Urine Drug Testing in Pain Management
Policy No. 017
Utilization Review Criteria

Department	Medical Management
Purpose	To ensure services are reasonable and necessary for the diagnosis or treatment of an illness or injury and within the scope of a benefit category
Applicability	All Lines of Business
Approved	
Approved	Tara Bryant
Approver Title	Chief Medical Officer
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Purpose
Urine drug testing (UDT) provides objective information to assist clinicians in identifying the presence or absence of drugs or drug classes in the body and making treatment decisions.
This policy details:

- The appropriate indications and expected frequency of testing for safe medication management of prescribed substances in risk stratified pain management patients *and*
- Designates documentation, by the clinician in the patient's medical record, of medical necessity for, and testing ordered on, an individual patient basis

Definitions

1. **Qualitative (i.e. screening) Drug Testing** - Used when medically necessary to determine the presence or absence of drugs or drug classes in a urine sample; Results expressed as negative or positive or as a numerical result; Includes competitive immunoassays (IA) and thin layer chromatography.
2. **Quantitative (i.e. confirmatory) Drug Testing**- Used when medically necessary to identify specific medications, illicit substances and metabolites; Reports the results of drugs absent or present in concentrations of ng/ml; Limited to GC-MS and LC-MS/MS testing methods only
3. **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 pH, specific gravity, oxidants and creatinine
4. **Point of Care Testing (POCT)** - Used when medically necessary by clinicians for immediate test results for the immediate management of the patient; Available when the patient and physician are in the same location; IA test method that primarily identifies drug classes and a few specific drugs; Platform consists of cups, dipsticks, cassettes, or strips; Read by the human eye
5. **Immunoassay (IA)** - Ordered by clinicians primarily to identify the presence or absence of drug classes and some specific drugs; Biochemical tests that measure the presence above a cutoff level of a substance (drug) with the use of an antibody; Read by photometric technology
6. **Standing Orders** - 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.
7. **Blanket Orders** - Test request that is not for a specific patient; rather, it is an identical order for all patient's in a clinician's practice without individualized decision making at every visit.
8. **Reflex Testing** - Laboratory testing that is performed reflexively after initial test results to identify further diagnostic information essential to patient care. Testing performed as a step necessary to complete a physician's order is not considered reflex testing.

Covered Indications for Urinary Drug Testing (UDT) in the Treatment of Patients on Chronic Opioid Therapy (COT)

A physician who is writing prescriptions for medications to treat chronic pain can manage a patient better if the physician knows whether the patient is consuming another medication or substance, which could suggest the possibility of substance use disorder or lead to drug-drug interactions. Additionally, UDT may help the physician monitor for medication adherence, efficacy, side effects, and patient safety in general.

1. COT UDT Testing Objectives

A. Identifies absence of prescribed medication and potential for abuse, misuse, and diversion;
B. Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances;
C. Identifies substances that contribute to adverse events or drug-drug interactions;
D. Provides objectivity to the treatment plan;
E. Reinforces therapeutic compliance with the patient;
F. Provides additional documentation demonstrating compliance with patient evaluation and monitoring;
G. Provide diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

2. COT Testing Guidelines

A. **Qualitative** (i.e., screening) **urine drug testing meets** Viva Health's medical criteria for coverage in pain management programs for patients with chronic non-cancer pain and is considered **medically necessary** up to four **(4) times per year** for:

- Baseline screening prior to initiating chronic pain therapy using a controlled substance when **all** of the following conditions are met:
  - An adequate clinical assessment of patient history and risk of substance abuse is performed;
  - Clinicians have knowledge of test interpretation;
  - There is a plan in place regarding how to use test findings clinically

- Subsequent monitoring of chronic pain therapy using a controlled substance.

B. **Quantitative** (i.e., confirmatory) **urine drug testing meets** Viva Health's medical criteria for coverage for up to four (**4) quantitative tests per qualitative urine drug screen** when specifically requested by the treating

physician and the test results are necessary for treatment planning under the following conditions:

- The result of the qualitative drug screen is positive
- The result of the qualitative drug screen is negative and the negative finding is unexpected or inconsistent with the patient's current medication program

3. <u>Medical Necessity documentation guidance</u>

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, be available upon request and minimally include the following elements:

a. Patient history, physical examination and previous laboratory findings
b. Current treatment plan
c. Prescribed medication(s)
d. Risk assessment plan

Drugs or drug classes for which testing are performed should reflect only those likely to be present, based on the patient's medical history, current clinical presentation and current medication program. Drugs for which specimens are being tested must be indicated by the ordering health care provider in a written order.

A comprehensive screening panel should only be considered for initial testing when appr**o**priate or when the patient's behavior suggests the use of drugs not commonly identified on a basic screening panel. Medical documentation must support the justification for conducting a comprehensive screening panel. Subsequent testing should only be conducted for those substances identified on the patient's initial profile.

Note: A "profile" differs from a "panel" in that a profile responds to the clinical risks of a particular patient, whereas a panel encourages unnecessary or excessive testing when no clinical cause exists

When a quantitative (laboratory-based specific identification) test is performed, the record must show that an inconsistent positive finding was noted on the qualitative testing or that there was no available, commercially or otherwise, qualitative test to evaluate the presence of a semi-synthetic or synthetic controlled substance in a member who met the medical necessity criteria in this policy.

The risk-level for an individual patient should include a global assessment of risk factors, and monitoring for the presence of aberrant behavior. Standardized risk assessment tools are available, such as the 5-item opioid risk tool (ORT). Another screening instrument is the SOAPP-R, a 24-item tool.

*Note: The ORT is a copyrighted instrument

Aberrant behavior is defined by one or more of the following:
• Multiple lost prescriptions
• Multiple requests for early refill
• Obtained controlled substances from multiple providers
• Unauthorized dose escalation
• Apparent intoxication during previous visits

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 qualitative positive UDT using quantitative UDT (GC-MS or LC-MS/MS) before reporting the qualitative 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 qualitative UDT in the laboratory for a prescribed medication listed by the ordering clinician

2. Direct to quantitative UDT without a qualitative UDT is reasonable and necessary, when individualized for a particular patient, in the following circumstances:
    a. To identify a specific substance or its metabolite that is in a large class of drugs, or that is inadequately detected or not detected by qualitative UDT, such as fentanyl, meperidine, synthetic cannabinoids, and other synthetic/analog drugs;
    b. For use in a differential assessment of medication efficacy, side effects, or drug-drug interactions;
    c. To identify non-prescribed medication or illicit substance use for ongoing safe prescribing of controlled substances, where clinician has documented concerns related to safety risks attendant to failure to identify specific substances suspected based upon clinical review and judgment; or
    d. To identify drugs when a quantitative concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan)

3. Quantitative testing to confirm a negative qualitative 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 qualitative UDT; or
c. To rule out an error as the cause of a negative qualitative UDT result

4. Quantitative testing to confirm a qualitative 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

Non-Covered Services

1. Blanket Orders
2. Reflex quantitative UDT is not reasonable and necessary when qualitative 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 quantitative 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 qualitative test result)
3. Routine standing orders for all patients in a physician's practice are not reasonable and necessary
4. It is not reasonable and necessary for a physician to perform qualitative POCT and order qualitative IA testing from a reference laboratory. In other words, Viva will only pay for one qualitative test result per patient per date of service regardless of the number of billing providers
5. It is not reasonable and necessary for a physician to perform qualitative IA testing and order qualitative IA testing from a reference laboratory with or without reflex testing. Viva will only pay for one qualitative test result per patient per date of service regardless of the number of billing providers
6. It is not reasonable and necessary for a reference laboratory to perform and bill IA qualitative UDT prior to quantitative testing without a specific physician's order for the qualitative testing
7. IA testing, regardless of whether it is qualitative or semi-quantitative (numerical), may not be used to "confirm" or quantitatively identify a qualitative test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods.

Quantitative UDT provides specific identification and/or quantification by GC-MS or LC-MS/MS

8. Drug testing of two different specimen types (i.e. blood and urine) from the same patient on the same date of service for the same drugs/metabolites/analytes
9. UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges
10. Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine
11. The use of comprehensive quantitative panels (not to be confused with a comprehensive screening panel

For Dates of Service January 1, 2016 and following:

Viva Health will follow the CMS coding guidelines for reporting drug testing procedures, as outlined in the CMS Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Final Determinations document posted on the CMS website.

Submit claims for drug testing services to Viva Health for all Commercial and Medicare Advantage lines of business using CMS codes G0477 – G0483 as appropriate.

- Only one of the three presumptive codes (G0477, G0478, G0479) may be billed per day. Select the most appropriate code for the method of testing performed.
- Only one of the four definitive codes (G0480, G0481, G0482, G0483) may be billed per day. Select the most appropriate code for the testing performed.
    - For definitive testing, the documented factor used to determine the appropriate definitive G code to bill is "drug class."
    - The available drug classes are specified by CMS
    - The AMA CPT Manual may be consulted for examples of individual drugs within each drug class.
- A maximum of one service unit per procedure code per date of service may be billed when submitting G0477 – G0483.
- Drug confirmation tests are no longer eligible to be separately reported under any procedure code, unlisted codes or otherwise.
- Specimen validity testing is not eligible to be separately billed under any procedure codes (e.g. 81000, 81001, 81002, 81003, 81005, 81099, 82570, 83986, or any other code). This is because for all codes in range G0477 – G0483, the code description indicates that this testing is included if it was performed.
- Services submitted with CPT codes 80150, 80162, 80163, 80165, 80171, 80299, and 80300–80377 will be denied to provider liability as bundled to the CMS codes.

Codes and Definition

Procedure Code	Procedure Code Description	Valid for Dates of Service:
G0477	Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg, immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.	01/01/2016-Current
G0478	Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg, immunoassay) read by instrument-assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.	01/01/2016-Current
G0479	Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers (eg, immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service.	01/01/2016-Current
G0480	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 and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.	01/01/2016-Current
G0481	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 and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.	01/01/2016-Current
G0482	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 and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed.)	01/01/2016-Current
G0483	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 and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed.	01/01/2016-Current

For monitoring of patient compliance in a drug treatment program, use ICD-10-CM code Z03.89 as the primary diagnosis and the specific drug dependence diagnosis as the secondary diagnosis. For the monitoring of patients on methadone maintenance and chronic pain patients with opioid dependence, suspected of abusing other illicit drugs, use code Z79.891.

Physicians are to select the most appropriate diagnosis code. Labs are not to pre-populate requisition forms with diagnosis codes.

For Dates of Service August 1, 2015 through December 31, 2015

Use of CPT codes **80300-80304** are not reimbursed separately**. G0431** or **G0434** should be billed for urine drug screen testing (qualitative). One unit of either code (**G0431** or **G0434**) will be reimbursed per encounter if the above criteria are met. Use of CPT codes **80320-80377** are not reimbursed separately and the appropriate corresponding G codes (**G6030-G6058**) should be billed for quantitative/confirmatory testing.

HCPCS Codes:
G0431(1 unit only) Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter (Should only be billed by CLIA accredited labs)
G0434 (1 unit only) Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter
G6030 Assay of amitriptyline
G6031 Assay of benzodiazepines
G6032 Assay of desipramine
G6034 Assay of doxepin
G6036 Assay of imipramine
G6037 Assay of nortriptyline
G6040 Assay of alcohol (ethanol); any specimen except breath
G6041 Alkaloids, urine, quantitative
G6042 Assay of amphetamine or methamphetamine
G6043 Assay of barbiturates, not elsewhere specified
G6044 Assay of cocaine or metabolite
G6045 Assay of dihydrocodeinone
G6046 Assay of dihydromorphinone
G6050 Assay of ethchlorvynol
G6051 Assay of flurazepam
G6052 Assay of meprobamate
G6053 Assay of methadone
G6056 Opiate(s), drug and metabolites, each procedure
G6058 Drug Confirmation, each procedure

Bill Type Codes:
N/A
Revenue Codes:
N/A
CPT/HCPCS Codes
Group 1

G0431	DRUG SCREEN, QUALITATIVE; MULTIPLE DRUG CLASSES BY HIGH COMPLEXITY TEST METHOD (E.G., IMMUNOASSAY, ENZYME ASSAY), PER PATIENT ENCOUNTER
G0434	DRUG SCREEN, OTHER THAN CHROMATOGRAPHIC; ANY NUMBER OF DRUG CLASSES, BY CLIA WAIVED TEST OR MODERATE COMPLEXITY TEST, PER PATIENT ENCOUNTER
G6030	AMITRIPTYLINE
G6031	BENZODIAZEPINES
G6032	DESIPRAMINE
G6034	DOXEPIN
G6036	ASSAY OF IMIPRAMINE
G6037	NORTRIPTYLINE
G6040	ALCOHOL (ETHANOL); ANY SPECIMEN EXCEPT BREATH
G6041	ALKALOIDS, URINE, QUANTITATIVE
G6042	AMPHETAMINE OR METHAMPHETAMINE
G6043	BARBITURATES, NOT ELSEWHERE SPECIFIED
G6044	COCAINE OR METABOLITE
G6045	DIHYDROCODEINONE
G6046	DIHYDROMORPHINONE
G6048	DIMETHADIONE
G6051	FLURAZEPAM
G6052	MEPROBAMATE
G6053	METHADONE
G6054	METHSUXIMIDE
G6056	OPIATE(S), DRUG AND METABOLITES, EACH PROCEDURE
G6057	PHENOTHIAZINE
G6058	DRUG CONFIRMATION, EACH PROCEDURE

ICD-9 Codes that Support Medical Necessity

Group 1 Codes:

276.2	ACIDOSIS
295.00 - 295.30	SIMPLE TYPE SCHIZOPHRENIA UNSPECIFIED STATE - PARANOID TYPE SCHIZOPHRENIA UNSPECIFIED STATE
303.90	OTHER AND UNSPECIFIED ALCOHOL DEPENDENCE UNSPECIFIED DRINKING BEHAVIOR
304.00	OPIOID TYPE DEPENDENCE UNSPECIFIED USE
304.01	OPIOID TYPE DEPENDENCE CONTINUOUS USE
304.80	COMBINATIONS OF DRUG DEPENDENCE EXCLUDING OPIOID TYPE DRUG UNSPECIFIED USE
304.90	UNSPECIFIED DRUG DEPENDENCE UNSPECIFIED USE
305.90	OTHER MIXED OR UNSPECIFIED DRUG ABUSE UNSPECIFIED USE
338.29	OTHER CHRONIC PAIN
338.4	CHRONIC PAIN SYNDROME
345.10 - 345.11	GENERALIZED CONVULSIVE EPILEPSY WITHOUT INTRACTABLE EPILEPSY- GENERALIZED CONVULSIVE EPILEPSY WITH INTRACTABLE EPILEPSY
345.3	GRAND MAL STATUS EPILEPTIC
345.90 - 345.91	EPILEPSY UNSPECIFIED WITHOUT INTRACTABLE EPILEPSY –

	EPILEPSY UNSPECIFIED WITH INTRACTABLE EPILEPSY
426.10 - 426.13	ATRIOVENTRICULAR BLOCK UNSPECIFIED - OTHER SECOND DEGREE ATRIOVENTRICULAR BLOCK
426.82	LONG QT SYNDROME
427.0 - 427.1	PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA – PAROXYSMAL VENTRICULAR TACHYCARDIA
719.40	PAIN IN JOINT SITE UNSPECIFIED
721.0	CERVICAL SPONDYLOSIS WITHOUT MYELOPATHY
721.3	LUMBOSACRAL SPONDYLOSIS WITHOUT MYELOPATHY
722.52	DEGENERATION OF LUMBAR OR LUMBOSACRAL INTERVERTEBRAL DISC
723.1	CERVICALGIA
724.2	LUMBAGO
724.4	THORACIC OR LUMBOSACRAL NEURITIS OR RADICULITIS UNSPECIFIED
729.1	MYALGIA AND MYOSITIS UNSPECIFIED
729.2	NEURALGIA NEURITIS AND RADICULITIS UNSPECIFIED
780.01	COMA
780.09	ALTERATION OF CONSCIOUSNESS OTHER
780.1	HALLUCINATIONS
780.39	OTHER CONVULSIONS
963.0	POISONING BY ANTIALLERGIC AND ANTIEMETIC DRUGS 965.00
965.00 - 965.09	POISONING BY OPIUM (ALKALOIDS) UNSPECIFIED - POISONING BY OTHER OPIATES AND RELATED NARCOTICS
965.1	POISONING BY SALICYLATES
965.4	POISONING BY AROMATIC ANALGESICS NOT ELSEWHERE CLASSIFIED
965.5	POISONING BY PYRAZOLE DERIVATIVES
965.61	POISONING BY PROPIONIC ACID DERIVATIVES
966.1	POISONING BY HYDANTOIN DERIVATIVES
967.0 - 967.9	POISONING BY BARBITURATES - POISONING BY UNSPECIFIED SEDATIVE OR HYPNOTIC
969.00 - 969.9	POISONING BY ANTIDEPRESSANT, UNSPECIFIED - POISONING BY UNSPECIFIED PSYCHOTROPIC AGENT
972.1	POISONING BY CARDIOTONIC GLYCOSIDES AND DRUGS OF SIMILAR ACTION
977.9	POISONING BY UNSPECIFIED DRUG OR MEDICINAL SUBSTANCE
V15.81	PERSONAL HISTORY OF NONCOMPLIANCE WITH MEDICAL TREATMENT PRESENTING HAZARDS TO HEALTH
V58.69	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS
V58.83	ENCOUNTER FOR THERAPEUTIC DRUG MONITORING
V71.09*	OBSERVATION OF OTHER SUSPECTED MENTAL CONDITION Group 1

Group 1 Medical Necessity ICD-9 Codes Asterisk Explanation: **For monitoring of patient compliance in a drug treatment program, use ICD-9-CM code V71.09 as the primary diagnosis and the specific drug dependence diagnosis as the secondary diagnosis. For the monitoring of patients on methadone maintenance and chronic pain patients with opioid dependence, suspected of abusing other illicit drugs, use code V 58.69.

Physicians are to select the most appropriate diagnosis code. Labs are not to pre-populate requisition forms with diagnosis codes.

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