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MLN Matters® Number: MM6800

Related Change Request (CR) #: 6800

Related CR Release Date: February 5, 2010

Effective Date: April 1, 2010

Related CR Transmittal #: R1905CP

Implementation Date: April 5, 2010

Note: This article was updated on November 23, 2012, to reflect current Web addresses. All other information remains unchanged.

New Waived Tests

Provider Types Affected

This article is for clinical laboratories and providers that submit claims to Medicare carriers or Medicare Administrative Contractors (MACs) for laboratory test services provided to Medicare beneficiaries.

Provider Action Needed

This article, based on Change Request (CR) 6800, alerts clinical laboratories and providers that the Centers for Medicare & Medicaid Services (CMS) has listed the latest tests approved by the Food and Drug Administration (FDA) as waived tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The tests newly added to the waived tests are in the table in the Background section of this article. Be sure your billing staffs are aware of these changes.

Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a laboratory facility to be appropriately certified for each test it performs. To ensure that Medicare & 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.

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CPT Code	Effective Date	Description
80101QW, G0430QW	July 1, 2009 for 80101QW, January 1, 2010 for G0430QW	Inverness Medical Innovations Signify ER Drug Screen
82274QW, G0328QW	September 9, 2009	Germaine Laboratories AimStep Immunological Fecal Occult Blood Test (iFOBT)
81003QW, 82044QW, 82570QW	September 14, 2009	Siemens Clinitek 50 Urine Chemistry Analyzer
87880QW	September 15, 2009	CLIA waived inc Rapid Strep A Test
82044QW	October 26, 2009	Genzyme Diagnostics OSOM ImmunoDip Urinary Albumin Test

CMS identifies waived tests by providing an updated list of waived tests to Medicare contractors on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA waived tests have unique Healthcare Common Procedure Coding System (HCPCS) procedure codes and some must have a QW modifier (CLIA Waived Test) included with the HCPCS code.

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

However, please note that the codes for the tests mentioned on the first page of the attachment to CR 6800, at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1905CP.pdf>, do not require a QW modifier to be recognized as a waived test (i.e., CPT codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651).

Other Key Points of CR 6800

- CR 6800 also announces that CMS was informed by Bayer Healthcare that the following tests are no longer manufactured or distributed; Hence, the following tests were removed from the attachment to CR 6800:
 - Bayer Multistick Pro 7G Reagent Strips;
 - Bayer Multistick Pro 10LS Reagent Strips;
 - Bayer Multistick Pro 11 Reagent Strips;
 - Bayer Clinitek 50 Urine Chemistry Analyzer,
 - Bayer Clinitek Status Urine Chemistry Analyzer;
 - Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine;

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- Bayer Diagnostics/ Microalbumin Reagent Strip; and
 - Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine.
2. Based on a concern received from the laboratory industry on correct coding, the CPT code assigned to the following tests has been changed from 83518QW to 82044QW with an effective date of April 1, 2010:
- Beckman Coulter ICON Microalb;
 - Boehringer Mannheim Chemstrip Micral;
 - Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test;
 - Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick); and
 - Roche Diagnostic Chemstrip Micral (urine dipstick).
3. For 2010, the Healthcare Common Procedure Coding System (HCPCS) included the following new codes:
- G0430 – Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure; and
 - G0431 – Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class.

Therefore, the HCPCS code G0430QW was added to the following test systems since they are qualitative drug screening tests for multiple drug classes using a non-chromatographic method:

- Abbott Diagnostics Signify ER Drug Screen Test;
- Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) and Cocaine (COC);
- Accu-Stat Drugs of Abuse Home Test for Marijuana, Cocaine, Amphetamine, Methamphetamines, Opiates and Phencyclidine;
- Accutest Multi-Drug, Multi-Line Screen Test Device;
- Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use);
- ADC CLIA Waived Marijuana (THC) and Cocaine Test;
- ADC CLIA Waived Multiple Drug Test Card;
- Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test;
- Advantage Diagnostics Corporation ADC Multiple Drug Test Card;
- Alatec Scientific Peace of Mind Multiple Drugs of Abuse Test;
- Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Test;

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- Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Cup Test;
- Amedica Biotech Amedica Drug Screen Test Cup;
- American Bio Medica Rapid TOX;
- Aventir Biotech LLC Home Check Multiple Drug Test Cup;
- Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version};
- Biotechnostix Rapid Response Multi-Drug, Multi-Line Screen Test Card with Integrated Cup;
- Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device;
- Branan Medical Corporation Fastect II Drug Screen Dipstick Test;
- Branan Medical Corporation, FasTox Multiple Drug Dipcard;
- Branan Medical Corporation, QuickTox Drug Screen Dipcard;
- Branan Medical Corporation ToxCup Drug Screen Cup;
- BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine);
- BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine);
- Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup;
- First Check Diagnostics First Check Multi Drug Cup;
- First Check Diagnostics First Check 12 Drug Test;
- Forefront Diagnostics Drugfree@Home THC/COC Test Kit;
- iCassette Multi-Drug, Multi-Line Screen Test Device;
- Innovacon Integrated E-Z Split Key Cup II {Professional Use};
- Innovacon Multi-Clin Drug Screen Test Device;
- Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device;
- 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II;
- Phamatech At Home Drug Test (Model 9150T);
- Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use};
- RediScreen Multi-Drug, Multi-Line Screen Test Device;
- Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use};

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- Syntron Bioresearch Quikscreen Multiple Drug Cup Test {Professional version};
 - Twin Spirit, Inc. DrugSmart Cup;
 - Wolfe Drug Testing RealityCheck Integrated Specimen Cup;
 - Worldwide Medical Corporation, First Check® Home Drug Test (THC-COC); and
 - Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET),
4. In addition, the HCPCS code G0431QW was added to the following test systems since they are qualitative drug screening tests using a single drug class method:
- Accu-Stat Drugs of Abuse Home Test for Marijuana (THC);
 - ADC CLIA Waived Marijuana (THC) Test;
 - DyanGen NicCheck II Test Strips;
 - First Check Diagnostics LLC, First Check Home Drug Test Marijuana;
 - Mossman Associates, Inc. NicCheck I Test Strips;
 - Phamatech At Home Drug Test (Model 9068);
 - Phamatech At Home Drug Test (Model 9073);
 - Phamatech At Home Drug Test (Model 9073T);
 - Phamatech At Home Drug Test (Model 9078);
 - Phamatech At Home Drug Test (Model 9078T);
 - Phamatech At Home Drug Test (Model 9083);
 - Phamatech At Home Drug Test (Model 9133);
 - Phamatech QuickScreen One Step Cocaine Screening Test;
 - Phamatech QuickScreen One Step Methamphetamine Test;
 - Phamatech QuickScreen One Step Opiate Screening Test;
 - Phamatech QuickScreen One Step PCP Screening Test; and
 - Worldwide Medical Corporation, First Check® Home Drug Test (THC).

You should be aware that your carrier or MAC will not search their files to either retract payment or retroactively pay claims processed prior to implementation of CR 6800. However, they should adjust claims that you bring to their attention.

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Additional Information

You can find the official instruction, CR 6800, issued to your carrier or MAC by visiting <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1905CP.pdf> on the CMS website. You will find a table containing the tests granted waived status under CLIA as an attachment to that CR.

If you have questions, please contact your Medicare Carrier and/or MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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