Annual Medicare Notice
Oregon Regional Laboratory Services

December 2023

To all Medical Staff,

The Office of Inspector General (OIG) requires laboratories to annually notify physicians of Medicare rules for clinical laboratory testing. Please carefully review this summary from Oregon Regional Laboratory Services (ORLS).

1. **Providence Laboratory Billing Policy:** All tests that are both ordered and performed are billed to the appropriate payer under the guidelines provided by the payer and in accordance with all federal, state, and local laws and regulations.

2. **Orders:** Our laboratory can only perform tests when properly ordered by an authorized provider. Orders must include the patient's full legal name, a second unique patient identifier (such as date of birth or medical record number), reason for the test ordered (diagnosis), date and time of collection, source when applicable, and ordering provider's name. Even though the provider's signature is not required, we **strongly encourage signing all requisitions.**

   We want to emphasize the importance of including the actual **date and time of specimen collection** for all samples collected in your office. Medicare considers the date of collection to be the date of service for billing purposes. In addition, having the time of collection helps you better interpret the results and helps ORLS monitor specimen quality.

   The test requisition training module, *Laboratory Test Requisition Education*, is available in HealthStream and Rise.

   The Test Menu is updated regularly and is designed to assist in the selection of the correct orderable. The Test Menu is linked here for reference. https://cdos.halfpenny.com/Labcorp/PRL

3. **Recurring (standing) orders** are only valid for up to one year and must include both the frequency and duration of the testing ordered. If any **new** standing order constitutes a change in occurrence or frequency of an existing standing order, the existing order will be discontinued and replaced with the more current order. As for all lab orders, the patient's full legal name, a second unique patient identifier (such as date of birth or medical record number) and reason for the test ordered (diagnosis) are required.

4. **Diagnosis Codes:** The ordering practitioner is required to provide the indication for testing. An ICD-10 code best describes the patient's condition and documents the reason for ordering the test. An **ICD-10-CM code provides the highest degree of accuracy and specificity**. If a diagnosis requires further specification, to properly translate, every effort will be made to obtain clarification from the requesting provider or their representative.

5. **Notice of Medicare's National Medical Necessity Policy**: Medicare will only pay for tests that meet the Medicare definition of "medical necessity." Therefore, payment for a test that the physician believes is appropriate (such as a screening test) may be denied because it does not meet the Medicare definition of medical necessity.

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6. **CMS guide for Preventative and Screening Services:** Medicare does not cover preventive or screening services except for certain exceptions. Please refer to the *Preventative and Screening Guideline* for guidance on test orders such as PSA, Fecal Occult Blood, Diabetes screening, Cardiovascular Disease, HIV and Sexually Transmitted infection screening.

7. **National Coverage Determination (NCDs) & Local Coverage Determination (LCDs):** The NCDs and LCDs limit coverage for particular laboratory tests to specific medical diagnoses, which must be reflected in the patient's medical record. Orders for Lab tests must include the medical need for the test. ICD-10 codes guarantee correct interpretation of your patient records. Some tests are also subject to frequency restrictions. CMS provides these limitations of coverage and requires that when a provider believes Medicare may not pay, an Advance Beneficiary Notice (ABN) must be delivered to the Patient, prior to providing the service. ABN delivery is a Condition of Participation for all Medicare participating providers. The LCD policies are available on-line here. The Medicare Laboratory National Coverage Determinations (NCD) are available here.

8. **Advance Beneficiary Notice of Non-coverage (ABN):** When the ICD-10 code you provide with a NCD or LCD test does not meet medical necessity requirements, Medicare patients must be advised in advance. Use the CMS approved ABN form to document your discussion. This gives you the opportunity to review the need for the test with the patient, notifies them that they may be responsible for the charges, and provides the patient with the options for having their test(s) performed. After this discussion, have your patient choose an option, sign, and date the form.

9. **Panel Tests:** Organ or disease related panels are charged and reimbursed only when all components are medically necessary and reasonable to treat or diagnose an individual patient. The diagnostic information in the form of an **ICD-10-CM code provides the highest degree of accuracy and specificity.** All components of panels are available for individual order. ORLS may not recognize custom panel orders designed by other laboratories.

10. **Supplies:** ORLS will provide supplies required for the collection of specimens that are to be sent to our laboratory. Anti-Kickback statutes govern these practices, and our laboratory monitors the volume of supplies provided to your offices. Supply volumes must reasonably match the volumes of testing received.

11. **Medicare Laboratory Fee Schedule:** Medicare has published the reimbursement fee schedule for 2021 on the CMS site, click here. Fee schedules for previous years are also located at this site. The Medicaid reimbursement amount will be equal to or less than the amount of Medicare reimbursement.

12. **Reflex Testing:** Some laboratory tests will trigger additional automatic orders and appropriate charges based on laboratory policy approved by the medical staff. Examples include:

    - The presence of pathological organisms on cultures will reflex to include appropriate organism identification and susceptibility testing.
    - Lower respiratory, deep wound, body fluid and CSF cultures include Gram Stains.

13. **Clinical Consultant:** Clinical Laboratory Improvement Amendments ("CLIA") requires laboratories to provide a designated clinical consultant responsible for providing consultation regarding appropriateness of the testing ordered and interpretation of results. The ORLS laboratory clinical consultant is Douglas Blackall, MD, MPH.

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We value your business and appreciate your time and effort to review these Medicare requirements. We trust that this annual notification will assist in informing you of the policies that govern medical diagnostic laboratory services. If you have questions regarding this notification, please contact the ORLS quality and compliance department.

Sincerely,

Providence Oregon Laboratory Services

ORLS Quality and Compliance
Providence Office Park | Portland, Oregon

URL addresses for links above:
LCD's: Local Coverage Decisions

https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Washington&bc=gAAAAAAAAAA&=&

NCD's: National Coverage Decisions

http://www.cms.gov/medicare-coverage-database/indexes/lab-ncd-index.aspx?bc=AgAAAAAAAAAA&

ABN form (CMS-131) download:

https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-131.html

CMS Pub 100-04 (letter sections 8, 9 and 10): http://www.cms.hhs.gov/manuals/downloads/clm104c18.pdf

Laboratory Fee Schedule:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html