Drug Testing in Pain Management

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating providers and hospitals
Page Number(s):	1 of 6

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary drug testing in pain management.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Presumptive tests – Tests are usually performed at the point of service (POS). Immunoassay tests are based on the principle of competitive binding and use antibodies to detect a particular drug or drug metabolite in a sample.

Definitive tests – Always performed in a laboratory and assess multiple drugs at one time. Individual tests are specific to one drug only. Definitive testing is a panel that includes individual drug tests and the associated levels of the specific drugs. Definitive drug testing is more cost effective than individual testing. Gas chromatography/mass spectrometry (GC/MS) is considered to be the gold standard for confirmatory testing.

PROCEDURE COVERED

1. Prior authorization is not required.

2. Routine presumptive urine drug testing in substance use disorder treatment (i.e., testing at every visit or without consideration for specific individual risk factors) is considered not medically necessary.

3. Presumptive Tests

   - Presumptive drug testing may be considered medically necessary and will only be allowed one (1) per date of service, regardless of the number of drug classes tested. Quantity level limits (QLLs) are considered not medically necessary when the frequency guideline above is exceeded.
   - Presumptive drug testing, when billed in any combination, may be considered medically necessary and will be limited to 24 tests in a benefit period regardless of test performed. QLLs are considered not medically necessary when the frequency guidelines above are exceeded.
   - Specimen validation testing is inherent to presumptive and confirmatory testing and is considered medically necessary.

CPT Code	Description
80306	Item provided without cost to provider, supplier or practitioner, or credit received for replacement device; examples include, but not limited to, covered under warranty, replaced due to defect, free samples.
80307	Partial credit received for replaced device.
82542	Column chromatography/mass spectrometry, if performed (e.g., GC/MS, or HPLC/MS), non-drug analyte not elsewhere specified; qualitative or quantitative, each specimen.
82570	Creatinine; other source.
83986	Ph, body fluid, not otherwise specified.
84311	Spectrophotometry, analyte not elsewhere specified.
84315	Specific gravity (except urine).
83992	Assay of Phencyclidine.

4. Definitive drug testing may be considered medically necessary under ANY ONE of the following conditions:

   - When performed as a reflex by a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory after a positive presumptive test when ANY ONE of the following are met:
     - To verify a presumptive positive urine drug test before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or
     - In specific situations for which definitive testing is required for clinical decision making and would significantly change a treatment plan (e.g., to distinguish drug supplementation from products of minor metabolic pathways; to help identify individuals diverting medications); or
     - To identify non-prescribed medication or illicit substance use so as to allow safe prescribing of controlled substances, where the clinician has documented concerns

related to safety risks that may arise due to failure to identify non-prescribed medications or illicit substances; or

- When presumptive drug tests are not available for the drug(s) for which there is a suspicion of abuse or misuse, and ALL of the following criteria are met:
    - The clinical presentation of the individual being tested supports the need for the specific drug testing being requested; and
    - Results of testing will impact treatment; and
    - Testing is performed in a CLIA certified laboratory.

Definitive and presumptive drug testing is considered not medically necessary when the above criteria are not met.

Definitive drug testing, when billed in combination, may be considered medically necessary and will be allowed one (1) service per date with a limit of 24 tests per benefit period. QLLs are considered not medically necessary when the frequency guidelines listed above are exceeded.

CPT Code	Description
G0480	Drug test(s), definitive, utilizing one (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 one (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; 8-14 drug class(es), including metabolite(s) if performed
G0482	Drug test(s), definitive, utilizing one (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 one (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; 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

PROCEDURE NONCOVERED

The following tests are considered noncovered:

- Nonforensic testing (i.e., job related testing)

Individual drug tests are not considered medically necessary.

80320	80321	80322	80323	80324	80325	80326
80327	80328	80332	80333	80334	80335	80336
80337	80338	80345	80346	80347	80348	80349
80350	80351	80352	80353	80354	80355	80356
80357	80358	80359	80360	80361	80362	80363
80364	80365	80366	80367	80368	80369	80370
80371	80372	80373	80374	83992		

The following drug tests are considered experimental/investigational, and therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature:

- Hair drug testing; and
- Oral fluid drug testing; and
- Meconium drug testing

EXCEPTIONS

Benefit year limits do not apply to the following:

- Emergency room visits
- Inpatient admissions
- Federally regulated testing

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

Post-Payment Audit Statement

The medical record should include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service

Experimental/Investigational (E/I) services are not covered regardless of place of service.

Drug testing is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

SUMMARY OF LITERATURE

42 CFR 8.12 - Federal opioid treatment standards 2017

An Opioid Treatment Programs (OTPs) organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid use disorder which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

Centers for Disease Control and Prevention (CDC) 2016

When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

The guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.

Substance Abuse and Mental Health Service Administration (SAMHSA) 2015

Medication-Assisted Treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders. Research shows that a combination of medication and therapy can successfully treat these disorders, and for some people struggling with addiction, MAT can help sustain recovery.

Federal legislation, regulations, and guidelines govern MAT for opioid addiction. SAMHSA's Division of Pharmacologic Therapies (DPT), part of the SAMHSA Center for Substance Abuse Treatment (CSAT), oversees accreditation standards and certification processes for OTPs. DPT also works with the Drug Enforcement Administration (DEA) and the states to regulate certain medications used in MAT.

Additionally, DPT works directly with MAT professionals to improve treatment outcomes and to meet regulatory criteria.

American Society of Addiction Medicine (ASAM) 2017

Appropriate Use of Drug Testing in Clinical Addiction Medicine was published by ASAM in 2017.

- "As a general principle, drug testing should be scheduled more frequently at the beginning of treatment. The Expert Panel recommends that a patient in early recovery be tested at least weekly. As the patient becomes more stable in recovery, the frequency of drug testing should be decreased, but performed at least on a monthly basis. Individual consideration may be given for less frequent testing if a patient is in stable recovery. If the patient returns to substance use after a period of abstinence, the provider should resume the early recovery testing schedule, possibly in conjunction with an adapted or intensified treatment plan."

References

42 CFR 8.12 - Federal opioid treatment standards. 2017.

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Hayes, Inc. Hayes Medical Technology Directory Report. Pharmacogenetic and Pharmacogenomic Testing to Improve Outcomes Related to Opioid Use Disorder. Lansdale, PA: Hayes, Inc; 01/27/2022.

Socias ME, Ahamad K, Le Foll B, et al. The OPTIMA study, buprenorphine/naloxone and methadone models of care for the treatment of prescription opioid use disorder: Study design and rationale. Contemp Clin Trials. 2018; 69:21-27.

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POLICY UPDATE HISTORY

08/19/2021	Approved in Medical Policy Committee
01/26/2022	Annual review, approved in medical policy committee
02/2022	Approved in QI/UM
02/22/2023	Annual review; approved in Medical Policy Committee
02/28/2023	Approved in QI/UM