




Policy No: PI_Payment Policy 33 Date Issued: 08/11/2021 Department: Molina Payment Integrity Office Title: Outpatient Definitive Drug Testing - Marketplace Applies to (Lines of Business): <input type="checkbox"/> Medicare and Medicaid Plan (MMP) <input type="checkbox"/> Medicaid <input type="checkbox"/> Medicare <input checked="" type="checkbox"/> Marketplace	Supersedes and Replaces:
	Revision Date(s): MM/DD/YYYY
	Applies to related policy(s):
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I. Purpose

Drug testing is a key diagnostic and therapeutic tool for patients with substance use disorder (SUD), opioid use disorder (OUD), chronic pain and other medical conditions. National data indicates a rise in testing that is excessive and not consistent with evidence-based practice. To ensure drug testing is medically necessary, Molina uses established nationally accepted industry standards and coding principles to develop this policy regarding reimbursement for drug testing performed in the outpatient setting.

Molina reserves the right to review submitted medical documentation to support the need for definitive and/or presumptive drug testing post-service in the outpatient setting. This process is implemented to evaluate if this policy was followed and criteria were satisfied. When a claim is submitted to Molina, it will be assessed for medical necessity. **Outpatient drug testing that does not meet the criteria in this policy will not be reimbursed.**

II. Overview

Drug use and abuse is a prevalent issue in the United States. Approximately 8 million people a year over the age of 12 meet diagnostic criteria for drug dependence or abuse. In a 2018 survey, an estimated 12% of adults (18 years of age or older) and 8% of adolescents (12 to 17 years of age) reported unhealthy use of prescription or illegal drugs in the United States. Younger adults (18-25 years old) accounted for 24% of those with unhealthy drug use compared to older adults (10%) and adolescents (8%). The most commonly reported drugs used are psychotherapeutic medications (pain relievers), cannabis, and opioids; use of heroin, cocaine, hallucinogens, inhalants, or methamphetamines were reported in smaller percentages. Drug use leads to preventable death, injury and disability; 70,000 fatal overdoses were reported in 2017. Use during pregnancy leads to increased obstetric complications (e.g., placental abruption, preeclampsia, third trimester bleeding, and adverse fetal and infant outcomes [spontaneous abortion, abnormal brain growth, preterm delivery, low birth weight, neonatal abstinence syndrome]).¹

See the Appendix and Reference sections for more information, including accessibility to publications.

III. Policy

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

It is the responsibility of the Provider to perform medically necessary drug tests based on current evidence and clinical guidelines.

*Provider may only perform medically necessary drug tests based on current evidence and clinical guidelines. Outpatient definitive drug testing is **considered medically necessary** for Members when testing does not exceed seven (7) drugs/drug classes per Member per day AND when the following criteria below is met under A, B or C.*

Outpatient definitive testing for more than seven drug classes is considered a non-covered service and will not be reimbursed.

A. There is a documented history or suspicion of drug use by the Member including (but not limited to) illicit and prescription drug use, noncompliance, or high likelihood of non-adherence to a drug regimen prescribed by a Provider. In addition, ALL of the following must be met:

1. Presumptive testing has been performed within the previous 7 days (based on original date of service for definitive testing); **AND**,
2. Results from presumptive testing (positive or negative) are either:
 - a. Varying with respect to the expected results when reviewed with the Member's medical history, clinical presentation, and/or their individual statement following a discussion about their recent medication and drug use; **OR**,
 - b. Reflect the clinical documentation however, drug class-specific assays are necessary to identify the drug(s) that resulted in a positive test result.

AND

3. Definitive testing will confirm the discrepancy that is crucial to the Member's ongoing care; **AND**,
4. Request for definitive testing includes only the specific drug(s) or number of drug classes that initial testing resulted in unpredicted results.

OR

B. Provider anticipates that the presumptive test results will be positive (e.g., due to recent drug use) **AND**:

1. It is medically necessary to conduct definitive testing to determine the specific substance(s) used by a Member; **AND**
2. Established standards for specific substance(s) and/or drug class levels have been identified for making a medical necessity determination.

OR

C. Member requires definitive testing as it relates to serum drug therapeutic levels for the treatment of a specific disease of condition (confirmed by medical documentation submitted by the Provider).

See the "Definitions" section of the Appendix for additional information.

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

LIMITATIONS AND EXCLUSIONS

Drug testing (presumptive and definitive) is considered **not medically necessary** for the reasons below that include, but are not limited to:

1. Testing in asymptomatic Members (except as explained above).
2. Testing for medico-legal purposes (e.g., court-ordered testing that is not required by state regulations).
3. For the purpose of employment or pre-employment (e.g., as a condition for employment or continuation of employment) as these are conditions of employment and should be covered by the employer.
4. Inclusion of drug testing as part of a Member's routine medical examination (e.g. enrollment in school, military).
5. To participate in school, community or extracurricular athletic activities and/or programs as testing for these purposes are not the health plan's responsibility but rather a third party.
6. Testing as part of a medical examination for any reason not listed above (e.g., marriage licensure, insurance purposes, etc.).
7. For the validity of a specimen as this is part of a laboratory's quality control practices as such measures are not the responsibility of the health plan.
8. Testing using same-day methods of drug metabolites in a blood and urine specimen (performed by presumptive or definitive analyses).
9. Blanket orders.
10. Testing as part of routine or standing orders for all patients in a Provider's practice. (Physician-defined standing orders for pre-determined drug panels may be medically necessary if documented in the Member's profile for a limited sequential period).
11. Testing that is billed using individual definitive CPT codes when the request is for a comprehensive definitive drug testing panel (CDDP).
12. Use of reflex definitive drug tests if presumptive testing is performed at point of care.
13. Presumptive point of care testing and the ordering of presumptive immunoassay (IA) testing from a reference laboratory (includes requests with or without reflex testing).

IV. Coding

Place of Service

The *Outpatient Definitive Drug Testing* policy applies only to outpatient POS 81, 11, 19, 22, and 24. All other POS **are not addressed in this policy.**

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is covered or non-covered. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

Covered CPT Codes

CPT 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
80320	Alcohols
80321	Alcohol biomarkers; 1 or 2
80322	Alcohol biomarkers; 3 or more
80323	Alkaloids, not otherwise specified
80324	Amphetamines; 1 or 2
80325	Amphetamine; 3 or 4
80326	Amphetamines; 5 or more
80327	Anabolic steroids; 1 or 2
80328	Anabolic steroids; 3 or more
80329	Analgesics, non-opioid; 1 or 2
80330	Analgesics, non-opioid; 3-5
80331	Analgesics, non-opioid; 6 or more
80332	Antidepressants, serotonergic class; 1 or 2
80333	Antidepressants, serotonergic class; 3-5
80334	Antidepressants, serotonergic class; 6 or more
80335	Antidepressants, tricyclic and other cyclicals; 1 or 2
80336	Antidepressants, tricyclic and other cyclicals; 3-5
80337	Antidepressants, tricyclic and other cyclicals; 6 or more
80338	Antidepressants, not otherwise specified
80339	Antiepileptics, not otherwise specified; 1-3
80340	Antiepileptics, not otherwise specified; 4-6
80341	Antiepileptics, not otherwise specified; 7 or more
80342	Antipsychotics, not otherwise specified; 1-3
80343	Antipsychotics, not otherwise specified; 4-6
80344	Antipsychotics, not otherwise specified; 7 or more
80345	Barbiturates
80346	Benzodiazepines; 1-12
80347	Benzodiazepines; 13 or more
80348	Buprenorphine

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

80349	Cannabinoids, natural
80350	Cannabinoids, synthetic; 1-3
80351	Cannabinoids, synthetic; 4-6
80352	Cannabinoids; synthetic; 7 or more
80353	Cocaine
80354	Fentanyl
80355	Gabapentin, non-blood
80356	Heroin metabolite
80357	Ketamine and norketamine
80358	Methadone
80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)
80360	Methylphenidate
80361	Opiates, 1 or more
80362	Opioids and opiate analogs; 1 or 2
80363	Opioids and opiate analogs; 3 or 4
80364	Opioids and opiate analogs; 5 or more
80365	Oxycodone
80366	Pregbalin
80367	Propoxyphene
80368	Sedative Hypnotics (non-benzodiazepines)
80369	Skeletal muscle relaxants; 1 or 2
80370	Stimulants, synthetic
80371	Stimulants, synthetic
80372	Tapentadol
80373	Tramadol
80374	Stereoisomer (enantiomer) analysis, single drug class
80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3
80376	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6
80377	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more
83992	Phencyclidine (PCP)

Covered HCPCS Codes

HCPCS Code	Description
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(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

Non-Covered HCPCS Codes

HCPCS Code	Description
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); definitive, qualitative or quantitative, all sources(s), 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

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

Proprietary Laboratory Analyses or PLA services Codes

0007U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service
0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites
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
0143U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0144U	Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0145U	Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0146U	Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0147U	Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0148U	Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0149U	Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0150U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

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V. References

Government Agencies

1. United States Preventive Services Task Force (USPSTF). Unhealthy Drug Use: Screening. <https://uspreventiveservicestaskforce.org/uspstf/recommendation/drug-use-illicit-screening#fullrecommendationstart>. Published June 9, 2020. Accessed June 24, 2021.
2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>. Accessed June 24, 2021.
3. Food and Drug Administration (FDA). Drugs of abuse tests. <https://www.fda.gov/medical-devices/in-vitro-diagnostics/drugs-abuse-tests>. Updated July 26, 2018. Accessed June 24, 2021.

Professional Society Guidelines and Other Publications

4. Bukstein, O., American Academy of Child and Adolescent Psychiatry (AACAP) Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with substance use disorders. *J Am Acad Child Adolesc Psychiatry*. 2005;44(6):609-621. DOI:<https://doi.org/10.1097/01.chi.0000159135.33706.37>. Updated 2005. Accessed June 24, 2021.
5. American Society of Addiction Medicine (ASAM). Appropriate use of drug testing in clinical addiction medicine. <https://www.asam.org/Quality-Science/quality/drug-testing>. Published April 2017. Accessed June 24, 2021.
6. American Society of Addiction Medicine (ASAM). Public Policy Statement, *The Ethical Use of Drug Testing in the Practice of Addiction Medicine*. <https://www.asam.org/Quality-Science/quality/drug-testing>. Published April 2019. Accessed June 24, 2021.
7. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. *J Addict Med*. 2015 Sep-Oct;9(5):358-67. doi: 10.1097/ADM.0000000000000166. Accessed June 24, 2021.
8. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. *J Addict Med* 2020;14(2S):1–91. <https://www.asam.org/Quality-Science/quality/2020-national-practice-guideline>. Accessed June 24, 2021.
9. American College of Obstetricians and Gynecologists (ACOG). Committee opinion no. 711: Opioid use and opioid use disorder in pregnancy. <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy>. Updated 2017. Accessed June 24, 2021.
10. Substance Abuse and Mental Health Services Administration (SAMHSA). Federal guidelines for opioid treatment programs. <https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP>. Published January 2015. Accessed June 25, 2021.
11. Substance Abuse and Mental Health Services Administration (SAMHSA). Clinical drug testing in primary care. Technical Assistance Publication (TAP) 32. HHS Publication No. (SMA) 12-4668. Rockville, MD: Substance Abuse and Mental Health Services Administration. <https://store.samhsa.gov/product/TAP-32-Clinical-Drug-Testing-Primary-Care/SMA12-4668>. Published 2012. Accessed June 24, 2021.
12. Substance Abuse and Mental Health Services Administration (SAMHSA). Substance abuse: Clinical issues in intensive outpatient treatment. Treatment Improvement Protocol (TIP) Series, No. 47. DHHS Publication No. (SMA) 13-4182. Rockville, MD. <https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182>. Published December 2013. Accessed June 24, 2021.

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

13. American Society of Addiction Medicine (ASAM). Consensus statement: Appropriate use of drug testing in clinical addiction medicine. https://www.asam.org/docs/default-source/quality-science/the-asam-appropriate-use-of-drug-testing-in-clinical-addiction-medicine-full-document.pdf?Status=Temp&sfvrsn=700a7bc2_2. Adopted April 5, 2017. Accessed July 8, 2021.

Other Reviewed Publications

14. Argoff CE, Alford DP, Fudin J, et al. Rational urine drug monitoring in patients receiving opioids for chronic pain: consensus recommendations. *Pain Medicine*, Jan 2018; 19(1), p. 97–117. doi: 10.1093/pm/pnx285. Accessed June 24, 2021.
15. Centers for Disease Control and Prevention (CDC). Clinical Laboratory Improvement Amendments (CLIA): Law and regulations. <https://www.cdc.gov/clia/law-regulations.html>. Updated August, 6, 2018. Accessed June 24, 2021.
16. Centers for Disease Control and Prevention (CDC). Urine drug testing. https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-UrineDrugTesting_FactSheet-508.pdf. Accessed June 24, 2021.
17. Christo PJ, Manchikanti L, Ruan X, et al. Urine Drug Testing in Chronic Pain. *Pain Physician* 2011;14:123-143. <https://pubmed.ncbi.nlm.nih.gov/21412368/>. Accessed June 24, 2021.
18. Jannetto PJ, Langman LJ, eds. Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients. American Association of Clinical Chemistry (AACC) Laboratory Medicine Practice Guidelines. Washington, DC: AACC; 2018. <https://www.aacc.org/science-and-research/practice-guidelines>. Accessed June 24, 2021.
19. Jarvis M, Williams J, Hurford M, et al. Appropriate Use of Drug Testing in Clinical Addiction Medicine. *J Addict Med*. 2017;11(3):163-173. doi: 10.1097/ADM.0000000000000323. Accessed June 24, 2021.
20. Snyder ML, Fantz CR, Melanson S. Immunoassay-Based Drug Tests Are Inadequately Sensitive for Medication Compliance Monitoring in Patients Treated for Chronic Pain. *Pain Physician*. 2017 Feb;20(2S):SE1-SE9. <https://pubmed.ncbi.nlm.nih.gov/28226337/>. Accessed June 24, 2021.

VI. Policy History Update

MM/DD/2021 New policy.

VII. Appendix

Below is a summary of publications from applicable national and specialty organizations when building this policy. For links, please see the *Reference* section.

Government Agencies

Centers for Medicare and Medicaid Services (CMS). At the time of publication, a National Coverage Determination (NCD) was not available. To locate LCDs for your specific state, go to <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx> – search “drug testing”.^{2,3}

United States Food and Drug Administration. The FDA regulates the types of tests that are available for drug testing as well as the design and performance of tests. Device Advice is also available by the FDA to provide information on many tests.³

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

United States Preventive Service Task Force (USPSTF). While the USPSTF does not provide recommendations about drug testing with biological specimens, it is recommended that Providers screen adults age 18 years or older by asking questions regarding unhealthy drug use. Screening is beneficial in providing an accurate diagnosis, effective treatment, and appropriate care.¹

Professional Organization and Society Guidelines

American Academy of Child and Adolescent Psychiatry (AACAP). The American Academy of Child and Adolescent Psychiatry (AACAP) recommends that testing be part of the individual's formal evaluation and ongoing assessment of substance use (during and after treatment). There is no guidance for testing limits for this population.⁴

American Society of Addiction Medicine (ASAM). The American Society of Addiction Medicine (ASAM) published a Consensus Statement, *Appropriate Use of Drug Testing in Clinical Addiction Medicine*. The aim is to offer guidance regarding the effective use of testing to identify, diagnose and treat patients.⁵

The Society also published a Public Policy Statement, *The Ethical Use of Drug Testing in the Practice of Addiction Medicine*. Inappropriate or unethical use of drug testing can cause adverse outcomes, including the quality of addiction treatment and a reason for testing by providers.⁶

- Testing for drugs of abuse should be utilized when medically necessary; tests should be based on the patient's individual clinical assessment.
- The rationale for the drug tests being requested should document the medical necessity as well as inclusion of expected clinical decisions and/or outcomes per testing results.
- Over- or underutilization of drug testing panels by applying them to every patient at every testing time (irrespective of clinical history and needs) may be inappropriate.
- Awareness of drug tests and costs of various methods should be understood by Providers in an effort to limit the financial outcome with respect to deductibles, copays, or coinsurance costs (especially when out-of-network).

ASAM published the *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*⁷; it was followed by a *Focused Update* in 2020 that included revisions to the 35 existing recommendations and 13 new recommendations.⁸ Highlights are focus on assessment and treatment planning; the use of Naloxone and the importance of educating a patient's significant others in its use in case of overdose; transitioning treatment using methadone to buprenorphine; and providing immediate referrals for pregnant woman diagnosed with OUD for services related to emergent or urgent medical conditions.^{7,8}

American College of Obstetricians and Gynecologists (ACOG). The College recommends that drug testing be conducted with consent and that a positive result will not deter care, a disqualifier for coverage under publicly-funded programs, or the sole factor in determining family separation.⁹

Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment (SAMHSA). The agency published the following documents concerning drug testing:

- The *Federal Guidelines for Opioid Treatment Programs* describe SAMHSA's federal opioid treatment standards (Title 42 of the Code of Federal Regulations Part 8 [42 CFR § 8]) that OTPs must satisfy. Also, a section is included on the medical documentation that should be included when submitting a request.¹⁰

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

- To assist Providers on how to effectively implement drug testing, SAMHSA published *Clinical Drug Testing in Primary Care (Technical Assistance Publication [TAP] 32)*. Guidance includes the importance of drug testing in the assessment, diagnosis and treatment of individuals in the primary care setting. Chronic pain is also addressed when treating SUDs.¹¹
- For additional guidance on drug testing, see Appendix B of the *Treatment Improvement Protocol (TIP) – Substance Abuse: Clinical Issues in Intensive Outpatient Treatment*. Information is also included on alternative testing methods for monitoring drug use.¹²

Definitions¹³

Term	Definition
Chromatography	A high-complexity method of drug testing involving the passing of a mixture that is dissolved in a mobile phase through to a stationary phase. This method isolates various molecules by type; each type can then be identified and measured. Performed in a CLIA-accredited laboratory.
Clinical Laboratory Improvement Amendments (CLIA)	A national program that regulates laboratories performing testing on specimens with the aim of ensuring accurate and reliable test results.
Cross-Reactivity	Immunoassays suffer from a lack of specificity – they will react to compounds with similar chemical structures and target compounds present in the body for reasons other than the consumption of illicit substances. An example is consuming poppy seeds; drugs derived from the poppy plant will both metabolize to detectable amounts of morphine in the body.
Definitive (or Quantitative) Confirmation	Definitive testing is performed using a method with high sensitivity and specificity that can identify specific drugs, their metabolites, and/or drug quantities. Such testing likely takes place in a laboratory and each individual test can be expensive. Gas or liquid chromatography combined with mass spectrometry is the gold standard method in definitive drug testing.
Fixed Testing Schedule	A predictable timeframe when drug testing will occur – for example, every Monday or every 10 days. This is not recommended as patients can use knowledge of the routine to strategically use substances on days when the detection risk is smallest.
High-Complexity Test	Used to confirm results of a presumptive test via specific chromatography or spectrometry techniques. Performed in a CLIA-accredited laboratory which adheres to quality control standards. The complexity of a test is designated by the FDA.
Maintenance	Pharmacotherapy on a consistent schedule for persons with an addiction, usually with an agonist or partial agonist, which mitigates cravings and withdrawal symptoms. Maintenance treatments are also designed to mitigate against the risk of overdose. Depending on the individual, these treatment plans can be time-limited or remain in place lifelong. Methadone, buprenorphine, and naltrexone are often prescribed.
Office-Based Opioid Treatment (OBOT)	Physicians in private practices (and Nurse Practitioners and Physician Assistants who have recently been given the authority to prescribe under the 2016 Comprehensive Addiction and Recovery Act) or a number of public sector clinics can be authorized to prescribe outpatient supplies of the partial opioid agonist buprenorphine. There is no regulation

Policy No. PI Payment Policy 33	Department: Molina Payment Integrity
Title: Outpatient Definitive Drug Testing - Marketplace	MOLINA HEALTHCARE

	per se of the clinic site itself, but of the individual physician who prescribes buprenorphine.
Opioid Treatment Program (OTP)	A certified SAMHSA program comprised of a facility, staff, administration, patients, and services, that engages in supervised assessment and treatment. It utilizes methadone, buprenorphine, or naltrexone for individuals addicted to opioids. Settings of OTPs include, but are not limited to, intensive outpatient, residential, and hospital settings. Services may include medically supervised withdrawal and/or maintenance treatment, along with various levels of medical, psychiatric, psychosocial, and other types of supportive care.
Opioid Treatment Services (OTS)	Includes a variety of pharmacological and non-pharmacological treatment modalities and broadens understanding of opioid treatments (including all medications used to treat OUDs and the psychosocial treatment that is offered concurrently with these pharmacotherapies). Pharmacological agents include opioid agonist medications (methadone and buprenorphine) and opioid antagonist medications (naltrexone).
Point-of-Care Test	Conducted at a collection site (e.g., provider's office) using dipsticks, cups, cards, cartridges or instrumented test systems (e.g., discrete multichannel chemistry analyzers utilizing immuno- or enzyme assay. A simple test with a low-risk of incorrect results.
Presumptive Drug Class Procedures	Presumptive testing is performed using a method with lower sensitivity and/ or specificity which establishes preliminary evidence regarding the absence or presence of drugs or metabolites in a sample. Results are qualitative as they detect the presence or absence of particular compound, not their quantity. Immunoassays can identify true negative samples (high sensitivity) and are well suited for use as a screen to eliminate cases from further analysis.
Provider	A broad term that includes participants who provide care to patients with addiction including, but not limited to, staff at specialty addiction treatment centers (or other healthcare settings) providing treatment.
Random Testing Schedule	A recurring drug testing plan with varying amounts of days between testing that cannot be predicted; clinical consensus favors random testing schedules to fixed testing.
Reflex Testing	A practice where a laboratory automatically performs definitive testing on positive presumptive results for the purposes of refining the information the sample can provide; requires additional Provider order.
Standing Orders	A high-complexity test used to measure the quantity of a substance in a specimen. Performed in a CLIA-accredited laboratory.
Validity Testing	A test used to determine if a specimen is adulterated, diluted, substituted, or otherwise invalid.
Window of Detection	The range of time when a substance can be detected in a biological sample given the cutoff values for the test being performed. Refers both to the time to detection (time to be absorbed and distributed to sample material) and time to clearance (time to be metabolized/ eliminated/excreted). A test conducted before the substance or its metabolites have adequately entered the biological sample reads as negative. Each matrix and analyte has a different window of detection, ranging from minutes to months.