207 Perry Parkway, Gaithersburg, MD 20877
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www.genedx.com

Date: March 2021

Re: 2021 Annual Notification to Ordering Providers

Dear Valued Client:

Thank you for allowing GeneDx, Inc. ("GeneDx") to serve the healthcare needs of your patients. We are dedicated to providing you and your patients the highest quality service. We are equally committed to complying with any and all applicable federal and state healthcare laws, rules and regulations, including guidance published by the United States Department of Health and Human Services Office of Inspector General (the "OIG") available at https://oig.hhs.gov/fraud/docs/complianceguidance/thirdparty.pdf The OIG recommends clinical laboratories send notices to physicians and other health care providers who use their services, at least once a year, to inform the recipients of the laboratory's policies for test ordering and billing and provide certain other information regarding to the laws and regulations that govern laboratory services. This Annual Notice is provided pursuant to that recommendation.

NEW POLICIES:

Signed Requisitions: There has been increased review efforts by payors verifying that the ordering provider has signed the requisitions for laboratory tests ordered. The requisition needs to be signed; the order can be through an electronic medical record or ordering system; or documentation needs to be in the patient medical record at the treating provider site clearly indicating intent to order the test(s) and signed by the ordering provider e.g. MD. We ask that you sign the hard copy requisition when ordering any testing submitted to our laboratory. This will mitigate the risk of BioReference Laboratories reaching out to your staff to retrieve evidence of the signed test order in your patient chart.

Pre-Authorization for Laboratory Testing: Insurance payors continue to increase oversight and restrict access by requiring pre-authorization for certain laboratory testing including but not limited to certain types of genetic carrier biomarkers and infectious disease panels. Any pre-authorization paperwork *must accompany* the laboratory requisition and specimen from the ordering provider. Please include the pre-authorization number on the test requisition. If we do not receive this at the time of the test order, it risks delay to your patient's testing.

ABN: If a 'non-covered' diagnosis is used, the patient must be notified prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice (ABN). The ABN must be completed for any Medicare patient where claim denial is suspected based on medical necessity or frequency limitations. The signed, original ABN must be attached to the original lab order prior to submission. In order for the laboratory to bill the patient, Medicare (and other payers) require that a patient sign an Advance Beneficiary Notice ("ABN") informing them of the non-covered status of a test prior to the test being performed. Since we do not interact directly with patients, it is the responsibility of the ordering provider to be familiar with applicable NCD and LCD coverage rules, including ABN requirements, to ensure that informed medical necessity determinations, which take into consideration a patient's financial ability, are made for each patient and are supported by a signed order in the patient's medical record. Link: www.medicare.gov

CONTINUED POLICIES:

Coverage Standards: As you know, Medicare and Medicaid only cover laboratory tests that are reasonable and necessary for the treatment or diagnosis of a patient. It is each ordering provider's responsibility to order only those tests that are reasonable and necessary for each patient that ordering provider intends to use in the care of the patient. Medicare and its contractors have developed National and Local Coverage Determinations ("NCDs" and "LCDs") that provide guidelines regarding Medicare coverage of certain laboratory 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. You can find NCDs and LCDs online. Medicare reimbursement for each laboratory test

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can be found in the Medicare Clinical Laboratory Fee Schedule and the Medicare Physician Fee Schedule. It is the policy of GeneDx to only bill for panels when all the component tests are medically necessary, so the ordering provider agrees to only order panels when all component tests are medically necessary.

Test Ordering Options: Regulations require that the performing laboratory have a written or electronic request for patient testing from an authorized person to order testing as defined by state law per the Clinical Laboratory Improvement Amendments ("CLIA"). The GeneDx test requisition forms are designed to emphasize physician choice and encourage ordering providers to order only those tests, which he/she believes are appropriate and medically necessary for the diagnosis or treatment of each patient. If GeneDx receives a test order on a non-GeneDx test requisition form or an incomplete GeneDx test requisition form, processing of your test order may be delayed. GeneDx has three (3) options available by which an authorized provider may order GeneDx testing. They include: 1) manual paper test requisitions; 2) online test ordering via the GeneDx Clinician Portal, our proprietary electronic ordering system; and 3) EMR interface. Online ordering and EMR interface ordering are the more efficient methods of test ordering and help reduce potential human errors in the order creation and entry process. Failure to provide a complete, clear and accurate test requisition may result in a delay in processing of a test order.

Verbal Test Orders: If an authorized person orders a test by telephone or wishes to add a test to an existing order, GeneDx will fax or email a change in test authorization ("CITA") form detailing the verbal order to the ordering provider and request that the provider sign and send the order form to GeneDx.

Billing Information: GeneDx test requisitions allow space to denote all information required for our Billing Department to submit claims to Medicare, Medicaid and all commercial, Federal, and State funded insurance payers. The following information is necessary with any request for testing. Failure to provide the required information may result in GeneDx contacting the ordering provider's office via telephone, fax, or HIPAA secure email to obtain the missing billing information.

- Patient's full, legal name as listed on their current health insurance policy
- Patient's mailing address, including city, state, and zip code
- Patient's date of birth
- Patient's biological gender at birth
- Patient's insurance company name, complete ID or policy number and complete group number, if applicable (if possible, a copy of the front and back of the patient's insurance card should be sent along with the test requisition)
- Patient contact telephone number and email address
- Signed Patient Informed Consent
- Referring provider's name (must be an authorized provider with GeneDx)
- ICD-10 diagnosis code(s) to the highest level of specificity for each test ordered. ICD-10 diagnosis code(s) must be documented in the patient's medical record
- Any Prior Authorization Forms required by the patient's health plan
- If using GeneDx manual paper test requisitions, the signature of the ordering provider
- Advanced Beneficiary Notice (ABN) when applicable (Medicare)

Failure to provide a complete, clear and accurate test requisition may result in a delay in processing of a test order. GeneDx will not bill government or private payers for tests and services that are not medically reasonable and necessary, so the ordering provider agrees to only order tests that are medically necessary. GeneDx is audited from time to time by Medicare, Medicaid and Commercial Payers and it may be necessary to contact the ordering provider to obtain medical records to support the test(s) ordered and the claim submitted by GeneDx to the payer. GeneDx encourages you to promptly comply with any and all Payer requests for supporting patient medical documentation.

GeneDx
an OPKO Health Company

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Authorized Test Ordering: Federal regulations require that a laboratory can only bill Medicare and Medicaid for testing ordered by a licensed physician or other non-physician practitioner ("NPP") authorized by state law to order laboratory tests. If your license has been revoked or suspended, it is your responsibility to notify our laboratory immediately. You represent and warrant that neither you, nor any employee, contractor or agent performing services on behalf of you has been excluded, debarred, suspended, proposed for debarment, or otherwise declared ineligible from any federal healthcare program or federal procurement or non-procurement program or convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7a. You further covenant that you will disclose any such debarment, suspension, exclusion, proposed debarment, or ineligibility to GeneDx immediately upon discovery. Medicare requires that physicians ordering laboratory testing on Medicare beneficiaries, must be registered in the Center for Medicare and Medicaid Services' ("CMS") Provider Enrollment, Chain and Ownership System ("PECOS"). It is GeneDx's policy to only bill Medicare for laboratory testing ordered by a PECOS enrolled physician and performed by GeneDx, per Medicare regulations. Additional information can be found at: https://pecos.cms.hhs.gov

Panels: GeneDx offers you the opportunity to create a custom panel. It is each ordering provider's responsibility to determine whether each gene in a custom panel is appropriate for a given patient. As the ordering provider, you have complete discretion concerning the tests you order for each of your patients. You may order tests individually or modify your custom panel(s) by adding or removing genes as appropriate for any given patient, using the GeneDx Clinician Portal or test requisition form. It is the policy of GeneDx to only bill for panels when all the component tests are medically necessary, so the ordering provider agrees to only order panels when all component tests are medically necessary.

Diagnosis: Ordering providers solely determine which tests are reasonable and necessary for their patients. GeneDx solely relies on providers to make that determination and expects them to provide accurate diagnostic information on their test requisitions. GeneDx can provide a list of commonly used ICD-10 diagnosis codes but cannot recommend or suggest specific diagnosis codes to be used. Each ordering provider should document each patient's diagnosis in the patient's medical record and, by order of Section 4317 of the Balanced Budget Act of 1997, should include this diagnosis on any test requisition form submitted to GeneDx through use of the correct ICD-10 diagnosis code(s) to the highest level of specificity. Ordering providers who do not provide required diagnosis information may be contacted by GeneDx via telephone, fax or email. Per Medicare requirements, the physician or qualified NPP who orders the laboratory tests must maintain documentation of medical necessity in the beneficiary's medical record for the laboratory testing ordered. GeneDx will not bill government or private payer for tests and services that are not medically reasonable and necessary, The ordering provider agrees to only order tests that are medically necessary.

The OIG takes the position that a qualified ordering 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.

Ordering of Discretionary Tests: The billing to a federally funded health care program, such as Medicare or Medicaid, of a test that is not reasonable and necessary for the diagnosis or treatment of a federal health care program beneficiary may be considered to be the submission of a false claim under the federal False Claims Act. The OIG has warned that physicians or other individuals authorized by law to order laboratory tests are subject to sanctions and other remedies under criminal, civil and administrative law if they knowingly cause the submission of a false claim to any federally funded health care program. If you determine that a test for a Medicare beneficiary is not reasonable and necessary, it is your responsibility to inform the beneficiary that Medicare will not pay for the test.

Compliance: We at GeneDx are committed to compliance. Our Code of Conduct and Business Ethics identifies the values and obligations that all GeneDx employees, officers, directors, consultants, and sales force must follow https://www.bioreference.com/about/code-of-ethics/ A full copy of our Code of Conduct and Business Ethics is available by written request directed to the BioReference Laboratories, Inc. ("BRLI") Compliance Department at 481 Edward H. Ross Drive Elmwood Park, NJ 07407, email at ComplianceDepartment@bioreference.com or verbally by

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calling our anonymous GeneDx Compliance Hotline at (888) 227-5556. If you have any questions or concerns about compliance, please call or write. Please also remember that federal law prohibits any person from offering or paying any remuneration, *i.e.*, anything of value, to induce the referral of tests that are covered by Medicare, Medicaid, or any other federal healthcare program. Any form of kickback, payment, or other remuneration that is intended to secure the referral of federal healthcare program testing business to GeneDx is strictly prohibited and should be reported to the anonymous GeneDx Compliance Hotline referenced-above.

Patient Privacy (HIPAA): Under the Health Insurance Portability and Accountability Act (HIPAA), GeneDx is a healthcare 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 genedx.com/privacy.

Clinical Consultant: The laboratory's Director of Technical Operations and Medical Director are available to discuss appropriate testing and test ordering. If you have any questions, please do not hesitate to contact Customer Service at (888) 729-1206 for assistance. Please review this information with your staff as appropriate. We value your business and appreciate the opportunity to serve your diagnostic laboratory genetic testing needs in conjunction with these initiatives.

Best regards,

Chris Sands

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[1] NCDs that apply to clinical laboratory testing: https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx GeneDx, Inc. submits Medicare claims to the following MAC, for which the complete list of LCDs can be found on the Novita's website, https://www.novitas-solutions.com

[2] The Medicare Clinical Laboratory Fee Schedule: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files

[3] The Medicare Physician Fee Schedule: https://www.cms.gov/apps/physician-fee-schedule/overview.aspx