

Physician Annual Notice 2017

Dear Valued Clients,

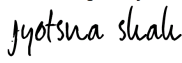
IGeneX, Inc. is providing this annual notice in accordance with the recommendations made by the Office of Inspector General (OIG) as part of our Compliance Policy. As part of our compliance efforts, we are advising our clients about program updates and information related to federally funded health care program and many responsibilities we share.

The enclosure is designed to assure that you are aware of and understand IGeneX, Inc. test panels, their Medicare reimbursement rate, and currently used CPT (Current Procedural Terminology) Codes.

Please take a few minutes to review the attached information

Thank you for choosing IGeneX, Inc. for your specialized testing. We value your business and appreciate the opportunity to provide services in conjunction with these initiatives. If there are further questions regarding this notice, please contact our Chief Financial Officer, Tom Paskert at (800) 832-3200 ext.170.

Sincerely,

DocuSigned by:

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Jyotsna Shah, Ph.D
President/ CEO
IGeneX, Inc.



IGeneX, Inc.

795 San Antonio Road | Palo Alto, CA 94303-4801 | Tel: (800) 832-3200 | Fax: (650) 424-1196

Licensed Physicians

A clinical laboratory may only bill Medicare for testing ordered by a licensed physician or other individuals authorized by law to order laboratory tests. If your license has been revoked or suspended, please notify the laboratory immediately. Effective April 7, 2014, the Center for Medicare and Medicaid Services requires all individuals referring physicians to be enrolled in Provider Enrollment, Chain and Ownership System (PECOS).

Additional information on PECOS and how to enroll in the system may be viewed at:

<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>

Medicare Medical Necessity Policy

Tests that are medically necessary for the diagnosis and/or treatment of a Medicare patient are covered and will be reimbursed. An approved panel must only be ordered when every test in such panel is medically necessary. If all components of the panel are not medically necessary, you should order individual tests or a panel that contains only the medically necessary tests. As a Medicare participating provider, IGeneX, Inc. has a responsibility to make good faith efforts to ensure that 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 individuals authorized by law to order 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.

Diagnosis Information

Section 4317 of the Balanced Budget Act of 1997 requires all physicians or authorized ordering party to submit diagnosis information on the laboratory order for submission of a Medicare claim. The diagnosis information supplied should accurately describe the patient's condition on the date of service as documented in the patient's medical record. Physicians will be contacted by IGeneX, Inc. for all test requisitions that do not include this required information, and this communication may occur via telephone call, fax, or electronic mail.

ICD-10 became effective on October 1, 2015.

<https://www.cms.gov/Medicare/Coding/ICD10/2017-ICD-10-CM-and-GEMs.html>

Medicare Clinical Laboratory Fee Schedule

IGeneX, Inc. services are paid based on a fee schedule in accordance with Section 1833(h) of the Social Security Act. Payment is lesser of the amount billed, the local fee for a geographic area, or a national limit. Co-payments and deductibles do not apply to services paid under Medicare clinical laboratory fee schedule.

The 2017 Medicare Clinical Laboratory Fee Schedule may be viewed and downloaded at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files-Items/17CLAB.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>

Medicare Laboratory Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs)

The Centers for Medicare and Medicaid Services has authorized Noridian Healthcare Solution, LLC, Northern California's Medicare Part B carrier, to develop Local Coverage Determinations (LCD) These guidelines may supplement or be in addition to the National Coverage Determinations (NCD) and give direction for medical necessity on selected tests.

COMPLIANCE POLICY: Physician Annual Notice

BS-PROC-073 REV. 002 02-09-2017



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For a complete list of LCD/NCD policies, with test name(s), CPT's and covered ICD-10 code(s), please view:

LCD: <https://www.noridianmedicare.com/partb/coverage/active.html>

NCD: <https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx?bc=BAAAAAAAAAAAAA>

Noridian Healthcare Solutions, LLC: <https://www.noridianmedicare.com/>

Advanced Beneficiary Notice of Non-coverage (ABN)

Not all laboratory services are covered by Medicare. For services that are statutorily excluded or does not meet the definition of any Medicare benefit, IGeX, Inc. may bill Medicare patients directly. For certain laboratory tests, an Advance Beneficiary Notice of Non-coverage (ABN) is used to document that the patient has been made aware that Medicare may not pay for services and has agreed to pay the laboratory in the event payment is denied. A separate ABN must be used for each encounter. IGeX, Inc. will provide ABN forms to clients at their request. Completed ABN must be attached to the test requisition form when specimens are submitted to the laboratory.

Information about ABNs may be viewed at:

<https://www.cms.gov/MEDICARE/medicare-general-information/bni/abn.html>

Billing Information

To ensure accurate processing and testing, efficient patient identification and registration, and timely reporting of test results, IGeX, Inc. requires the following information:

- ✓ Patient's full legal name
- ✓ Patient's complete address, city, state, and zip code
- ✓ Patient's gender
- ✓ Patient's date of birth
- ✓ Patient's Medicare Number
- ✓ Patient's signature
- ✓ A front and back copy of patient's current Medicare card, Primary Insurance card, and/or Medicare Advantage Plan card
- ✓ Signed and completed ABN if physician has ordered CD57
- ✓ Licensed referring physician's name, practicing location address, and National Provider Identifier (NPI) Number

Reflex Testing

Reflex testing occurs when initial test result is indeterminate and indicates that a second related test is recommended for clinical diagnosis.*IGeX, Inc. currently does not offer any reflex testing.

Clinical Consultant

IGeX, Inc. Clinical Consultant and Laboratory Director are available to discuss appropriate testing and test ordering. Please call (800) 832-3200 for assistance.