Payment Policy: CLIA Editing

Reference Number: LA.PP.501
Product Types: ALL
Effective Date: 08/2019
Date of Last Revision~~ew Date~~: ~~08/2020~~ 02/23 Revision Log

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

Policy Overview
The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory services and testing performed on humans in the U.S to ensure quality laboratory testing. All entities that perform lab test must meet federal requirements, including waived tests must be registered and assigned a CLIA certification number. Entities can register with CLIA program by completing the *Clinical Laboratory Improvement Amendments of 1988 Application for Certification Form (CMS-116)* found (here).

The purpose of this policy is to outline Louisiana Healthcare Connections process for CLIA certification validation. This policy applies to all professional services and independent laboratory providers on claims submitted for laboratory services, including CLIA waived tests.

Code Editing Overview
Effective for dates of service on or after Aug. 1, 2019, Medicaid will require all professional service and independent laboratory providers to include a valid CLIA number on all claims submitted for laboratory services, including CLIA waived tests. Claims submitted with an absent, incorrect or invalid CLIA number will deny. CLIA number is not required for UB-04 claims.

LHCC system reads directly from the CMS Provider of Service (POS) CLIA file to validate CLIA information. CMS updates this file every three months. To ensure your claims process correctly, LHCC will apply CLIA claim edits to all claims for laboratory services that require a CLIA certification.

While code editing software is a useful tool to ensure provider compliance with correct coding, to ensure your claims process correctly and the POS files are current, we strongly advise that provider's proactivity submit an updated CLIA certificate three months prior to the CLIA certification expiration date.

CLIA Claim Submission Requirements
The CLIA number will be required in box/field 23 of the hardcopy CMS-1500 claim form or in the 2300 loop of an electronically billed claim form. The number must include the "X4" qualifier, followed by the CLIA certification number, which includes the two-digit state code, followed by the letter "D" and the unique CLIA number assigned to the provider.

Example of valid CLIA number formatting: X419DXXXXXXX

- Example of unacceptable format: CLIA19DXXXXXXX, CLIA:19DXXXXXXX – do not add the letters CLIA to the ten character CLIA number.
- The laboratory services rendered should be appropriate for the certificate level of the CLIA number indicated on the claim.
- The CLIA number must be active on the most recent CMS POS file on the date the services were rendered.
    - If the *CLIA* number is not active on the most recent CMS POS file, then the claim will deny.
        - LHCC strongly encourages providers to update *CLIA* certification expiration information at least three months prior to the *CLIA* certificate expiration date.
        - LHCC uses the most recent CMS POS file to confirm *CLIA* validity and *CLIA* levels. If your *CLIA* certificate is renewed after the posting of the CMS POS file, then claims will deny until the *CLIA* certificate is listed as active on the next CMS Provider of Services file.
- CLIA Waiver certificates and provider-performed microscopy certificates require providers to bill a QW modifier for specific laboratory services.
- A Categorization of CLIA Tests can be found (here).

Related Documents or Resources

1. Louisiana Department of Health, Informational Bulletin 19-8, Revised January 3, 2020. Available (here)

   https://ldh.la.gov/assets/docs/BayouHealth/Informational_Bulletins/2019/IB19-8/IB19-8_revised_1.3.20.pdf

2. Louisiana Department of Health, Health Plan Advisory 19-9, Revised January 3, 2020. Available (here)

   https://ldh.la.gov/assets/docs/BayouHealth/HealthPlanAdvisories/2019/HPA19-9/HPA19-9_revised_1.3.20.pdf

References

1. *Centers for Medicare & Medicaid Services, ~~2019~~2021*

Revision History	Revision Date	Approval Date
~~08/15/2020~~Converted corporate to local policy	~~Converted corporate to local policy~~08/15/2020	
Annual review; reference updated, no change. Reformatted revision log~~02/2023~~	~~Annual review; reference updated, no change~~02/2023	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions 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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical 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 clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical 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/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees 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/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

~~**POLICY AND PROCEDURE APPROVAL**~~

~~The electronic approval retained in RSA Archer, Centene's P&P management software, is considered equivalent to an actual signature on paper.~~

~~Senior Director of Network Accounts: _____Electronic Signature on File_~~