Guide to CLIA waived lab services and modifier QW

Scope

- This policy applies to all providers, non-physician providers and subcontractors who submit CLIA waived laboratory codes.

Background

- Clinical Laboratory Improvement Amendments (CLIA) waived tests include tests cleared by the Food and Drug Administration (FDA) for home use, and those tests approved for waiver under the CLIA criteria. The maintenance of waived tests is identified by the Center for Medicare and Medicaid Services (CMS) by the addition of "Modifier QW".
- When a provider submits a claim with one of the CLIA approved tests, when the place of service is office (11), and the QW is not appended, the charge should not be allowed.

Purpose

- This policy is designed to establish proper use of the QW modifier with approved CLIA waived laboratory tests.

Definitions

- CLIA: Clinical Laboratory Improvement Amendments of 1988.
- Modifier QW: Defined as a Clinical Laboratory Improvement Amendment (CLIA) waived test.

Policy

- CareOregon has established a policy to deny CLIA waived procedures when they are submitted without Modifier QW in the first position on the claim line and the place of service is Office (11).
- CLIA waived tests requiring Modifier QW are considered simplified analysis tests. The QW modifier is used to identify waived tests and must be submitted in the first modifier field.
- CLIA requires all laboratory testing sites to have a current certification to legally perform clinical laboratory testing. All clinical diagnostic laboratories must include their CLIA numbers on all claims.
- The CLIA number is not required on the ASC X12 institutional claim data set or its related paper form CMS-1450.
  NOTE: A CLIA waived test still requires you to include your CLIA number on the claim.

Appropriate use:

- Any test on the CMS CLIA waived test list that has a QW beside the procedure code is appropriate. For example: 80047QW

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Inappropriate use:

- Any code that is not on the CLIA waived test list
- Any test on the CMS CLIA waived test list that does not have a QW beside the procedure code

Regulations

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (Pub. L. 100-578) (CLIA'88), codified at 42 U.S.C. 263a, to ensure the accuracy and reliability of testing in all laboratories, including but not limited to those that participate in Medicare and Medicaid, that test human specimens for purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of health of human beings.

Related

CPT CODE(S)
cdc.gov/clia/docs/tests-granted-waived-status-under-clia.pdf

Waived Tests | CDC
cdc.gov/labquality/waived-tests.html

Categorization of Tests | CMS
cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests

HCPCS Codes & Clinical Laboratory Improvement Amendments Edits: April 2023 | CMS
cms.gov/files/document/mm13024-hcpcs-codes-clinical-laboratory-improvement-amendments-edits-april-2023.pdf

These guidelines have been developed to accompany and complement the official conventions and instructions provided within the American Medical Association's Current Procedural Terminology (CPT) itself. Additions and deletions conform it to the most recent publications of CPT and HCPCS Level II and to changes in CareOregon and its affiliates coverage policy and payment status, and as such these guidelines are current as of 01/01/2023. Every reasonable effort has been taken to ensure that the educational information provided is accurate and useful. CareOregon and its affiliates make no claim, promise or guarantee of any kind about the accuracy, completeness or adequacy of the content for a specific claim, situation or provider office application, and expressly disclaim liability for errors and omissions in such content. As CPT codes change annually, you should reference the current version of published coding guidelines and/or recommendations from nationally recognized coding organizations for the most detailed and up-to-date information.

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