

## Therapeutic Drug Monitoring (Urine drug testing)

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Developed By: Medical Necessity Criteria Committee

### I. Description

Therapeutic drug monitoring is used to evaluate member compliance with long-term therapy for chronic conditions requiring medications with therapeutic levels. Blood and/or urine testing may be ordered based on the drug therapy and the member's diagnosis. Tests results are used to evaluate the member's compliance with drug therapy and misuse or abuse of prescribed/non-prescribed medications. It is also used to make adjustments to the prescribed medication dosage to achieve the desired therapeutic effect.

The use of prescription opioids to manage chronic non-cancer pain has increased in the last decade. This has increased the need to manage and evaluate patients for appropriate use of the prescribed medication. Urine drug testing (UDT) is the preferred test substance (sample source) for monitoring patients receiving ongoing pain management therapy. Concentrations of drugs and metabolites tend to be high in urine allowing longer detection times than concentrations in serum. The standard urine drug screen evaluates for the presence or absence (presumptive) of amphetamines, cannabinoids, cocaine, opiates, and PCP. Additional drugs may be screened as well depending on the patient's circumstances and history (i.e. benzodiazepines, alcohol, tricyclic antidepressants, SSRIs, or methadone). For a positive presumptive UDS, definitive testing may be performed. Urine drug screening cannot establish the length of time since last ingestion, overall duration of abuse, or state of intoxication.

The current recommendation for therapeutic drug monitoring for chronic pain management would include base line drug testing prior to initiation of opioid therapy, compliance monitoring within one to three months after baseline monitoring, and random monitoring every 6-12 months with provision for more frequent monitoring if unexpected results, complaints or behavior patterns are documented

### II. Definitions

**Enzyme-linked Immunoassay (EIA):** a presumptive laboratory technology using drug-class specific antibodies to screen for the presence of a drug.

**Gas Chromatography/Mass Spectrometry (GC/MS) High-performance liquid chromatography (HPLC):** laboratory technologies used to confirm the presence of specific drug or metabolite when the EIA is positive.

**Liquid Chromatography/Mass Spectrometry (LC/MS):** Liquid chromatography is used to separate the different components in a specimen, and mass chromatography is used to specifically identify the components of the specimen.

### III. Criteria

- A. OHSU Health Services will cover presumptive urine drug screening of multiple drug classes up to 12 units per plan year when billed with one of the following per date of service; **80305, 80306, 80307**, for
  - a. Members with a diagnosis where there is a suspicion of drug misuse or abuse.
  - b. Members with a diagnosis where drug toxicity may be a contributing factor
  - c. Pregnant members where there is possible exposure of the fetus to drug abuse
  - d. Members being treated for chronic non-cancer pain with opioid therapy to establish a baseline and random monitoring for adherence or diversion of prescribed medications
  - e. Members currently in treatment for chemical dependency. More frequent urine drug testing may be required to monitor compliance with the treatment program. Up to 32 units per plan year can be approved after verification of chemical dependency treatment. Additional units beyond 32 per plan year may be considered medically necessary with evidence of individualized need.
- B. Specimen validity testing (SVT) (pH and creatinine) is NOT covered as it is included in the **80305, 80306, or 80307**, for urine drug screening
- C. OHSU Health Services will cover definitive testing for the appropriate number of drug class(es) up to 12 units per plan year for one unit per one of the following bundled codes with documentation of positive presumptive screening for G0480 or G0481. (Only one of the codes may be billed per date of service).
- D. OHSU Health Services will **NOT** consider G0482, G0483, 0082U and 0227U as medically necessary
- E. OHSU Health Services will **NOT** cover additional definitive urine drug testing when the screening presumptive test is negative.
- F. OHSU Health Services will **NOT** cover urine Spectrophotometry, and Column Chromatography/Mass Spectrometry separately as they are included as part of the bundled codes for presumptive or definitive testing and may not be billed separately.
- G. OHSU Health Services will **NOT** cover therapeutic urine drug monitoring tests without proper clinical documentation and diagnoses to support the requested tests or without a signed physician's order with the specific tests requested.
- H. OHSU Health Services will cover definitive drug testing for blood levels of medications necessary for medical conditions (i.e. Lamictal for seizure control)

### IV. Information Submitted with the Prior Authorization Request:

1. Chart notes or emergency department records including history and physical, physician's orders, and any previous UDT results that documents the testing is required as part of the patient's medical or drug treatment program.
2. Documentation of specific diagnosis that supports the requested drug testing with identification, frequency, and maximum number of times each laboratory test or tests are to be performed

## V. Applicable CPT or HCPC codes

OHSU Health Services will cover one of the following codes for presumptive urine drug testing per member per day up to 12 units per plan year for commercial members.

Codes	Description
80305	Drug test(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
80306	Drug test(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
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service

OHSU Health Services will cover one of the following codes for definitive urine drug testing per member per day if presumptive test is positive for a Drug Class up to 12 units per plan year for commercial members.

Codes	Description
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 (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative and 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 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)); qualitative and quantitative, all sources, includes specimen validity testing per day, 8-14 drug class(es), including metabolite(s) if performed.

Not covered:

Codes	Description
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 and 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 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 and quantitative, all sources, includes specimen validity testing per day, 22 or more drug class(es), including metabolite(s) if performed.
0082U	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service
0227U	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation

Not covered: Quantitative testing (Including but not limited to and no longer valid):

Codes	Description
80320 – 80377	CPT codes for presumptive and definitive drug testing. OHSU Health Services does not accept CPT Codes for individual drug tests – please use appropriate bundled code above
82075	Alcohol (ethanol); breath
82570	Creatinine; other source
82491/80299	Methaqualone (quantitative)
83986	pH; body fluid, not otherwise specified
83992	Phencyclidine (PCP) (quantitative)
80299	Quantitation of therapeutic drug, not elsewhere specified
83789	Mass spectrometry and tandem mass spectrometry, non-drug analyte(s) not elsewhere specified; qualitative or quantitative, each specimen

Not covered: Included in the appropriate codes for presumptive or definitive testing:

Codes	Description
82542	Column chromatography/mass spectrometry (e.g., GC/MS, or HPLC/MS), non-drug analyte(s) not elsewhere specified; qualitative or quantitative, each specimen
84311	Spectrophotometry, analyte not elsewhere specified

## VI. References

1. Heit HA, [Gourlay DL.](#), Urine drug testing in pain medicine. [J Pain Symptom Manage.](#) 2004 Mar;27(3):260-7.
2. Chou R, Fanciullo GJ, Fine PG, et al, Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain, [J Pain.](#) 2009 Feb;10(2):113-30.
3. Katz NP, Sherbourne S, Beach M, et al, Behavioral monitoring and urine toxicology testing in patients receiving long-term opioid therapy, [Anesth Anal](#) 2003;97:1097-102.
4. Christo, PJ, Manchikanti L, Ruan X, et al, Urine drug testing in chronic pain, [Pain Phys](#) 2011; 14:123-143
5. Moeller KE, Lee KC, Kissack JC, Urine Drug Screening: Practical Guide for Clinicians, [Mayo Clin Proc](#), Jan 2008;83(1):66-76
6. Gourlay DL, Heit HA, Urine Drug Testing in Clinical Practice, California Academy of Family Physicians CME, May 31, 2010, PharmaCom Group, Inc.
7. CPT 2012, American Medical Association, Professional Edition
8. CMS. "Medicare Drug Screen Testing." [MLN Matters](#), SE1105, February 14, 2011. <https://www.cms.gov/MLN MattersArticles/Downloads/SE1105.pdf>.
9. Physician Advisors

## VII. Annual Review History

Review Date	Revisions	Effective Date
08/2013	Annual Review: Added table with review date, revisions, and effective date. Added criteria to cover for blood quantitative level of medications for specific medical conditions.	08/28/2013
08/2014	Annual Review:	08/30/2014
11/2014	Added criteria regarding specimen validity testing and codes not covered for alcohol and alcohol breath testing.	12/3/2014
01/2015	Annual Review: Revised and added new codes for 2015 and deleted codes flagged.	01/28/2015
01/2016	Annual Review: Revised to new CMS HCPC codes for coverage. Deleted termed codes, continue to not cover 80300 - 80377	01/18/2016

01/2017	Annual Review: Updated with new CPT codes for presumptive testing. Deleted sections in criteria that applied to old drug codes.	01/25/2017
01/2018	Annual Review: Updated to new template. No changes	01/25/2018
01/2019	Annual Review: Updated LCD link, updated CPT and HCPC codes	02/01/2019
07/2019	Revised and updated criteria to indicate codes to be covered and codes no longer covered; removed deleted codes	10/01/2019
09/2020	Annual Review: No changes	10/01/2020
12/2020	Update: Added 0227U as non-covered code	1/1/2021
08/2021	Annual Review: No changes	09/01/2021
07/2022	Annual Review: No changes	08/01/2022
08/2023	Annual Review: No changes	08/01/2023

## Appendix 1 – Covered Diagnosis Codes

For Medicare members – check Noridian LCD: L36707 – Controlled Substance Monitoring and Drugs of Abuse Testing

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

<b>Jurisdiction(s): 5, 8</b>	<b>NCD/LCD Document (s): L36707</b>
<a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36707&amp;ver=21&amp;Date=01%2f01%2f2019&amp;DocID=L36707&amp;SearchType=Advanced&amp;bc=KAA AABAAAA&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36707&amp;ver=21&amp;Date=01%2f01%2f2019&amp;DocID=L36707&amp;SearchType=Advanced&amp;bc=KAA AABAAAA&amp;</a>	

<b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b>		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC