



Related MLN Matters Article #: MM5715

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Related CR #: 5715

New Waived Tests

Key Words

MM5715, CR5715, R1346CP, Waived, Test

Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare carriers and/or Part A/B Medicare Administrative Contractors (A/B MACs) for services provided to Medicare beneficiaries

Key Points

- The effective date of the instruction is October 1, 2007.
- The implementation date is October 1, 2007.
- Change Request (CR) 5715 informs carriers and A/B MACS of new waived tests approved by the Food and Drug Administration (FDA) under Clinical Laboratory Improvement Amendments of 1988 (CLIA).
- The CLIA regulations require a facility to be appropriately certified for each test they perform.
- Laboratory claims are currently edited at the CLIA certificate level in order to ensure that the Centers for Medicare & Medicaid Services (CMS) only pays for laboratory tests categorized as waived complexity under CLIA (for facilities with a CLIA certificate of waiver).
- New waived tests are approved by the FDA on a flow basis, and the tests are valid as soon as they are approved.
- The new waived tests announced by CR5715 are in the table on pages 2 and 3 of MLN Matters article MM5715.

Note: The Current Procedural Terminology (CPT) codes for these new waived tests must have the modifier QW to be recognized as a waived test.

- The new waived CPT/Healthcare Common Procedure Coding System (HCPCS) code, 82310QW, has been assigned for the total calcium test performed using the Arkay SPOTCHEM EZ Chemistry Analyser (Spotchem II Basicpanel 1) {Whole Blood}.
- The new waived CPT/HCPCS code, 82565QW, has been assigned for the creatinine test performed using the Arkay SPOTCHEM EZ Chemistry Analyser (Spotchem II Basicpanel 1) {Whole Blood}.
- The new waived CPT/HCPCS code, 89321QW, has been assigned for the semen motility test performed using the Fertell Male Fertility Test.

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- The provider's Medicare carrier or A/B MAC will not automatically adjust claims processed prior to the implementation of these changes. However, they will adjust such claims that the provider brings to their attention.

Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5715.pdf> on the CMS website.

The official instruction (CR5715) regarding this change may be viewed at

<http://www.cms.hhs.gov/transmittals/downloads/R1346CP.pdf> on the CMS website.

The attachment to CR5715 includes the list of tests granted waived status under CLIA, and the tests mentioned on the first page of the attachment do not require a QW modifier to be recognized as a waived test.

If providers have questions regarding this issue, they may contact their carrier or A/B MAC at their toll-free number, which may be found at

<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.