Mass General Brigham
Health Plan

Medical Policy
Outpatient Drug Screening and Testing

Policy Number: 041

	Commercial and Qualified Health Plans	MassHealth
Authorization required		
No Prior Authorization	X	X

Overview
The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical appropriateness for drug screening and testing for Mass General Brigham Health Plan members.

Coverage Guidelines
Drug screening and drug testing must be focused on detecting known illicit drugs or controlled substances or specified drug(s) of concern based on the member's medical history or current clinical presentation. The testing result must impact clinical decision making. The frequency of testing is limited to the lowest level necessary to detect the drug(s) or controlled substance of concern needed to effectively manage the patients' health.

Reflex testing for circumstances other than what is required by the treatment plan to isolate the presence or absence of a drug is not considered medically necessary and therefore not covered.

Mass General Brigham Health Plan covers qualitative drug screening when it is medically necessary to monitor adherence with a prescribed controlled substance medication regimen and/or to detect known or suspected use of illicit drugs or illicitly used controlled substances. Mass General Brigham Health Plan covers the screening when criteria are met, and documentation is in the member's medical record supporting the drug screening as described in this policy.

Mass General Brigham Health Plan only covers quantitative drug testing when it is medically necessary and integral to the treatment plan to obtain quantitative drug levels after qualitative drug screening and when criteria and documentation requirements are met.

Coverage Criteria

Qualitative Urine and Oral Fluid Drug Screening

1. **Prescribed Controlled Substance Medication Regimen—Medical Adherence**
   Mass General Brigham Health Plan covers medically necessary qualitative drug screening when one of the following indications is present and when all the documentation requirements are met:
   a. Assessment of the member's baseline prior to initiating treatment or at the time treatment is initiated to detect known or suspected illicit drug use or illicitly used controlled substances;
   b. Monitoring adherence to the treatment regimen;
   c. When non-adherence, diversion, or a significant pre-test probability of non-adherence or diversion to the prescribed drug regimen is suspected and documented in the medical record.

2. **Substance Use Disorder Treatment Program**

Mass General Brigham Health Plan covers medically necessary qualitative drug screening when a member is participating in a plan-approved substance use disorder treatment program, when one of the following indications is present and when all documentation requirements noted are met:

a. During the pre-treatment phase, to assess for abstinence or recent drug use to determine likelihood of withdrawal.
b. During the induction phase, to determine a member's drug profile and detoxification regimen weekly drug screening may be medically appropriate. For patients initiating buprenorphine or naltrexone, drug screening may be required more frequently during the initial week to assess the member's risk of withdrawal.
c. During the stabilization phase, once a patient is clinically stable, to conduct weekly randomized or targeted drug screening if documentation supports the medical necessity of this screening.
d. During the maintenance phase, to assess the patient's adherence to the substance use disorder treatment program (targeted qualitative screenings is considered medically necessary once every 1-3 months.)
e. Following a relapse, when treatment intensification is medically necessary.

3. Known or Suspected Illicit Drug Use or Illicitly Used Controlled Substances

Mass General Brigham Health Plan covers medically necessary qualitative drug screening when one of the following indications is documented:

a. Diagnosis of possible exposure of fetus to illicit drugs taken by mother;
Note: Bi- monthly drug screening until delivery and once in labor for individuals who are at risk of exposing the fetus to illicit drugs is medically appropriate.
b. Unexplained coma;
c. Unexplained altered mental status in the absence of a clinically defined toxic syndrome;
d. Seizures with an undetermined history;
e. Severe or unexplained cardiovascular instability (cardiotoxicity);
f. Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome;
g. Detection of known or suspected illicit drug use or illicitly controlled substances as evidence by office visit or other progress notes.

Quantitative Urine Drug Testing

Mass General Brigham Health Plan only covers quantitative drug testing when quantitative drug levels are required for clinical decision making under the following conditions and when all documentation requirements are met:

1. For the drug class identified as positive on an initial qualitative drug screening, only when the quantitative drug levels are medically necessary for clinical decision making;
2. When qualitative drug screening is positive for an illicit drug and only for the illicit drug classification that was positive;
3. When a qualitative drug screen is negative for prescribed medications and only for that prescribed medications; or
4. When there is not a qualitative drug screening test in existence to detect:
   a. the drug being monitored for adherence; or
   b. the drug known or suspected of use.

Mass General Brigham Health Plan does not consider quantitative drug testing medically necessary to monitoring adherence with a prescribed controlled substance medication regimen and/or to detect known or suspected illicit drug use or illicitly used controlled substances except in the circumstances as noted above.

Documentation Requirements for Qualitative and Quantitative Testing[1]

All drug screening and drug testing requires an explicit order by the authorized provider and documentation in the member's medical record that must include all the following:

Provider Order

All drug screening and drug testing requires written orders by the authorized provider within 30 days prior to the proposed testing that must include all of the following:

a. Member name;
b. Prescriber name;
c. Diagnoses and complete list of all prescribed medications;
d. Specific drugs, drug classes, or drug panels to be tested
e. Name of the specific laboratory test such as qualitative drug screening or quantitative drug testing; and
f. For standing orders, frequency for performing each specific test.

Note:
Orders that include statements such as "conduct additional testing as needed" or "custom profile" are not acceptable.

Documentation—Progress Notes

a. Member history including: prior or current use of illicit drugs or illicitly used controlled substances and prior treatment;
b. Assessment of the member's condition and response to treatment;
c. The controlled substance of interest, dose, and frequency administered as applicable;
d. The results of each test and date of reporting;
e. A summary of the individual treatment plan and member characteristics that necessitate the specific drug testing being requested;
f. When monitoring of a controlled substance, the specific diagnosis for which the controlled substance is prescribed, and the treatment plan including the substance of interest, dosage, and frequency of administration and a controlled substance contract agreement with controlled substance dosage and frequency of administration; and
g. With repeated testing, the rational for the requested frequency and duration of testing;
h. Acknowledgement and clinical response to testing results and treatment plan based on results.

Exclusions

Mass General Brigham Health Plan does not consider the following conditions for drug screening or drug testing medically necessary and therefore screening or testing are not covered:

1. When mandated by a third party including but not limited to:
    a. Court;
    b. Residential facilities;
    c. School programs;
    d. Athletic or extra circular activities;
    e. Employment or pre-employment;
    f. Enrollment in the military.

[1] Drug screening and drug testing must be focused on detecting known illicit drug use or controlled substances or specified drug(s) of concern based on the member's medical history or current clinical presentation. The results must significantly impact clinical decision making. The frequency of testing is limited to the lowest level necessary to detect the illicit drug(s) or controlled substance of concern needed to effectively manage the patients' health. Generally, greater than 20 dates of service in a benefit period are not considered medically necessary.

2. Routine and repetitive qualitative or quantitative drug screening or drug testing (e.g., testing at every visit without consideration for specific patient risk factors or without consideration for whether quantitative testing is required for clinical decision making).
3. Testing that is indiscriminately carried out without a clear indication, treatment plan and decision-making response to either a positive or negative result;
4. That does not meet all the required documentation requirements as noted in this policy;
5. Custom panels routinely requested that are not specific to the member's documented clinical condition;
6. Quantitative drug testing without the results of qualitative drug screening unless there isn't a qualitative drug screening in existence to detect the drug being monitored for adherence, or the drug known or suspected of use;
7. Greater than 1 multi drug (qualitative) drug screening or drug testing per calendar day;
8. Reflex testing for circumstances other than what is required by the treatment plan to isolate the presence or absence of a drug; and
9. Generally, greater than 20 dates of service in a benefit period are not considered medically necessary. Dates of service exceeding 20 when billed during the benefit period will deny for the required documentation to support medical necessity as specified under the documentation requirements in this policy.

Definitions

Authorized Provider

A practitioner authorized under Massachusetts law to prescribe medications.

Baseline Testing

Testing that is used to identify the presence of illicit substances prior to prescribing controlled medications or to confirm the presence or absence of prescribed drug/drug class.

Clinical Laboratory Improvement Amendments (CLIA)

The CLIA of 1988 (CLIA 88) are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. CLIA 88 congressional legislation promulgates quality assurance practices in clinical labs and require them to measure performance at each step of the testing process from the beginning to the end-point of a response to a test result.

Drug Screening/Testing

There are two main categories of urine drug screening and testing. Qualitative drug screening is conducted to identify classes of drugs present in the urine and typically is done using immunoassay. They rely on a set threshold above which a positive result is produced and therefore do not detect lower concentrations of a drug. Quantitative or confirmatory drug tests are used for further analysis of a sample—to confirm a positive or sometimes, negative, result and typically are done using gas chromatography/mass spectrometry (GC/MS) or high-performance liquid chromatography (HPLC). Quantitative testing can identify a specific drug.

Qualitative Drug Screening

Qualitative drug screening otherwise referred to as presumptive or initial drug screening, use qualitative analysis to determine whether a specific drug, drug metabolite or substance is detectable above a threshold concentration in a sample. The results may be read by direct optical observation with or without instrument assistance. If detectable, the result is considered positive, if the drug/metabolite/substance is not detected, it is considered a negative result. Immunoassays are most commonly used for qualitative drug screening. They may detect low-concentrations of a substance with a high degree of specificity and are the most common laboratory method used for qualitative testing. Testing methods include Enzyme Immunoassays (EIA), Radioimmunoassay (RIA), Enzyme Linked Immunoassay Sorbent Assay (ELISA), Enzyme Multiplied Immunoassay Test (EMIT), Cloned

Enzyme Donor Immunoassay (CEDIA), Fluorescence Polarization Immunoassay (FPIA) and enzymatic methods (e.g. alcohol dehydrogenase).

Quantitative Drug Testing
Quantitative drug testing, otherwise referred to as definitive or confirmatory, use laboratory methods that identify (confirm) the type and amount of a drug/metabolite/substance in a sample and may be qualitative, quantitative or a combination of both. Methods typically used for quantitative testing include gas chromatography with single or tandem mass spectrometry (GC/MS), thin layer chromatography and liquid chromatography single or tandem mass spectrometry (LC/MS) and exclude immunoassays and enzymatic methods (e.g., alcohol dehydrogenase). Chromatography/spectrometry methods offer a highly sensitive and specific technique for detecting drugs or metabolites. These high-complexity tests should be performed in a CLIA (CMS-certified) accredited laboratory where national quality control standards for testing and laboratory personnel training have been established.

Individualized Treatment Plan
A documented plan that describes the patient's condition and procedure(s) that will be needed, detailing the treatment to be provided and expected outcome, and expected duration of the treatment prescribed by the physician.

Standing Order
An instruction or prescribed procedure in force permanently or until changed or canceled.

Urine Drug Testing (UDT)
The collection and analysis of urine samples for the detection of alcohol, nicotine or other drugs or their metabolites.

Relevant Regulation
Clinical Laboratory Improvement Amendments (CLIA)
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C

Related Policies
- Urine Drug Testing Provider Payment Guidelines

Codes

Authorized CPT/HCPCS Codes	Code 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 (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or 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; read by instrument assisted direct optical observation (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or 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
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 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 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

Effective
November 2022: Annual update. References updated.
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