**APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

**DISCLAIMER**

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

**BACKGROUND**

Testing for drugs of abuse is performed to detect the use of prescription medications and illegal substances for the purpose of medical treatment. A presumptive test is used to determine the presence or absence of one or more drugs or drug classes. Confirmatory testing is an additional test which may be completed to verify the results of the presumptive drug tests through the identification of specific medications, substances or metabolites. CMS has experienced a dramatic increase in reimbursement for testing for drugs of abuse and has changed the coding system by which testing and screening is reimbursed for Medicare and Medicaid. A detailed description of WellCare’s drug screening/testing policy is below. As a general rule:
Drug testing should not routinely include a panel of all drugs of abuse.
• The test should be focused on the detection of specific drugs.
• The frequency of testing should be at the lowest level to detect the presence of drugs.
• Testing should be based on medical necessity and a complete clinical assessment of the individual’s risk potential for abuse and diversion, using a validated risk assessment interview or questionnaire.
• Periodic monitoring should be performed on a random basis.
• In the monitoring phase, the drug classes test should be tailored to the individual and include those drugs that are prescribed and common drugs of abuse. If testing for other drugs or drug classes is ordered, the provider must document the clinical rationale.
• Periodic monitoring addresses two potential risks:
  o Abuse and diversion of controlled medications; and
  o Abuse of illicit drugs or drugs not prescribed as part of a treatment plan and obtained from an undisclosed/unsanctioned source.

Testing frequency should be based in part on the validated risk assessment process and the potential that the patient will engage in medication-aberrant behavior (or illicit drug use behavior). Individuals assessed at a higher risk for medication misuse and illicit drug use may require more frequent testing than those assessed at a lower risk for such behavior. In the absence of specific symptoms of aberrant behavior or misuse, qualitative drug testing is only reasonable and necessary when titrated to patient risk potential.1

POSITION STATEMENT

Applicable To:
- Medicaid – All Markets, excluding Hawaii Behavioral Health (ZBH)
- Medicare – All Markets, excluding Hawaii Behavioral Health (ZBH)

Exclusions

Any of the following is sufficient criteria for exclusion from coverage:
- Confirmation or Quantitative testing is excluded from coverage if performed for forensic or legal purposes.
- Qualitative and Quantitative testing of blood and urine, saliva and blood or urine, or any multiple source specimens on the same date of service is excluded.
- Quantitative (or definitive) testing requires a positive screening test and shall be performed only for the drug class represented by the positive screening. It is otherwise excluded.
- Quantitative testing (or definitive) for negative screening results is excluded without written documentation of medical necessity.

The following services are not medically reasonable or necessary, and therefor are excluded from coverage:1,3
- Blanket orders
- Reflex definitive drug tests when presumptive testing is performed at point of care. The Provider may not need to order definitive testing (e.g., the patient admits to a particular drug and the clinician is satisfied that he or she knows everything he or she needs to know, or the immune assay (IA) cut-off is sufficiently low that the physician is comfortable with the test result).
- Routine standing orders for all patients in a physician’s practice. Physician-defined standing orders for predetermined drug panels according to specific patient profiles for a limited sequential period may be reasonable and necessary and must be documented in the patient’s medical record.
- Billing of individual definitive CPT codes when a comprehensive definitive drug testing panel (CDDP) is ordered.
- Direct to Definitive drug test without presumptive positive drug test; this practice encourages excessive and unnecessary testing.
- Confirmation/definitive identification of a presumptive drug test negative result except when a patient on prescribed medication should have had a presumptive positive result.
- Performing presumptive point of care testing (POCT) and ordering presumptive IA testing from a reference laboratory.
- Performing presumptive IA testing and ordering presumptive IA testing from a reference laboratory with or without reflex testing.
• Performing IA presumptive screening prior to a definitive testing without a specific physician’s order for the presumptive testing.
• IA testing, regardless of whether it is qualitative or semi-quantitative used to “confirm” or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other CLIA-waived methods. Semi-quantitative IA testing provides a presumptive test (numerical) result. Definitive UDT provides specific identification and/or quantification 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 including, but not limited to, pH, specific gravity, oxidants, creatinine.

In addition, drug testing is not covered in any of the following circumstances:
• Testing ordered by third parties (e.g., schools, courts, or employers) or requested by a provider for the sole purpose of meeting the requirements of a third party, except where required by law.
• Testing for residential monitoring.
• Routine urinalysis for confirmation of specimen integrity.
• As a condition for employment, participation in school or community activities (e.g., athletics, extra circular activities), or enrollment in a school or in the military;
• Court ordered drug testing;
• Forensic/criminal situations;
• Required drug testing in the school or work place;
• Administrative, or social service agency investigations, proceedings, or monitoring activities;
• Activities related to testing that do not have a clear role in treatment and decision making (negative or positive results);
• Divorce and/or child custody cases;
• Assessment for substances not identified initially;
• For residential monitoring purposes;
• Routine specimen collection and preparation for the purpose of clinical laboratory analysis.

Coverage

Presumptive urine drug testing (UDT) to verify compliance with treatment, identify undisclosed drug use or abuse, or evaluate aberrant* behavior is considered medically necessary beginning at the start of treatment, as part of a routine monitoring program for individuals who are:

A. Receiving treatment for chronic pain with prescription opioid or other potentially abused medications; OR
B. Undergoing treatment for, or monitoring for relapse of, opioid addiction or substance use disorder.

*Aberrant behavior includes, but is not limited to, lost prescriptions, repeated requests for early refills, and prescriptions from multiple providers, unauthorized dose escalation, and apparent intoxication.

Presumptive urine drug testing is also considered medically necessary for the following:

A. To assess an individual when clinical evaluation suggests use of non-prescribed medications or illegal substances; OR
B. On initial entrance into a pain management program or substance use disorder recovery program.

Definitive urine drug testing is considered medically necessary when all of the following criteria are met:

A. The presumptive urine drug testing was done for a medically necessary reason; AND
B. The presumptive test was negative for prescribed medications, positive for a prescription drug with abuse potential which was not prescribed, or positive for an illegal drug (for example, but not limited to methamphetamine or cocaine); AND
1. The specific definitive test(s) ordered are supported by documentation specifying the rationale for each quantitative test ordered; AND
2. Clinical documentation reflects how the results of the test(s) will be used to guide clinical care.

Definitive urine drug testing is considered medically necessary when ALL of the following criteria are met:

- Presumptive urine drug testing is medically necessary; AND
- Presumptive test was negative for prescribed medications, positive for a prescription drug with abuse potential which was not prescribed, or positive for an illegal drug (e.g., but not limited to methamphetamine or cocaine); AND
- Clinical documentation supports the rationale for each definitive test ordered; AND
- Clinical documentation justifies the reason for testing for each individual drug/metabolite on the ordered panel; AND
- Clinical documentation reflects how the results of the test(s) will be used to guide clinical care.

The use of blood samples as an alternative to urine for drug testing is considered medically necessary when the use of urine is not feasible (for example, when an individual has advanced kidney failure).

**Coding**

**Covered CPT Codes**

**Presumptive Drug Class Screening**

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 (e.g., utilizing immunoassay [e.g., 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 (e.g., utilizing immunoassay [e.g., 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 (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

**Definitive Drug Testing**

80320 Alcohols
80321 Alcohol biomarkers; 1 or 2
80322 Alcohol biomarkers; 3 or more
80323 Alkaloids, not otherwise specified
80324 Amphetamines; 1 or 2
80325 Amphetamines; 3 or 4
80326 Amphetamines; 5 or more
80327 Anabolic steroids; 1 or 2
80328 Anabolic steroids; 3 or more
80332 Antidepressants, serotonergic class; 1 or 2
80333 Antidepressants, serotonergic class; 3-5
80334 Antidepressants, serotonergic class; 6 or more
80335 Antidepressants, tricyclic and other cyclicals; 1 or 2
80336 Antidepressants, tricyclic and other cyclicals; 3-5
80337 Antidepressants, tricyclic and other cyclicals; 6 or more
80338 Antidepressants, not otherwise specified
80339 Antiepileptics, not otherwise specified; 1-3
80340 Antiepileptics, not otherwise specified; 4-6
80341 Antiepileptics, not otherwise specified; 7 or more
80342 Antipsychotics, not otherwise specified; 1-3
80343 Antipsychotics, not otherwise specified; 4-6
80344 Antipsychotics, not otherwise specified; 7 or more
80345 Barbiturates
80346 Benzodiazepines; 1-12
80347 Benzodiazepines; 13 or more
80348 Buprenorphine
80349 Cannabinoids, natural
80350 Cannabinoids, synthetic; 1-3
80351 Cannabinoids, synthetic; 4-6
80352 Cannabinoids, synthetic; 7 or more
80353 Cocaine
80354 Fentanyl
80355 Gabapentin, non-blood
80356 Heroin metabolite
80357 Ketamine and norketamine
80358 Methadone
80359 Methylendioxyamphetamine
80360 Methylphenidate
80361 Opiates, 1 or more
80362 Opioids and opiate analogs; 1 or 2
80363 Opioids and opiate analogs; 3 or 4
80364 Opioids and opiate analogs; 5 or more
80365 Oxycodone
80366 Pregabalin
80368 Sedative hypnotics (non-benzodiazepines)
80369 Skeletal muscle relaxants; 1 or 2
80370 Skeletal muscle relaxants; 3 or more
80371 Stimulants, synthetic
80372 Tapentadol
80373 Tramadol
80374 Stereoisomer (enantiomer) analysis, single drug class
80375 Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3
80376 Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6
80377 Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more
83992 Phencyclidine (PCP)
0006U Detection of interacting medications, substances, supplements and foods, 120 or more analytes, definitive chromatography with mass spectrometry, urine, description and severity of each interaction identified, per date of service
0011U Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites

Covered HCPCS Codes
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 [eg, IA, EIA, ELISA, EMIT, FPIA] and enzymatic methods [eg, 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
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 [eg, IA, EIA, ELISA, EMIT, FPIA] and enzymatic methods [eg, alcohol dehydrogenase]), (2) stable isotope or other universally recognized internal standards in all samples (eg., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (eg., 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

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 [eg, IA, EIA, ELISA, EMIT, FPIA] and enzymatic methods [eg, alcohol dehydrogenase]), stable isotope or other universally recognized internal standards in all samples (eg., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (eg., 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

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 [eg, IA, EIA, ELISA, EMIT, FPIA] and enzymatic methods [eg, alcohol dehydrogenase]), stable isotope or other universally recognized internal standards in all samples (eg., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (eg., 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

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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, 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

Covered ICD-10 Diagnosis – All applicable diagnosis.

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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