

# One-Time Notification

|             |                |                       |                     |
|-------------|----------------|-----------------------|---------------------|
| Pub. 100-20 | Transmittal: 5 | Date: October 1, 2003 | Change Request 2791 |
|-------------|----------------|-----------------------|---------------------|

**SUBJECT: New Waived Tests – October 1, 2003**

## 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.

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.

Genzyme OSOM Mono Test, Effective: March 6, 2003, CPT code: 86308QW;

GI Supply, Div. Chek-Med Systems HP One, Effective: March 24, 2003, CPT code: 87077QW;

ADC CLIA Waived Marijuana (THC) Test, Effective: 4/29/2003, CPT code: 80101QW;

ADC CLIA Waived Multiple Drug Test Card, Effective: 4/29/2003, CPT code: 80101QW; and

ADC CLIA Waived Marijuana (THC) and Cocaine Test, Effective: 4/30/2003, CPT code: 80101QW.

### 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.

### C. Provider Education: N/A

## II. BUSINESS REQUIREMENTS

*"Shall" denotes a mandatory requirement*

*"Should" denotes an optional requirement*

| Requirement # | Requirements | Responsibility |
|---------------|--------------|----------------|
|---------------|--------------|----------------|

|               |                                                                                                                                                                                  |                 |
|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <b>2791.1</b> | The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.                                                                | All Contractors |
| <b>2791.2</b> | 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 |

### 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.

| <b>X-Ref Requirement #</b> | <b>Instructions</b> |
|----------------------------|---------------------|
|                            |                     |

#### B. Design Considerations: N/A

| <b>X-Ref Requirement #</b> | <b>Recommendation for Medicare System Requirements</b> |
|----------------------------|--------------------------------------------------------|
|                            |                                                        |

#### 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

|                                                                                                                                                                                                                           |                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| <b>Effective Date:</b> June 1, 2003<br><b>Implementation Date:</b> October 1, 2003<br><b>Pre-Implementation Contact(s):</b> Kathy Todd (410) 786-3385<br><b>Post-Implementation Contact(s):</b> Kathy Todd (410) 786-3385 | <b>These instructions should be implemented within your current operating budget</b> |
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Attachment