Dear Physician Colleague:

Genoptix Medical Laboratory is committed to complying with all applicable laws and regulations governing the health care industry. We have adopted a compliance program based on the Office of Inspector General’s (OIG) Compliance Program Guidance for Clinical Laboratories. As part of our compliance efforts, we are providing you with this Annual Notice, and the following important updates:

- Medicare medical necessity requirement
- Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) for laboratory tests
- The 2014 Physician Fee Schedule and 2014 Clinical Laboratory Fee Schedule
- Financial assistance programs
- Contact information for Genoptix hematopathologists
- Medicare billing update for clinical laboratory and anatomic pathology services

This information is also available on www.genoptix.com. Genoptix will send notices throughout the year to update physicians when our policies or services change. Please read these notices carefully as they contain important information regarding the services you order for your patients.

If you have any questions concerning our Annual Notice or appropriate test use and ordering, please contact info@genoptix.com or 800.755.1605. I hope you find the information provided in this Annual Notice helpful.

Sincerely,

Bashar Dabbas, M.D.
Medical Director
Genoptix, Inc.
MEDICARE NATIONAL COVERAGE DETERMINATIONS (NCDS) AND LOCAL COVERAGE DETERMINATIONS (LCDs)

Genoptix is a Medicare participating provider. Genoptix is subject to Medicare national coverage determinations (NCD) and the local coverage determinations (LCD) of the Part B Medicare Administrative Contractor (MAC) for Jurisdiction E, Noridian Healthcare Solutions. Additional information can be obtained online at: https://med.noridianmedicare.com/web/jeb/policies/lcd/active

LOCAL COVERAGE DETERMINATION (LCD) FOR FLOW CYTOMETRY

Contractor Name: Noridian Administrative Services, LLC
Contractor Number: 01182
Contractor Type: MAC - Part B
LCD ID Number: L33526
LCD Title: Flow Cytometry
Primary Geographic Jurisdiction: California — Southern
Original Determination Effective Date: For services performed on or after 09/01/2014

LOCAL COVERAGE DETERMINATION (LCD) FOR CIRCULATING TUMOR CELLS

Contractor Name: Noridian Administrative Services, LLC
Contractor Number: 01182
Contractor Type: MAC - Part B
LCD ID Number: L35217
LCD Title: Circulating Tumor Cell Marker Assays
Primary Geographic Jurisdiction: California — Southern
Original Determination Effective Date: For services performed on or after 09/22/2014

LOCAL COVERAGE DETERMINATION (LCD) FOR MOLECULAR DIAGNOSTICS TESTS

Contractor Name: Noridian Administrative Services, LLC
Contractor Number: 01182
Contractor Type: MAC - Part B
LCD ID Number: L33541
LCD Title: Molecular Diagnostic Tests (MDT)
Primary Geographic Jurisdiction: California — Southern
Original Determination Effective Date: For services performed on or after 09/01/2014

MEDICARE MEDICAL NECESSITY REQUIREMENT

Tests ordered that will be reimbursed by Medicare or any federal health care program should be carefully reviewed and considered reasonable and necessary for the diagnosis and/or treatment of an illness. Individuals who knowingly submit false claims to Medicare or other health care programs are subject to civil, criminal and administrative action as outlined by the Office of the Inspector General (OIG). In addition, the OIG takes the position that a physician who orders medically unnecessary tests for which Medicare reimbursement is claimed may be subject to civil penalties.

Genoptix insists that only medically necessary tests are ordered by its physician clients and requires documentation to ensure only medically necessary services are billed. It is the responsibility of the physician to document the diagnosis in the patient’s medical record. Disease-specific profiles can only be billed and paid when all of the profile’s components are medically necessary.

Diagnosis information is requested from ordering physicians in order to support the medical necessity of each test ordered. ICD-9 codes are required on the test requisition. However, narrative descriptions for diagnosis and/or conditions are acceptable. We will contact our clients to obtain diagnosis information for reasons including, but not limited to the following:
1) A diagnosis code or narrative description is not provided.

2) The provided diagnosis narrative description appears inconsistent with the patient’s demographic, the patient’s medical condition, or the testing services being ordered.

3) The provided diagnosis or narrative description does not meet the coverage criteria as supporting medical necessity for testing services covered by a Medicare National (NCD) or Local (LCD) coverage determination.

Because Genoptix performs specialty testing services, such as flow cytometry, immunohistochemistry, cytogenetics, fluorescent in-situ hybridization, and molecular diagnostics, an order for an analysis or profile that contains these procedures is actually an authorization for Genoptix to perform up to the highest number of the described range of antibodies, stains, or probes on a particular specimen. When a member of the Genoptix medical staff determines that testing above the authorized range is necessary, the ordering physician will be notified for approval. As tests are included or added to profiles and the price for the enhanced profile increases, Genoptix is obligated to ensure that the overall price of the profile is never below cost. Medicaid reimbursement for tests will be equal to, or less than, Medicare reimbursement.

CUSTOM PROFILES

Genoptix customized profiles should be billed to Medicare only when every component of the customized profile is medically necessary. Genoptix offers groups of tests based on accepted clinical practice, as well as those that are defined by the American Medical Association Current Procedural Terminology (CPT). All individual components of these profiles may also be ordered individually, unless otherwise indicated. CPT codes include all services usually performed as part of the procedure as a standard of medical/surgical practice. A physician should not separately report these services simply because CPT codes exist for them.

Ordering of profiles may result in the ordering of medically unnecessary tests. Any individual that knowingly causes medically unnecessary testing to be performed and billed to federally funded health care programs may be subject to sanctions and remedies available under civil, criminal, and administrative law.

GENOPTIX TEST REQUISITION

The Genoptix Test Requisition has been designed to facilitate the ordering of medically necessary and appropriate tests and to obtain information as required by private and federal health care providers. To encourage this practice, the Genoptix Test Requisition includes the statement “Medicare and other third-party payors require that services be medically necessary for coverage. Medicare generally does not cover routine screening tests.” Medicare may not pay for tests that are not FDA approved or are experimental. Moreover, the Genoptix Test Requisition generally includes the option to order tests within a profile individually. Individuals are directed to only order the profile when all of the tests included therein are medically necessary. If all of the tests included in a profile are not medically necessary, the individual is instructed to only order those individual tests that are medically necessary.

2014 MEDICARE PHYSICIAN FEE SCHEDULE (MPFS)

For the many anatomic pathology services we provide, we are reimbursed under the Medicare physician fee schedule, and beneficiaries are responsible for applicable coinsurance and deductible amounts. The amounts paid under the physician fee schedule are based on geographically adjusted relative value units, or RVUs, for each procedure or service, adjusted by a budget neutrality adjustor, and multiplied by an annually determined conversion factor.

More information regarding the 2014 Medicare Physician Fee Schedule (MPFS), can be obtained online at: http://www.cms.hhs.gov/physicianFeeSched/

2014 MEDICARE CLINICAL LABORATORY FEE SCHEDULE (CLFS)

The clinical laboratory fee schedule sets the maximum amount payable under Medicare for each specific laboratory billing code. We bill the program directly and must accept the scheduled amount as payment in full for covered tests performed on behalf of Medicare beneficiaries.

The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule. Payment under the clinical laboratory fee schedule has been limited from year to year by Congressional action such as imposition of national limitation amounts and freezes on the otherwise applicable annual consumer price index, or CPI, updates.

The 2014 Clinical Laboratory Fee Schedule (CLFS) can be obtained online at: http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html
**FINANCIAL ASSISTANCE PROGRAMS**

Genoptix will reduce or waive charges only after determining in good faith that a patient requires financial assistance, and/or after we have made reasonable collection efforts. Financial assistance will be determined on a case-by-case basis.

The offering of a professional courtesy (i.e., reducing or waiving charges to physicians or other individuals who order services from us), is a practice that the federal government believes may constitute a financial benefit given to those individuals for the purpose of inducing referrals. Such inducements are illegal under the federal anti-kickback statute. Consequently, we do not offer professional courtesies.

**PROMPT PAY DISCOUNT:**

Patients are entitled to a 15% prompt pay discount if payment is received along with the test requisition form, or within 45 days from receipt of their first statement.

Please note: Discounts are not available on all services and do not apply to balances after insurance is applied, such as deductibles, co-payments, co-insurances, and share of costs.

**PAYMENT PLANS:**

All patients are eligible for payment plans regardless of insurance status. Patients should call 800.755.1605 upon receipt of their first bill if they are interested in requesting a payment plan. There are no fees or interest charges for this program.

**CHARITY CARE:**

If a patient receives Charity Care from a facility that sent us the specimen, a copy of the Charity Care approval letter/card should be attached to the test requisition form. The approval letter/card should state the amount of assistance the patient receives, along with the start and end date of eligibility.

**PATIENT FINANCIAL HARDSHIP REQUEST FROM PHYSICIAN OR FACILITY:**

If a physician or facility grants a patient financial assistance based on a documented financial hardship, that physician or facility may request that Genoptix honor a similar financial assistance. Request forms can be requested from the Genoptix billing department.

**GENOPTIX FINANCIAL HARDSHIP PROGRAM:**

Patients with a financial hardship should call 800.755.1605. To determine eligibility, patients will be asked to submit supporting documentation so that Genoptix can evaluate based on a predetermined criteria, set in the federal poverty guidelines.

**BILLING CONTACT INFORMATION**

Genoptix Medical Laboratory
Billing Department
1811 Aston Avenue
Carlsbad, CA 92008
Telephone: 800.755.1605
Fax: 760.516.6062
Email: billing@genoptix.com

**CLINICAL CONSULTANT AND HEMATOPATHOLOGIST CONTACT INFORMATION**

**For Clinical Consultant:** Appropriate test use and ordering may be discussed with the Genoptix Medical Director, Bashar Dabbas, M.D. Dr. Dabbas can be reached by email at info@genoptix.com or by calling 800.755.1605.

**For Genoptix Hematopathologists:** Any Genoptix hematopathologist can be contacted by calling 800.755.1605 during the following business hours (Pacific Time):

Monday–Friday 5:00 a.m.–7:00 p.m.
Saturday 8:00 a.m.–4:00 p.m.

If a physician has an urgent patient matter that requires consultation after normal business hours, an on-call hematopathologist can be accessed by dialing 800.755.1605 option 1.
MEDICARE BILLING UPDATE

In keeping with our ongoing efforts to ensure that our clients remain current on Medicare billing rules and regulations applicable to our business, we are providing you with guidance on billing for clinical laboratory and anatomic pathology services provided to your patients. Generally, whether an independent laboratory, such as Genoptix, can bill the Medicare program directly for its services depends, among other things, on the patient’s status (i.e., inpatient, outpatient, or non-patient) and the type of services provided (i.e., the professional component or technical component of anatomical pathology or clinical testing).

In most circumstances, Genoptix is required to bill Medicare directly for clinical laboratory services provided to non-hospital patients (i.e., patients who are neither hospital inpatients nor outpatients) and is allowed to bill either the Medicare program or the patient for anatomical pathology services if the patient is not a hospital patient. If the patient is a hospital inpatient or outpatient (collectively, a “hospital patient”), Genoptix must bill the hospital, rather than Medicare, for clinical laboratory testing and the technical component (TC) of anatomical pathology services. Genoptix almost always can bill either Medicare or the patient for the professional component (PC) of anatomical pathology services. There are, however, exceptions to these rules.

Below we have summarized the detailed rules and regulations that govern patient status and related determinations, and we have explained the ways in which we can work together to make sure that only the appropriate party bills the Medicare program for our services. Please pay particular attention if you are employed by a hospital or routinely treat hospital outpatients.

MEDICARE BILLING RULES APPLICABLE TO INDEPENDENT LABORATORY SERVICES PROVIDED TO HOSPITAL INPATIENTS AND OUTPATIENTS

As you likely know, hospitals receive bundled-payment reimbursement for Medicare Part A services provided to inpatients pursuant to a prospective payment system (PPS). The amount paid per discharge is a set rate, except for geographical adjustments, and it covers most services, including all clinical laboratory services, furnished in connection with the hospital stay.

Medicare Part B covers services furnished to hospital outpatients under a prospective payment system commonly referred to as “OPPS.” Under this system, CMS bundles most of the costs associated with a particular procedure, including the technical component of anatomic pathology services.

CLINICAL LABORATORY SERVICES

Payments made to hospitals for Medicare inpatient services cover clinical laboratory services. In 2013 and prior years, clinical laboratory services furnished to outpatients were separately reimbursed. Starting in 2014, clinical laboratory testing was bundled into the hospital outpatient E&M payment and is not separately reimbursed, with the exception of molecular diagnostics testing, where separate reimbursement is permitted. However, as in prior years, Medicare statutes and regulations require the hospital to bill and receive reimbursement for such services pursuant to Medicare’s Clinical Laboratory Fee Schedule.

ANATOMIC PATHOLOGY SERVICES — PROFESSIONAL COMPONENT (PC)

Bundled payments made under PPS or OPPS do not cover the costs of physician services furnished to inpatients or outpatients. As a result, an independent laboratory, such as Genoptix, can always bill Medicare Part B for physician services, including the PC of anatomic pathology services.

ANATOMIC PATHOLOGY SERVICES — TECHNICAL COMPONENT (TC)

The cost of the TC of anatomic pathology services typically is included in bundled payments made under PPS or OPPS. Genoptix is required to bill the facility for these services.

DETERMINATION OF DATE OF SERVICE WHEN TESTING IS PERFORMED ON A SPECIMEN TAKEN DURING A HOSPITAL STAY

In some situations, Medicare rules and regulations may prohibit an independent laboratory, such as Genoptix, from billing the Medicare program for laboratory testing even after a patient’s date of discharge. Specifically, if a test is performed on a specimen that has been stored for 0 to 13 days or less (a “non-archived specimen”), the date of service is the date of specimen collection, which means that the laboratory must bill the hospital for testing performed on specimens collected during a hospital stay. The date of service becomes the date the testing is reported for testing on an archived specimen where the order date is 14 to 30 days from the date of discharge, which means that the laboratory, rather than the hospital, may bill the Medicare program.

The date of service for testing on an archived specimen (i.e., one that has been stored for more than 30 calendar days before testing) is the date the specimen was obtained from storage, which means that the laboratory, rather than the hospital, must bill the Medicare program.
To clarify when a laboratory test is considered to be provided to a Medicare beneficiary during a hospital stay or procedure, CMS adopted a regulation often referred to as the “14 Day Rule.” Under this regulation, the date of service for laboratory testing performed on a non-archived specimen is the date of test performance, which means that the independent laboratory can bill separately for the test, if:

- It was ordered by the patient’s physician at least 14 days after the patient’s date of discharge;
- The specimen was collected during a hospital surgical procedure;
- Collection of the specimen at any other time would have been medically inappropriate;
- The results of the test were not used to guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

HOW YOU CAN HELP

To ensure that we have the information needed to determine whether Genoptix or the hospital must bill the Medicare program for clinical laboratory or TC services ordered from us, we ask that you provide as much information as possible about your patient’s recent hospital stay, if applicable, when ordering our testing. In addition to noting the patient’s status at the time the specimen was collected, we request that you also provide the date of discharge and the date of collection, if known. This information is vital to our ability to confirm whether your patient should be classified as a hospital patient (whether an inpatient or outpatient), in which case the hospital must take responsibility for billing the Medicare program for our clinical laboratory and TC services.

You also should note that our requisition form asks you to identify the patient’s status as hospital inpatient, outpatient, or non-patient. Please provide this information so that we know whom to bill. It is critical that we receive this information from you, and we thank you in advance for providing it. We will, of course, be relying on the information that you provide when we determine whom to bill, which is why we wanted you to have this summary of the Medicare billing rules and regulations that apply to us.