

## CMS Guidance on Qualitative Drug Testing March 25, 2010

On March 19, the Centers for Medicare and Medicaid Services (CMS) issued Transmittal 653, Change Request 6852, providing special instructions for billing Qualitative drug tests using the following specific HCPCS codes:

***80100** – Drug screen, qualitative; multiple drug classes chromatographic method, each procedure*

This CPT code remains unchanged and is to be used to report all multiple drug class assays employing chromatographic methods. It can be reported once for each procedure (i.e. unique combination of stationary and mobile phase) employed.

Medicare reimbursement will continue to be \$20.83.

***80101** – Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class*

This CPT code will no longer be covered by Medicare after April 1, 2010, but will remain available for use by non-government payers.

***80101QW** – Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class, CLIA waived test.*

This code will be deleted from the Medicare Laboratory Fee Schedule effective April 1, 2010.

***G0430** – Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure*

This HCPCS code must be used when reporting any **qualitative, non-chromatographic, multiple drug class assays**. The code is reported only once per procedure. Urine cups, test cards, test strips or other point-of-care devices which provide results for more than one class of drug will be paid only \$20.83 no matter how many drug classes are determined.

Medicare reimbursement for G0430 will continue to be \$20.83

**G0430QW** – *Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure, CLIA waived test*

This new HCPCS code will become effective April 1, 2010, and must be used when reporting **qualitative, non-chromatographic, multiple drug class assays classified as “CLIA waived” by the FDA.**

Medicare reimbursement for G0430QW will be \$20.83 after April 1, 2010.

**G0431** – *Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class*

This HCPCS code must be used when reporting any **qualitative single drug or drug class assay**. This includes individual drug or drug class assays performed using CLIA moderate or high complexity instruments as well as point of care devices which produce results for only one drug or class of drugs.

Medicare reimbursement for G0431 will continue to be \$19.72.

**G0431QW** – *Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class, CLIA waived test*

This new HCPCS code will become effective April 1, 2010, and must be used when reporting **qualitative, single drug class assays classified as “CLIA waived” by the FDA.**

Medicare reimbursement for G0431QW will be \$19.72 after April 1, 2010.

A key difference between codes G0430 and G0431 is that G0430 is reported *per procedure*, while G0431 is reported for *each drug class*. Also, G0430 applies only to non-chromatographic methods, while G0431 can be used for any method.

The definition of a *procedure* is typically a single device (such as a test cup, test strip or card) or a separate set of reagents used with an instrument to produce one or more test results. Thus, G0431 would be used to report individual drugs or drug classes determined using immunoassay instruments employing discrete reagent sets. The code would be reported once for each drug or drug class determined.

Likewise, if more than one point-of-care test device for a single drug or single drug class is employed, the test results from each device would be separately reported using G0431.

At present CMS has assigned no frequency limits for G0430 and G0431. Since these are new codes, they have not yet been assigned Correct Coding Initiative frequency limits (MUEs). It is expected that, in the near future, G0430 will be assigned an MUE value of

1 since CMS would not expect the code to be reported more than one time for each date of service. G0431 will probably be assigned a higher, but unpublished, frequency limit. It is CMS policy to keep frequency limits they believe may be abused confidential.

Medically necessary services that exceed MUE frequency limits may be reported as separate line items using an appropriate modifier such as 59 (separate and distinct service) or 91 (repeat clinical test) to identify them as medically necessary. Since each line of a claim is individually adjudicated, this allows the MUE edit to be bypassed and all medically necessary codes to be paid. However, excessive use of the 59 modifier to bypass MUE edits has been targeted by the Office of Inspector General as a possibly abusive practice. Thus, care should be taken to document medical necessity of such tests in the patient record.

HCPCS codes G0430QW and G0431QW may be used to report any test cleared by the FDA as “waived”. Any correctly coded, medically necessary assay currently cleared by the FDA should be reimbursed by Medicare/Medicaid contractors after April 1, 2010.

The following table summarizes the use of qualitative drug testing codes for Medicare claims submitted after April 1, 2010.

	<i>CLIA Waived</i>	<i>CLIA Non-waived</i>
<i>Chromatography:</i>		
<i>Multiple drug classes</i>	N/A*	80100
<i>Single drug or drug class</i>	G0431QW	G0431
<i>Other methods:</i>		
<i>Multiple drug classes</i>	G0430QW	G0430
<i>Single drug or drug class</i>	G0431QW	G0431

\*there are no CLIA waived, chromatographic, qualitative drug procedures, thus 80100QW is not included on the Medicare Laboratory Fee Schedule.