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CLIENT ANNUAL COMPLIANCE LETTER
2017

Medical Necessity: Advanta Analytical Laboratories ("Advanta") requisitions are designed to emphasize physician choice. Only tests that are medically necessary for the diagnosis or treatment of the patient will be reimbursed.

The Centers for Medicare and Medicaid Services (CMS) has 23 National Coverage Determinations (NCDs) regarding clinical laboratory tests. These decisions state the medical conditions for which laboratory tests are covered, reasonable and necessary on a national level. Additionally, Medicare carriers and fiscal intermediaries have the authority to develop and implement Local Coverage Determinations (LCDs) for the local area that does not conflict with the national determinations. The CMS national policies are listed at: http://www.cms.hhs.gov/center/clinical. Medicare generally does not cover routine screening medical exams and screening tests (Exception: entry physical within first 6 months of enrollment into Medicare program). Of note, the Office of Inspector General (OIG) takes the position that a medical provider who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed, may be subject to civil, criminal or administrative penalties under the False Claims Act.

Medicare Advance Beneficiary Notice Of NonCoverage (ABNs): In an effort to remain compliant with federal billing regulations and avoid notions and perceptions of possible inducement violations and the filing of false claims to CMS, Advanta requests from its clients that a completed copy of the Medicare ABN accompany the lab requisition and specimens when the ordering entity suspects a lab tests may not be covered by Medicare. Please ensure that all lab orders are submitted with the appropriate ICD-10 diagnoses codes.

Inducements: Advanta does not offer any inducements to clients in order to secure Medicare and Medicaid billings. We do not offer any unfair advantages such as accepting and billing for lab services deemed not medically necessary by CMS. All supplies and equipment provided to customers are directly related to specimen collection, processing, and reporting of test results.

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Problem Requisitions / Specimens: Claims for reimbursement are submitted only for tests which have been both ordered and performed. If the laboratory receives a specimen without a test ordered or with unclear testing instructions, the ordering physician will be contacted and asked to provide a revised requisition to the lab (or detailed instructions). Laboratory staff may not add or change tests ordered to the unclear lab requisition.

Medicare Part B Claims: an ICD-10 codes must be included on all Medicare Part B Claims when a diagnostic test is ordered to establish medical necessity. Therefore, all requisitions must include the ICD-IO code as the reason for the test.

Required Information: Please use laboratory requisitions preprinted with your location information. The following information is required on all laboratory requisitions:

Patient's Name
Social Security Number
Birth date
Physician Name
All Insurance Information and Copies of Insurance Card/s
Payable ICD-10 Diagnosis Code(s) Indication of Test(s) to be performed Date & Time of Specimen Collection ABN - if applicable

Add-on Test Request: In an effort to ensure that "add-on" requests for clinical laboratory tests are properly documented in accordance with federal guidelines and laboratory policies, all "add-on" requests must be submitted via a faxed lab requisition to our Client Services Department Fax: (903)-839-2494

Reflex Testing: Reflex testing may be performed in the absence of a specific written order when results of initial testing indicate that a second related test is medically appropriate.

Panel Testing: All routine chemistry tests should be ordered separately except for those contained in federally defined laboratory panels. No tests are provided to customers or potential customers free-of-charge or at below cost either as a professional courtesy or in order to secure additional business. We cannot accept custom panel orders for third party insurance billing. Lab requisitions received with such requests will be delayed until clarification can be obtained from the ordering entity. Delays for testing and results may exceed 24 hours from time of receipt.

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Prohibited Referrals: It is Advanta's Clinical Laboratories' policy to comply with all aspects of the self-referral prohibitions and exceptions established by Stark I and II.

Monitoring: All laboratory testing sites are regularly monitored to safeguard against unintentional violations of federal compliance guidelines. Monitoring activities are also aimed at raising awareness of federal guidelines and assisting in developing mechanisms for successfully meeting them.

Web Sites: **Clinical Laboratory Center/ Medicare**
http://www.cms.hhs.gov/center/clinical

OIG Compliance Program Guidance for Clinical Laboratories
http://oig. hhs.gov/authori ties/docs/cpglab.pdf

The False Claims Act
http://oig.hhs.gov/'fraud/falseclaimsact.asp

The Sarbanes-Oxley Act of 2002
http:// www.soxlaw.com/

HIPAA Privacy Rule
http://www.hhs.gov/ocr/hipaa/

Anti-kickback Statute - Safe Harbor Regulations http:// www.oig.hhs.gov/fraud/safeharboiTegu1at ions.asp

Physician Self-Referral Law, Stark I, II, III
http://www.cms.hhs.gov/physicianselfreferral/

Advanced Beneficiary Notices http://www.cms.hhs.gov/BNl/

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Signature Date