REIMBURSEMENT POLICY
CMS-1500

Clinical Laboratory Improvement Amendments (CLIA) ID Requirement Policy

<table>
<thead>
<tr>
<th>Policy Number</th>
<th>Annual Approval Date</th>
<th>Approved By</th>
<th>Reimbursement Policy Oversight Committee</th>
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<tr>
<td>2017R6000A</td>
<td>7/12/2017</td>
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IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Community Plan reimbursement policies uses Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS) or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms. Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general reference resource regarding UnitedHealthcare Community Plan's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare Community Plan may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare Community Plan enrollees.

Other factors affecting reimbursement supplement, modify or, in some cases, supersede this policy. These factors include, but are not limited to: federal &/or state regulatory requirements, the physician or other provider contracts, the enrollee's benefit coverage documents, and/or other reimbursement, medical or drug policies.

Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare Community Plan due to programming or other constraints; however, UnitedHealthcare Community Plan strives to minimize these variations.

UnitedHealthcare Community Plan may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

(CPT® is a registered trademark of the American Medical Association)

Application

This reimbursement policy applies to UnitedHealthcare Community Plan Medicaid product. This reimbursement policy applies to services reported using the 1500 Health Insurance Claim Form (a/k/a CMS-1500) or its electronic equivalent or its successor form. This policy applies to all products and all network and non-network physicians and other qualified health care professionals, including, but not limited to, non-network authorized and percent of charge contract physicians and other qualified health care professionals.

Payment Policies for Medicare & Retirement, UnitedHealthcare Community Plan Medicare and Employer & Individual please use this link.
Medicare & Retirement and UnitedHealthcare Community Plan Medicare Policies are listed under Medicare Advantage Reimbursement Policies.
Employer & Individual are listed under Reimbursement Policies-Commercial.

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## Policy

### Overview

This policy describes the information that is required on certain claims that are reported for laboratory services under the Clinical Laboratory Improvement Amendment (CLIA) 1988 statute and regulations.

All services described in this policy may be subject to additional UnitedHealthcare Community Plan reimbursement policies including, but not limited to, the Rebundling Policy, the Laboratory Services Policy, and the Professional/Technical Component Policy.

### Reimbursement Guidelines

#### Background

CLIA was established to strengthen federal oversight of clinical laboratories to ensure the accuracy and reliability of patient test results. CLIA applies to all laboratories that examine “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.” This applies if even one test is to be performed. CLIA regulatory requirements vary according to the kind of test(s) each laboratory conducts. All entities that meet the definition of a “Laboratory” under the CLIA statutes and regulations must obtain an appropriate CLIA certificate prior to conducting patient testing.

#### Purpose

For purposes of this policy, a valid CLIA Certificate Identification number will be required for reimbursement of clinical laboratory services reported on a1500 Health Insurance Claim Form (a/k/a CMS-1500) or its electronic equivalent.

#### Claims Submission Process

Laboratory service providers should use the following guidelines to submit their CLIA Identification number and servicing provider location elements on claims for UnitedHealthcare Community Plan.
members.

<table>
<thead>
<tr>
<th>Claim Format and Elements</th>
<th>CLIA Number Location Options</th>
<th>Ordering Provider Name and NPI Number Location Options</th>
<th>Servicing Laboratory Physical Location</th>
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<tbody>
<tr>
<td>CMS-1500 (formerly HCFA 1500)</td>
<td>Must be represented in field 23</td>
<td>Submit the ordering provider name and NPI number in fields 17 and 17b, respectively.</td>
<td>Submit the servicing provider name, full physical address and NPI number in fields 32 and 32A, respectively if the address if not equal to the billing provider address. The servicing provider address must match the address associated with the CLIA ID entered in field 23.</td>
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<tr>
<td>HIPAA 5010 837 Professional</td>
<td>Must be represented in the 2300 loop, REF02 element</td>
<td>Submit the ordering provider name and NPI number in the 2310A loop, NM1 segment.</td>
<td>Physical address of servicing provider must be represented in the 2310C loop, if not equal to the billing provider address and must match the address associated with the CLIA ID submitted in the 2300 loop, REF02.</td>
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<tr>
<td>HIPAA 5010 837 Institutional</td>
<td>Not applicable for institutional claims</td>
<td>Submit the ordering provider name and NPI number in 2310A loop, NM1 segment.</td>
<td>Not applicable for institutional claims</td>
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This information within this policy describes specific requirements intended to supplement, not replace, all requirements in the ANSI X12N implementation guides.

Additional information regarding CLIA, applying for or renewing a certificate, or regarding assigned test complexity levels can be found at the following website.

Clinical Laboratory Amendments (CLIA) Website

Modifier QW

Inclusion of this modifier when any applicable laboratory service is reported on a CMS 1500 claim form will be necessary to evaluate the claim to determine eligibility for benefit coverage of the laboratory services performed based upon the CLIA certification. Additional information regarding the categorization of laboratory tests by CLIA may be found at the website below.

CLIA Categorization of Laboratory Tests

Summary

Any claim that does not contain the CLIA ID, invalid ID, and/or the complete servicing provider demographic information will be considered incomplete and may be rejected or denied. Claim line edits may also be applied if the lab certification level does not support the billed service code. Laboratory service providers who do not meet the reporting requirements and/or do not have the appropriate level of CLIA certification for the services reported may not be reimbursed.
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 251,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA Program. More information is available at: Clinical Laboratory Amendments (CLIA) Website

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”

Modifier QW  CLIA Waived Test

Questions and Answers

1 Q: How do the Centers for Medicare & Medicaid Services (CMS) determine CLIA applicability?  
A: CLIA applicability is determined using the regulatory definition of “laboratory” quoted above. United Healthcare is acknowledging the CDC, FDA, and CMS CLIA regulations.  
Specifically, CLIA applies when:
(1) patient-specific results are reported from the laboratory to another entity; AND
(2) the results are made available “for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.” As stated above, whether a test service is billed to Medicare has no bearing on CLIA applicability. Therefore, if a facility performs tests for the above-stated purposes, it is considered a laboratory under CLIA and must obtain a certificate that corresponds to the complexity of testing performed.

2 Q: Where is there more information about the ANSI X12N implementation guidelines?  
A: More information can be found at www.x12.org or www.wpc-edi.com.

Attachments


Resources

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and
services

Centers for Medicare and Medicaid Services, Clinical Laboratory Improvement Amendments (CLIA)

US Food and Drug Administration (FDA)

Centers for Disease Control and Prevention (CDC)
Individual state Medicaid regulations, manuals & fee schedules

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<tr>
<td>7/14/2017</td>
<td>Application Section: Removed UnitedHealthcare Community Plan Medicare products as applying to this policy. Added location for UnitedHealthcare Community Plan Medicare reimbursement policies</td>
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<td>8/1/2016</td>
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