Clover

Clover Health Clinical Laboratory Improvement Amendments (CLIA) Policy

Policy # RP-025

Policy Title	Clinical Laboratory Improvement Amendments (CLIA) Policy
Policy Department	Payment Strategy and Operations
Effective Date	1/1/2022
Revision Date(s)	3/1/2022
Next Review Date	

Disclaimer:

Clover Health applies CMS criteria and guidelines, National Coverage Determinations (NCD), Local Coverage Determinations (LCD), Clover Policies, and MCG for determining medical necessity. Clover Policies are intended to provide a standard guideline but are not used to preempt providers' judgment in rendering services. Providers are expected to provide care based on best practices and use their medical judgment for appropriate care.

Description:

This policy outlines Clover's adherence to Clinical Laboratory Improvement Amendments (CLIA) reimbursement guidelines according to Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Centers for Medicare & Medicaid Services (CMS) regulations. Clover applies CLIA reimbursement rules to both contracted and non-contracted providers for all Medicare Advantage products.

Definitions:

- Clinical Laboratory Improvement Amendments (CLIA)
  - Clinical Laboratory Improvement Amendments (CLIA) Programs establish regulatory guidelines to strengthen federal oversight of clinical laboratories for testing human specimens. This ensures labs provide accurate, reliable, and timely patient test results regardless of the testing location.
- Laboratory
  - The CLIA regulations define a laboratory to be "a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived

from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body"

Policy:

Clinical Laboratory Improvement Amendments (CLIA) Programs establish regulatory guidelines to strengthen federal oversight of clinical laboratories for testing human specimens. This ensures labs provide accurate, reliable, and timely patient test results regardless of the testing location. Using the CLIA guidelines, CMS oversees all lab testing on humans in the U.S. with the exception of some research.

Clover requires all lab services reported on a CMS-1500 claim form or its electronic equivalent include a valid CLIA Certificate Identification for reimbursement of clinical laboratory services.

Providers should submit the QW modifier (CLIA waived test) in the first modifier position for any test on the CMS CLIA waived test list that has a QW beside the procedure code. Do not submit the QW modifier for codes that are not included in the CLIA waived test list or those codes on the CMS CLIA waived test list that do not have QW along with the procedure code.

Claim Codes (if applicable)	• QW Modifier ○ CLIA waived test • CMS CLIA waived test list

References
MLN006270
Clinical Laboratory Amendments (CLIA) Website
Categorization of CLIA Tests

CMS Manual System, Transmittal 11188