

Acūtis

2024
Annual
Physician
Notice

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Dear Healthcare Provider,

Acutis Diagnostics Inc. maintains an active compliance program that reflects our commitment to conduct business in compliance with all federal, state, and local laws. The Office of Inspector General for the U.S. Department of Health and Human Services (“OIG”) has requested that clinical laboratories annually send an educational notice to physicians and practitioners authorized by law to order laboratory tests and are reimbursed by Medicare, Medicaid, or another federally funded healthcare program (*hereafter, “Federal Programs”*). As part of our corporate compliance program, Acutis is sending this Annual Update to all physicians and practitioners who order tests from us. Please carefully review the information contained in this notice. If you have any questions, please contact Acutis at (844) 522-8847 and ask to speak with either our Compliance Officer or Medical Director.

Authorized Ordering Providers/Excluded Providers

A clinical laboratory may examine a specimen only when the test has been ordered by a licensed physician, a qualified practitioner or non-physician practitioner authorized by law to order laboratory testing. All ordering providers must have a valid National Provider Identifier (NPI#), available via <https://nppes.cms.hhs.gov/#/>

Medicare requires individuals referring orders for laboratory services to be registered in the CMS Provider Enrollment, Chain and Ownership System (PECOS). Providers have the choice of either enrolling, or officially ‘opting-out’ – and MUST do one or the other. Additional information on PECOS and how to enroll, or how to OPT-OUT, may be viewed at: <https://pecos.cms.hhs.gov/pecos/login.do#headingLv1>

It is your responsibility to stop ordering tests and to immediately notify us if:

- (a) your license has been revoked or suspended;
- (b) you have been excluded from the Federal Programs;
- or (c) if your enrollment in Federal Programs has been revoked or suspended.

All orders shall consist of either (a) handwritten signature of name or initials, or (b) electronic or computer-generated signature of name or unique identifier acceptable to the Centers for Medicare and Medicaid Services (CMS).

Medical Necessity and Diagnosis Codes

Federal Programs will only pay for tests if the test is covered, reasonable, and medically necessary for the beneficiary, given their clinical condition. A medically necessary test is defined as one that is reasonable and necessary for the diagnosis or treatment of an illness or injury. Physicians/practitioners should only order those tests that they believe are medically necessary for the diagnosis and treatment of their patient. Your medical records must document the medical necessity for the tests ordered and, upon receipt of test results, updated to show how you used the information in the care and treatment of your patient.

CMS has developed National Coverage Determinations (*NCDs*) that define medical necessity for certain tests. Local Coverage Determinations (*LCDs*) are also published by contractors, such as NGS. You should review the *NCDs* and *LCDs* – particularly the medical necessity requirements – for the tests that you order. *NCDs* and *LCDs* can be viewed at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list%20type=ncd>.

In addition, physicians who order laboratory tests must provide diagnostic information at the time that the test is ordered. Acutis' requisition forms have designated space for you to include these codes as required. The ICD-10 codes selected by you must be accurate and as specific as possible, based on the patient's actual condition and information that is otherwise documented in the medical record. If you are ordering a test and cannot yet determine a diagnosis, you must provide the appropriate ICD-10 code that describes the patient's signs and symptoms. Please note that laboratories are prohibited from using diagnostic information provided by the physician/practitioner from earlier dates of service, and from inserting diagnosis codes based on their own evaluation of the patient's probable or most likely diagnosis, or from speaking with a patient. If the information your office has provided to Acutis is inadequate or incomplete, we will contact your office in accordance with *OIG* guidance.

Practices Ordering Toxicology Testing

Providers are responsible for knowing each payor's policy (*whether it be Medicare, Medicaid, or commercial insurance*) prior to ordering a test for a patient (*this includes knowing the testing frequency permitted by a payor*). As it relates to drug tests, medical records must support the need for each drug or drug class being tested.

Definitive (*confirmation*) testing should **ONLY** be ordered when medically necessary and in compliance with applicable federal and state laws, regulations, and/or payor rules and policies.

In general, samples should first have presumptive (*screen*) testing performed, and definitive/confirmatory testing may be ordered **ONLY** if:

- Results will inform decisions with major implications for the patient, such as a change in treatment
- Screen results are inconsistent with the clinical situation

Definitive testing may be ordered directly when medically necessary if there is no presumptive testing commercially available for the compound(s) needed to be tested.

To help guide physicians who order toxicology testing, Medicare administrative contractors have issued Local Coverage Determinations and Articles regarding Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing, available at LCD - Controlled Substance Monitoring and Drugs of Abuse Testing (*L35006*) (*cms.gov*) New York State Medicaid provides coverage and reimbursement policies for both Medicaid Managed Care (*MMC*) and Medicaid Fee-For-Service (*FFS*) for drug testing at the following link:

- https://www.health.ny.gov/health_care/medicaid/program/update/2021/no10_2021-08.htm#drugtest

In addition, there are a variety of educational resources available to ordering providers. The American Society of Addiction Medicine ("ASAM") and the National Institute on Drug Abuse are examples of organizations that provide online resources for providers ordering drug tests and treating patients with drug addiction.

Practices Ordering Acutis Reveal™ Infectious Disease Testing

Please note the performance of the tests has not been established for patients without signs and symptoms of infection. Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the practitioner who is evaluating and/or treating the patient. Viral and bacterial nucleic acids may persist *in vivo*, independent of organism viability.

Acutis Reveal™ COVID-19

Acutis providers are encouraged to review and assess Federal, State, and payer guidelines for proper ordering of COVID-19 tests. Continued guidance on testing can be found on the Centers for Disease Control and Prevention (CDC) website here:

- <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>
- <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

Please note CDC guidelines do not constitute payer coverage, which may vary by state and health plan.

Our clinical consultants are available to speak with you to provide the information you need. Please feel free to reach out via secure email at service@acutis.com or via secure phone line at (844) 522-8847.

Test Ordering

All tests are available to be ordered by paper requisition forms and through a secure electronic portal. The Acutis requisition form (*whether ordering through the secure portal or on paper requisition form*) is designed to emphasize the importance of ordering only what is medically necessary as noted in the Medical Necessity section above. The patient's full legal name, date of birth, reason for each test ordered (*ICD10 code*), date and time of collection, specimen source and the licensed ordering practitioner's name, address and NPI#. Hand-written orders (*i.e.: scripts*) must be signed and dated by the provider. Signature stamps are NOT acceptable. The required fields must be completed to ensure proper sample processing without any delays. For instances where the required fields are incomplete, Acutis will make best efforts to contact the ordering practitioner and organization to obtain the necessary information. Providers are responsible and required to notify Acutis of any test ordered in error.

We appreciate your cooperation in submitting valid orders.

Custom Profiles

With guidance and direction received from Medicare Administrative Contractors, other government regulatory authorities, and commercial insurers, Acutis Diagnostics will prohibit the use of custom test profiles. The decision not to allow custom test profiles was made to ensure that laboratory services ordered by clinicians for each patient are medically necessary.

American Medical Association (AMA) Defined Organ/Disease Panels

These panels may only be ordered when all components are medically necessary. Physicians/practitioners should order individual tests or a less inclusive profile if all tests in a panel are not medically necessary for an individual patient. The OIG takes the position that ordering unnecessary tests within a profile, even without a specific intent to defraud, may subject the ordering physician to civil, criminal, and administrative penalties.

Standing Orders and Reflex Tests

Acutis Diagnostics does not permit the use of standing orders.

Reflex confirmatory testing may be performed depending on the testing ordered by the physicians/providers. Reflex testing occurs when the initial test results are positive and/or inconsistent with expected results based on the patient's prescribed therapy and indicate that a second related test is medically appropriate. It is the physicians/providers' responsibility to ensure documentation is present in the patient's medical record to support reflex testing.

Advance Beneficiary Notice of Non-coverage

If you believe it clinically appropriate to order a test that Medicare may find to be medically unnecessary and thus not reimbursable, we ask that you have the patient complete and sign a Medicare Advance Beneficiary Notice of Non-coverage form. This notice informs that patient that the test may not be covered by Medicare and that he or she thus may be liable for paying for the test. In cases in which medically unnecessary tests are performed for a Medicare patient, the patient generally may not be billed for the service without such a notice having been completed. You can find the Advance Beneficiary Notice of Non-coverage Form (CMS-R-131), instructions on using the form, and more information from CMS on this topic here:

- <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ABN-Tutorial/formCMSR131tutorial111915f.html#:~:text=The%20Advance%20Beneficiary%20Notice%20of%20Non-coverage%20%28ABN%29%2C%20Form,may%20not%20be%20medically%20necessary>

Medicare Clinical Laboratory Fee Schedule

The current Medicare fee schedule for all clinical lab testing can be found at this link:

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

Please note that Medicaid fees vary in each State and are usually at or below the above schedule.

CPT and HCPCs

Acutis will provide all related CPT and HCPC codes to providers upon request. To request a listing of CPT and HCPC codes, contact PayerRelations@acutis.com

Contact

Should you have any questions on these materials, please contact the Acutis Compliance Office at 844-522-8847. Acutis' anonymous Compliance Hotline can be reached at 631-606-4192.

David Goldberg

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