

October 1, 2013

Dear St. Jude Medical Staff Member,

101 East Valencia Mesa Dr. Fullerton, California 92835-3875 714.871.3280 Tel

We would like to clarify the CMS (Centers for Medicare and Medicaid Services) policies relative to ordering and performing laboratory tests for Medicare beneficiaries. In general, Medicare covers Part B services (such as outpatient lab tests) which it considers to be 'medically necessary' to treat a disease or condition, or to diagnose a specific illness (such as influenza A). Medicare actively reviews all billings for outpatient laboratory testing, using contracted services for local medical necessity review, according to its own guidelines, and requires that each test and those in a panel of tests meet these rules of medical necessity. CMS/Medicare accepts individually ordered tests and only certain organ/disease panels which have been pre-approved and which are medically indicated. Therefore, the ordering of all tests and panels requires valid ICD-9 diagnostic codes and also requires that these codes be consistent with the documentation recorded in the patient's medical record on the date of service.

As our partner in providing healthcare to members of our communities, we are informing you of the following, as directed by the federal Office of Inspector General (OIG):

- 1. Only medically necessary tests should be ordered. In general, 'screening tests' are not reimbursed.
- 2. Medicare rules prohibit the laboratory from billing the patient for laboratory tests for which the ICD-9 code(s) indicated by the provider do not support 'medical necessity', unless an 'Advance Beneficiary Notice' (ABN) has been signed by the patient. If a patient chooses not to sign the ABN, laboratory services may be withheld, or patients may decline to be tested.
- 3. Panels, including organ and disease panels, should only be ordered when all panel components are medically necessary.
- 4. The ordering of 'custom panels' may result in ordered tests that are not covered, as they are not considered to be medically necessary, and therefore are not reimbursed by federal, state, and most private health benefit payers. We strongly discourage the requesting and use of such custom panels.
- 5. The ordering of any individual component tests in a profile will be billed to Medicare as individual tests.
- 6. The MediCal reimbursement amount for a test will be less than or equal to Medicare reimbursement.
- 7. Links to billing resources for Medicare national policy and Medicare contractor local medical review:
 - National Coverage Decisions and Medical National Coverage Determinations Manual: http://www.cms.gov/medicare-coverage-database/overview-and-quick-serarch.aspx
 - Local Medical Review policies for Southern California: http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf
- The OIG has taken the position that any individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies under civil, criminal, or administrative law.

If you have any questions concerning the above information, or if you require assistance in ordering appropriate laboratory tests, please contact the laboratory's Medical Director, Victor W. Lee, M.D., at (714) 992-3908.

Victor W. Lee, M.D., PhD

Medical Director, Laboratory Services

Administrative Director, Laboratory Services

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