REMINDER: Medical necessity is the driving force for the payment of any Medicare service. If a service is not medically necessary, it cannot be paid by Medicare.

Prior to Ordering ANY Lab Services:

- Document your diagnosis (why the patient needs the test ordered), not just the ICD-10 code. The reason must be documented CLEARLY in the medical records.
- Document and sign in the medical record comments that supports the physician/practitioner’s intent to order tests (e.g. “order Lab”, “check blood”, “repeat urine”).
- Medicare coverage extends to tests ordered by a licensed provider (for example-MD, DO, NP). The physician or other eligible professional who is treating the beneficiary MUST order all diagnostic laboratory tests. Tests, not ordered by the physician or eligible professional, are not considered reasonable and necessary.
- All diagnostic laboratory tests must be ordered for the treatment of the individual patient.

Requisitioning/Placing Order:

- Use either the lab portal of the respective lab or use one of the processes listed below.
- A written document signed by the treating physician/eligible professionals, which is hand-delivered, mailed, or faxed to the testing facility; Although no signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services, documentation in the medical record must show intent to order and medical necessity for the testing.
- A telephone call by the treating physician/eligible professional or his/her office to the testing facility; If the order is communicated via telephone, both the treating physician/eligible professional or his/her office and the testing facility must document the telephone call in their respective copies of the beneficiary’s medical records.
- Electronic mail can be sent to the testing facility by the treating physician/eligible professional or his/her office.

Routine Orders:

Routine orders are for services and treatments that apply to patients with the same or similar medical condition(s). These frequently called “routine, protocol or standing orders” are based on an assessment of a given condition in patients with medical illness or injury.

- Medicare defines any order(s) that does not specifically address an individual patient’s unique illness, injury or medical status, as not reasonable and necessary.
- As required by law, Medicare does not accept such “standing orders” as supporting medical necessity for the individual patient.
- Services related to population-based or condition-based orders are not reimbursable.
Treatment Protocols:
Treatment protocols may be reimbursable since these protocols are individualized to each patient.

- For example, the use of chemotherapeutic drug protocols that suggest drugs, dosage ranges, frequency and/or duration specifically ordered for an individual patient.

Recurring Orders:
Reimbursement of tests or services provided under a standing order for a recurring or serial evaluation is subject to medical necessity review.

- All such orders must be written for a specific patient, and each instance of the test or service must be necessary.
- Each result must be reviewed with appropriate action taken by the treating physician, including any appropriate change in the frequency or duration of testing.

Laboratory Orders:
Preprinted orders are not covered by Medicare. However, preprinted or electronic lists of potential orders are permitted if the provider individually affirms, defines, or otherwise modifies each component as appropriate for an individual patient's clinical circumstances.

Standing orders for recurring diagnostic tests may be appropriate when all of the following conditions are met:

- Each ordered test must be appropriate and necessary for the treatment of the individual patient on a specific date of service.
- The frequency and number of repeated testing must not be greater than medically necessary.
- The diagnosis must be indicated for each test with sufficient clarity to permit accurate ICD-10-CM coding to the highest level of specificity.
- The treating physician must review each test result, making any indicated adjustments in frequency and number of repeated studies.
- All lab tests must be reviewed and documentation must support that the appropriate clinical action was taken.

Signature Requirements for Orders:
If the signature is missing from an order, ACs, MACs, PSCs, ZPICs and CERT shall disregard the order during the review of the claim.

There are some circumstances for which an order does not need to be signed. For example, orders for clinical diagnostic tests are not required to be signed. The rules in 42 CFR 410 and the Medicare Benefit Policy Manual, chapter 15, section 80.6.1, state that if the order for the clinical diagnostic test is unsigned, there must be medical documentation by the treating physician (e.g., a progress note) that he/she intended the clinical diagnostic test be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature.
References:

- 42CFR482.24(c)(1): Condition of Participation: Medical Record Services - All patient (https://www.law.cornell.edu/definitions/index.php?width=840&height=800&iframe=true&def_id=a7b754745b3208b7071ab7fb0db5c5cf&term_occur=4&term_src=Title:42:Chapter:IV:Subchapter:G:Part:482:Subpart:C:482.24) medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital (https://www.law.cornell.edu/definitions/index.php?width=840&height=800&iframe=true&def_id=a305beb7cd53a9674c95afe2cde0b03a1&term_occur=10&term_src=Title:42:Chapter:IV:Subchapter:G:Part:482:Subpart:C:482.24) policies and procedures: https://www.law.cornell.edu/cfr/text/42/482.24

- CMS Publication 100-08 Program Integrity Manual; Chapter 3 Verifying Potential Errors & Taking Corrective Action; sec 3.3.2.4 Signature Requirements: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf


This Fact Sheet is for informational purposes only and is not intended to guarantee payment for services, all services submitted to Medicare must meet Medical Necessity guidelines. The definition of “medically necessary” for Medicare purposes can be found in Section 1862(a)(1)(A) of the Social Security Act – Medical Necessity (http://www.ssa.gov/OP_Home/ssact/title18/1862.htm).

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