Dear Client,

At Keck Medical Center our mission and ongoing commitment is to provide the highest level of patient care with timely and accurate laboratory test results. This includes educating physicians and other ordering health care providers on medical necessity and laboratory billing compliance. The Office of Inspector General (OIG) and the Centers for Medicare/Medicaid Services (CMS) have regulations and guidance pertaining to these topics. Please carefully review this summary of Medicare rules, billing guidelines and related laboratory policies and procedures.

**Medical Necessity** – Medicare will only pay for those tests which meet Medicare coverage requirements and are medically necessary for the diagnosis and treatment of the individual patient. Medicare generally does not cover routine screening tests. In addition, Organ or disease-related panels will only be paid and must only be billed when all components are medically necessary.

As the health care provider, you are responsible for ensuring documentation of medical necessity in the patient’s permanent medical record and for providing appropriate diagnostic information in the form of ICD-10 codes. The OIG takes the position that a health care provider who orders medically unnecessary tests or otherwise knowingly causes submission of a false claim for which federally funded program reimbursement is claimed may be subject to penalties available under civil, criminal and administrative law, such as the federal False Claims Act.

**Advance Beneficiary Notices (ABNs)** – ABNs are used when there is a likelihood that an ordered service will not be covered. The form is provided to beneficiaries before the service is provided, allowing them to choose to receive the service with the potential for payment liability, or to decline the service. Beneficiaries should not be asked to sign blank ABNs nor should a general notice be provided for all claims and services.

**Reflex testing** – Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate. A Keck Medical Center laboratory will perform a reflex test only when reflex testing is explicitly ordered by the physician.
Confirmatory testing – Confirmatory testing may be performed when regulatory requirements dictate or in certain analytical scenarios. This type of test is not explicitly ordered by the physician. However, when these additional tests are performed, additional fee(s) will be incurred.

Tests covered by claims for reimbursement – Only those tests that are 1) ordered by an authorized provider, 2) are performed to completion and 3) meet Medicare’s conditions of coverage are reimbursable by Medicare.

Documentation to Support Billing -- Physicians or other authorized individuals are required to document necessary program information for appropriate laboratory billing, including:

a. Patient’s full legal name  
b. Diagnosis (ICD-10)  
c. Source (when applicable)  
d. Date of birth  
e. Date and time of collection  
f. Licensed ordering provider’s name & address

Inducements – It is a criminal offense to knowingly offer, pay, solicit or accept any remuneration - meaning anything of value or compensation - to induce the referral of tests or reward those referrals that are reimbursable by Medicare, Medicaid or other federal health care programs. Accordingly, laboratories may not charge physicians a price below fair market value for non-federal health program tests that could be viewed as an inducement to capture Federal health care business.

Resources:
1. Medicare national policy and Medicare contractor local medical review policy for lab tests can be found at: CMS Medical Review and Education
2. National and Local Coverage Determinations can be found at: Noridian Medicare
3. Medicare Laboratory Fee Schedule can be found at: CMS Clinical Laboratory Fee Schedule
4. Test sample & collection requirements can be found at Keck Medicine of USC Laboratory Test Directory

Thank you for allowing us to help you deliver Beyond Exceptional Medicine at Keck Medical Center of USC. Should you have any questions, our clinical team may be reached at 323-865-3270.

Sincerely,

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