National Medical Policy

Subject: **Outpatient Testing for Drugs of Abuse**

Policy Number: **NMP542**

Effective Date*: **January 2016**

This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

For Medicaid Plans: Please refer to the appropriate State's Medicaid Manual(s), publication(s), citation(s), and documented guidance for coverage criteria and benefit guidelines prior to applying Health Net Medical Policies

The Centers for Medicare & Medicaid Services (CMS)

For Medicare Advantage members please refer to the following for coverage guidelines first:

Use	Source	Reference/Website Link
	National Coverage Determination (NCD)	
	National Coverage Manual Citation	
	Local Coverage Determination (LCD)*	
	Article (Local)*	
	Other	
X	None as of the date of this policy	Please check Medicare Coverage Database

Instructions

- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under "Reference/Website" and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)
- If more than one source is checked, you need to access all sources as, on occasion; an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Definitions

Qualitative Testing:

Used when medically necessary to determine the presence or absence of drugs or drug classes in a urine sample; results expressed as negative or positive or as a numerical result; includes competitive immunoassays (IA) and thin layer chromatography. Examples consist

of various platforms including cards, dipsticks, cassettes and cups based on qualitative competitive immunoassay methodology with one or more analytes in the test.

Quantitative Testing:
Used when medically necessary to identify specific medications, illicit substances and metabolites; reports the results of analytes absent or present typically in concentrations such as ng/mL. Definitive methods include complex technologies with separation capabilities of gaseous or liquid chromatography with the analytical capabilities of mass spectrometry, such as Gas Chromatography coupled with Mass Spectrometry (GC-MS) and Liquid Chromatography coupled with Mass Spectrometry (LC-MS/MS).

Specimen Validity Testing:
Urine specimen testing to ensure that it 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.

Current Policy Statement

Health Net considers outpatient quantitative drug testing for drugs of abuse (DOA) as medically necessary for confirmatory testing for a specific drug when members meet the criteria in A or B:

A. Member has a documented history or suspicion of illicit or prescription drug use or noncompliance or a high probability of non-adherence to a prescribed drug regimen documented in the medical record; *and all of the following*
    1. A qualitative drug test has been previously performed; *and*
    2. The findings from that qualitative test (either positive or negative) are either:
        a. Inconsistent with the expected results as suggested by the member's medical history, clinical presentation, and/or member's own statement after a detailed discussion about their recent medication and drug use, or
        b. The qualitative test yields results consistent with the clinical scenario but drug class-specific assays are needed to identify the precise drug(s) that resulted in the positive test result, without which, treatment may be delayed or incorrect, *and*
    3. Resolving the inconsistency is essential to the ongoing care of the member, *and*
    4. The requested quantitative test is only for the specific drug for which qualitative analysis has yielded unexpected results.

    OR

B. The request is for a serum therapeutic drug level in relation to the medical treatment of a disease or condition (e.g. Phenobarbital level in the treatment of seizures).

Not Medically Necessary

Outpatient drug testing is considered not medically necessary if provided for reasons that include but are not limited to the following:

A. As a condition of:
    1. Employment or pre-employment purposes (pre-requisite for employment or as a requirement for continuation of employment)
    2. Participation in school or community athletic activities or programs
    3. Participation in school or community extra circular activities or programs
B. Screening for medico-legal purposes such as court-ordered drug screening (unless required by state regulations)
C. Screening in asymptomatic patients
D. As a component of a routine physical/medical examination; e.g. (enrollment in school, enrollment in the military, etc.).

E. As a component of a medical examination for any other administrative purposes not listed above (e.g., for purposes of marriage licensure, insurance eligibility, etc.).
F. Same-day screening of drug metabolites in both a blood and a urine specimen by either qualitative or quantitative analyses.
G. Specimen validity/adulteration testing, as this is considered part of the laboratory quality control practices.

Testing Frequency

- All urine drug testing should be performed at an appropriate frequency based on clinical needs. The frequency of testing should be at the lowest level to detect the presence of drugs.
- Substance abuse treatment adherence is often best measured through random testing rather than frequent scheduled testing.

Qualitative Testing for Substance Use Disorder

The testing frequency must meet medical necessity and be documented in the clinician's medical record.

a. For patients with 0 to 30 consecutive days of abstinence, qualitative testing may be performed randomly but no more often than 3 qualitative tests per week.
b. For patients with 31 to 90 consecutive days of abstinence, qualitative testing may be performed randomly but no more often than weekly.
c. For patients with > 90 consecutive days of abstinence, qualitative testing May be performed randomly but no more often than twice per month.

Quantitative Testing for Substance Use Disorder

The patient's medical record must include an appropriate testing frequency based on the stage of screening, treatment, or recovery; the rationale for the drugs/drug classes ordered; and the results must be documented in the medical record and used to direct care.

a. For patients with 0 to 30 consecutive days of abstinence, quantitative testing is expected at a frequency not to exceed 1 physician-directed testing profile in one week.
b. For patients with 31 to 90 consecutive days of abstinence, quantitative testing is expected at a frequency of 1-3 physician-directed testing profiles in one month.
c. For patients with > 90 day of consecutive abstinence, quantitative testing is expected at a frequency of 1-3 physician-directed testing profiles in three months.

Authorization Protocols

A clinical laboratory may not bill for a service unless it has received a written request to perform that specific service from an authorized prescriber who is treating the member and will use the test for the purpose of diagnosis, treatment, or an otherwise medically necessary reason as defined in this policy. Any claim for a service for which a prior-authorization has not been provided may be subject to denial. Any clinical laboratory billing for a service must maintain such request in its records, and make such records available upon request.

All documentation must be maintained in the member's medical record and available to Health Net upon request. Health Net may request documentation for medical necessity for drug test including:

- A signed and dated physician order for the drug screening and/or testing is required. Copies of test results alone without the proper clinician's order for the test are not sufficient documentation to support a claim.
- The physician's order must specifically match the number, level and complexity of the testing panel components performed.

- Orders for "custom profiles," "standing orders," or to "conduct additional testing as needed," are not sufficiently detailed and may not be covered since they would not verify medical necessity for the specific tests.

Panels

The use of qualitative or quantitative testing panels is considered not medically necessary unless all components of the panel have been determined to be medically necessary based on the criteria above. A full panel screen should only be considered for initial testing when appropriate or when the behavior suggests the use of drugs not identified on the original screening. Medical documentation must support the justification for conducting a full panel screening.

Codes Related To This Policy

ICD-10 Codes (may not be an all inclusive list)

F11 Opioid dependence
F12 Cannabis dependence
F13 Sedative, hypnotic or anxiolytic dependence
F14 Cocaine dependence
F15 Other stimulant dependence
F16 Hallucinogen dependence
F18 Inhalant dependence
F19 Other psychoactive substance dependence

CPT Codes

Codes Deleted as of 12/31/2015:
G0431, G0434, G6031, G6040, G6041, G6042, G6043, G6044, G6045, G6046, G6048, G6051, G6052, G6053, G6056, G6057, G6058

HCPCS Codes

G0477 Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
G0478 Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
G0479 Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers (e.g., immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service
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 or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(as), 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 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 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 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 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 or quantitative, all sources, includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed

Scientific Rationale

Drug testing is a key diagnostic and therapeutic tool that is useful for patient care and monitoring of adherence to a controlled substance treatment regimen (eg, for chronic non-cancer pain) and to identify drug misuse or addiction prior to starting or during treatment with controlled substances.

Drug of abuse is defined as a drug, chemical, or plant product known to be misused for recreational purposes. In the United States, the basic screening test for DOA includes five drugs: amphetamine, cocaine, marijuana, opioids, and phencyclidine. Other common drugs tested for include benzodiazepines, a wider range of opioids, barbiturates, and methamphetamine. These tests can vary by region based on epidemiologic trends. There currently is no uniformity for what is included in extended DOA assay testing, or what cutoff values should be used for detection of drugs that are not covered by workplace testing laws.

The three methods of drug assays include immunoassay, chromatography, and gas-chromatography/mass spectrometry (GC/MS). Immunoassay is the most widely used method for initial testing for DOA and offers results within minutes. They are able to detect low concentrations of a drug with a high degree of specificity. This can be most easily performed using point-of-care test kits such as a urine drug cup. Unfortunately, in the clinical setting point-of-care testing does not perform to manufacturers' claims and untrained staff can improperly interpret test results.

Chromatography and GC/MS require highly trained lab staff and instruments to provide a highly sensitive and specific technique for detecting drugs or metabolites. It often takes many hours to obtain results, thus these methods are generally not used for initial screening in the clinical setting. The mass spectrometer is capable of detecting even minute amounts of a given substance and is considered to have the highest specificity of all lab detection methods. It is most commonly used for confirmatory test results that are primarily of forensic importance. GC/MS rarely provides results that are clinically necessary or useful beyond those obtained by standard immunoassays or chromatography.

The ordering clinician must be knowledgeable regarding the type of testing being requested, level of suspicion for drug use or exposure, the purpose for obtaining the test, and the likelihood of false-positive or false-negative results. Knowledge of potential drug exposure allows a clinician working in an addiction or chronic pain management program to include

testing for a metabolite of a parent drug instead of simply testing for the parent drug for a patient with a tendency for opioid abuse. If initial screening does not correlate with expected findings, then confirmatory testing improves the accuracy of initial results especially with concern of false-positive or false-negative results.

Immunoassays can yield false-positive results when cross-reacting medications or drugs are present. Cross-reacting substances can be found in common prescription medications, over-the- counter cold medications, and even in some food substances. The highest false-positive results occur with amphetamine testing due to the chemical structure of amphetamine being present in many over-the counter medications and herbal supplements. False-negative results can occur from improper specimen collection, transport, or testing procedures or from patient attempts to subvert the testing. The most common cause of false-negative results is a test failure to detect a specific drug within a given class of drugs.

Review History

January 2016 Initial Approval by Health Net Medical Advisory Council

This policy is based on the following evidence-based guidelines:

1. American Society of Addiction Medicine. Public Policy Statement on Drug Testing as a Component of Addiction Treatment and Monitoring Programs and in Other Clinical Settings. Revised October 2010.Center for Substance Abuse Treatment. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2005. (Treatment Improvement Protocol (TIP) Series, No. 43.)
2. Interagency Guideline on Prescribing Opioids for Pain. Developed by the Washington State Agency Medical Directors' Group (AMDG) in collaboration with an Expert Advisory Panel, Actively Practicing Providers, Public Stakeholders, and Senior State Officials. June 2015.

References

1. Becker W, Starrels JL. Prescription drug misuse: Epidemiology, prevention, identification, and management. In: UpToDate, Saxon AJ (Ed), UpToDate, Waltham, MA.
2. Center for Substance Abuse Treatment. Substance Abuse: Clinical Issues in Intensive Outpatient Treatment. Treatment Improvement Protocol (TIP) Series 47. DHHS Publication No. (SMA) 06-4182. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2006.
3. Christo PJ, Manchikanti L, Ruan X, et al. Urine Drug Testing in Chronic Pain. Pain Physician 2011;14:123-143.
4. Gourlay DL, Heit HA, Caplan YH. Urine Drug Testing in Clinical Practice. The Art and Science of Patient Care. Edition 5. Presented by the Johns Hopkins University School of Medicine. 2012.
5. Hoffman RJ. Testing for drugs of abuse (DOA). In: UpToDate, Traub SJ (Ed), UpToDate, Waltham, MA.
6. Manchikanti L, Malla Y, Wargo BW, et al. Comparative Evaluation of the Accuracy of Immunoassay with Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) of Urine Drug Testing (UDT) Opioids and Illicit Drugs in Chronic Pain Patients. Pain Physician 2011;14:175-187.
7. Moeller KE, Lee KC, Kissack JC. Urine Drug Screening: Practical Guide for Clinicians. Mayo Clin Proc 2008;83(1):66-76.
8. Wilfong A. Seizures and epilepsy in children: Initial treatment and monitoring. In: UpToDate, Nordli DR (Ed), UpToDate, Waltham, MA.

Important Notice

General Purpose.
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

No Medical Advice.
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member's Contract Controls Coverage Determinations.
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member's contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. The Policies do not replace or amend the Member's contract.

Policy Limitation: Legal and Regulatory Mandates and Requirements
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Reconstructive Surgery
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. "Reconstructive surgery" means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

(1) To improve function or

(2) To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

Reconstructive Surgery after Mastectomy

California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

Policy Limitations: Medicare and Medicaid

Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.