

Title: Urine Drug Testing	Division: Medical Management Department: Utilization Management
Approval Date: 4/6/18	LOB: Medicaid, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II, Market Plus, Essential, HARP
Effective Date: 4/6/18	Policy Number: UM- MP218
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1. POLICY DESCRIPTION:

In accordance with NYS Medicaid drug testing policy, the MetroPlus Health Plan Urine Drug Testing Policy consists of a screen (presumptive) and confirmatory (quantitative) testing structure. Presumptive drug class screening using CPT codes 80305, 80306 or 80307 is the first step in the process. Only substances that return a positive result on screen (presumptive) or are inconclusive or inconsistent with clinical presentation are reimbursable for confirmation (quantitative) testing using CPT codes 80320 – 80377. Definitive or direct confirmation testing using CPT code G0480-G0483 or G0659 is only reimbursable when no screening method is available.

Urine drug/alcohol screening/testing is used to detect alcohol, prescription medications and illegal substances for the purpose of medical treatment. Screening and testing should focus on the detection of specific drugs and not routinely include a panel of drugs of abuse.

The two laboratory methods for measuring urine drug testing are:

1. **Immunoassay (qualitative/presumptive) testing**
2. **Chromatography/mass spectrometry (quantitative testing)**

For the Medicare and UltraCare lines of business, MetroPlusHealth determines medical necessity based on applicable Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD).

<https://www.cms.gov/medicare-coverage-database/search.aspx>

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claims Department, Provider Contracting.

3. DEFINITIONS:

- a. **Presumptive/Qualitative Drug Testing** “Presumptive” urine drug testing (UDT) – Used to determine the **presence or absence of a drug or class of drugs** in a urine sample; results expressed as negative or positive or as a numerical result. Includes competitive immunoassays and thin layer chromatography.
- b. **Immunoassay** “Qualitative immunoassay” – Used to identify the presence or absence of drug classes and some specific drugs; biochemical tests **measure the**

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presence above a cutoff level of a substance (drug) with the use of an antibody.
Read by photometric technology.

An immunoassay involves an antibody that reacts best with the stimulating drug, and reacts to a lesser extent (cross-reactive) or not at all with other drugs in the drug class. While presumptive tests vary in their ability to detect illicit drugs such as tetrahydrocannabinol (THC), cocaine, 3,4-methylenedioxy-N-methylamphetamine (MDMA; “ecstasy”) and phencyclidine (PCP), they may not be optimal tests for many prescription drugs, such as opiates/opioids, barbiturates, and benzodiazepines.

- c. **Quantitative** UDT – Used to **identify specific medications, illicit substances and metabolites**; reports the results of analytes absent or present typically in concentrations such as ng/ml.
 - i. **Confirmatory** testing is used to confirm the results of a presumptive test.
 - ii. **Definitive** testing is used for specific drugs that are unable to be detected by qualitative testing.

Quantitative methods include, but are not limited to gas chromatography coupled with mass spectrometry (GC-MS) and liquid chromatography (LC-MS) testing methods only. These high-complexity tests should be performed in a Clinical Laboratory Improvement Amendment (CLIA) certified laboratory where national quality control standards for testing and laboratory personnel training have been established.

- d. **Specimen Validity Testing** – Urine specimen testing to ensure that urine 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.
- e. **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.

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- f. **Blanket Orders** – 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.
- g. **Reflex Testing** – Laboratory testing that is performed automatically 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)
- h. **Opioids** – Opioids are a class of drugs that include the illegal drug **heroin**, synthetic opioids such as **fentanyl**, and pain relievers available legally by prescription, such as oxycodone (OxyContin®), hydrocodone (Vicodin®), codeine, morphine, and many others. These drugs are chemically related and interact with opioid receptors on nerve cells in the body and brain.
- i. **Heroin** – Heroin is an opioid drug made from morphine, a natural substance taken from the seed pod of the Asian opium poppy plant.
- j. **Fentanyl** – Fentanyl is a powerful synthetic opioid analgesic that is similar to morphine but is 50 to 100 times more potent. It is a schedule II prescription drug and is typically used to treat patients with severe pain or to manage pain after surgery. It is also sometimes used to treat patients with chronic pain who are physically tolerant to other opioids.
- k. **Naloxone** – Naloxone is an opioid antagonist medication used to rapidly reverse opioid effects. It binds to opioid receptors and can reverse and block the effects of other opioids.
- l. **Suboxone** – Suboxone (buprenorphine and naloxone) sublingual film is a partial-opioid agonist indicated for treatment of opioid dependence.

4. POLICY:

A. Testing Frequency

- a. Qualitative testing frequency (80305, 80306 or 80307)

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- i. Not to exceed 1 unit per date of service
- ii. Not to exceed 52 units per year
- iii. Analysis must be lab-based.
- iv. Baseline (initial test) then qualitative testing should be conducted randomly
 - 1. Does not need to be at each office visit
 - 2. Does not need to be the same drug(s) for each testing
- v. Targeted testing: Frequency is based on documentation of suspicious behaviors such as self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion or other documented change in affect or behavioral pattern

b. Quantitative/Confirmation testing frequency (80320 – 80377)

- i. Not to exceed 1 unit per date of service
- ii. Not > 6 times within 12 months
- iii. Quantitative/Confirmation testing requires either a positive qualitative screening test or an inconsistent result and shall be performed only for the drug class represented by the positive screening or inconsistent result.
- iv. Analysis must be lab-based.

c. Quantitative/Definitive testing frequency (G0480, G0481, G0482, G0483, G0659)

- i. Not to exceed 1 unit per date of service
- ii. Not > 6 times within 12 months
- iii. Shall be performed when a qualitative test is not available (e.g., in the case of selected synthetic or semi-synthetic opioids)
- iv. Analysis must be lab-based.

5. BACKGROUND

A. Urine drug/alcohol testing is considered medically necessary when the following

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criteria are met:

- a. If requested, medical record documentation substantiates that testing will impact treatment
- b. One of the following conditions is present:
 1. Altered mental status
 2. Medical/psychiatric condition where drug/alcohol toxicity may be a contributing factor
 3. Perinatal maternal drug use (e.g. current pregnancy with possible exposure of the fetus to illicit drugs taken by the mother, or history of recent delivery of infant diagnosed with Neonatal Abstinence/Neonatal Withdrawal Syndrome)
 4. Need to assess adherence to prescribed medications
 5. Need to assess and treat members with substance abuse disorders including alcohol

c. Quantitative Testing is indicated if:

1. Qualitative screening is positive
 - i. Will only cover the drug class represented by the positive screening
 - ii. Will not cover if the results are confirmed by member's self disclosed admission
2. Confirmation by quantitative testing requires either a positive qualitative screening test or an inconsistent result and shall be performed only for the drug class represented by the positive screening or inconsistent result.
3. Definitive quantitative testing is indicated when the drug concentration sought for a specific drug in question is not detected by qualitative testing.

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- B. New patient screening – New patient screening typically involves the following drugs/dug classes: Alcohol, amphetamines/methamphetamine, barbituates, cannabinoids, cocaine, methadone, opiates.

Request for specialty screening or direct-to-chromatography quantitative analysis, for expanded benzodiazepines and opioid panels to determine the specific drugs in the member's system, may be medically necessary if supported by documentation that substantiates the clinical rationale for the expanded test.

- C. On-going monitoring – typically sufficient with a screening qualitative immunoassay without the need for confirmation or quantitative testing unless documentation and specific rationale supports additional testing. (The need for testing [i.e., that it impacts treatment] must be established at each encounter with previous testing documented in the record)
- D. Chronic Opioid Therapy
- Qualitative drug and alcohol screens will only be covered if documentation includes all of the following: History; current treatment plan; medication prescribed; risk potential for abuse, misuse and diversion accompanied by prescription drug monitoring data or pharmacy profile
 - Periodic qualitative monitoring is used to address risk potentials of abuse and diversion of controlled medications and/or abuse of illicit drugs, alcohol or drugs not prescribed as part of the treatment plan and obtained from an undisclosed/unsanctioned source
 - Targeting and select testing of limited drugs of abuse may be medically necessary when there is documentation of suspicious behaviors such as self-escalation of dose, doctor-shopping, indications/symptoms of illegal use, evidence of diversion or other documented change in affect or behavioral pattern
 - Confirmatory and/or quantitative drug testing may be considered medically necessary when reliable validation (member self-report, prescription drug

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monitoring data, pharmacy profile, communication from prescribing clinician) is not available and ≥ 1 of the following is documented:

- i. Member reports taking a prescribed opioid, but the drug screen is negative
- ii. Screening is positive for stimulant, barbiturate or benzodiazepine class of drug
- iii. Screening is negative, but results are inconsistent with medical history and there is documentation to support the need for confirmatory testing
- iv. A qualitative test is not available (e.g., in the case of selected synthetic or semi-synthetic opioids)

6. LIMITATIONS/EXCLUSIONS

- A. Blanket Orders (i.e., routine standing orders for all patients in a physician's practice) are not considered reasonable and necessary, and therefore are not covered.
- B. It is not reasonable and necessary for a reference laboratory to perform and bill immunoassay presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.
- C. Immunoassay 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.
- D. Drug testing of two different specimen types from the same member on the same date of service for the same drugs/metabolites/analytes is not covered.
- E. Specimen validity testing, including, but not limited to, pH, specific gravity, oxidants and/or creatinine is not separately covered. Drug testing providers performing validity testing on urine specimens utilized for drug testing should not separately bill the validity testing.
- F. High complexity testing is not covered if performed in the office-based setting.

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- G. Testing of saliva, blood, hair and nails is not covered, as the medical necessity of such testing has not been established due to insufficient evidence of therapeutic value.
- H. Testing must coincide with a paid office visit.
- I. CPT Codes G0481, G0482, G0483, G0659 are not covered by MetroPlus Health for Medicaid plans (Medicaid, HARP, SNP-HIV plans).

7. APPLICABLE PROCEDURE CODES

CPT	DESCRIPTION
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers
80320	Alcohol
80321-80322	Alcohol Biomarkers
80323	Alkaloids, not otherwise specified
80324-80326	Amphetamines
80327-80328	Anabolic steroids
80329-80331	Analgesics, non-opioid
80332-80334	Antidepressants, serotonergic class

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80335-80337	Antidepressants, Tricyclic and other cyclicals
80338	Antidepressants, not otherwise specified
80339-80341	Antiepileptics, not otherwise specified
80342-80344	Antipsychotics, not otherwise specified
80345	Barbiturates
80346-80347	Benzodiazepines
80348	Buprenorphine
80349	Cannabinoids, natural
80350-80352	Cannabinoids, synthetic
80353	Cocaine
80354	Fentanyl
80355	Gabaopentin, non-blood
80356	Heroin metabolite
80368	Hypnotics, sedative (non- benzodiazepines)
80357	Ketamine and Norketamine
80358	Methadone
80359	Methylenedioxyamphetamines
80360	Methylphenidate
80357	Norketamine
80368	Non-Benzodiazepines

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80361	Opiates
80362-80364	Opioids and opiate analogs
80365	Oxycodone
80392	Phencyclidine
80366	Pregabalin
80367	Propoxyphene
80368	Sedative Hypnotics (non-benzodiazepines)
80369-80370	Skeletal muscle relaxants
80371	Stimulants synthetic
80372	Tapentadol
80373	Tramadol
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

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	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

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	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

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9. REVISION LOG:

REVISIONS	DATE
Creation date	4/6/2018
Annual Review	6/8/2020
Annual Review	5/24/2021
Annual Review	5/31/2022
Annual Review	5/30/2023
Annual Review	5/28/2024
Annual Review	5/27/2025

Approved:	Date:	Approved:	Date:
David Ackman, MD VP Medical Director		Sanjiv Shah, MD Chief Medical Officer	

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Medical Guideline Disclaimer:

Property of Metro Plus Health Plan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication.