IGeneX Inc.

556 Gibraltar Drive
Milpitas, CA 95035, USA
Tel: (800) 832-3200 | Fax: (408) 935-8272

Physician Annual Notice 2022

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 rates, the appropriate use of Advance Beneficiary Notices, 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,

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

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Licensed Physicians/Submitting Valid Test Requisitions

A clinical laboratory must be 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 If your license has been revoked or suspended, please notify the laboratory immediately.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). Please be aware of your status and complete required paperwork in a timely manner to avoid being ineligible to order services for Medicare beneficiaries.

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

To ensure timely reporting of test results, test order(s) must include patient's full legal name, date of birth, gender, patient or responsible party's signature, collection date and storage of condition of specimen, source (if applicable), and eligible referring physician's name, credential, practicing location address, National Provider Identification (NPI) Number, medical necessity laboratory test(s), appropriate diagnosis code(s), and authorized signature. Each collected specimen must also be labeled with at least two unique identifiers, e.g. patient's full legal name and date of birth.

For updates to test and collection information, please refer to IGeneX's website: https://www.igenex.com Select: Resources/Forms and Policies

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.

Effective October 1, 2015, with the implementation of ICD-10, it is necessary for physicians to be more aware of sending the most appropriate and specific diagnosis code(s) that describes the patients' signs, symptoms or condition. The laboratory will not assign diagnosis codes.

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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 2022 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

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

The Centers for Medicare and Medicaid Services has authorized Noridian Healthcare Solution, LLC, and 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.

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.noridianmediciare.com/partb/coverage/active.html
NCD: https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx?bc=BAAAAAAAAAAA

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 do not meet the definition of any Medicare benefit, IGeneX, Inc. may bill

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Medicare beneficiaries 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 that are considered as medically reasonable and necessary, or exceeded frequency limits, for eligible Medicare beneficiaries. The ABN allows the beneficiary to make an informed decision about whether to get the item or service that may not be covered and accept financial responsibility of Medicare does not pay.

A separate ABN, form CMS-R-131, must be used for each encounter. IGeneX, Inc. will provide ABN(s) to clients at their request. Completed ABN must be attached to the test requisition form when specimens are submitted to the laboratory before providing certain Medicare Part B items or services.

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, IGeneX, 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 [1]Medicare Beneficiary Identifier (if applicable)
- ✓ Patient's or responsible party's signature
- ✓ A front and back copy of patient's current Medicare card, Primary Insurance card, and/or Medicare Advantage Plan card (required for Medicare beneficiary ONLY)
- ✓ Licensed referring physician's name, practicing location address, and National Provider Identifier (NPI) Number

Reflex Testing

*IGeneX, Inc. does not offer reflex test.

[1] The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) required CMS to remove SSNs from all Medicare cards. CMS replaced the SSN-based HICN with a new, randomly generated MBI. The MBI hyphens on the card are for illustration purposes: do not include the hyphens or spaces on transactions. The MBI uses number 0-9 and all uppercase letters except for S, L, O, I, B, and Z. We exclude these letters to avoid confusion when differentiation some letters and numbers (for example, between "0" and "O".
For details please refer to MBI specifications format at https://www.cms.gov/Medicare/New-Medicare-Card/Understanding-the-MBI.pdf

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Patient Privacy (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), IGeneX, Inc. is a provider and a covered entity. It is our policy to fully comply with the HIPAA privacy and security standards.

Clinical Consultant

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