

## Billing for Quantitative Analysis Using a Desktop Analyzer

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### Question: What is a Qualitative Test?

**Answer:** Qualitative Tests measure the presence or absence of a substance. Results of Qualitative Tests are expressed in descriptive, non-numerical values. Examples of descriptors include, “positive”, “negative”, “reactive”, “non-reactive”, “normal”, or “abnormal.”<sup>1</sup>

### Question: What is a Semi-Quantitative Test?

**Answer:** Semi-Quantitative Tests measure the presence or absence of a substance, but also include an estimate of how much of a measured substance is present. Semi-Quantitative Tests are more specific than Qualitative Tests, but provide a relative value of an analyte as compared to another. Results are typically expressed as, “trace amount, 1+, 2+, 3+, or positive at 1:160 (titer or dilution).”<sup>2</sup>

### Question: What is a Quantitative Test?

**Answer:** Quantitative Tests measure a precise amount of an analyte in a substance, yielding a numeric result. Because Quantitative Tests have numerical values, statistical tests can be run between the tested substance and the control material to determine whether the substance results fall within or outside of established limits.<sup>3</sup>

### Question: Do the AMA 2011 CPT Codebook distinguish between these various test methods?

**Answer:** Yes. Instances where it is appropriate to use the billing codes for Quantitative Tests for Semi-Quantitative or Qualitative Tests are specifically noted. For example, the AMA’s CPT Codebook, under the “Chemistry” section, states: “The examination is quantitative unless specified”<sup>4</sup>. Similarly, when Semi-Quantitative Tests can be billed using specific codes, those codes are noted as such. The following are some examples within the Chemistry section of codes that can be billed when Qualitative Tests are used:

- 82009 – Acetone or other ketone bodies, serum; qualitative.
- 82016 – Acylcarnitines; qualitative, each specimen.
- 82120 – Amines, vaginal fluid, qualitative.
- 82127 – Amino acids; single, qualitative, each specimen.
- 82128 – (Amino acids) multiple, qualitative, each specimen.
- 82131 – (Amino acids) single, quantitative, each specimen.
- 82145 – Amphetamine or methamphetamine (For qualitative analysis, see 80100-80103).
- 83840 – Methadone (For methadone qualitative analysis, see 80100-80103) (Methamphetamine, see 80100-80103, 82145) (Methanol, use 84600).

Semi-Quantitative analysis is specifically mentioned in the Chemistry section of the 2011 CPT Codebook as follows:

- 82044 – urine, microalbumin, semiquantitative (eg, reagent strip assay).
- 83516 – Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method.
- 83518 – Qualitative or semiquantitative, single step method (eg, reagent strip).

There are other examples where semiquantitative analysis is specifically noted as a permitted code:

- 81005 – Urinalysis; qualitative or semiquantitative, except immunoassays.

- 86294 – Immunoassay for tumor antigen, qualitative or semiquantitative (eg, bladder tumor antigen)

**Question: Is there a difference between a Qualitative Test and a Semi-Quantitative Test?**

**Answer:** No. The Qualitative Test and a Semi-Quantitative Test conducted by enzyme immunoassay are the same test with the only difference being two- versus five- point calibration curves. From a clinical perspective, both methods produce results at high sensitivity levels (*i.e.*, cutoff levels), both methods test broad drug classes (*i.e.*, not drug or metabolite specific) and both tests are subject to cross reactivity resulting in false positives and false negatives. Although some tests, cocaine for example, are less susceptible to cross reactivity, other tests are more susceptible to cross reactivity and are therefore less reliable in identifying specific drug use, *e.g.*, amphetamines, or for distinguishing which drug has been identified, *e.g.*, opiate testing for semisynthetic/synthetic opioids. Because of this, the more specific Quantitative Test using LC/GC-MS can provide definitive identification of a specific drug and/or its metabolite in 3 specific circumstances: “(1) to specifically confirm the presence of a given drug; for example, that morphine is the opiate causing the positive immunoassay response; (2) to identify drugs not included in an immunoassay test; and (3) when results are contested.”<sup>5</sup>

**Question: Can urine drug testing performed by an enzyme immunoassay desktop analyzer be billed using quantitative analysis codes?**

**Answer:** No. Unless specifically permitted or defined as noted above, billing codes for Quantitative Tests require definitive identification that cannot be achieved with a Qualitative or Semi-Quantitative Test. Even if the results yielded from a Semi-Quantitative or Qualitative Test method provide sufficient information for a physician to reach an appropriate clinical conclusion, these tests do not provide definitive information on the drug and/or its metabolite to constitute “Quantitative Tests.” Therefore, unless and until such time as an enzyme immunoassay desktop analyzer is approved by CMS as satisfying the “Quantitative Test” criteria, physicians who bill using Quantitative Test codes, and the analyzer manufacturers that advise them, are exposing themselves to investigations, civil and criminal fraud charges, restitution, fines, penalties, and, in extreme cases, exclusion from participation in Federal health care programs.

Based on information published by CMS, the AMA 2011 CPT Codebook, past settlements, and industry standards, it can be concluded:

1. That Quantitative specimen analysis and the codes associated therewith is performed by laboratories using liquid chromatography (LC) or gas chromatography (GC) and mass spectrometry (MS) testing equipment.
2. The only support to bill Quantitative Test codes for an enzyme immunoassay desktop analyzer is based on a slim interpretation of the existing guidance.
3. The use of Quantitative Test codes for Qualitative and Semi-Quantitative Tests not only risks recoupment of overpayments, but also liability under the False Claims Act for criminal and civil prosecution and penalties of up to three times the amount of the claim, plus \$11,000 per false claim.
4. To mitigate the risk of civil and criminal penalties, if a desktop analyzer manufacturer recommends billing under the Quantitative codes for tests performed on its analyzer, a provider should require documentation from CMS to validate that the manufacturer’s test results qualify as Quantitative testing.

**Rationale:** When new codes were published by CMS on January 1, 2011, CMS distinguished high complexity testing methods that would be done by a laboratory (G0431) from testing methods that could be done through in-office, CLIA-waived testing (G0434 and G0434QW).<sup>6</sup>

To bill using G0431, a physician practice must:

1. Be licensed as a laboratory and have a CLIA certificate of compliance or accreditation; and
2. Perform the tests “using instrumented systems (i.e., durable systems capable of withstanding repeated use).”

However, even though testing under G0431 is considered “high complexity,”<sup>7</sup> it is still defined as “qualitative.” Moreover, the definitions included by CMS in this guidance (and the guidance released in Transmittal 653 on March 19, 2010<sup>8</sup>) repeatedly refer by example to immunoassay and enzyme assay as “qualitative” tests that fall under CPT codes 80101 and HCPCS code G0431 and G0434, indicating that unless otherwise specified, testing performed by immunoassay and enzyme assay constitutes qualitative and not quantitative testing.

There has been some confusion about billing using Quantitative Chemistry codes where a Semi-Quantitative result is achieved. Specifically, some physicians have been advised that they may bill a Quantitative Chemistry code for “drugs of abuse” assays when the testing method can only produce a Semi-Quantitative result. An exception to this is CPT 82055, Alcohol (ethanol); any specimen except breath, where enzyme immunoassay can provide the level of specificity required to warrant billing using a Quantitative Chemistry code. Although enzymatic immunoassay tests, which produce Semi-Quantitative results, may be used for the initial, Qualitative screen, confirmation testing is highly specific and ordinarily involves LC/GC-MS Quantitative analysis.<sup>9</sup> Therefore, the advice to bill a Quantitative Test code for a Semi-Quantitative result is risky at best because it erroneously relies on an assumption that the results produced by enzymatic immunoassay are specific enough to qualify as “Quantitative” results.

Industry publications further support the conclusion that Quantitative testing is limited to LC/GC-MS testing methods. Carolina Liquid Chemistries Corp., for example, refers to its BioLis 24i as an Enzyme Immunoassay machine that is capable of “both qualitative and semi-quantitative” testing, but states, “If a laboratory chooses to use the semi-quantitative mode with quantitative results it should be confirmed by LC/GC and they should consider using the specific drug code.”<sup>10</sup> Other laboratory companies have published statements or interviews that provide insight on their perspectives of what constitutes a Quantitative versus Qualitative Test.<sup>11 12</sup> Thus, with the limited exception of testing for alcohol (ethanol), CPT 82055, it appears that Quantitative testing is reserved for laboratories using LC/GC-MS testing methods.

A review of investigative activity also provides instructive guidance on this issue. In 2005 and 2007, Dominion Diagnostics entered into two settlement agreements with the States of New Hampshire and Vermont respectively to resolve billing fraud allegations involving upcoding.<sup>13 14</sup> Specifically, Dominion was accused of billing for quantitative testing when it performed qualitative testing. The settlements recovered the amount of the overpayments, plus a damages multiplier. Under the Federal False Claims Act, liability for false claims is the amount of the claim<sup>15</sup>, plus up to three times the amount of the overpayment AND a fine of up to \$11,000 per false claim filed<sup>16</sup>. In addition, criminal prosecution can occur for repeated willful or intentional conduct. Even if a civil or criminal investigation is avoided, the Federal government’s efforts to eliminate fraud, waste and abuse in the Medicare program have increased the likelihood of external review of claims submitted by physicians.<sup>17</sup>

**Conclusion:** Billing for Quantitative testing is not as simple as merely plugging in a desktop analyzer, testing specimens and applying quantitative codes. To comply, a physician practice must become a licensed, surveyed and CLIA-certified laboratory, and meet all of the compliance standards and staffing requirements. Even with the CLIA certification in place, a lab that tests using only a desktop analyzer appears to be limited in most circumstances to code G0431 for qualitative, high complexity testing, and not the more detailed quantitative analysis performed by LC/GC-MS. Therefore, because: (1) It is recognized that immunoassay and enzyme assay do not provide the same level of specificity as a LC/GC-

MS method; (2) Dominion Diagnostics was fined by two states after unsuccessfully attempting to expand the definition of quantitative analysis; and (3) Industry publications identify a distinction between quantitative LC/GC-MS and qualitative immunoassay and enzyme assay, ***a provider that knowingly and intentionally bills using quantitative analysis codes for immunoassay and enzyme assay testing, except where explicitly permitted, is placing him/herself and the practice at risk for criminal prosecution, civil prosecution, reimbursement or recoupment of payments, three times the amount of the original claim (treble damages) for repeated claims, and fines of up to \$11,000 per claim.***

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## Notes and Supporting Information:

<sup>1</sup> World Health Organization, International Health Regulations Laboratory Quality Management System (LQMS) training toolkit, Content Sheet 8-1: Overview of Quality Control for Qualitative and Semi-quantitative Procedures, available at: [http://www.who.int/ihr/training/laboratory\\_quality/8\\_b\\_content\\_qualqc.pdf](http://www.who.int/ihr/training/laboratory_quality/8_b_content_qualqc.pdf)

<sup>2</sup> Id.

<sup>3</sup> World Health Organization, International Health Regulations Laboratory Quality Management System (LQMS) training toolkit, Content Sheet 7-1: Overview of Quality Control for Quantitative Tests, available at: [http://www.who.int/ihr/training/laboratory\\_quality/7\\_b\\_content\\_quant\\_qc.pdf](http://www.who.int/ihr/training/laboratory_quality/7_b_content_quant_qc.pdf)

<sup>4</sup> American Medical Association, 2011 Common Procedural Terminology Codebook, p. 407

<sup>5</sup> Gourlay, *et. al.*, “Urine Drug Testing in Clinical Practice, The Art and Science of Patient Care”, PharmaCom Group, Inc. 2010, pp. 3, 9-10.

<sup>6</sup> Effective January 1, 2011, CMS published guidance (MLN Matters Number: SE1105) on the changes to and use of HCPCS codes: G0431, G0434, and G0434QW. Page 2 of the document explains that HCPCS code G0430 was deleted and broken into the two more specific codes, G0431 and G0434.

- G0431 is used for more detailed testing in a laboratory setting, with a higher reimbursement, and G0434 and G0434QW are used for any urine drug testing that is less sophisticated than the high complexity testing covered under G0431.
- G0431 is now defined on page 3 as a qualitative drug screen of multiple drug classes by high complexity test.
  - Supersedes the prior definition of a single drug class method for drug screen, including CLIA waived, in-office testing (*See note 3, page 3*).
  - On page 3, CMS states that G0431 cannot be used with a QW modifier (indicating CLIA waived) and therefore must be performed by a CLIA certified laboratory.
- The guidance includes as examples on page 3 immunoassay, enzyme assay and states:
  - “[U]sed to report more complex testing methods, such as multi-channel chemistry analyzers, where a more complex instrumented device is required to perform some or all of the screening tests for the patients.”
  - Immunoassay, enzyme assay is consistently characterized as “qualitative” analysis.
- G0431 is to be used by laboratories, not physician practices, meaning a physician practice must be licensed as a laboratory and have a CLIA certificate of compliance or accreditation in order to use this code.
  - “G0431 may only be reported when tests are performed using instrumented systems (i.e., durable systems capable of withstanding repeated use)” (*See page 3*).
- G0434 and G0434QW is defined on page 2 as an other than chromatographic drug screen for any number of drug classes by CLIA waived test or moderate complexity test.
  - The guidance states that this code is used “to report very simple testing methods, such as dipsticks, cups, cassettes, and cards, that are interpreted visually, with the assistance of a scanner, or are read utilizing a moderately complex reader device outside the instrumented laboratory setting (i.e., non-instrumented devices).”
- On page 2, CMS states that G0434 is “also to be used to report any other type of drug screen testing using test(s) that are classified as Clinical Laboratory Improvement Amendments (CLIA) moderate complexity test(s)[.]”

<sup>7</sup> CMS, “Calendar Year 2011 CMS New Clinical Laboratory Fee Schedule Test Codes and Preliminary Payment Determinations”, page 4, available at: <https://www.cms.gov/ClinicalLabFeeSched/Downloads/CY2011-Rationale-CLFS-New-Test-Codes.pdf>. CMS introduces the “high complexity” test by defining code G0431 as a “Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), each specimen.” In its rationale, CMS states:

CMS recommends changing the descriptor for this test code to more accurately reflect the high complexity confirmatory drug screening tests performed in the laboratory setting. By setting the payment at a multiple of five (5) times the price of testing for one drug of abuse, we are recognizing that multiple drugs are often tested through one specimen and that the high complexity tests that are performed in the laboratory setting require more resources than the simple dipstick test kit tests performed outside the laboratory setting.

<sup>8</sup> On March 19, 2010, CMS published Special Instructions (Pub 100-20, Transmittal 653, Change Request 6852) for the Clinical Laboratory Fee Schedule (CLFS), specifically for CPT codes: 80100, 80101, 80101QW, and HCPCS codes: G0430, G0430QW, G0431, and G0431QW. Although this was superseded by the January 1, 2011 changes (See note 1), it is instructive for determining how immunoassay, enzyme assay is defined.

- CPT 80100 is defined as a qualitative drug screen for multiple drug classes using a chromatographic method, for each procedure.
- CPT 80101 is defined on page 2 as a qualitative drug screen for a single drug class method.
  - The guidance explicitly includes immunoassay, enzyme assay in this category
- HCPCS code G0430 was established to limit the billing of non-chromatographic testing to one time per procedure.
- HCPCS code G0431 was a replacement for CPT 80101 when billing government payors.
- The G-codes are applied to government payors; commercial payors may still use the 801XX codes.

<sup>9</sup> Gary M. Reisfield, *et. al*, “Rational Use and Interpretation of Urine Drug Testing in Chronic Opioid Therapy”, *Annals of Clinical & Laboratory Science* 37:301-314 (2007). Under the section labeled, “Analytical Methods” at the bottom of page 3, it states: “Confirmatory methods, on the other hand, are highly specific, but also are expensive and not adaptable to rapid turnaround or high throughput applications. Confirmatory methods ordinarily involve a combination of either liquid or gas chromatographic separation and specific detection by mass spectrometry.”

<sup>10</sup> Carolina Liquid Chemistries Corp., BioLis 24i Executive Summary, p.2

<sup>11</sup> PainEDU.org, “Urine Drug Testing: A Strategy for Risk Reduction”, available at:

<http://www.painedu.org/spotlight.asp?spotlightNumber=59&UserID=0>. PainEDU.org interviewed Arthur J. Rodrigues, RPh, Director of Clinical Services, Dominion Diagnostics regarding the use of urine drug testing. When asked, “What is the accuracy of urine drug screening,” Mr. Rodrigues responded, “Not all testing methodologies provide an unequivocal identification of every a drug. Some techniques, such as enzyme immunoassays (EIA) provide the clinician with a presumptive result for a drug or drug class. Other testing methods, such as Ultra Performance Liquid Chromatography/Tandem Mass Spectrometry (UPLC MS / /MS), can give you very specific results.”

<sup>12</sup> ARUP Pain Management Tests, available at: <http://www.aruplab.com/pain-management/tests.html>. A list of lab tests from ARUP Laboratories lists, with a single exception for “Ethanol, Serum or Plasma – Medical” (CPT code 82055), immunoassay and enzyme assay as qualitative and LC/GC-MS as quantitative.

<sup>13</sup> Medical Newswire, “Overcharging Medicaid For Qualitative Tests Earns Big Fines”, available at: [http://medicalnewswire.com/artman/publish/article\\_5989.shtml](http://medicalnewswire.com/artman/publish/article_5989.shtml).

<sup>14</sup> Lawyersandsettlements.com, Dominion Diagnostics, June 8, 2007, available at:

<http://www.lawyersandsettlements.com/settlements/08365/urine-drug-testing.html>.

<sup>15</sup> Reimbursement of payments is not limited to the difference between the quantitative and the qualitative testing reimbursement amount. Instead of an offset, the full amount must be reimbursed, then rebilled using the correct codes. However, it is common for overpayments and recoupments to occur after the rebilling period has expired. As a result, the recoupment or repayment occurs, but the provider loses the opportunity to rebill using the correct charge meaning that the full payment is lost.

<sup>16</sup> It is very common for the Department of Justice to interpret the assessed fine for each false claim as each individual line item that is incorrect and not just the overall claim submitted. This aggressive interpretation exponentially increases the amount of the penalty sought by the government and is typically done to encourage quick settlement by the defendant. In virtually every case, a settlement is reached and therefore, the issue of whether the government’s interpretation of the assessment of penalties is accurate has never been brought before a court.

<sup>17</sup> The Federal government has contracted with private agencies to serve as the Medicare Administrative Contractor (“MAC”) to identify, review and recoup Medicare overpayments. Similar programs exist for the Medicaid program. In September 2010, Palmetto GBA, the MAC for California, Hawaii, and Nevada announced the pre-payment probe review of laboratory services. These reviews select a sample of claims for which to request additional



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documentation to determine whether the claim should be paid. In particular, these reviews focused on the following codes: 80102, 80154, 80299, 82306, 83898, 83925, 86706, 88319 and 88381. These reviews typically result in a denial of payment or a recoupment of payments made. The MAC reports its activities and results to Medicare. As a result, repeated non-compliant billing practices could result in further investigation. Although Palmetto GBA is not the MAC for Florida, it indicates that lab billing is an area of interest and subject to scrutiny.