

# Quantitative and Qualitative Drug Testing

Reimbursement Policy ID: RPC.0039.0100

Recent review date: 05/2024

Next review date: 05/2025

*Keystone First reimbursement policies and their resulting edits are based on guidelines from established industry sources, such as the Centers for Medicare and Medicaid Services (CMS), the American Medical Association (AMA), state and federal regulatory agencies, and medical specialty professional societies. Reimbursement policies are intended as a general reference and do not constitute a contract or other guarantee of payment. Keystone First may use reasonable discretion in interpreting and applying its policies to services provided in a particular case and may modify its policies at any time.*

*In making claim payment determinations, the health plan also uses coding terminology and methodologies based on accepted industry standards, including Current Procedural Terminology (CPT); the Healthcare Common Procedure Coding System (HCPCS); and the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), and other relevant sources. Other factors that may affect payment include medical record documentation, legislative or regulatory mandates, a provider's contract, a member's eligibility in receiving covered services, submission of clean claims, and other health plan policies, and other relevant factors. These factors may supplement, modify, or in some cases supersede reimbursement policies.*

*This reimbursement policy applies to all healthcare services billed on a CMS-1500 forms or its electronic equivalent and, when specified, billed on UB-04 forms or its electronic equivalent.*

## Policy Overview

This policy addresses reimbursement limitations for quantitative and qualitative drug testing.

Urine drug testing is a diagnostic and therapeutic tool that is useful for patient care and monitoring of adherence to a controlled substance treatment regimen, (e.g., for chronic noncancer pain or to identify drug misuse or addiction prior to starting or during treatment with controlled substances).

Quantitative tests indicate drug levels in the urine. A quantitative drug test can estimate the amount of drug present in a specimen.

Qualitative tests indicate the presence or absence of a specific substance. The results are not expressed numerically, but in qualitative terms such as positive, negative, reactive, nonreactive, normal, or abnormal.

Drug screen testing includes:

- Presumptive drug class screening is used to identify possible use or non-use of a drug or drug class. It is done on a random basis or for cause, the latter of which should be documented in the medical record.
- Definitive drug class screening is comprised of qualitative (drug is present or absent), semi-quantitative, or quantitative (measured) tests to identify possible use or non-use of a specific drug. Typically

therapeutic drug assay procedures are quantitative tests. Definitive testing may be used to detect specific substances not identified by presumptive methods and to refine the accuracy of the test results when the results are needed to inform clinical decisions.

## Exceptions

N/A

## Reimbursement Guidelines

Outpatient drug testing for drugs of abuse is reimbursable for confirmatory/definitive (quantitative) testing for a specific drug(s) when members meet the criteria in A, B, or C:

- A. The member has a documented history or suspicion of illicit or prescription drug use or noncompliance or a high probability of non-adherence to a prescribed drug regimen documented in the medical record, and all of the following conditions are met:
  - Preliminary/presumptive drug test has been previously performed, unless no reliable test is available; and
  - The findings from that preliminary/presumptive (qualitative) test (either positive or negative) are either:
    - Inconsistent with the expected results as suggested by the member's medical history, clinical presentation, and/or member's own statement after a detailed discussion about their recent medication and drug use; or
    - Consistent with the clinical scenario but drug class-specific assays are needed to identify the precise drug(s) that resulted in the positive test result.
  - Resolving the inconsistency is essential to the ongoing care of the member, and
  - The requested confirmatory/definitive test is only for the specific drug(s) or number of drug classes for which preliminary analysis has yielded unexpected results.
- B. The provider expects the presumptive test to be positive, i.e., the member reports recent use, information regarding specific substance and/or quantity is desired, and there are established benchmarks for clinical decision making based on quantitative levels.
- C. The request is for a serum therapeutic drug level in relation to the medical treatment of a disease or condition (e.g., phenobarbital level in the treatment of seizures).

Urine drug testing is not reimbursable if provided for reasons that include, but are not limited to, the following:

- A. As a:
  - Condition of employment or pre-employment purposes (e.g., as a prerequisite for employment or a requirement for continuation of employment).
  - Condition of participation in school or community athletic or extracurricular activities or programs.
  - Screening tool for medico-legal purposes such as court-ordered drug screening (unless required by state regulations).
  - Screening tool in asymptomatic patients.
- B. As a component of a routine physical/medical examination (e.g., enrollment in school or enrollment in the military).
- C. As a component of a medical examination for any other administrative purposes not listed above (e.g., for purposes of marriage licensure or insurance eligibility).

- D. Same-day screening of drug metabolites in both a blood and urine specimen by either preliminary or confirmatory/definitive analyses.
- E. Specimen validity/adulteration testing, as this is considered part of the laboratory quality control practices.

When a definitive drug testing code for “any number of drug classes” (see code description below) is reported with a definitive drug testing code for a specific number of drug classes, only the “any number of drug classes” definitive drug testing code (G0659) will be eligible for reimbursement. When a definitive drug testing code and a presumptive drug testing code using instrumented chemistry analyzers (80307) are reported on the same date of service for the same member by the same independent clinical laboratory, the Plan does not allow separate reimbursement for the definitive drug testing code. Presumptive drug testing (80305-80307) will be denied when billed more than one combined unit per day.

#### Applicable codes

Code	Description
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only. Includes sample validation when performed per date of service.
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation. Includes sample validation when performed, per date of service.
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA], chromatography [e.g., GC, HPLC], and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC/MS, GC/MS/MS, LC/MS, LC/MS/MS, LDTD, MALDI, TOF)). Includes sample validation when performed, per date of service.
G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays [e.g., IA, EIA, ELISA, EMIT, FPIA] and enzymatic methods [e.g., alcohol dehydrogenase]), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences, and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources. Includes specimen validity testing, per day; 1 —7 drug class(es), including metabolite(s) if performed.
G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays [e.g., IA, EIA, ELISA, EMIT, FPIA] and enzymatic methods [e.g., alcohol dehydrogenase]), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences, and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources. Includes specimen validity testing, per day; 8 —14 drug class(es), including metabolite(s) if performed.
G0482	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays [e.g., IA, EIA, ELISA,

	EMIT, FPIA] and enzymatic methods [e.g., alcohol dehydrogenase]), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences, and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources. Includes specimen validity testing, per day; 15 —21 drug class(es), including metabolite(s) if performed.
G0483	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, reimbursable but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays [e.g., IA, EIA, ELISA, EMIT, FPIA] and enzymatic methods [e.g., alcohol dehydrogenase]), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences, and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources. Includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed.
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources. Includes specimen validity testing, per day, any number of drug classes.

Independent Laboratory providers must append modifier 90 to all reported laboratory services. The place of service (POS) reported on the claim should be the location where the specimen was obtained. For example, a specimen removed from a hospitalized patient and sent to the laboratory would be reported with POS 21 or 22; a sample taken at a physician's office and referred to the laboratory would be reported with POS 11. If the Independent or Reference Laboratory did the blood drawing in its own setting, it should report POS 81.

## Definitions

### Clinical Laboratories Improvement Amendments (CLIA)

Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing and require clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing.

### Independent laboratory

A laboratory certified to perform diagnostic and/or clinical tests independent of an institution or a provider's office. It must meet federal and state requirements for certification and proficiency testing under the Clinical Laboratories Improvement Amendment (CLIA).

### Presumptive drug testing

Presumptive drug tests are used to detect the presence or absence of a drug or drug class; they do not typically indicate a specific level of drug but rather give a positive or negative result.

### Definitive drug testing

Definitive drug tests are used to identify specific drugs/metabolites present.

## Edit Sources

- I. Current Procedural Terminology (CPT).
- II. Healthcare Common Procedure Coding System (HCPCS).
- III. International Classification of Diseases, 10<sup>th</sup> Revision, Clinical Modification (ICD-10-CM), and associated publications and services.
- IV. Centers for Medicare and Medicaid Services (CMS).
- V. The National Correct Coding Initiative (NCCI)
- VI. file:///C:/Users/pt08810/Downloads/PA.CP.MP.50%20Outpatient%20Testing%20for%20Drugs%20of%20Abuse\_9.2018.pdf
- VII. Pennsylvania Medicaid Fee Schedule(s).

## Attachments

N/A

## Associated Policies

N/A

## Policy History

05/2024	Reimbursement Policy Committee Approval
04/2024	Revised preamble
08/2023	Removal of Policy Implemented by Keystone First from Policy History section
01/2023	Template Revised <ul style="list-style-type: none"><li>• Revised preamble</li><li>• Removal of Applicable Claim Types table</li><li>• Coding section renamed to Reimbursement Guidelines</li><li>• Added Associated Policies section</li></ul>