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MLN Matters® Number: SE1105
Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

Medicare Drug Screen Testing

Provider Types Affected

This article is for clinical laboratories billing Medicare Carriers, Fiscal Intermediaries (FIs), or Part A/B Medicare Administrative Contractors (A/B MACs).

Provider Action Needed

This article describes how clinical diagnostic laboratories should bill for certain types of tests that are covered under Medicare and paid based on the Clinical Laboratory Fee Schedule (CLFS). Specifically, the article addresses the billing of two CLFS Healthcare Common Procedure Coding System (HCPCS) test codes - G0431 (Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter) and G0434 (Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter) - beginning January 1, 2011. HCPCS code G0434 is new for Calendar Year (CY) 2011. Please be certain that your billing staffs are aware of these changes.

Background

Each year, the Centers for Medicare and Medicaid Services (CMS) hosts an Annual Public Meeting to discuss test codes that have been established by the

Common Procedural Terminology (CPT) committee, and may be covered by Medicare, and paid based on the CLFS in the upcoming calendar year.

During the 2009 Annual Public Meeting, CMS introduced two new CY 2010 HCPCS codes for reporting qualitative drug screen testing - G0430 (Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure), which was reported once per procedure and G0431, which is reported once per drug class. (Please note that G0430 was deleted beginning January 1, 2011). After the introduction of these codes, CMS determined that it needed to further refine these drug screen testing codes and revise the descriptors to avoid unnecessary or excessive utilization of code G0431 for relatively simple point-of-care tests that screen for multiple substances. During the 2010 Annual Public Meeting, CMS introduced code G0434 to report qualitative point-of-care drug screen testing and to limit billing for such testing to one time per patient encounter. CMS also revised the descriptor for code G0431 to emphasize that the code describes all screening for multiple drug classes per patient encounter.

CMS recognizes that there could be rare instances where a patient requires multiple, medically necessary screening tests for drugs of abuse to be performed in a single day. For instance, a patient seen in an outpatient pain clinic who requires a drug screening test as a part of his/her care is later admitted to an emergency department after an automobile accident and requires another medically necessary drug screening test. The use of "per patient encounter" will allow payment to be made for this rare circumstance.

Effective January 1, 2011, CMS will utilize two test codes to report drug screen testing:

- G0434 (Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter) will be 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). This code is also 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), keeping the following points in mind:
    - G0434 includes qualitative drug screen tests that are waived under CLIA as well as dipsticks, cups, cards, cassettes, etc, that are not CLIA waived.

  - Laboratories with a CLIA certificate of waiver may perform only those tests cleared by the Food and Drug Administration (FDA) as waived tests. Laboratories with a CLIA certificate of waiver shall bill using the QW modifier.
  - Laboratories with a CLIA certificate of compliance or accreditation may perform non-waived tests. Laboratories with a CLIA certificate of compliance or accreditation do not append the QW modifier to claim lines.
  - Only one unit of service for code G0434 can be billed per patient encounter regardless of the number of drug classes tested and irrespective of the use or presence of the QW modifier on claim lines.

- G0431 (Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter) will be used 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 patient. Note that the descriptor has been revised for CY 2011. This code may only be reported if the drug screen test(s) is classified as CLIA high complexity test(s) with the following restrictions:
  - G0431 may only be reported when tests are performed using instrumented systems (i.e., durable systems capable of withstanding repeated use).
  - CLIA waived tests and comparable non-waived tests may not be reported under test code G0431; they must be reported under test code G0434.
  - CLIA moderate complexity tests should be reported under test code G0434 with one (1) Unit of Service (UOS).
  - G0431 may only be reported once per patient encounter.
  - Laboratories billing G0431 must not append the QW modifier to claim lines.

CMS has also made changes to the following related tests:

- G0430 was deleted as of January 1, 2011;
- Code 80100 has not been priced under Medicare effective January 1, 2011; and
- Code 80104 has not been priced under Medicare effective January 1, 2011.

Also, please remember that code 80101 has not been priced under Medicare since July 1, 2010.

Additional Information

CMS publishes a list of test products with CLIA waived status each quarter. Providers may use this list to determine if a particular test product can be appropriately performed by a laboratory with a CLIA waiver and is eligible to be billed using the QW modifier. Concerning CLIA moderate or high complexity tests, providers should confirm a test's status with the test manufacturer.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found at http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS website.

Additional information concerning the CLFS can be found at http://www.cms.hhs.gov/ClinicalLabFeeSched on the CMS website.

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