March 2023

# 2023 Annual Physician Notice

Dear Valued Client,

Thank you for allowing GeneDx, LLC to serve the healthcare needs of your patients. We are dedicated to providing you and your patients with the highest quality service. We are equally committed to complying with 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/documents/compliance-guidance/806/cpglab.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.

## Ordering Policies:

**Medical Necessity:**
Third-party payors will only pay for tests that are medically necessary for the diagnosis or treatment of the individual patient. Criteria to establish medical necessity for testing must be based on patient-specific elements identified during the clinical assessment and documented by the clinician in the patient's medical record. GeneDx has a responsibility to make a good faith effort to ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations. As the ordering physician, you are responsible for documenting medical necessity in the patient's medical record (including physician signature) and for providing appropriate diagnostic information in the form of ICD-10-CM codes to the highest level of specificity or a narrative to GeneDx.

***The OIG takes the position that physicians or other ordering providers authorized by law to order clinical laboratory tests, who knowingly cause a false claim to be submitted to any federally funded program, may be subject to sanctions or remedies available under civil, criminal and administrative law, such as the False Claims Act.***

**Signed Requisitions**:
Although the provider signature is not required on laboratory requisitions, if signed, the requisition will serve as acceptable documentation of a physician order for the testing. This will mitigate the risk of GeneDx reaching out to your staff to retrieve evidence of

the signed test order in your patient chart, and so is strongly encouraged. In the absence of a signed requisition, documentation of your intent to order each laboratory test must be included in the patient's medical record and available to GeneDx upon request, as needed. Documentation must accurately describe the individual tests ordered; it is not sufficient to state 'labs ordered'. Upon request by GeneDx or its payors/auditors, ordering providers are required to provide any/all chart documentation (including physician signature) that reflect the actual lab order and supports the authenticity and medical necessity of the lab order(s) submitted.

**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, infectious disease panels, and whole exome and genome sequencing. 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 delaying your patient's testing. If the ordering provider is using an agnostic third-party preauthorization service, then documentation the payors deem necessary to make a determination must be provided to GeneDx. GeneDx will work with the provider to obtain the preauthorization information, as necessary.

**CMS National Coverage and Reimbursement Policy:**

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-CM codes that support coverage. You can find NCDs and LCDs online[1,2]. Additionally, Medicare reimbursement for laboratory tests can be found in the Medicare Clinical Laboratory Fee Schedule or Physician Fee Schedule[3,4]. Medicaid reimbursement amounts will be equal to or less than the amount of Medicare reimbursement.

[1] National Coverage Determinations (NCD):
https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx

[2] Local Coverage Determinations (LCD):
Novitas (NJ, MD, DC, PA): https://www.novitas-solutions.com/webcenter/portal/MedicalPolicy_JL/LCDInfo
Novitas (TX): https://www.novitas-solutions.com/webcenter/portal/MedicareJH/LcdSearch
CGS Medicare (OH): https://cgsmedicare.com/partb/medicalpolicy/index.html
FCSO (FL): https://medicare.fcso.com/Coverage_Find_LCDs_and_NCDs/0488392.asp
Noridian (CA): https://med.noridianmedicare.com/web/jeb
NGS (NY): https://www.ngsmedicare.com/web/ngs/medical-policies?lob=96664&state=97133&region=93623

[3] Clinical Laboratory Fee Schedule (CLFS):
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files

[4] Physician Fee Schedule:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched

**Advance Beneficiary Notice (ABN)[5]:**
If a patient is diagnosed with a "non-covered" service based on Medicare coverage criteria, the patient must be notified prior to specimen collection and given the opportunity to sign an ABN. The ABN must be completed for any Medicare patient where claim denial is suspected based on medical necessity, frequency limitations or other Medicare policy. The signed, original ABN must be attached to the original lab order prior to submission. Since GeneDx does 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 are made for each patient and are supported by a signed order in the patient's medical record. A copy of the ABN should be submitted with the order.

**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 provider choice and encourage authorized ordering providers to order only those tests which they believe 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:**
Third-party payors generally require that all orders for laboratory testing be in writing. If an authorized provider 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. Testing will not be performed until the signed confirmation or a properly completed GeneDx requisition or CITA form is returned to the laboratory.

**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 payors. The following information is necessary with any

[5] Advance Beneficiary Notice (ABN):
https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN

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 sex 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 consents
- Ordering provider's name (must be an authorized provider with GeneDx)
- ICD-10-CM diagnosis code(s) to the highest level of specificity for each test ordered. ICD-10-CM diagnosis code(s) must be supported in the patient's medical record.
- Any prior authorization forms required by the patient's health plan
- Advanced Beneficiary Notice (ABN), when applicable (e.g., Medicare)

Failure to provide a complete, clear, and accurate test requisition may delay processing a test order. GeneDx will not bill government or private payors 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 payors it may be necessary to contact the ordering provider to obtain medical records to support the test(s) ordered, diagnoses reported, and the claim submitted by GeneDx to the payer. GeneDx encourages you to promptly comply with all Payer requests supporting patient medical documentation.

**Authorized Test Ordering:**

Generally, a laboratory can only bill third-party payors, including 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. Additionally, Medicare requires that physicians ordering laboratory testing on Medicare beneficiaries must be registered in the Centers 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

**Diagnosis:**

Authorized ordering providers are solely responsible for determining 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-CM 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-CM diagnosis code(s) to the highest level of specificity. GeneDx may contact ordering providers who do not provide the required diagnosis information via telephone, fax, or email. The physician or qualified non-physician practitioner 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 payors for tests and services that are not medically reasonable and necessary. The ordering provider agrees to only order tests that are medically necessary.

**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. A full copy of our Code of Conduct and Business Ethics is available by written request directed to the GeneDx Compliance Department at 333 Ludlow Street, North Tower, 6th Floor, Stamford, CT 06902, email at Compliance@GeneDx.com or verbally by calling our Compliance Helpline: (651) 294-8554, or Toll free: +1 (844) 736-2434. 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 kickback, payment, or other remuneration intended to secure the referral of federal healthcare program testing business to GeneDx is prohibited and should be reported to the anonymous 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 notice of privacy practices is available at https://www.genedx.com/hipaa-notice-of-privacy-practices.

**Clinical Consultant:**

GeneDx's CLIA Laboratory Director, Kathleen Hruska, is available to discuss appropriate testing and test ordering. If you have any questions, please contact Customer Service at (800) 298-6470 for help.

Please review this information with your staff as appropriate. We value your business and appreciate the chance to serve your diagnostic laboratory genetic testing needs with these initiatives.