should give the patient before receiving a service if, based on Medicare coverage rules, you have reason to believe Medicare will not pay for the service. You must issue an ABN when an item or service is not considered reasonable and necessary under Medicare Program standards. Common reasons for Medicare to deny an item or service as not medically reasonable and necessary include care that is:

- Experimental and investigational or considered "research only"
- Not indicated for diagnosis and/or treatment in this case
- Not considered safe and effective
- More than the number of services Medicare allows in a specific period for the corresponding diagnosis

ABN Form CMS-R-131 is issued by providers (including independent laboratories), physicians, and practitioners to Medicare fee-for-service beneficiaries in situations where Medicare payment is expected to be denied.

Patients must have sufficient time to make an informed decision on whether or not to receive the test in question and accept potential financial liability.

CMS Form R-131 and instructions for use and completion can be found at: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN

ACL's ABN Form CMS-R-131 can be found at: https://www.acllaboratories.com/patients/billing/

## Reflex Testing

Reflex testing occurs when initial test results are positive or outside normal parameters and general medical practice indicates a second related test is medically appropriate 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 also necessary to document the reflex order in the patient's medical record, e.g., CBC **w/diff**, Lipid Panel **w/LDL reflex**, UA **w/microscopic exam**.

The ACL Directory of Services lists reflex and/or confirmation criteria under the "Test Performance" heading within a specific test. When indicated, ACL will bill for reflex tests along with the initial test.

## Recurring Orders

Recurring orders are permissible when all of the following criteria are met:

- The order identifies an individual patient.
- The order specifies each ordered test.
- The order indicates the frequency and duration of testing (e.g., Hemoglobin A1c, every 3 mos for 1 yr).
- The diagnosis provided supports the frequency of testing (e.g., Hemoglobin A1c, ICD-10 code E11.9).

Recurring orders are valid for a maximum of 365 days from original order date and must be renewed annually.

## Clinical Consultant

ACL Laboratories is affiliated with over 90 board-certified Pathologists in a variety of specialties that are available to provide technical or consultative services regarding appropriate test use and ordering. Please call ACL Client Services department at 1.800.877.7016 to request laboratory testing assistance.

## Additional Test Information and Website References

An electronic version of ACL Laboratories Directory of Services (DOS) can be accessed on the following web site: https://www.acllaboratories.com/providers/test-directory/

ACL's DOS includes our clinical test menu, test order codes, and CPT codes. Correct CPT coding can vary by carrier; therefore, the codes referenced are intended as general guidelines and should not be used without confirming their appropriateness with applicable payers.

## OIG False Claims Guidance

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

To avoid a false claim submission, be sure to:

1. Order only those tests necessary for diagnosis or treatment. Note: Each component of a panel must be necessary for the panel to qualify for Medicare reimbursement.
2. Provide a diagnosis, sign or symptom for each test ordered.
3. Document this information in the patient's medical record.
4. Obtain an ABN from the Medicare patient when tests do not meet medical necessity criteria.

ACL Laboratories
Now part of ADVOCATEHEALTH

Created: 08/2022 | Created by: M. O'reilly – Advocate Health Compliance & Integrity | Designed by: K. Voskuil – KV Graphics | Revised: 09/2023