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OVERVIEW

This policy documents the criteria and documentation requirements for immunoassay (IA) testing (also called presumptive or qualitative testing, screening) and definitive testing (also called confirmatory or quantitative testing) drug toxicology tests (Hereafter called “presumptive” and “definitive” drug testing).

This policy is applicable to Commercial Products only. For BlueCHiP for Medicare, see related policy for BlueCHiP for Medicare National and Local Coverage Determinations.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products

Blue Cross and Blue Shield of Rhode Island (BCBSRI) follows the Centers for Medicare and Medicaid Services (CMS) coverage guidelines for Urine Drug Testing.

Presumptive Urine Drug Testing (UDT) may be ordered by the clinician caring for a beneficiary when it is necessary to rapidly obtain and/or integrate results into clinical assessment and treatment decisions.

In addition, BCBSRI considers Presumptive testing not eligible for reimbursement as described below:

- Testing as required for or as part of participation in an inpatient or intermediate care substance use disorder program
- Routine testing (i.e., testing at every visit)
- Testing ordered by or for third parties for the sole purpose of meeting the requirements of a third party

Definitive UDT is reasonable and necessary for the following circumstances:

- Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT;
- Definitively identify specific drugs in a large family of drugs;
- Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs;
- Identify drugs when a definitive concentration of a drug is needed to guide management (e.g., is continuation of THC use according to a treatment plan);
- Identify a negative, or confirm a positive, presumptive UDT result that is inconsistent with a patient’s self-report, presentation, medical history, or current prescribed pain medication plan;
- Rule out an error as the cause of a presumptive UDT result;
- Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances; and
- Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.

Definitive UDT may be reasonable and necessary based on patient specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions.

Physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders and rationale should be individualized based on clinical history and risk assessment, and must be documented in the medical record.

Frequency of Presumptive UDT for Substance Use Disorder (SUD):

The testing frequency must meet medical necessity and be documented in the clinician's medical record.

- For patients with 0 to 30 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 presumptive UDT per week. More than 3 presumptive panels in one week is not reasonable and necessary and not allowed.
- For patients with 31 to 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT per week. More than 3 presumptive UDT in one week is not reasonable and necessary and not allowed.

Frequency of Definitive UDT for SUD:

Depending on the patient's specific substance use history, definitive UDT to accurately determine the specific drugs in the patient's system may be necessary. Definitive testing may be ordered when accurate and reliable results are necessary to integrate treatment decisions and clinical assessment. The frequency and the rationale for definitive UDT must be documented in the patient's medical record.

- For patients with 0 to 30 consecutive days of abstinence, definitive UDT is expected at a frequency not to exceed 1 physician-directed testing profile in one week. More than 1 physician-directed testing profile in one week is not reasonable and necessary and is not allowed.
- For patients with 31 to 90 consecutive days of abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in one month. More than 3 UDT in one month is not reasonable and necessary and is not allowed.
- For patients with > 90 day of consecutive abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in three months. More than 3 definitive UDT in 3 months is not reasonable and necessary and is not allowed.

Medical Necessity Guidance:

Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements:

- Patient history, physical examination and previous laboratory findings;
- Current treatment plan;
- Prescribed medication(s)

Other Covered Services

1. Reflex Testing by Reference Laboratories – since reference laboratories do not have access to patient-specific data, reflex testing under the following circumstances is reasonable and necessary:

- a. To verify a presumptive positive UDT using definitive methods that include, but are not limited to GC-MS or LC-MS/MS before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or
- b. To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician.

2. Direct to definitive UDT without a presumptive UDT is reasonable and necessary, when individualized for a particular patient.
3. Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:
 - a. The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
 - b. Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or
 - c. To rule out an error as the cause of a negative presumptive UDT result.
4. Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan.

Services considered not medically necessary:

- Blanket Orders, defined as a test request that is not for a specific patient; rather, it is an identical order for all patients in a clinician's practice without individualized decision making at every visit.
- Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result).
- Routine standing orders for all patients in a physician's practice are not reasonable and necessary. Standing orders is defined as a test request for a specific patient representing repetitive testing to monitor a condition or disease for a limited number of sequential visits; individualized orders for certain patients for pre-determined tests based on historical use, risk and community trend patient profiles; clinician can alter the standing order.
- It is not reasonable and necessary for a physician to perform presumptive Point of Care Testing (POCT) and order presumptive IA testing from a reference laboratory. In other words, payment will be made for one presumptive test result per patient per date of service regardless of the number of billing providers.
- It is not reasonable and necessary for a reference laboratory to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.
- IA testing, regardless of whether it is qualitative or semi-quantitative (numerical), may not be used to "confirm" or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods. Definitive UDT provides specific identification and/or quantification typically by GC-MS or LC-MS/MS.
- Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.
- UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges.
- Specimen Validity Testing - Urine specimen testing to ensure that it is consistent with normal human urine and has not been adulterated or substituted, may include, but is not limited to pH, specific gravity, oxidants and creatinine.

Medical records must document the medical necessity of billed services and must be made available to Blue Cross & Blue Shield of Rhode Island (BCBSRI) upon request.

COVERAGE

Benefits may vary. Please refer to the appropriate Benefit Booklet or Subscriber Agreement for applicable laboratory benefits/coverage.

BACKGROUND

Drug Testing Panels or Profiles

A. Presumptive UDT Panels

Presumptive UDT testing typically involves testing for multiple analytes based on the beneficiary's clinical history and risk assessment, and must be documented in the medical record.

A. Definitive UDT Panels

Physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record.

Specimen Type

Urine or oral fluid is the preferred biologic specimen for testing because of the ease of collection, storage, and cost effectiveness. UDT cannot detect the dosage of drug ingested/used, the time of use, or the means of delivery (intravenous vs. oral vs. inhaled). Detection time of a substance in urine is typically 1-3 days depending on the drug, rate of metabolism, and rate of excretion. Lipid-soluble drugs, such as marijuana, may remain in body fat and be detected upwards of a week or more.

Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:

- Patient history, physical examination, and previous laboratory findings
- Stage of treatment or recovery;
- Suspected abused substance;
- Substances that may present high risk for additive or synergistic interactions with prescribed medication (e.g., benzodiazepines, alcohol).

The patient's medical record must include an appropriate testing frequency based on the stage of screening, treatment, or recovery; the rationale for the drugs/drug classes ordered; and the results must be documented in the medical record and used to direct care.

CODING

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Note: It is incorrect to bill creatinine, pH, specific gravity, aldehyde, chromate, oxidase, or any other test for specimen validity testing in addition to the drug testing codes. The code descriptions for the codes below include sample validation, if performed.

The following CPT/HCPCS codes are covered when payment guidelines are met:

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 (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), 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 (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), 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 (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, 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, 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

The following CPT codes; CPT code range 80320 through 80377, 80184, 83992 are invalid for BlueCHiP for Medicare and Commercial products. As a result, they should not be used as they will be denied as “use alternate code”. BCBSRI requires claims for definitive testing to be filed with one of the appropriate HCPCS G codes listed above.

RELATED POLICIES

Behavioral Health Services Inpatient and Intermediate Levels of Care
BlueCHiP for Medicare National and Local Coverage Determinations
Proprietary Laboratory Analyses (PLA) Codes

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REFERENCES:

CMS.gov Centers for Medicare and Medicaid Services Local Coverage Determination (LCD):
Urine Drug Testing (L36037)

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