Payment Policy: Clinical Labatory Improvement Amendments (CLIA)

Reference Number: CC.PP.022
Product Types: ALL
Effective Date: 01/01/2013
Last Review Date: 02/27/2018

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy Overview

In an effort to ensure quality lab testing and reporting, Congress passed the Clinical Laboratory Improvement Amendments (CLIA). CLIA was established in 1988 and mandates that all laboratories, (including physician's office laboratories), which perform non-research testing on human specimens, provide accurate laboratory procedures that will assess, diagnose, prevent or treat diseases and impairments.

Under the CLIA program, laboratories must obtain certification to perform certain laboratory tests to receive Medicare or Medicaid payments.

CLIA is administered by the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). CMS has responsibilities which include enforcement of regulatory compliance, publishing CLIA rules, and issuing certificates and inspections. The CDC's responsibilities include conducting laboratory quality improvement studies, development and distribution of educational materials and development of technical standards and laboratory practice guidelines. The FDA's responsibilities include categorization of tests based on complexity and reviewing applications for CLIA waiver requests.

CMS issues five types of laboratory certifications 1) certificate of waiver, 2) certificate of PPMP, 3) certificate of registration, 4) certificate of compliance; and 5) certificate of accreditation.

1. ***Certificate of Waiver*** (COW) applies to tests that are simple in nature, and have a reduced risk of error when done appropriately. Examples include pregnancy tests, fecal occult blood tests and some urine tests
2. ***Certificate of Provider-Performed Microscopy Procedures*** (PPMP) represents a laboratory where a physician, mid-level practitioner or dentists perform only specific microscopy procedures and waived tests.
3. ***Certificate of Registration (COR)*** is a temporary certification granted to a COC or COA lab while the lab completes the certification process. This temporary certification expires after two years. This applies to labs performing moderate and high complexity tests.
4. ***Certificate of Compliance***. This is granted after the lab has gone through an on-site survey and findings indicate the lab is compliant with all CLIA requirements. This applies to labs performing moderate and high complexity tests. They must be surveyed every two years.

5. ***Certificate of Accreditation*** applies to laboratories that perform moderate and high complexity tests, which meet the standards of a non-profit accreditation organization approved by CMS.

Application
This policy applies to all laboratory testing sites that evaluate human specimens for testing including physician's office laboratories.

Reimbursement
The health plan's claims adjudication system will edit provider claims to determine if the CLIA number identified by the laboratory is certified to perform the test (described by the HCPCS code) billed. The CLIA number is 10 digits. Certain positions within the 10-digit numbered system contain information such as 1) the state code which represents the lab's physical location; and 2) the CLIA system assigned number that identifies the laboratory. This number is unique and no other laboratory shares the same information.

Utilization
Validation of CLIA Certification includes the following:

1. Check to determine if the CLIA number is valid (formatting and etc.)
2. If CLIA valid, then validate Type of Certificate (TOC) for provider
3. Confirm that the date of service on the claim falls within the TOC begin and end dates
4. **If the CLIA number is invalid, only the service lines with HCPCS codes that apply to CLIA will be denied. All other services lines with non-CLIA HCPCS codes will process normally**.
5. If yes, validate the TOC against the procedure code(s) billed to ensure the provider can receive reimbursement for the labs billed. If not, services are denied

Independent Pathologists
This policy does not apply to independent pathologists rendering the professional component of a laboratory service. A pathologist who reviews the diagnostic test performed and interprets the results to formulate a clinical opinion, is rendering the professional component. Independent pathologists are not required to obtain CLIA certification; but the laboratory testing site must be CLIA certified.

Pathologists should append the modifier -26 to the laboratory procedure code when rendering the professional component. If the procedure code billed already describes only the professional component of the service; it is not necessary that the pathologist report modifier -26.

CMS publishes the list of HCPCS codes and updates them annually. CMS provides the following:

1. New HCPCS codes (non-waived, non-provider-performed procedures), including any modifiers subject to CLIA edits.
2. New HCPCS codes in the 80000 series that are excluded from CLIA edits. A CLIA certificate is not required for these codes.

Providers Billing CLIA Services to the Health Plan must have a valid CLIA number according to the certificate granted the following documentation requirements are met.

Documentation Requirements

Paper Claims

1. A valid and appropriate CLIA number must be included in Box 23 of the CMS-1500 form.

EDI claims,

1. If a single claim is submitted for those laboratory services for which CLIA certification or waiver is required, report the CLIA certification or waiver number in: X12N 837 (HIPAA version) loop 2300, REF02. REF01 = X4.
2. If a claim is submitted with both laboratory services for which CLIA certification or waiver is required and non-CLIA covered laboratory test, in the 2400 loop for the appropriate line report the CLIA certification or waiver number in: X12N 837. (HIPAA version) loop 2400, REF02. REF01 = X4.

References

1. *Current Procedural Terminology (CPT®)*, 2017
2. *HCPCS Level II*, 2017
3. *International Classification of Diseases*, Ninth Revision, Clinical Modification (ICD-9-CM), 2017
4. *ICD-10-CM Official Draft Code Set*, 2017
5. Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services.

Revision History	
09/01/2016	Updated
02/28/2018	Converted to revised template conducted review

Important Reminder

For the purposes of this payment policy, "Health Plan" means a health plan that has adopted this payment policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any other of such health plan's affiliates, as applicable.

The purpose of this payment policy is to provide a guide to payment, which is a component of the guidelines used to assist in making coverage and payment determinations and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage and payment determinations and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable plan-level administrative policies and procedures.

This payment policy is effective as of the date determined by Health Plan. The date of posting may not be the effective date of this payment policy. This payment policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this payment policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. Health Plan retains the right to change, amend or withdraw this payment policy, and additional payment policies may be developed and adopted as needed, at any time.

This payment policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This payment policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this policy are independent contractors who exercise independent judgment and over whom Health Plan has no control or right of control. Providers are not agents or employees of Health Plan.

 Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this payment policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this payment policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and

LCDs should be reviewed prior to applying the criteria set forth in this payment policy. Refer to the CMS website at http://www.cms.gov for additional information.