Billing and Coding Guidelines

Contractor Name
Wisconsin Physicians Service Insurance Corporation

Contractor Number
00951, 00952, 00954, 05101, 
05201, 05301, 05401, 05102, 
05202, 05302, 05402, 52280, 
08101, 08102, 08201, 08202

LCD Title
Qualitative Drug Testing

Contractor's Determination Number
PATH - 035

Primary Geographic Jurisdiction

Carrier B: Wisconsin, Illinois, Minnesota


MAC A/B: Iowa, Missouri, Nebraska, Kansas
MAC A/B: Indiana, Michigan

Revision Effective Date

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CMS National Coverage
Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.
Code of Federal Regulations (CFR) Title 42, Part 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) 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. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see section 411.15 (k)(1) of this chapter). Medicare regulations at 42 CFR 410.32(a) state in part, that “…diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, 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.” Thus, except where other uses have been authorized by statute, Medicare does not cover diagnostic testing used for routine screening or surveillance.

CMS Internet-Only Manual (IOM) Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 130.6, Treatment of drug abuse

CMS Transmittal 653, Change Request 6852, Clinical Laboratory Fee Schedule (CLFS)- Special Instructions for Specific Test Codes (CPT CODE 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW and G0431QW)

CMS Transmittal 1905, Change Request 6800, February New Waived Tests

Coding Guidelines:

Part A Program Instructions:

A. Reasons for Denial

1. All other indications not listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of the related LCD.
2. Service(s) rendered is not consistent with accepted standards of medical practice.
3. The medical record does not verify that the service described by the CPT/HCPCS code was provided.
4. The service does not follow the guidelines of the related LCD.
5. The service is considered:
   a. Investigational;
   b. For routine screening;
   c. A program exclusion;
   d. Otherwise not covered;
   e. Never medically necessary.

B. Coding Guidelines

1. Refer to the Correct Coding Initiative (CCI) for correct coding guidelines and specific applicable code combinations prior to billing Medicare. Provisions of this LCD do not take precedence over CCI edits.
2. Diagnosis (es) must be present on any claim submitted and coded to the highest level of specificity for that date of service.
3. Qualitative drug testing codes (G0431 & G0434) should only be billed once per patient encounter as indicated by the code description and should only be billed at one unit.
4. All coverage criteria must be met before Medicare can reimburse this service.

5. When billing for this service in a non-covered situation (e.g., does not meet indications of the related LCD), use the appropriate modifier (see below). To bill the patient for services that are not covered (investigational/experimental or not reasonable and necessary) will generally require an Advance Beneficiary Notice (ABN) be obtained before the service is rendered.

6. **Modifiers:**

   **GA**: Waiver of liability statement issued as required by payer policy, individual case. (Use for patients who do not meet the covered indications and limitations of this LCD and for whom an ABN is on file.) (ABN does not have to be submitted but must be made available upon request.)

   **GZ**: Waiver of liability statement is not on file. (Use for patients who do not meet the covered indications and limitations of this LCD and who did **not** sign an ABN.)

   **GY**: Item or service is statutorily excluded or does not meet the definition of any Medicare benefit.

**Specific coding guidelines for this policy:**

For dates of service on, or after 04/01/2011, append modifier **QW** to G0434 to indicate a CLIA waived test.

For dates of service on or after 04/01/2011, code G0431QW will be denied for claims submitted by facilities with a valid, current CLIA certificate of waiver. Code G0431 describes a high complexity test, and should not be reported with a QW modifier; the QW modifier indicates a Clinical Laboratory Improvement Amendments (CLIA) waived test.

C. **Hospital inpatient claims:**

1. The hospital should report the patient's principal diagnosis in Form Locator (FL) 67 of the UB-04. The principal diagnosis is the condition established after study to be chiefly responsible for this admission.

2. The hospital enters ICD-9-CM codes for up to eight additional conditions in FLs 67A–67Q if they coexisted at the time of admission or developed subsequently and had an effect upon the treatment or the length of stay. It may not duplicate the principal diagnosis listed in FL 67.

3. For inpatient hospital claims, the admitting diagnosis is required and should be recorded in FL 69. (See CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 25, Section 75 for additional instructions.)

**This LCD does not apply to acute inpatient claims.**

D. **Hospital outpatient claims:**

1. The hospital should report the full ICD-9-CM code for the diagnosis shown to be chiefly responsible for the outpatient services in FL 67. If no definitive diagnosis is made during the outpatient evaluation, the patient's symptom is reported. If the patient arrives without a referring diagnosis, symptom or complaint, the provider should report an ICD-9-CM code for
Persons Without Reported Diagnosis Encountered During Examination and Investigation of Individuals and Populations (V70–V82).

2. The hospital enters the full ICD-9-CM codes in FLs 67A–67Q for up to eight other diagnoses that coexisted in addition to the diagnosis reported in FL 67.

3. For dates of service on or after January 1, 2010, append modifier QW to CPT codes G0430 and G0431 to indicate a Clinical Laboratory Improvement Amendments (CLIA) waived test.

4. For dates of service on or after January 1, 2011, append modifier QW to CPT code G0434 to indicate a CLIA waived test.

5. For services requiring a referring/ordering physician, the name and National Provider Identifier (NPI) of the referring/ordering physician must be reported on the claim.

6. A claim submitted without a valid ICD-9-CM diagnosis code will be returned to the provider as an incomplete claim under Section 1833(e) of the Social Security Act. The diagnosis code(s) must best describe the patient’s condition for which the service was performed.

7. For diagnostic tests, report the result of the test if known; otherwise, the symptoms prompting the performance of the test should be reported.

8. See also “Bill Type” and “Revenue Code” sections in the NCD.

**Part B Program Instructions:**

*A. Reasons for Denial*

1. All other indications not listed in the “Indications and Limitations of Coverage” section of the related LCD.
2. Service(s) rendered is not consistent with accepted standards of medical practice.
3. The medical record does not verify that the service described by the CPT/HCPCS code was provided.
4. The service does not follow the guidelines of the related LCD.
5. The service is considered:
   a. Investigational.
   b. For routine screening.
   c. A program exclusion.
   d. Otherwise not covered.
   e. Never medically necessary.

*B. Coding Guidelines*

1. Refer to the Correct Coding Initiative (CCI) for correct coding guidelines and specific applicable code combinations prior to billing Medicare. Provisions of this LCD do not take precedence over CCI edits.
2. Diagnosis (es) must be present on any claim submitted and coded to the highest level of specificity for that date of service.
3. To report these services, use the appropriate HCPCS or CPT code(s).
4. All coverage criteria must be met before Medicare can reimburse this service.
5. When billing for this service in a non-covered situation (e.g., does not meet indications of the related LCD), use the appropriate modifier (see below). To bill the patient for services that are not covered (investigational/experimental or not reasonable and necessary) will generally require an Advance Beneficiary Notice (ABN) be obtained before the service is rendered.
6. **For claims submitted to the carrier or Part B MAC:**
   All services/procedures performed on the same day for the same beneficiary by the physician/provider should be billed on the same claim. Qualitative drug testing codes (G0431 & G0434) should only be billed once per patient encounter as indicated by the code description and should only be billed at one unit.

   Claims for qualitative drug screening services are payable under Medicare Part B in the following places of service: office (11), urgent care (20), independent clinic (49), federally qualified health center (freestanding) (50), rural health clinic (freestanding) (72), and independent laboratory (81).

7. **Modifiers:**
   **GA:** Waiver of liability statement issued as required by payer policy, individual case. Use this modifier for patients who do not meet the covered indications and limitations of this LCD and for whom an ABN is on file. (ABN does not have to be submitted but must be made available upon request.)

   **GZ:** Waiver of liability statement is not on file. Use this modifier for patients who do not meet the covered indications and limitations of this LCD and who did **not** sign an ABN.

   **GY:** Item or service is statutorily excluded or does not meet the definition of any Medicare benefit.

**Other Comments**
1. Limitation of liability and refund requirements apply when denials are likely, whether based on medical necessity or other coverage reasons. The provider/supplier must notify the beneficiary in writing, prior to rendering the service, if the provider/supplier is aware that the test, item or procedure may not be covered by Medicare. The limitation of liability and refund requirements do not apply when the test, item or procedure is statutorily excluded, has no Medicare benefit category or is rendered for screening purposes.

2. Bill Type codes only apply to providers who bill these services to the fiscal intermediary (Part A MAC). Bill Type codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier or Part B MAC.

3. For dates of service prior to April 1, 2010, FQHC services should be reported with Bill Type 73X. For dates of service on or after April 1, 2010, Bill Type 77X should be used to report FQHC services.

**This LCD does not apply to acute inpatient claims.**

**Date Published**
06/01/2012

**Revision History, Explanation/Number**

**Notes:**
Italicized lettering (font) indicates CMS wording

* An asterisk indicates most recent publishing or revision
NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.