2018 Annual Notice to Physicians

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) recommends that clinical laboratories notify physicians and other ordering providers who use their services, at least once a year, of the laboratory's programs for compliance with Federal law as part of their Corporate Compliance Program. Clinical Genomics Pathology Inc. ("Clinical Genomics") is issuing this annual notice in accordance with this recommendation and to inform the recipients of the laboratory's policies for test ordering and billing and provide certain other information regarding the laws and regulations that govern laboratory services.

Medical Necessity

The OIG has advised clinical laboratories to remind physicians (and other individuals authorized by law to order tests, collectively the "provider" or "providers") that the Government and private third party payers will only pay for tests that are medically necessary for the diagnosis or treatment of the individual patent. It is the responsibility of the authorized ordering provider to ensure claims being submitted for payment to federally funded programs or private third party payers only occur when services are covered, reasonable and medically necessary. It is the responsibility of the provider to document each ordered test and the corresponding diagnosis information in the patient's medical record and to provide appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to Clinical Genomics. *The OIG takes the position that a provider who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.*

Medicare National And Local Coverage Determination

The Medicare Program publishes National Coverage Determinations (NCDs) and local Medicare Administrative Contractors publish Local Coverage Determinations (LCDs) for certain tests. These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare, typically by reference to specific ICD-10 codes that are deemed to support coverage. Coverage determinations may be viewed at:

https://www.cms.gov/medicare-coverage-database/

At this time, Colvera™, a PCR-based assay that detects hypermethylated *BCAT1* and *IKZF1* DNA in the blood of patients previously diagnosed with CRC and utilized as an aid to physicians in the management of and detection of recurrent CRC or minimal residual CRC disease in those patients, is not included among the tests covered under the LCD titled "Biomarkers for Oncology" (L35396) issued by Novitas Solutions, Inc. ("Novitas"), the Medicare Administrative Contractor for the state of New Jersey.

This LCD may be viewed at:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35396&ContrId=325&ver=118&ContrVer=1&CntrctrSelected=325*1&Cntrctr=325&name=Novitas+Solutions%2c+Inc.(Novitas+Solutions%2c+Inc.++(07102%2c+A+and+B+MAC%2c+J+-+H))&s=All&DocType=Active%7cFuture&bc=AggAAAQAAAAA&

Medicare regulations prohibit laboratories from billing the patient for laboratory tests that are not covered or reimbursed by Medicare or for which the ICD-10 code(s) indicated by the provider do not support medical necessity unless an Advance Beneficiary Notice (ABN) has been properly signed by the patient. It is the provider's responsibility to ensure that the ABN is signed and sent with the test requisition.

Test Ordering

A standard Clinical Genomics test requisition form should be used when ordering tests. If Clinical Genomics receives an incomplete test requisition or a test order on a non-Clinical Genomics requisition form, processing of your test order may be delayed. As necessary, Clinical Genomics will contact physicians to have them resubmit the test order on a Clinical Genomics test requisition form or clarify the test being ordered. The test requisition is the tool used to communicate the physician order to the lab and is designed to encourage physicians to order only those tests which the physician believes are appropriate and medically necessary for the diagnosis or treatment of each patient. Upon request by Clinical Genomics or its payers/auditors, ordering providers are required to provide any/all chart documentation (including physician signature), that reflects the actual lab order and/or supports the authenticity and medical necessity of the lab order(s) submitted. Signature stamps are NOT acceptable. Orders must include legibly written or electronic signatures.

Medicare Laboratory Fee Schedule

Clinical Genomics is reimbursed under the Medicare Clinical Laboratory Fee Schedule for testing that is covered or reimbursable under an existing NCD or LCD. Beneficiaries are responsible for any applicable coinsurance and deductible amounts. The Medicare Clinical Laboratory Fee schedule can be obtained online at:

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

Clinical Consultants

Clinical Genomics' clinical consultants are available to discuss appropriate test use, test orders and interpretation of test results. Please contact Customer Services at 855-870-0096 for assistance.

Inducements
Federal law prohibits offering or paying any remuneration – meaning anything of value – to induce the referral of tests that are covered by Medicare, Medicaid or other federal health care programs. Any form of kickback, payment or other remuneration that is intended to secure the referral of federal health care program testing business is strictly prohibited and should be reported to the Clinical Genomics compliance hotline by emailing at compliance@clinicalgenomics.com.

Prohibited Referrals
It is the policy of Clinical Genomics to comply with all aspects of the laws and regulations governing physician self-referral, most notably including the federal Stark law. The Stark law's self-referral ban states that if a financial relationship exists between a physician (or an immediate family member) and a laboratory (or certain other kinds of healthcare providers), and the relationship does not fit squarely into one of the law's exceptions, then (a) the physician may not refer Medicare patients to the laboratory, and (b) the laboratory may not bill Medicare for services referred by the physician. The kinds of relationships between laboratories and physicians that may be affected by these laws include the lease or rental of space or equipment and the purchase of medical or other services by a laboratory from a referring physician.

PATIENT PRIVACY (HIPAA)
Under the Health Insurance Portability and Accountability Act (HIPAA), Clinical Genomics is a health care provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy and security standards. Our privacy policy is available at: https://clinicalgenomics.com/hipaa-privacy/.

Financial Assistance Programs
Clinical Genomics 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. Clinical Genomics is committed to delivering the best patient care to all, and to meet this objective has established a financial assistance program. This financial assistance program helps ensure affordable access to Clinical Genomics' services. Patients with special financial needs may be eligible for support to help defray some of Clinical Genomics' testing costs. Clinical Genomics encourages those patients who may not be able to pay fully for Clinical Genomics' services to contact us for an assessment of eligibility for financial assistance in accordance with federal guidelines.

Patient Billing Policy

Insured patients are billed Deductibles, Co-Insurance and Co-Payments as required by their Insurance Provider. Clinical Genomics reserves the right to use resources available to search for active insurance if information is not provided or if the order is marked “Self-Pay”, “Uninsured”, or “Patient Does Not Have Insurance Coverage.”

Under HIPAA, patients may opt out of using their insurance benefits in order to prevent reporting this service to their insurance carrier. Clinical Genomics must be informed at the time of ordering if the patient is choosing this option and the patient’s insurance information must be provided. The patient will be billed at Medicare rates for the services performed. If payment is not received within 60 days, Clinical Genomics will bill the patient’s insurance in order to secure reimbursement.

If the patient is found to have no insurance, Clinical Genomics may offer an uninsured rate. In addition, Clinical Genomics offers various programs designed to assist patients with the billing process or to offer need-based reductions in billed charges. Patients are encouraged to contact us if they believe there is a billing error, believe they may qualify for a reduced billing rate based on financial eligibility, need to establish payment arrangements or have questions about their bill.

If you have any questions related to this Notice, please contact the Clinical Genomics Compliance Department at compliance@clinicalgenomics.com.

Laboratory Director, John Alsobrook, Ph.D.
Medical Director, Robert Boorstein, M.D., Ph.D.