Medically Necessary Laboratory Testing

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Description

All delegated lab service procedure codes are subject to this guideline. Refer to the specific Health Plan's procedure code list for management requirements.

Background

Laboratory testing represents approximately 4% of healthcare expenditures.[1] While a relatively small contributor to overall healthcare expense, laboratory testing is a high volume service commonly performed during healthcare encounters with a critical role in informing downstream medical decisions.[2,3] Therefore, inappropriate over- or under-utilization of laboratory tests presumably also influences the medical costs associated with those medical services informed by test results.[1]

Laboratory tests are imperfect due to the overlap between disease and health as well as the fact that laboratory errors can occur in any phase of the laboratory process from specimen collection through specimen reporting and interpretation.[4] Even under ideal testing conditions, approximately 5% of healthy patients will have results outside of the reference range simply due to the method used to calculate most reference ranges for laboratory tests. Most reference ranges represent the central 95% of the results (e.g. the mean +/- two standard deviations) for a population of reasonably healthy individuals.[5] The individuals used for a reference range calculation are often people who are accepted as blood donors. When a result occurs outside the reference range in a healthy individual, that result is a setup for an erroneous interpretation, such as a false positive, which can lead to a false diagnosis. False diagnoses can lead to low value healthcare in the form of unnecessary interventions that can be dangerous and expensive.

Excessive testing

Testing that is unfocused, not indicated for routine prevention, and not specific to a patient's symptoms has an increased likelihood of false positives. As the number of tests ordered increases, so does the likelihood that at least one result will fall outside the reference range in a healthy individual. Therefore, large wellness panels in asymptomatic individuals or individuals with nonspecific signs and symptoms

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associated with daily life will nearly always lead to false positive tests and a potentially expensive medical diagnostic odyssey.

Appropriate test use

Laboratory tests are routinely used to screen for common disease, diagnose disorders in patients with signs or symptoms, inform effective treatment plans, and monitor therapies. Thus, correct test choice and interpretation is critical.

For individuals with suspected or diagnosed disease, appropriate laboratory testing may be defined in guidelines issued by the professional societies that guide care for those individuals. However, a substantial number of tests and indications will not be addressed in clear evidence-based guidelines, therefore requiring ongoing evaluation of the primary literature.

Laboratory testing is considered medically necessary when proven to be clinically useful for routine preventive screening or to diagnose, treat, monitor, or otherwise manage significant illness, infirmity, disability, or suffering.

Guidelines and Evidence

This section includes relevant guidelines and evidence pertaining to medically necessary laboratory testing.

U.S Preventive Task Force (USPSTF)

The U.S. Preventive Services Task Force, with the support of the Agency for Healthcare Research and Quality, develops evidence-based preventive service recommendations, including laboratory screening tests, that are generally accepted as the standard of care in screening otherwise healthy individuals. USPSTF describes its scope as follows:[6]

- “The recommendations apply only to people who have no signs or symptoms of the specific disease or condition under evaluation, and the recommendations address only services offered in the primary care setting or services referred by a primary care clinician.”

Note: This benefit/harm statement only applies to those jurisdictions that do not have Medicare guidance. Based upon the guidelines and evidence provided in the clinical policy, following EviCore's criteria for medically necessary laboratory testing will ensure that testing will be available to those members most likely to benefit from the information provided by the assays. For those not meeting criteria, it ensures alternate diagnostic/ management strategies are considered. However, it is possible that some members who would benefit from the testing, but do not meet clinical criteria, will not receive an immediate approval for testing.

Criteria

Introduction

Requests for medically necessary laboratory testing are reviewed using these criteria.

Criteria: General Coverage Guidance

In order for a test to be considered medically necessary, the following criteria must be met:

- Be a preventive service as defined by the U.S. Preventive Services Task Force, Centers for Disease Control and Prevention, or other widely recognized preventive service guideline authors, OR
- Be necessary for the member's indication based on strong evidence-based professional society practice guidelines, OR
- Meet ALL of the following criteria:
  - Clinical signs, symptoms, treatment or monitoring needs are consistent with the test being performed, and
  - Technical and clinical validity: The test must be accurate, precise, sensitive and specific, based on sufficient, quality scientific evidence to support the claims of the test, and
  - Clinical utility: Healthcare providers can use the test results to provide significantly better medical care for the individual, and
  - Reasonable use: The test is cost-effective when compared with equally acceptable alternatives and its usefulness is not significantly offset by negative factors, AND
- Testing must be ordered by a qualified healthcare provider who is actively managing the member's medical care, AND
- Rendering laboratory is a qualified provider of service per the Health Plan policy.

Other considerations

- Tests should not be duplicative or overlap in clinical intent with other performed services.
- Tests should not be repeated more often than is recommended and necessary.
- Direct-to-consumer lab testing is not eligible for reimbursement. This includes laboratory services supported by physicians serving in the role of ordering provider without having an active role in managing the member's healthcare.
- Expanded health and wellness panels that exceed routine preventive care services are not eligible for reimbursement.

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References

Introduction

These references are cited in this guideline.

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