

CLIA NON-WAIVED TESTS IN OFFICE (POS 11)

Scope

This policy applies to:

- | | | |
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| <input checked="" type="checkbox"/> Kaiser Permanente Health Plan of Washington | <input checked="" type="checkbox"/> Kaiser Permanente Health Plan of Washington Options, Inc. | |
| <input checked="" type="checkbox"/> Commercial | <input checked="" type="checkbox"/> Medicare | <input type="checkbox"/> Medicaid |

Policy

Original Effective Date: 07/01/2023

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) will deny CLIA non-waived tests when billed with Place of Service office (11).

Billing/Coding Guidelines

[CLIA Waived tests and CPT Codes](#)

Policy Definitions

Clinical Laboratory Improvement Amendments (CLIA) – The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 260,000 laboratory entities. The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA Program.

The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

QW Modifier – This modifier is used to identify waived tests and must be submitted in the first modifier field. CLIA waived tests requiring the QW modifier are considered simplified analysis tests.

CLIA waived tests – By the CLIA law, waived tests are those tests that are determined by CDC or FDA to be so simple that there is little risk of error. Some testing methods for glucose and cholesterol are waived along with pregnancy tests, fecal occult blood tests, some urine tests, etc.

CLIA non-waived tests – Non-waived testing refers to moderate and high complexity testing. Laboratories or sites that perform these tests need to have a CLIA certificate, be inspected, and must meet the CLIA quality standards described in 42 CFR Subparts H, J, K and M.

Prerequisite(s)

Not applicable

References

[Clinical Laboratory Improvement Amendments \(CLIA\)](#) – US Department of Health & Human Services

[Medical Test Site Licensing Applications](#) – Washington State Department of Health

Frequently Asked Questions

Not applicable

Revision History

07/18/2022 – New payment policy

Note: This information is intended to serve only as a general reference resource regarding reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, we may use reasonable discretion in interpreting and applying this policy to services being delivered in a particular case. Further, the policy does not cover all issues related to reimbursement for services rendered to our enrollees as legislative mandates, the provider contracts, the enrollee's benefit coverage documents, and the Provider Manual all may supplement or in some cases supersede this policy. This policy may be modified from time to time by publishing a new version of the policy on Kaiser Permanente provider website; however, the information presented in this policy is believed to be accurate and current as of the date of publication.