

Frequently Asked Questions Regarding 2011 CMS Reimbursement Changes For Rapid Diagnostic Drug Tests (Immunoassay Tests)

DISCLAIMER: The below listed FAQs are our summary and interpretation only of the CMS materials currently available. Under no circumstances does Alfa guarantee reimbursement by private insurance carriers or Medicare/Medicaid. Always refer to CMS or your relevant insurance carrier for up-to-date and state by state reimbursement information.

1) When do the new Centers for Medicare and Medicaid Services (CMS) codes take effect?

January 1, 2011

2) What was the overall change that was made?

Over the last few years CMS saw a dramatic increase in reimbursements for rapid diagnostic tests. In order to curb the potential abuse of over-reimbursement, they attempted to change the coding system in April 2010. Since that time however, CMS has re-evaluated their coding system and changed codes and definitions in order to further manage the reimbursements paid out on rapid drug tests by Medicare/Medicaid.

3) Can I receive multiple reimbursements for a multi-drug test device?

While previously you could with Non-Medicare Carriers now you cannot. Please refer to Point 7 for a summary chart.

- For Medicare/Medicaid

You can only be reimbursed once. The current rate is \$20.47.

New HCPCS code = G0434QW (CLIA-Waived) or G0434

- For Private Insurance Carriers (Non-Medicare/Medicaid)

The reimbursement is now per test device (regardless of number of drugs being tested). CMS forced these Non-Medicare Carriers to create a new CPT code for a multi-drug test device (i.e. panel or cup).

Generally speaking the average reimbursement rate usually mirrors that of CMS at \$20.47 however it is always best to check with the carrier and state for the most up-to-date information.

New CPT code = 80104QW (CLIA-Waived) or 80104

4) How can I be reimbursed for single-drug test devices?

You must be using single devices such as the Alfa Single Dip Cassette. This means that there is only one drug strip per test device. Please refer to Point 7 for a summary chart.

- Medicare/Medicaid - since CMS redefined HCPCS code G0431 you can no longer use that for this type of device. G0431 has been redefined as a high complexity test. See note in Point 5 for a definition. Therefore, the only code that the single device would fall under is the multi-drug code G0434 which provides only one reimbursement (regardless of number of drugs being tested). Add QW if using a CLIA-Waived device.
- Private Insurance Carrier - use the current CPT code 80101QW (CLIA-Waived) or 80101 per drug CLASS. It is important to note that while you are not limited to

the number of reimbursements per patient, it is not per DRUG it is per drug CLASS. Please see Point 11 for more information.

5) **What is a High Complexity test according to CMS?**

According to CMS code G0431 now applies to a high complexity test only. This test (with its higher reimbursement rate of \$120.33) is specific to its FDA approved complexity in its 510(k) application. A high complexity lab must perform this test. The personnel required in this lab must meet the specified CLIA Clinical Laboratory Personnel Requirements. The details of these requirements can be found at: http://www.mass.gov/Eeohhs2/docs/dph/clinical_lab/clia_lab_qualifications.pdf

6) **Why do some codes use QW?**

This is a modifier to indicate CLIA-Waived. If a CLIA approved facility or physician is using a CLIA-Waived test they must indicate this on the code being used for reimbursement purposes. Physicians must have either one of the following to qualify for CLIA status:

- COW - CLIA Certificate of Waiver
- COA - CLIA Certificate of Accreditation

7) **Coding Summary Chart**

Insurance: Medicare/Medicaid						
Multiple Drug Screens (i.e. immunoassay tests)		Maximum # of Units Billable	Single Drug Screen (High Complexity*) <i>* see note in Point 5 as to what now constitutes high complexity</i>		Maximum # of Units Billable	
G0434 (Average reimbursement ~\$20.47)		1	G0431 (Average reimbursement ~\$120.33)		1	
Insurance: Private/Non-Medicare						
Multiple Drug Screens (i.e. immunoassay)	Maximum # of Units Billable	Single Drug Class (i.e. immunoassay test)	Maximum # of Units Billable	Multiple Drug Screens (Chromatographic)	Maximum # of Units Billable	
80104	1	80101	# of drug CLASSES not drugs being tested	80100	1	

8) **What does HCPCS stand for?**

Healthcare Common Procedure Coding System

9) **What does CPT mean?**

Current Procedural Terminology

10) **Where can I find out more information about the CMS reimbursement changes or apply for a CLIA certificate?**

www.cms.gov

11) What drugs fall under what drug CLASSES?

AMPHETAMINES

- Amphetamines (AMP)
- Methamphetamines (MET or mAMP)
- Ecstasy (XTC or MDMA)

BARBITURATES

- Barbiturates (BAR)

BENZODIAZEPINES

- Benzodiazepine (BZD or BZO)

COCAINE

- Cocaine (COC)

METHADONE

- Methadone (MTD)

OPIATES

- Morphine/Opiate (MOR, MOR/OPI or OPI)
- Oxycodone (OXY)

PHENCYCLIDINE

- Phencyclidine (PCP)

PROPOXYPHENE

- Propoxyphene (PPX)

MARIJUANA

- Marijuana (THC)

TRICYCLIC ANTIDEPRESSANT

- Tricyclic Antidepressant (TCA)

12) What does Alfa offer to meet my CLIA-Waived needs?

Part #	Description	Cut Off Level
Single-Drug Test Devices		
03-3012QW	AMP DIP CASSETTE	1000 ng/mL
03-3152QW	BAR DIP CASSETTE	200 ng/mL
03-3132QW	BZD DIP CASSETTE	300 ng/mL
03-3052QW	COC DIP CASSETTE	300 ng/mL
03-3032QW	MET DIP CASSETTE	1000 ng/mL
03-3092QW	OPI/MOR DIP CASSETTE	2000 ng/mL
03-3093QW	OPI/MOR DIP CASSETTE	300 ng/mL
03-2863QW	OXY DIP CASSETTE	100 ng/mL
03-3172QW	MTD DIP CASSETTE	300 ng/mL
03-3112QW	PCP DIP CASSETTE	25 ng/mL
03-2972QW	TCA DIP CASSETTE	1000 ng/mL
03-3072QW	THC DIP CASSETTE	50 ng/mL
03-2952QW	XTC (MDMA) DIP CASSETTE	500 ng/mL
Multi-Drug Test Devices		
03-3940QW	11 PANEL DIP CARD (AMP, BAR, BZD, COC, MET, MOR/OPI, PC, TCA, THC, XTC)	See Above
03-3965QW	12 PANEL DIP CARD (AMP, BAR, BZD, COC, MET, MOR/OPI 300, MTD, OXY, PCP, TCA, THC, XTC)	See Above
<p>Many other configurations also available in stock in 5 or more drug combinations. Contact Customer Service for more details or visit our website at http://www.alfascientific.com/resources/sales-brochures for our most up-to-date product list.</p>		

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