



2017 ANNUAL NOTICE TO PHYSICIANS

February 2017

The Office of Inspector General (OIG) of the Department of Health and Human Services recommends in its Model Laboratory Compliance Plan that laboratories send an annual notice to physicians and other providers advising them of the elements of the laboratory's compliance program. This letter serves as the annual notice and provides helpful information regarding the ordering and processing of clinical laboratory tests.

Genomic Health asks ordering providers to review the information contained in this notice. If you have any questions, please contact Customer Services at +1 (866) ONCOTYPE (866-662-6897) or customerservice@genomichealth.com.

Medical Necessity

Medicare will pay only for tests that meet Medicare coverage criteria and are reasonable and necessary for the diagnosis and/or treatment of an illness.

As a participating provider in the Medicare Program, Genomic Health has the responsibility to make good faith efforts to ensure all tests requested are performed and billed in a manner consistent with all federal and state laws and regulations. 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, may be subject to sanctions or remedies available under civil, criminal and administrative law.

Medicare National and Local Coverage Determination

These Medicare policies define the medical conditions through the inclusion of a list of ICD-10 (diagnosis) codes for which tests are covered or reimbursed by Medicare. HIPAA regulations require ICD-10 codes to be listed on each claim field. Healthcare professionals must provide the ICD-10 diagnosis code for each test ordered.

Note: Coverage determinations may be viewed at: <https://www.cms.gov/medicare-coverage-database/>

Clinical Consultants

Genomic Health's Clinical Consultants are available to discuss appropriate test use, test orders and interpretation of test results. Please contact Customer Services at +1 (866) ONCOTYPE (866-662-6897) for assistance.

Medicare Physician Fee Schedule

Genomic Health is reimbursed under the Medicare physician fee schedule for the Immunohistochemistry Stain. Beneficiaries are responsible for applicable coinsurance and deductible amounts. Medicaid reimbursement will be equal to, or lesser than, Medicare reimbursement.

The Medicare Physician Fee schedule can be obtained online at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>

Custom Profiles

Genomic Health does not establish nor accept non-patient specific custom profile test orders from ordering physicians.

Clinical Laboratory Director

Patrick Joseph, M.D.