Lab Billing Codes for Confirmation Testing

Scenario 1:
A clinic does Point of Care screening. If the Point of Care shows positive for non-prescribed drugs or negative for prescribed drugs, the clinic sends the sample to the laboratory. The laboratory then screens for the drugs and, if positive, also performs confirmation testing. The clinic bills the 80104 to commercial insurance, the G0434 to Medicare or for cash patients, bills the patient directly. The laboratory bills the 80101 to commercial insurance or the G0431 to Medicare and also bills the 80102 confirmation code or the quantification code to insurance. If the patient has no insurance, the lab bills a discounted rate to the patient.

In Scenario 1, the issue is whether the lab should bill 80101 and G0431 in addition to the 80102 confirmation code or quantification code.

Scenario 2:
The clinic does the Point of Care screening described above and bills the 80104 or the G0434. They send the specimen to the laboratory to confirm all drugs that were screened and the laboratory bills the confirmation code of 80102 for all 10 drugs the clinic normally screens. In this case, the confirmation would be done on all ten drugs even though only one drug might have been abnormal in the Point of Care Testing.

In Scenario 2, the issue is whether it is appropriate for the lab to bill the confirmation code for all 10 drugs screened by the clinic.

There are several rules that are implicated by the above scenarios. Commercial payers use a series of codes to reimburse for qualitative urine drug screening: 80100, 80101, 80102, and 80104. When billing Medicare, the 80101 and 80104 codes are replaced by G0431 and G0434 respectively.

80100 Drug screen, qualitative; multiple drug classes chromatographic method, each procedure[1] – This code is reserved for qualitative testing of each drug class using a chromatographic method that includes a stationary phase and a mobile phase. [2] [3] Anthem Blue Cross Blue Shield provides the following commentary regarding CPT 80100:

> In **80100**, the screening test must be performed by a chromatographic technique that has good sensitivity, although it may not be as specific as a confirmatory test. Thin-layer chromatography is a common chromatographic technique for drug screening tests. It is performed by applying a thin layer adsorbent to a rectangular plate in the stationary phase. The specimen is applied to the plate and the end of the plate is placed in a solvent. As the solvent rises along the adsorbent on the plate, the

[1] American Medical Association Current Procedural Terminology 2012.
[2] Codapedia, *CPT Codes 80100-80101, 80102*, http://codapedia.com/article_585_CPT-Codes-80100-80101-80102.cfm (last accessed April 12, 2013).
[3] CMS Manual System, Pub 100-20 One-Time Notification, *Transmittal 653*, March 19, 2010.

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> different components of the specimen are carried along at varying rates and deposited along the plate. The different components can be separately visualized and analyzed.[4]

80101 Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class[5] – This code is used for qualitative urine drug testing with immunoassay or enzyme assay. The code can be used for each single drug class method/class tested and reported.[6] [7] Anthem Blue Cross Blue Shield provides the following commentary regarding CPT 80101:

> The screening test should be performed by a technique that has good sensitivity, although it may not be as specific as a confirmatory test. A number of different methods are available to screen for single drugs or drug classes, including simple drug screening kits that rely on immunoassay for detection of a single specific drug or drug class. For example, Placidyl (aka ethchlorvynol) can be screened in urine with a very simple colorimetric test where equal parts of urine and a single reagent are mixed and observed for a visual color change. This would be reported with **80101**. Positive tests are always confirmed with a second method.[8]

In 2011, Medicare replaced 80101 with G0431, Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), each specimen.[9]

G0431 Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter – This code is used to report testing performed by more complex testing methods, such as multi-channel chemistry analyzers, that are instrumented systems, *i.e.*, durable systems capable of withstanding repeated use.[10]

80102 Drug confirmation, each procedure[11] – This code is used for qualitative confirmation of drug testing and is billed for each procedure necessary for confirmation.[12] Anthem Blue Cross Blue Shield provides the following commentary on the use of 80102:

> This test may be requested as drug screen confirmation. It is performed when the initial drug screen (**80100 - 80101**) is positive. Confirmatory tests must be both

[4] Anthem Blue Cross Blue Shield, *Testing*, http://www.anthem.com/painmanagement/testing.html (last accessed April 12, 2013).
[5] American Medical Association Current Procedural Terminology 2012.
[6] Codapedia.
[7] CMS Manual System, *Transmittal 653*.
[8] Anthem Blue Cross Blue Shield.
[9] Centers for Medicare & Medicaid Services, *New Clinical Laboratory Fee Schedule Test Codes And Preliminary Payment Determinations*, 2011.
[10] CMS, *MLN Matters Number: SE1105.*
[11] American Medical Association Current Procedural Terminology 2012.
[12] Neighborhood Health Plan Provider Payment Guidelines, *Urine Drug Testing*, http://www.nhp.org/PDFs/Providers/UrineDrugTestingPaymentGuidelines.pdf (last accessed April 12, 2013).

> sensitive and specific and involve a different technique than the initial screen. For example, if the initial screen is performed by thin layer chromatography identifying a spot on the chromatogram that is the right color and in the right place to be consistent with a particular drug, it is confirmed with a more specific method, like high performance liquid chromatography (HPLC), gas chromatography-mass spectrometry (GC-MS), or immunoassay. If the drug suspected is a barbiturate, for example, a confirmatory HPLC method might be done to prove that the compound had the correct retention time, etc., and to identify it exactly as a particular barbiturate. This would be reported with **80102**.[13]
>
> Includes: Qualitative test for drugs or drug classes such as those listed above

Novitas Solutions published a local coverage determination, LCD L32050 – Qualitative Drug Testing, in which it included a similar, but slightly modified, criteria for the use of 80102:

> Confirmation of drug testing (*80102)* is indicated when the result of the drug test is different than that suggested by the patient's medical history, clinical presentation or patient's own statement AND there is a positive inconsistent finding from the previously performed qualitative test. This test may also be used, when the coverage criteria of the policy are met AND there is no qualitative test available, locally and/or commercially, as may be the case for certain synthetic or semi-synthetic opioids. Frequent use of this code will be monitored for appropriateness.[14]

Codapedia provides the following similar description on the use of 80102:

> Confirmation of drug testing (80102) is indicated when (1) the results of the qualitative screen are presumptively positive or (2) results of the qualitative screen are negative and this negative finding is inconsistent with the patient's medical history. This test may also be used, when the coverage criteria of the policy are met AND there is no qualitative test available, locally and/or commercially, as may be the case for certain synthetic or semi- synthetic opioids.[15]

Unlike Anthem and Novitas Solutions, however, Codapedia distinguishes between a drug test and a drug screen, allowing greater discretion for confirmation of drug screens:

> Confirmation of drug screens (80102) is indicated when the result of the drug screen is different than that suggested by the patient's medical history, clinical presentation or patient's own statement.

CPT 80104 Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure[16] – This code is used to report a urine drug screen performed using a multi-plexed method for 2-15 drugs or drug classes, *e.g.*, a multi-drug screening kit.

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[13] Anthem Blue Cross Blue Shield.
[14] Novitas Solutions, *LCD L32050 – Qualitative Drug Testing*, Nov. 11, 2011, https://www.novitas-solutions.com/policy/mac-ab/l32050-r1.html (last accessed April 12, 2013).
[15] Codapedia.
[16] American Medical Association Current Procedural Terminology 2012.

This code was implemented in 2011 and utilizes the "QW" modifier for CLIA-waived tests. These tests include multiplex screening kits, urine cups, test cards, test strips, etc.[17] This code can be used once for each kit regardless of the number of drugs tested.[18] [19]

Anthem Blue Cross Blue Shield provided the following commentary on 80104:

> In **80104**, a number of different methods are available to screen for qualitative, non-chromatographic, multiple drug class assays, including multiplexed screening kits, urine cups, test cards, or test strips. Positive tests are always confirmed with a second method. Specimen type varies.

G0434 Drug screen, other than chromatographic; any number of drug classes, by clia waived test or moderate complexity test, per patient encounter – This is code is the Medicare equivalent to 80104 and is used for reporting very simple testing methods such as dipsticks, cups, cassettes, and cards that are interpreted visually using a non-instrumented device. Laboratories with a CLIA waiver should use the QW modifier.[20]

The Medicare regulations require that diagnostic testing performed by a laboratory must be ordered by the physician who is treating the beneficiary, meaning the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. The Medicare regulations specifically state that, "[t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary[.]"[21] For diagnostic laboratory tests, the regulations require the ordering physician to "maintain documentation of medical necessity in the beneficiary's medical record."[22] In order for laboratory to bill Medicare for testing performed for a beneficiary, "[a]ll procedures performed by the (independent diagnostic testing facility) must be specifically ordered in writing by the physician who is treating the beneficiary, that is, the physician who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."[23]

Scenario 1:

In Scenario 1, the clinic is performing an initial point-of-care urine drug screen. This screen is appropriately billed under the codes 80104 for commercial payers and G0434 for Medicare. The "QW" modifier should be used to designate the screen as CLIA-waived. When the sample is sent to the lab, the purpose for the ordered test, as documented by the

[17] Practice Management Planz, LLC, *Medical Billing CPT Urine Screen Codes*, Saturday May 19, 2012. http://practicemanagementplanz.blogspot.com/2012/05/medical-billing-cpt-urine-screen-codes.html (last accessed April 12, 2013).
[18] Codapedia.
[19] HealthPlan, *URINE DRUG TESTING (UDT) Coverage and Reimbursement Guidelines*, June 2012, http://www.healthplan.org/pdf/UrineDrugTesting.pdf (last accessed April 12, 2013).
[20] CMS, *MLN Matters Number: SE1105.*
[21] 42 C.F.R. §410.32(a).
[22] 42 C.F.R. §410.32(d)(2)(i).
[23] 42 C.F.R. §410.33(d).

ordering physician, is the determining factor in the selection of the code.

In Scenario 1, the lab is only sent samples when the point-of-care screen is positive for non-prescribed drugs or negative for prescribed drugs. The Medicare regulations require that the physician document the medical necessity for each test performed and limit the lab to billing only for those tests that are ordered by the physician. In this case, the reason for the diagnostic test appears to be limited to confirming the results of the point-of-care test. For that reason, the lab would similarly be limited to confirmation code, 80102 (and corresponding quantification codes), when doing its test on the sample. According to Novitas Solutions, another indication for CPT 80102 is when the preliminary test is not able to detect a specific drug, *e.g.*, Suboxone. In that case, because this is an initial qualitative test, non-chromatographic, for the substance, the initial test should be billed using the 80101 or G0431 code.

According to the guidance, confirmation is clearly indicated when the result of the initial screen is positive. However, the question of when confirmation testing is indicated varies based on the guidance. According to Codapedia, confirmation testing is indicated to confirm a positive result or to confirm a negative when the negative result is inconsistent with the patient's history. Similarly, on a urine drug screen, Codapedia's guidelines permit confirmation for any unexpected result. However, Anthem only indicates that confirmation is appropriate when the initial test result is positive, not distinguishing between a test and a screen. Similarly, Novitis Solutions indicates that confirmation is appropriate when the qualitative test, not screen, result is inconsistent with the patient's history AND "there is a positive inconsistent finding from the previously performed qualitative test." Accordingly, the use of 80102 may be different based on the payer. Notwithstanding the variability in the guidance, when a point-of-care drug screen is used initially, *i.e.*, a non-instrumented method with higher cut-off levels, and the results are inconsistent with the patient's medical history or the patient's own statement, if the physician documents the medical necessity for performing the confirmation, the use of 80102 to confirm more than just the positive results may be supported. However, even in that situation, if the physician requested all drugs to be included, because the point-of-care test was used to do the initial screen, the order would be limited to confirmation and not an initial, qualitative, instrumented urine drug test.

If, on the other hand, the physician is routinely sending samples to the laboratory with an order for qualitative immunoassay testing using an instrumented method (presumably to provide a more accurate result from an instrumented testing method than can be provided from a point-of-care cup) and confirmation of any positive results, then the laboratory is performing an initial test. As such, the laboratory would then perform the instrumented qualitative testing and bill for that test under CPT 80101 for commercial payers and G0431 for Medicare. In such a case, any positive results from the initial qualitative test performed by the laboratory could be confirmed under CPT 80102 (and corresponding quantification codes). There is no solid guidance for confirming negative results from a qualitative test billed under CPT 80101. However, if the physician were to determine that it is medically necessary to confirm negative results and the physician can document such necessity, then it could be appropriate to bill the confirmation code, CPT 80102 (and corresponding

quantification codes).

Therefore, in Scenario 1, the laboratory should only be billing the 80102 code (and quantification codes) for the samples it is sent because the clinic is only sending samples to confirm the initial point-of-care test. Unless the physician is specifically requesting an initial test be performed on the sample and documenting the medical necessity for that test, the laboratory has no order to permit the initial test. Moreover, because only samples with an unexpected outcome are sent, there is no clear medically necessary reason why initial testing should be performed by the laboratory on only these samples.

Scenario 2:

In Scenario 2, the laboratory is confirming all 10 drugs included in the point-of-care screen performed by the clinic. As with Scenario 1, the laboratory will be limited by the physician's order. If the result of the point-of-care screen is positive, then confirmation testing billed under CPT 80102 is appropriate. If the results are negative, but expected, there is no guidance to support confirmation of the expected results. However, if the physician has reason to question the point-of-care results and has documented the reason for the question, *e.g.*, cut-off levels higher than desired, then obtaining confirmation of all 10 drugs may be medically necessary. In that case, the laboratory could bill for confirmation using 80102 (and corresponding quantification codes).

Confirmation may be appropriate beyond the limited indication from Anthem and Novitis Solutions for only positive results. Because the stated indications for confirmation testing from Anthem and Novitis are limited to positive results, patient care can be negatively impacted. For example, limiting confirmation to only positive results overlooks the possibility that the point of care test provided a false or unexpected negative report for a specific drug. In some cases, a patient may have been prescribed a drug and the patient may report a recent intake of the drug but the qualitative test is negative for the drug. This could be due to an inaccurate report from the patient, false negative from the qualitative test, or other metabolic factors. In another example, a patient may have a recent history of taking a drug that is initially tested, but returns a negative result. In either example, the failure to perform confirmation testing could lead to a dangerous reliance on the initial qualitative negative test result and could lead to an inappropriate or hazardous action by the prescribing practitioner, such as discharge, or continuation or discontinuation of the prescribed medication. For that reason, the broader application of 80102 offered by Codapedia may be clinically indicated and more appropriate than the other interpretations.

Therefore, the confirmation code 80102 should only be used when the laboratory is confirming the unexpected results as ordered by the physician unless the physician specifically orders and documents medical necessity for confirming all 10 drugs in the initial screen. Unfortunately, even with the physician's order, some payers may reject the claim for confirmation of all 10 drugs. The best course of action for the laboratory to take is to collect data comparing the results of the point-of-care test to the results of the laboratory tests (including confirmation). This data can be used to empirically

demonstrate that confirmation is medically necessary to accurately determine the presence or absence of tested drugs in the patient.