

If a conflict arises between a Clinical Payment and Coding Policy ("CPCP") and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSOK may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSOK has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act ("HIPAA") approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing ("UB") Editor, American Medical Association ("AMA"), Current Procedural Terminology ("CPT®"), CPT® Assistant, Healthcare Common Procedure Coding System ("HCPCS"), ICD-10 CM and PCS, National Drug Codes ("NDC"), Diagnosis Related Group ("DRG") guidelines, Centers for Medicare and Medicaid Services ("CMS") National Correct Coding Initiative ("NCCI") Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

# Prescription Medication and Illicit Drug Testing in the Outpatient Setting

**Policy Number: CPCPLAB070** 

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# **Description**

BCBSOK has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

# **Reimbursement Information:**

This policy does not describe or define the legal responsibility of providers. Providers should refer to state and federal laws for such guidance.

This policy does not address the use of drug testing in the following circumstances:

A. State, federally regulated and legally mandated drug testing (i.e., court-ordered drug screening, forensic examinations).

- B. Non-forensic testing for commercial driver's licensing or any other job-related testing (i.e., as a prerequisite for employment or as a means for continuation of employment).
- C. As a component of routine physical/medical examination.
- D. As a component of care rendered in an urgent/emergency situation.
- E. As a routine component of a behavioral health assessment.

## Presumptive drug screening using urine samples

- 1. Presumptive drug screening using urine samples (qualitative, semi-quantitative or quantitative) **may be reimbursable** in ANY of the following situations:
  - To assess an individual being treated for chronic, non-cancer pain or substance abuse or dependence when clinical evaluation of the individual (history/signs/symptoms) suggests the use of non-prescribed medications or illegal substances at the following frequency:
    - Prior to initiating chronic opioid pain therapy in chronic non-cancer pain to determine if the individual has been exposed to controlled substances or potentially confounding illicit drugs.
    - ii. To verify an individual's compliance with treatment or identify undisclosed drug abuse as part of routine monitoring for individuals who are receiving treatment for non-cancer chronic pain with prescription opioid pain medication. The random testing interval and drugs selected for testing should be based on the individual's history, condition and treatment, as documented in the medical record.
      - Monitoring of low risk (as defined by a risk assessment tool) individuals on chronic opioid therapy, up to one (1) time per year after initiation of therapy.
      - 2. Monitoring of moderate risk (as defined by a risk assessment tool) individuals on chronic opioid therapy, up to two (2) times per year after initiation of therapy.
      - 3. Monitoring of high risk (as defined by a risk assessment tool) individuals on chronic opioid therapy, up to four (4) times per year after initiation of therapy.
      - 4. For individuals with aberrant behavior (lost prescriptions, multiple requests for early refills, and opioids from multiple providers, unauthorized dose escalation, apparent intoxication, etc.) testing at the time of visit meets coverage criteria.
  - b. In pregnant individuals at high-risk for substance abuse in whom the suspicion of drug use exists as a result of the answers to substance abuse screening questions or indicated by information from the prescription drug monitoring program (PDMP), as documented in the medical record.
  - c. In newborns when there is a history of maternal substance abuse or agitated/altered mental status in the birthing parent
  - d. In candidates for organ transplant who have a history of substance abuse (to demonstrate abstinence prior to transplant)
  - e. In individuals with a suspicion of or a diagnosis of mental illness, (e.g., anxiety disorders, schizophrenia, major depressive disorder, mood disorders, suicidal ideations, substance abuse disorders)
  - f. In individuals with attention-deficit hyperactivity and disruptive behavior disorders
  - g. In cancer patients on opioid pain medication
  - h. In individuals with epilepsy
  - i. For the management and compliance monitoring of an individual under treatment for substance abuse or dependence at the following frequency (after

baseline at initial evaluation) and must be documented in the individual's medical record:

- i. For individuals with 0 to 90 consecutive days of abstinence, qualitative drug testing at a frequency of 1 to 2 per week.
- ii. For individuals with > 90 consecutive days of abstinence, qualitative drug testing at a frequency of 1 to 3 in one month.
- j. In individuals where substance abuse is in the differential diagnosis of the presenting conditions

## **Definitive Drug Testing**

- 2. Confirmatory/definitive qualitative or quantitative drug testing up to seven (7) drug classes may be reimbursable when laboratory-based definitive drug testing is specifically requested, the rationale is documented by the individual's treating physician and ANY of the following conditions is met:
  - a. The result of the presumptive drug screen is different than that suggested by the individual's medical history, clinical presentation or individual's own statement; (e.g., test was negative for prescribed medications, test was positive for prescription drug with abuse potential which was not prescribed, test was positive for an illegal drug):
  - b. For diagnosing and monitoring individuals with substance use disorder or dependence, when accurate and reliable results are necessary for treatment decisions.
    - i. Individuals with 0 to 30 consecutive days of abstinence, random definitive drug testing at a frequency not to exceed 1 per week
    - ii. Individuals with 31 to 90 consecutive days of abstinence, random definitive drug testing at a frequency of 1 to 3 per month. No more than 3 definitive drug tests in one month will be allowed.
    - iii. Individuals with > 90 consecutive days of abstinence, definitive drug testing at a frequency of 1 to 3 every three months. No more than 3 definitive drug tests in a 3-month period will be allowed.
  - c. For monitoring of individuals on opioid therapy (to ensure adherence to the therapeutic plan, for treatment planning, and for detection of other, non-prescribed opioids).
  - d. A presumptive test does not exist or does not adequately detect the specific drug or metabolite to be tested (e.g., specific drugs within the amphetamine, barbiturate, benzodiazepine, tricyclic antidepressants, and opiate/opioid drug classes as well as synthetic/analog or "designer" drugs)
  - e. To definitively identify specific drugs in a large family of drugs
  - f. To identify drugs when a definitive concentration of a drug is needed to guide management.
- 3. When laboratory-based definitive drug testing is requested for larger than seven drug class panels, confirmatory/definitive qualitative or quantitative drug testing **is not reimbursable**.
- 4. Confirmatory/definitive qualitative or quantitative or presumptive (qualitative, semi-quantitative or quantitative) drug testing using proprietary tests (e.g., RiskViewRx Plus) is not reimbursable.

### **Specific Validity Testing**

5. Specimen validity testing, (e.g., urine specific gravity, urine creatinine, pH, urine oxidant level, genetic identity testing, [NextGen Precision™ Testing]), is included in the base code and therefore will not be separately reimbursed.

#### **Documentation Requirements**

The individual's medical record must contain documentation that fully supports the medical necessity for drug testing. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

The clinician's documentation must be patient specific and accurately reflect the need for each test ordered. Each drug or drug class being tested for must be indicated by the ordering clinician in a written order and documented in the patient's medical record.

# Laboratories that submit urine drug testing claims should possess, at a minimum, the following:

- A signed, valid requisition form from the ordering provider that specifies the tests being ordered, and
- Complete results of the tests performed.

## The requisition form should include the following:

- A list of the specific drugs or drug classes being tested. Reference to a standard order or a "custom panel" is not acceptable; "Reflex" (or automatic) testing is not acceptable
- The identity of the patient to include the patient name and date of birth;
- The identity of the ordering provider, including full name, credentials, and NPI number (preferred);
- A legible or appropriate electronic signature with the date signed from the ordering physician (not a stamp or photocopy, and it is not acceptable to state that the physician's signature is on file);
- The facility and location where the sample was collected (e.g., office, home, hospital, residential treatment center);
- The type of sample (i.e., urine, saliva, blood or hair);
- The date and time the sample was collected;
- The identity of the individual who collected the sample; and
- The date and time the sample was received in the laboratory.

#### Lab results should contain the following:

- The complete identification of the entity performing the testing (including name, address, and CLIA number);
- The patient's name and date of birth;
- The ordering provider's name and NPI number;
- Facility name, if applicable;
- The date the sample was collected;
- The date the sample was received in the laboratory;
- The date the test results were reported; and
- Complete test results, including validity testing if performed.

# **Orders**

Orders must be patient specific and include the rationale/need for the test requested. Panel testing is restricted to panels published in the current CPT manual. Orders must be signed and dated by the ordering health care professional.

**Note:** Retro orders are not acceptable.

## Reimbursement

The following IS reimbursed (see complete Reimbursement Information above) for:

- 1. Presumptive drug screening based upon appropriate clinical criteria (qualitative, semi-quantitative or quantitative);
- 2. Definitive drug testing (qualitative or quantitative) for up to seven drug classes when the presumptive drug screening meets one of the following criteria:
  - a. The test was negative for prescribed medications, or
  - b. Positive for a prescription drug with abuse potential which was not prescribed, or
  - c. Positive for an illegal drug with patient denial of using the drug, or
  - d. A presumptive test does not exist or does not adequately detect the specific drug or metabolite to be tested
- 3. Blood specimens in patients with anuric Chronic Renal Failure.

## The following will not be reimbursed:

- Any AMA definitive drug class codes;
- 2. Same-day testing of the same drug or metabolites from two different samples (e.g., both a blood and a urine specimen) by either presumptive or definitive analyses;
- 3. Blanket orders or routine standing orders for all patients in the physician's practice;
- 4. Samples with abnormal validity tests;
- 5. Drug testing for patients in a facility setting (inpatient or outpatient) are not separately billable from the facility fee.

Only urine or oral fluid specimens will be covered - except blood specimen will be covered for patients with anuric Chronic Renal Failure.

Confirmatory/definitive testing should be supported by documentation of rationale in the individual's medical record.

More than one presumptive test result per individual per date of service regardless of the number of billing providers **will not be reimbursed**:

- a. It is not reasonable or necessary for a provider to perform qualitative point-of-care testing and also order presumptive testing from a reference laboratory on the same specimen.
- b. It is not reasonable or necessary for a provider to perform presumptive immunoassay testing and also order presumptive immunoassay testing from a reference laboratory with or without reflex testing on the same specimen.

# **Procedure Codes**

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

#### Codes

80305, 80306, 80307, 80320-80377, 0007U, 0011U, 0051U, 0054U, 0079U, 0082U, 0093U, 0143U, 0144U, 0145U, 0146U, 0147U, 0148U, 0149U, 0150U, 0227U, 0328U, G0480, G0481, G0482, G0483, G0659

# **Additional Resources:**

#### **Clinical Payment and Coding Policy:**

CPCP020 Drug Testing (may apply for certain health benefit plans)

## **References:**

AACC. (2017). *Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients*. <a href="https://www.aacc.org/science-and-practice/practice-guidelines/using-clinical-laboratory-tests-to-monitor-drug-therapy-in-pain-management-patients">https://www.aacc.org/science-and-practice/practice-guidelines/using-clinical-laboratory-tests-to-monitor-drug-therapy-in-pain-management-patients</a>

AAFP. (2020). Clinical Preventive Service Recommendation Opioid Use Disorder (OUD): Screening. AAFP. Retrieved 1/26 from <a href="https://www.aafp.org/family-physician/patient-care/clinical-recommendations/oud.html">https://www.aafp.org/family-physician/patient-care/clinical-recommendations/oud.html</a>

AAN. (2018). *DIAGNOSTIC ASSESSMENT OF THE CHILD WITH STATUS EPILEPTICUS*. <a href="https://www.aan.com/Guidelines/home/GuidelineDetail/234">https://www.aan.com/Guidelines/home/GuidelineDetail/234</a>

AAPM. (2013). Use of Opioids for the Treatment of Chronic Pain. <a href="https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/pain-management-toolkit/docs/use-of-opioids-for-the-treatment-of-chronic-pain.ashx">https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/pain-management-toolkit/docs/use-of-opioids-for-the-treatment-of-chronic-pain.ashx</a>

AATOD. (2017). *Guidelines for Addressing Benzodiazepine Use in Opioid Treatment Programs (OTPs)*. <a href="https://www.aatod.org/advocacy/policy-statements/guidelines-for-addressing-benzodiazepine-use-in-opioid-treatment-programs-otps-april-6-2017/">https://www.aatod.org/advocacy/policy-statements/guidelines-for-addressing-benzodiazepine-use-in-opioid-treatment-programs-otps-april-6-2017/</a>

ACOG. (2017). *Opioid Use and Opioid Use Disorder in Pregnancy*. <a href="https://www.acog.org/media/Committee-Opinions/Committee-on-Obstetric-Practice/co711.pdf">https://www.acog.org/media/Committee-Opinions/Committee-on-Obstetric-Practice/co711.pdf</a>

ALFA. (2019).

https://www.cliawaived.com/web/items/pdf/ALF 03 3152 1 Panel Drug Test Insert~493file1 .pdf

Algren, D. A., & Christian, M. R. (2015). Buyer Beware: Pitfalls in Toxicology Laboratory Testing. *Mo Med*, 112(3), 206-210. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6170116/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6170116/</a>

Altunkaya, D., & Smith, R. N. (1990). Aberrant radioimmunoassay results for cannabinoids in urine. *Forensic Sci Int*, *47*(3), 195-205.

AMDG. (2015). *Interagency Guideline on Prescribing Opioids for Pain*. http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf

AMDG. (2018). Supplemental Guidance on Prescribing Opioids for Postoperative Pain. http://agencymeddirectors.wa.gov/Files/FinalSupBreeAMDGPostopPain091318wcover.pdf

APA. (2016). THE AMERICAN PSYCHIATRIC ASSOCIATION PRACTICE GUIDELINES FOR THE PSYCHIATRIC EVALUATION OF ADULTS.

https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890426760

Argoff, C. E., Alford, D. P., Fudin, J., Adler, J. A., Bair, M. J., Dart, R. C., Gandolfi, R., McCarberg, B. H., Stanos, S. P., Gudin, J. A., Polomano, R. C., & Webster, L. R. (2018). Rational Urine Drug Monitoring in Patients Receiving Opioids for Chronic Pain: Consensus Recommendations. *Pain Med*, *19*(1), 97-117. <a href="https://doi.org/10.1093/pm/pnx285">https://doi.org/10.1093/pm/pnx285</a>

ASAM. (2013). Drug Testing: A White Paper of the American Society of Addiction Medicine (ASAM). https://www.cmm.com.au/files/uploads/resources/20170817102442drug-testing-a-

### white-paper-by-asam.pdf

ASAM. (2017). Appropriate Use of Drug Testing in Clinical Addiction Medicine. file:///C:/Users/AHCS8430/OneDrive%20-

%20AVALON%20HEALTH%20SERVICES,%20LLC/Desktop/ASAM%20Guidelines%20Appropriate% 20Use%20of%20Drug%20Testing%20in%20Clinical%20Addiction%20Medicine.pdf

Becker, W., & Starrels, J. (2022, 11/7/2022). *Prescription drug misuse: Epidemiology, prevention, identification, and management*. Wolters Kluwer.

https://www.uptodate.com/contents/prescription-drug-misuse-epidemiology-prevention-identification-and-management

Bertron, J. L., Seto, M., & Lindsley, C. W. (2018). DARK Classics in Chemical Neuroscience: Phencyclidine (PCP). *ACS Chem Neurosci*, *9*(10), 2459-2474. https://doi.org/10.1021/acschemneuro.8b00266

Blank, A., Hellstern, V., Schuster, D., Hartmann, M., Matthee, A. K., Burhenne, J., Haefeli, W. E., & Mikus, G. (2009). Efavirenz treatment and false-positive results in benzodiazepine screening tests. *Clin Infect Dis*, 48(12), 1787-1789. https://doi.org/10.1086/599109

Böttcher, M., Lierheimer, S., Peschel, A., & Beck, O. (2019). Detection of heroin intake in patients in substitution treatment using oral fluid as specimen for drug testing. *Drug Alcohol Depend*, 198, 136-139. https://doi.org/10.1016/j.drugalcdep.2019.02.011

Brahm, N. C., Yeager, L. L., Fox, M. D., Farmer, K. C., & Palmer, T. A. (2010). Commonly prescribed medications and potential false-positive urine drug screens. *Am J Health Syst Pharm*, *67*(16), 1344-1350. <a href="https://doi.org/10.2146/ajhp090477">https://doi.org/10.2146/ajhp090477</a>

CDC. (2015, June 2015). *Nationwide Trends*. CDC. <a href="https://www.drugabuse.gov/publications/drugfacts/nationwide-trends">https://www.drugabuse.gov/publications/drugfacts/nationwide-trends</a>

CDC. (2017, 02/09/2017). *Opioid Data Analysis and Resources*. Centers for Disease Control and Prevention. Retrieved 10/01/2018 from https://www.cdc.gov/drugoverdose/data/analysis.html

CDC. (2018a, December 2018). *Monitoring the Future Survey: High School and Youth Trends*. CDC. <a href="https://www.drugabuse.gov/publications/drugfacts/monitoring-future-survey-high-school-youth-trends">https://www.drugabuse.gov/publications/drugfacts/monitoring-future-survey-high-school-youth-trends</a>

CDC. (2018b). Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain Retrieved 2/1/2021 from <a href="https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf">https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf</a>

CDC. (2019). Other Drugs. https://www.cdc.gov/drugoverdose/data/otherdrugs.html

CDC. (2022a). Drug Overdose Deaths. https://www.cdc.gov/drugoverdose/deaths/index.html

CDC. (2022b). *U.S. Opioid Dispensing Rate Maps*. <a href="https://www.cdc.gov/drugoverdose/rxrate-maps/index.html">https://www.cdc.gov/drugoverdose/rxrate-maps/index.html</a>

Chou, R., Fanciullo, G. J., Fine, P. G., Adler, J. A., Ballantyne, J. C., Davies, P., Donovan, M. I., Fishbain, D. A., Foley, K. M., Fudin, J., Gilson, A. M., Kelter, A., Mauskop, A., O'Connor, P. G., Passik, S. D., Pasternak, G. W., Portenoy, R. K., Rich, B. A., Roberts, R. G., . . . Miaskowski, C.

(2009). Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *The Journal of Pain*, 10(2), 113-130.e122. https://doi.org/10.1016/j.jpain.2008.10.008

Christo, P. J., Manchikanti, L., Ruan, X., Bottros, M., Hansen, H., Solanki, D. R., Jordan, A. E., & Colson, J. (2011). Urine drug testing in chronic pain. *Pain Physician*, *14*(2), 123-143. https://www.painphysicianjournal.com/current/pdf?article=MTQ0NA%3D%3D&journal=60

Chua, I., Petrides, A. K., Schiff, G. D., Ransohoff, J. R., Kantartjis, M., Streid, J., Demetriou, C. A., & Melanson, S. E. F. (2020). Provider Misinterpretation, Documentation, and Follow-Up of Definitive Urine Drug Testing Results. *J Gen Intern Med*, *35*(1), 283-290. https://doi.org/10.1007/s11606-019-05514-5

Cone, E. J., Bigelow, G. E., Herrmann, E. S., Mitchell, J. M., LoDico, C., Flegel, R., & Vandrey, R. (2015). Non-smoker exposure to secondhand cannabis smoke. I. Urine screening and confirmation results. *J Anal Toxicol*, *39*(1), 1-12. https://doi.org/10.1093/jat/bku116

Couto, J. E., Webster, L., Romney, M. C., Leider, H. L., & Linden, A. (2009). Use of an algorithm applied to urine drug screening to assess adherence to an oxycontin regimen. *J Opioid Manag*, *5*(6), 359-364.

Couto, J. E., Webster, L., Romney, M. C., Leider, H. L., & Linden, A. (2011). Use of an algorithm applied to urine drug screening to assess adherence to a hydrocodone regimen. *J Clin Pharm Ther*, *36*(2), 200-207. https://doi.org/10.1111/j.1365-2710.2010.01236.x

DOD. (2017). *VA/DoD CLINICAL PRACTICE GUIDELINE FOR OPIOID THERAPY FOR CHRONIC PAIN*. https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf

DOD. (2018). VA/DOD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF PREGNANCY. <a href="https://www.healthquality.va.gov/guidelines/WH/up/VADoDPregnancyCPG4102018.pdf">https://www.healthquality.va.gov/guidelines/WH/up/VADoDPregnancyCPG4102018.pdf</a>
Dowell, D., Haegerich, T. M., & Chou, R. (2016). CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep, 65(1), 1-49. <a href="https://doi.org/10.15585/mmwr.rr6501e1">https://doi.org/10.15585/mmwr.rr6501e1</a>

Drake, L. R., & Scott, P. J. H. (2018). DARK Classics in Chemical Neuroscience: Cocaine. *ACS Chem Neurosci*, *9*(10), 2358-2372. <a href="https://doi.org/10.1021/acschemneuro.8b00117">https://doi.org/10.1021/acschemneuro.8b00117</a>

DVA, & DOD. (2015). VA/DoD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF SUBSTANCE USE DISORDERS Retrieved 1/28/2021 from https://www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf

DWD. (2013). Chronic Opioid Clinical Management Guidelines for Wisconsin Worker's Compensation Patient Care. Dejpartment of Workforce Development, State of Wisconsin. <a href="https://dwd.wisconsin.gov/wc/medical/pdf/CHRONIC%20OPIOID%20CLINICAL%20MANAGEME">https://dwd.wisconsin.gov/wc/medical/pdf/CHRONIC%20OPIOID%20CLINICAL%20MANAGEME</a> NT%20GUIDELINES%20.pdf

Eaton, K., & Lyman, G. (2022, 10/21/2022). *Dosing of anticancer agents in adults*. Wolters Kluwer. <a href="https://www.uptodate.com/contents/dosing-of-anticancer-agents-in-adults">https://www.uptodate.com/contents/dosing-of-anticancer-agents-in-adults</a>

Eskridge, K. D., & Guthrie, S. K. (1997). Clinical issues associated with urine testing of substances of abuse. *Pharmacotherapy*, 17(3), 497-510.

Farkas, A., Lipanot, K., & Sherman, K. (2021). Routine Laboratory Screening for Acetaminophen and Salicylate Ingestion in Preadmission Psychiatric Patients Is Unnecessary. *Ann Emerg Med*,

FDA. (2018). *DRI Cocaine Metabolite Assay*. https://www.accessdata.fda.gov/cdrh\_docs/pdf18/K181499.pdf

FDA. (2019). 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY ASSAY ONLY TEMPLATE https://www.accessdata.fda.gov/cdrh docs/reviews/K112395.pdf

FSMB. (2017). *Guidelines for the Chronic Use of Opioid Analgesics*. Federation of State Medical Boards. Retrieved 10/01/2018 from

https://www.fsmb.org/globalassets/advocacy/policies/opioid\_guidelines\_as\_adopted\_april-2017\_final.pdf

Fucci, N. (2012). False positive results for amphetamine in urine of a patient with diabetes mellitus. *Forensic Sci Int*, 223(1-3), e60. <a href="https://doi.org/10.1016/j.forsciint.2012.08.010">https://doi.org/10.1016/j.forsciint.2012.08.010</a>

Grant, C. N., & Bélanger, R. E. (2017). Position Statement: Cannabis and Canada's children and youth. *Pediatric Child Health*, *22*(2), 98-102.

https://www.cps.ca/en/documents/position/cannabis-children-and-youth

Gray, C., Korczak, D., Andrews, D., & Bélanger, S. A. (2018). ADHD in children and youth: Part 1— Etiology, diagnosis, and comorbidity. *Paediatrics & Child Health*, *23*(7), 447-453. https://doi.org/10.1093/pch/pxy109

Greller, H., & Gupta, A. (2020, 10/20/2020). *Benzodiazepine poisoning and withdrawal*. Wolters Kluwer. Retrieved 1/28/2021 from <a href="https://www.uptodate.com/contents/benzodiazepine-poisoning-and-withdrawal?topicRef=13846&source=see">https://www.uptodate.com/contents/benzodiazepine-poisoning-and-withdrawal?topicRef=13846&source=see</a> link#H9

Herrmann, E. S., Cone, E. J., Mitchell, J. M., Bigelow, G. E., LoDico, C., Flegel, R., & Vandrey, R. (2015). Non-smoker exposure to secondhand cannabis smoke II: Effect of room ventilation on the physiological, subjective, and behavioral/cognitive effects. *Drug Alcohol Depend*, *151*, 194-202. <a href="https://doi.org/10.1016/j.drugalcdep.2015.03.019">https://doi.org/10.1016/j.drugalcdep.2015.03.019</a>

HHS. (2017). New HHS Guidelines for Drug Testing Panels Effective 10/1/17. https://www.federalregister.gov/documents/2017/01/23/2017-00979/mandatory-guidelines-for-federal-workplace-drug-testing-programs#h-114

Hoffman, R. (2022, 9/21/2022). *Testing for drugs of abuse (DOAs)*. Wolters Kluwer. https://www.uptodate.com/contents/testing-for-drugs-of-abuse-doas

Jamison, R. N., Ross, E. L., Michna, E., Chen, L. Q., Holcomb, C., & Wasan, A. D. (2010). Substance misuse treatment for high-risk chronic pain patients on opioid therapy: a randomized trial. *Pain*, 150(3), 390-400. <a href="https://doi.org/10.1016/j.pain.2010.02.033">https://doi.org/10.1016/j.pain.2010.02.033</a>

Jannetto, P., Bratanow, N., Clark, W., Hamill-Ruth, R., Hammett-Stabler, C., Huestis, M., Kassed, C., McMillin, G., Melanson, S., & Langman, L. (2017). *Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients*. AACC. Retrieved 10/01/2018 from <a href="https://www.aacc.org/science-and-practice/practice-guidelines/using-clinical-laboratory-tests-to-monitor-drug-therapy-in-pain-management-patients">https://www.aacc.org/science-and-practice/practice-guidelines/using-clinical-laboratory-tests-to-monitor-drug-therapy-in-pain-management-patients</a>

Jannetto, P. J., & Langman, L. J. (2018). Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients. *The Journal of Applied Laboratory Medicine: An AACC Publication*, 2(4), 471-472. <a href="https://doi.org/10.1373/jalm.2017.025304">https://doi.org/10.1373/jalm.2017.025304</a>

Jarvis, M., Williams, J., Hurford, M., Lindsay, D., Lincoln, P., Giles, L., Luongo, P., & Safarian, T. (2017). Appropriate Use of Drug Testing in Clinical Addiction Medicine. *J Addict Med*, *11*(3), 163-173. <a href="https://doi.org/10.1097/adm.000000000000323">https://doi.org/10.1097/adm.0000000000000323</a>

Jones, C. M., Mack, K. A., & Paulozzi, L. J. (2013). Pharmaceutical overdose deaths, United States, 2010. *Jama*, 309(7), 657-659. <a href="https://doi.org/10.1001/jama.2013.272">https://doi.org/10.1001/jama.2013.272</a>

Jones, J. (2016, 07/28/2016). *Clinical vs. Forensic: The Differences Cost More Than Just Money*. United States Drug Testing Laboratories. Retrieved 02/05/2019 from <a href="http://www.usdtl.com/media/mediaarticles/clinical-vs-forensic-the-differences-cost-more-than-just-money">http://www.usdtl.com/media/mediaarticles/clinical-vs-forensic-the-differences-cost-more-than-just-money</a>

Kale, N. (2019). Urine Drug Tests: Ordering and Interpreting Results. *Am Fam Physician*, 99(1), 33-39. https://www.aafp.org/afp/2019/0101/p33.pdf

Kampman, K. (2022, 7/11/2022). *Approach to treatment of stimulant use disorder in adults*. Retrieved 1/28/2021 from <a href="https://www.uptodate.com/contents/approach-to-treatment-of-stimulant-use-disorder-in-adults">https://www.uptodate.com/contents/approach-to-treatment-of-stimulant-use-disorder-in-adults</a>

Kandel, D. B., Hu, M. C., Griesler, P., & Wall, M. (2017). Increases from 2002 to 2015 in prescription opioid overdose deaths in combination with other substances. *Drug Alcohol Depend*, *178*, 501-511. <a href="https://doi.org/10.1016/j.drugalcdep.2017.05.047">https://doi.org/10.1016/j.drugalcdep.2017.05.047</a>

Katz, N. P., Sherburne, S., Beach, M., Rose, R. J., Vielguth, J., Bradley, J., & Fanciullo, G. J. (2003). Behavioral monitoring and urine toxicology testing in patients receiving long-term opioid therapy. *Anesth Analg*, *97*(4), 1097-1102, table of contents.

Katzman, M. A., Bleau, P., Blier, P., Chokka, P., Kjernisted, K., Van Ameringen, M., Canadian Anxiety Guidelines Initiative Group on behalf of the Anxiety Disorders Association of Canada/Association Canadienne des troubles, a., McGill, U., Antony, M. M., Bouchard, S., Brunet, A., Flament, M., Grigoriadis, S., Mendlowitz, S., O'Connor, K., Rabheru, K., Richter, P. M. A., Robichaud, M., & Walker, J. R. (2014). Canadian clinical practice guidelines for the management of anxiety, posttraumatic stress and obsessive-compulsive disorders. *BMC psychiatry*, *14 Suppl 1*(Suppl 1), S1-S1. <a href="https://doi.org/10.1186/1471-244X-14-S1-S1">https://doi.org/10.1186/1471-244X-14-S1-S1</a>

Kell, M. J. (1994). Utilization of plasma and urine methadone concentrations to optimize treatment in maintenance clinics: I. Measurement techniques for a clinical setting. *J Addict Dis*, 13(1), 5-26. https://doi.org/10.1300/J069v13n01 02

Knezevic, N. N., Khan, O. M., Beiranvand, A., & Candido, K. D. (2017). Repeated Quantitative Urine Toxicology Analysis May Improve Chronic Pain Patient Compliance with Opioid Therapy. *Pain Physician*, 20(2s), S135-s145.

Krasowski, M. D., McMillin, G. A., Melanson, S. E. F., Dizon, A., Magnani, B., & Snozek, C. L. H. (2020). Interpretation and Utility of Drug of Abuse Screening Immunoassays: Insights From Laboratory Drug Testing Proficiency Surveys. *Arch Pathol Lab Med*, *144*(2), 177-184. <a href="https://doi.org/10.5858/arpa.2018-0562-CP">https://doi.org/10.5858/arpa.2018-0562-CP</a>

Langman, L. J., & Jannetto, P. J. (2018). *Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients*. <a href="https://www.aacc.org/-/media/Files/Science-and-Practice-Guidelines/Pain-Management/LMPGPain-Management20171220.pdf?la=en&hash=19670524407619F78999AB60731A24CB4901939D">https://www.aacc.org/-/media/Files/Science-and-Practice-Guidelines/Pain-Management/LMPGPain-Management20171220.pdf?la=en&hash=19670524407619F78999AB60731A24CB4901939D</a>

Levine, B. S., & Smith, M. L. (1990). Effects of diphenhydramine on immunoassays of phencyclidine in urine. *Clin Chem*, *36*(6), 1258.

Ly, B. T., Thornton, S. L., Buono, C., Stone, J. A., & Wu, A. H. (2012). False-positive urine phencyclidine immunoassay screen result caused by interference by tramadol and its metabolites. *Ann Emerg Med*, *59*(6), 545-547. https://doi.org/10.1016/j.annemergmed.2011.08.013

Manchikanti, L., Abdi, S., Atluri, S., Balog, C. C., Benyamin, R. M., Boswell, M. V., Brown, K. R., Bruel, B. M., Bryce, D. A., Burks, P. A., Burton, A. W., Calodney, A. K., Caraway, D. L., Cash, K. A., Christo, P. J., Damron, K. S., Datta, S., Deer, T. R., Diwan, S., . . . Wargo, B. W. (2012). American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2--guidance. *Pain Physician*, *15*(3 Suppl), S67-116.

Manchikanti, L., Kaye, A. M., Knezevic, N. N., McAnally, H., Slavin, K., Trescot, A. M., Blank, S., Pampati, V., Abdi, S., Grider, J. S., Kaye, A. D., Manchikanti, K. N., Cordner, H., Gharibo, C. G., Harned, M. E., Albers, S. L., Atluri, S., Aydin, S. M., Bakshi, S., . . . Hirsch, J. A. (2017). Responsible, Safe, and Effective Prescription of Opioids for Chronic Non-Cancer Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines. *Pain Physician*, 20(2s), S3-s92.

Manchikanti, L., Malla, Y., Wargo, B. W., Cash, K. A., Pampati, V., Damron, K. S., McManus, C. D., & Brandon, D. E. (2010). Protocol for accuracy of point of care (POC) or in-office urine drug testing (immunoassay) in chronic pain patients: a prospective analysis of immunoassay and liquid chromatography tandem mass spectometry (LC/MS/MS). *Pain Physician*, *13*(1), E1-e22. <a href="https://www.painphysicianjournal.com/current/pdf?article=MTMwMg%3D%3D&journal=53">https://www.painphysicianjournal.com/current/pdf?article=MTMwMg%3D%3D&journal=53</a>

McClellan, J., & Stock, S. (2013). Practice Parameter for the Assessment and Treatment of Children and Adolescents With Schizophrenia. *Journal of the American Academy of Child & Adolescent Psychiatry*, 52(9), 976-990. <a href="https://doi.org/10.1016/j.jaac.2013.02.008">https://doi.org/10.1016/j.jaac.2013.02.008</a>

McEvoy, J., Millet, R. A., Dretchen, K., Morris, A. A., Corwin, M. J., & Buckley, P. (2014). Quantitative levels of aripiprazole parent drug and metabolites in urine. *Psychopharmacology (Berl)*, *231*(23), 4421-4428. https://doi.org/10.1007/s00213-014-3781-1

Michna, E., Jamison, R. N., Pham, L. D., Ross, E. L., Janfaza, D., Nedeljkovic, S. S., Narang, S., Palombi, D., & Wasan, A. D. (2007). Urine toxicology screening among chronic pain patients on opioid therapy: frequency and predictability of abnormal findings. *Clin J Pain*, *23*(2), 173-179. <a href="https://doi.org/10.1097/AJP.0b013e31802b4f95">https://doi.org/10.1097/AJP.0b013e31802b4f95</a>

Microgenics. (2015). *CEDIA(r) Phencyclidine (PCP) Assay*. Microgenics Corporation. http://tools.thermofisher.com/content/sfs/manuals/10007400-CEDIA-Phencyclidine-PCP-Assay-EN.pdf

Microgenics. (2016). *DRI(r) Amphetamines Assay*. Microgenics Corporation. Retrieved 02/12/2019 from <a href="http://tools.thermofisher.com/content/sfs/manuals/0138-DRI-Amphetamines-Assay-EN.pdf">http://tools.thermofisher.com/content/sfs/manuals/0138-DRI-Amphetamines-Assay-EN.pdf</a>

Moeller, K. E., Kissack, J. C., Atayee, R. S., & Lee, K. C. (2017). Clinical Interpretation of Urine Drug Tests: What Clinicians Need to Know About Urine Drug Screens. *Mayo Clin Proc*, *92*(5), 774-796. https://doi.org/10.1016/j.mayocp.2016.12.007

Nafziger, A. N., & Bertino, J. S., Jr. (2009). Utility and application of urine drug testing in chronic

pain management with opioids. *Clin J Pain*, 25(1), 73-79. https://doi.org/10.1097/AJP.0b013e31817e13cc

National Center for Drug Abuse Statistics. (2022). *Drug Abust Statistics* https://drugabusestatistics.org/

Nelson, L., & Odujebe, O. (2022, 6/7/2022). *Cocaine: Acute intoxication*. Retrieved 1/28/2021 from <a href="https://www.uptodate.com/contents/cocaine-acute-intoxication">https://www.uptodate.com/contents/cocaine-acute-intoxication</a>

NICE. (2018, April 2018). *Epilepsies: diagnosis and management*. https://www.nice.org.uk/guidance/cg137/chapter/1-Guidance

NICE. (2020). *Epilepsies: diagnosis and management*. https://www.nice.org.uk/guidance/cg137/chapter/1-Guidance

Nuckols, T. K., Anderson, L., Popescu, I., Diamant, A. L., Doyle, B., Di Capua, P., & Chou, R. (2014). Opioid prescribing: a systematic review and critical appraisal of guidelines for chronic pain. *Ann Intern Med*, *160*(1), 38-47. <a href="https://doi.org/10.7326/0003-4819-160-1-201401070-00732">https://doi.org/10.7326/0003-4819-160-1-201401070-00732</a>

OASAS. (2021). *Guidance on Toxicology Use in OASAS Certified Programs*. https://oasas.ny.gov/system/files/documents/2021/11/oasas-toxicology-guidance 0.pdf

Ordean, A., Wong, S., & Graves, L. (2017). No. 349-Substance Use in Pregnancy. *J Obstet Gynaecol Can*, 39(10), 922-937.e922. https://doi.org/10.1016/j.jogc.2017.04.028

Owen, G. T., Burton, A. W., Schade, C. M., & Passik, S. (2012). Urine drug testing: current recommendations and best practices. *Pain Physician*, *15*(3 Suppl), Es119-133.

Owusu Obeng, A., Hamadeh, I., & Smith, M. (2017). Review of Opioid Pharmacogenetics and Considerations for Pain Management. *Pharmacotherapy*, *37*(9), 1105-1121. https://doi.org/10.1002/phar.1986

Palamar, J. J., Le, A., Guarino, H., & Mateu-Gelabert, P. (2019). A comparison of the utility of urine- and hair testing in detecting self-reported drug use among young adult opioid users. *Drug Alcohol Depend*, 200, 161-167. https://doi.org/10.1016/j.drugalcdep.2019.04.008

Pesce, A., Krock, K., Ritz, D., Cua, A., Thomas, R., & Nickley, J. (2018). Observations on 6-MAM (6-Monoacetylmorphine) in Urine. *J Clin Toxicol*, 8(393), 2161-0495.1000393.

Pesce, A., West, C., Egan City, K., & Strickland, J. (2012). Interpretation of urine drug testing in pain patients. *Pain Med*, *13*(7), 868-885. <a href="https://doi.org/10.1111/j.1526-4637.2012.01350.x">https://doi.org/10.1111/j.1526-4637.2012.01350.x</a>

Phan, H. M., Yoshizuka, K., Murry, D. J., & Perry, P. J. (2012). Drug testing in the workplace. *Pharmacotherapy*, *32*(7), 649-656. <a href="https://doi.org/10.1002/j.1875-9114.2011.01089.x">https://doi.org/10.1002/j.1875-9114.2011.01089.x</a>

PMFT. (2019). PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE REPORT Updates, Gaps, Inconsistencies, and Recommendations PAIN MANAGEMENT FINAL REPORT https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

Rengarajan, A., & Mullins, M. E. (2013). How often do false-positive phencyclidine urine screens occur with use of common medications? *Clin Toxicol (Phila)*, *51*(6), 493-496. https://doi.org/10.3109/15563650.2013.801982 Rollins, D. E., Jennison, T. A., & Jones, G. (1990). Investigation of interference by nonsteroidal anti-inflammatory drugs in urine tests for abused drugs. *Clin Chem*, *36*(4), 602-606.

SAMHSA. (2007). *Guidelines for the Accreditation of Opioid Treatment Programs*<a href="https://www.samhsa.gov/sites/default/files/programs\_campaigns/medication\_assisted/2007-otp-accreditation-guidelines.pdf">https://www.samhsa.gov/sites/default/files/programs\_campaigns/medication\_assisted/2007-otp-accreditation-guidelines.pdf</a>

SAMHSA. (2015). FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS. https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf

SAMHSA. (2017). Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health.

https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf

SAMHSA. (2020). Mandatory Guidelines for Federal Workplace Drug Testing Programs— Oral/Fluid

https://www.samhsa.gov/sites/default/files/programs\_campaigns/division\_workplace\_programs\_s/final-mg-oral-fluid.pdf

SAMHSA. (2022). *Mandatory Guidelines for Federal Workplace Drug Testing Programs*. Federal Register. <a href="https://www.federalregister.gov/documents/2022/04/07/2022-06884/mandatory-guidelines-for-federal-workplace-drug-testing-programs#sectno-reference-2.2">https://www.federalregister.gov/documents/2022/04/07/2022-06884/mandatory-guidelines-for-federal-workplace-drug-testing-programs#sectno-reference-2.2</a>

Smith, P. E., & McBride, A. (1999). Illicit drugs and seizures. *Seizure*, 8(8), 441-443. https://doi.org/10.1053/seiz.1999.0346

Snyder, M. L., Fantz, C. R., & Melanson, S. (2017). Immunoassay-Based Drug Tests Are Inadequately Sensitive for Medication Compliance Monitoring in Patients Treated for Chronic Pain. *Pain Physician*, *20*(2s), Se1-se9.

https://www.painphysicianjournal.com/current/pdf?article=NDIwNw%3D%3D&journal=103

Starrels, J. L., Becker, W. C., Alford, D. P., Kapoor, A., Williams, A. R., & Turner, B. J. (2010). Systematic review: treatment agreements and urine drug testing to reduce opioid misuse in patients with chronic pain. *Ann Intern Med*, *152*(11), 712-720. <a href="https://doi.org/10.7326/0003-4819-152-11-201006010-00004">https://doi.org/10.7326/0003-4819-152-11-201006010-00004</a>

Trescot, A. M., Datta, S., Lee, M., & Hansen, H. (2008). Opioid pharmacology. *Pain Physician*, 11(2 Suppl), S133-153.

Vohra, V., Marraffa, J. M., Wojcik, S. M., & Eggleston, W. (2019). An assessment of urine THC immunoassay in healthy volunteers receiving an oral proton-pump inhibitor. *Clin Toxicol (Phila)*, 1-3. https://doi.org/10.1080/15563650.2019.1662917

Vopat, M. L., Messamore, W. G., Trent, J. J., Schmanke, K. E., Zackula, R., Yang, S. Y., & Bhargava, T. (2020). Urine Screening for Opioid and Illicit Drugs in the Total Joint Arthroplasty Population. *Kans J Med*, *13*, 71-76.

Weaver, M. F. (2015). Prescription Sedative Misuse and Abuse. *Yale J Biol Med*, *88*(3), 247-256. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4553644/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4553644/</a>

WFSBP. (2015). World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Schizophrenia Part 3: Update 2015 Management of special circumstances: Depression, Suicidality, substance use disorders and pregnancy and lactation

WHO. (2016). mhGAP Intervention Guide.

https://apps.who.int/iris/bitstream/handle/10665/250239/9789241549790-eng.pdf?sequence=1

Wilfong, A. (2021, 11/23/2021). *Management of convulsive status epilepticus in children*. https://www.uptodate.com/contents/management-of-convulsive-status-epilepticus-in-children

Wondfo. (2020). DRUG TESTS STRIP. <a href="http://wondfousa.com/test/strip/">http://wondfousa.com/test/strip/</a> Wong, S., Ordean, A., & Kahan, M. (2011). Substance use in pregnancy. J Obstet Gynaecol Can, 33(4), 367-384. <a href="https://doi.org/10.1016/s1701-2163(16)34855-1">https://doi.org/10.1016/s1701-2163(16)34855-1</a>

Xlar. (2002). THC One Step Marijuana Test Strip Package Insert. xlar.com/I/THC-STRIP-2.pdf

# **Policy Update History:**

11/1/2022	New policy
8/15/2023	Document updated with literature review. Reimbursement information
	revised for clarity. References revised; some added, others removed.