

One-Time Notification

Pub. 100-20	Transmittal: 12	Date: October 24, 2003	Change Request 2935
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SUBJECT: New Waived Tests – January 1, 2004

I. GENERAL INFORMATION

A. Background:

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

Listed below are the latest tests approved by the FDA as a waived tests under the CLIA. The Current Procedural Terminology (CPT) codes for these new tests must have the modifier QW to be recognized as a waived test.

CPT Code/Modifier	Effective Date	Description
87804 QW	05-08-03	Binax Now® Flu A Test
87804 QW	05-08-03	Binax Now® Flu B Test
83518 QW	05-13-03	Beckman Coulter ICON Microalb
85018 QW	05-14-03	Hemocue Donor Hemoglobin Checker System
87880 QW	06-12-03	Acon Strep A Twist Rapid Test
83001 QW	06-24-03	Applied Biotech, Inc. RU25 Plus FSH Menopause Test
87880 QW	07-03-03	Instant Technologies iStrep Strep A
87880 QW	08-06-03	Beckman Coulter Icon SC Strep A Test

B. Policy:

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

C. Provider Education: N/A

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
2935.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.	All Contractors

2935.2	Contractors need not search their files to either retract payment or retroactively pay claims, however, contractors should adjust claims if they are brought to their attention.	All Contractors
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III. SUPPORTING INFORMATION & POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

The attachment contains the complete list of waived tests, including the new waived tests listed previously. In the attachment, the information in the "Use" column explains the purpose of the waived test. If denial is appropriate, this explanation is unacceptable to use as the reason for the denial of a claim. Use the appropriate remittance advice message that describes why the test was denied.

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date: September 19, 2003</p> <p>Implementation Date: January 1, 2004</p> <p>Pre-Implementation Contact(s): Kathy Todd (410) 786-3385</p> <p>Post-Implementation Contact(s): Kathy Todd (410) 786-3385</p>	<p>These instructions should be implemented within your current operating budget.</p>
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Attachment