Get Your Specimens in Order:

New Law, New Policies, and Renewed Focus on Individualizing Patient Test Orders and Timely Use of Test Results

Prepared and presented by
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Disclosures for Jennifer Bolen, JD

- **Consultant/Independent Contractor:** Paradigm Labs/Paradigm Healthcare, relationship does not fully meet the disclosure requirement because I am not talking about a specific product at a CME event. However, I am disclosing this out of an abundance of caution and because this company will be at PainWeek and PainWeekend, and because I occasionally provide non-CME lectures for them.
- **Advisory Board:** Innovative Laboratory Solutions/Best Test Cups - relationship does not involve any fees, but disclosing out of an abundance of caution.

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Learning Objectives

Identify	Identify the Core Elements of Medical Necessity for Drug Testing
List	List Discussion Points for a Medical Necessity Protocol Considering: Patient Risk, Test Frequency, Test Menu, and Use of Test Results
Describe	Describe The Typical Payor Requirement of Individualized Testing
Describe	Describe a Basic Template for Patient Individualization that can be used in Daily Practice
Create	Create A Basic Template that Captures the Treating Provider's Rationale for Drug Test Orders and A Basic Triage Plan for Use of/Decision-Making Associated with Drug Test Results.

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Overview

Why are we still talking about medical necessity for urine drug testing in chronic pain management?

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Why are we still talking about drug testing?

- **FAILURE TO ORDER DRUG TESTS OR ORDER CLINICALLY NECESSARY TESTING**
  - **EXAMPLE 1:** Physician prescribes chronic opioid therapy to patients without first or ever obtaining a urine drug test.
  - **EXAMPLE 2:** Physician only orders immunoassay cup testing on patients to whom he/she prescribes fentanyl, gabapentin, tramadol and other drugs not detectable using immunoassay test cups.
- **What are the problems here? What if these actions constitute a pattern of practice of the physician?**
- **Assuming the examples represent failures in care, does the potential for legal liability increase if the physician is also billing for laboratory testing?**

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Why are we still talking about drug testing?

- **FAILURE TO TIMELY USE DRUG TEST RESULTS IN TREATMENT OF THE PATIENT:**
  - **EXAMPLE:** Physician prescribes morphine and hydrocodone to a patient who has had multiple UDTs positive for cocaine and negative for at least one of the Rx opioids--the hydrocodone.
  - Patient has a history of UDT aberrancies that span more than two years. Each time there's an aberrancy, the patient agrees to a block or an injection.
  - There are no referrals in the chart. The patient was ultimately discharged for cocaine use, but not until the third urine test result positive for cocaine.
- **What are the problems here? What if this action constitutes a pattern for the physician?**
- **Does the physician face additional legal exposure if the physician is also billing for laboratory testing?**

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General Background

Terminology, Test Methods, Basic Test Coding Structure, Basic Test Pricing (Medicare) Structure

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Basic Terminology and Test Methods

PRESUMPTIVE TESTING

Old term "Screening"

Immunoassay
Detects "class" not specific analytes
CANNOT TEST FOR MANY DRUG CLASSES

Liquid Chromatography with or without Mass Spectrometry
Detects specific analytes and may be reported with values

Others

DEFINITIVE TESTING

Old Term "Confirmation"

Gas Chromatography with Mass Spectrometry

Liquid Chromatography with Mass Spectrometry (LCMS)

Other

Detects specific analytes and reported with values, which may be of some use (or not)

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AMA-CPT Descriptors for Presumptive Testing (2019)

CPT/HCPCS Code	Description
Presumptive Drug Testing	
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 (e.g., utilizing immunoassay [e.g., 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 (e.g., utilizing immunoassay [e.g., 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 (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service

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Presumptive UDT Coding and Reimbursement Structure Today using 2019-Q3 Clinical Lab Fee Schedule (CLFS)

Cup, Dip	Cup with Reader	Immunoassay or Presumptive LCMS
80305	80306	80307
$12.60	$17.14	$64.65

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2016-2019 Drug class list (35 "classes"). Each "class" has its own CPT Code. Medicare uses "Tiers" divided by the number of drug classes in each Tier.

8. **AMA CPT® DRUG CLASS LIST**

Alcohol(s)	Benzodiazepines	Opiates
Alcohol Biomarkers	Buprenorphine	Opioids and opiate analogs
Alkaloids, not otherwise specified	Cannabinoids, natural	Oxycodone
Amphetamines	Cannabinoids, synthetic	Phencyclidine
Anabolic steroids	Cocaine	Pregabalin
Analgesics, non-opioid	Fentanyls	Propoxyphene
Antidepressants, serotonergic class	Gabapentin, non-blood	Sedative Hypnotics (nonbenzodiazepines)
Antidepressants, Tricyclic and other cyclicals	Heroin metabolite	Skeletal muscle relaxants
Antidepressants, not otherwise specified	Ketamine and Norketamine	Stereoisomer (enantiomer) analysis
Antiepileptics, not otherwise specified	Methadone	Stimulants, synthetic
Antipsychotics, not otherwise specified	Methylenedioxyamphetamines	Tapentadol
Barbiturates	Methylphenidate	Tramadol

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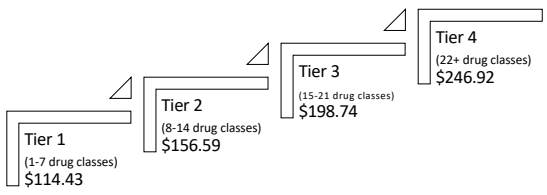

Definitive Testing (LCMS) Coding and 2019 Clinical Lab Fee Schedule (CLFS)(Medicare Reimbursement Rates).

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The Trouble with the AMA CPT Codes "Drug Classing" System

Opiate and Opioid-Related Drug Classes, including Analogs, Antagonists, Agonists	Common Illicit Drug Classes	BH-Related Drug Classes	Others	Classes Not commonly Used in Pain or Addiction
Buprenorphine	Amphetamines	Anti-depressants (serotonergic)	Alcohol	Anabolic Steroids
Fentanyls	Cannabinoids, Natural	Anti-depressants (tricyclic and other cyclicals)	Alcohol Biomarkers (EtG, EtS)	Non-Opioid Analgesics
Methadone	Cocaine	Anti-depressants (not otherwise specified)	Barbiturates	
Opiates (Codeine, Morphine, Hydrocodone, Hydromorphone)	Heroin	Anti-epileptics (not otherwise specified)	Cannabinoids, Synthetic	
Opiates & Opioid Analogs (Dextromethorphan, Dextrophan, Naloxone, Naltrexone, Meperidine, Kratom)	Ketamine	Anti-psychotics	Gabapentin	
Oxycodone/Oxymorphone	MDMA	Benzodiazepines	Pregabalin	
Propoxyphene* Rarely a true positive	PCP* Rarely a true positive	Methylphenidate	Skeletal Muscle Relaxants	
Tapentadol		Sedative Hypnotics	Stereoisomer	
Tramadol			Stimulants, Synthetic	
9 DRUG CLASSES	**7 DRUG CLASSES**	**8 DRUG CLASSES**	**9 DRUG CLASSES**	**2 DRUG CLASSES**

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Commercial Payor Policy Example

- **Payor Policy Non-Covers Tier 3** (15-21 drug classes) **and Tier 4** (22+ drug classes) **Definitive (LCMS) Testing.**
- **See CIGNA Policy 0513**, accessed 8/27/19 and available at https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0513_coveragepositioncriteria_drug_test.pdf.

Considered Not Medically Necessary:

CPT® Codes	Description
0008U	Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service

HCPCS Codes	Description
G0482	Drug test(s), definitive, (1) 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)) (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 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

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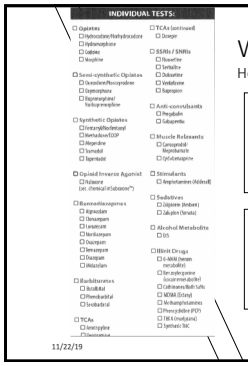

WHAT'S IN A LAB MENU LIST?

How many drug classes are you being "invited" to order?

Tier 1 (1-7 drug classes) $114.43	Tier 2 (8-14 drug classes) $156.59
Tier 3 (15-21 drug classes) $198.74	Tier 4 (22+ drug classes) $246.92

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Laboratory Positivity Rates are critical to ensuring a test menu supported by medical necessity

- What is a laboratory positivity rate report?
- What is the relevance of laboratory positivity rates to medical necessity?
- Where can you get information on your positivity rates?
- What if my laboratory will not provide positivity reports to me?

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OBJECTIVE 1 – Identify the Core Elements of Medical Necessity for Drug Testing and Create Discussion Points for a Medical Necessity Protocol Considering: Patient Risk, Test Frequency, Test Menu, and Use of Test Results.

Medical Necessity and Drug Testing

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Drug Testing: Whose Standards Govern Decision-Making?

Clinical Standards	Payor Standards	Licensing Board Standards
• Peer-reviewed Literature • Professional Society Consensus and Guidance Documents	• Medical Policies • Billing and Reimbursement Standards	• Rules • Guidelines/Position Statements

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Perspectives on medical necessity & drug-testing: The key is balance using data and a proper risk mitigation framework

Payor - Test Those Drugs that are Likely to Be Present Based on Patient's History and Patient Community Drug Use Patterns (Probability)

Provider - Test all drugs possible to avoid abuse, diversion, overdose death, etc.

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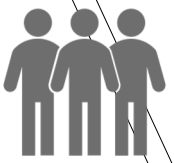

Medical Necessity – What is it?

- Payor definitions of medical necessity include reference to "prevailing standards of care" or "generally accepted standards of medical practice."
  - It is the responsibility of every ordering provider to ensure each drug test ordered is medically necessary for the treatment of the patient.

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Cigna HealthCare Definition of Medical Necessity for other Healthcare Providers

Except where state law or regulation requires a different definition, "Medically Necessary" or "Medical Necessity" shall mean health care services that a Healthcare Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

a. in accordance with the generally accepted standards of medical practice;
b. clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
c. not primarily for the convenience of the patient or Healthcare Provider, a Physician or any other Healthcare Provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means:

- standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community,
- Physician and Healthcare Provider Specialty Society recommendations,
- the views of Physicians and Healthcare Providers practicing in relevant clinical areas and
- any other relevant factors.

Preventive care may be Medically Necessary but coverage for Medically Necessary preventive care is governed by terms of the applicable Plan Documents.

SOURCE: CIGNA, at https://www.cigna.com/health-care-providers/coverage-and-claims/policies/medical-necessity-definitions, accessed 08-27-19.

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Medicare Regulations (42 CFR 410.32): Requirement for Lab Test Orders

§ 410.32 - Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Ordering diagnostic tests.* All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(1) *Mammography exception.* A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in § 410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(2) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

(b) *Diagnostic x-ray and other diagnostic tests.* (1) *Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) *Exceptions.* The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:

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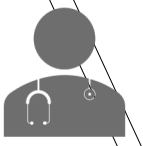
KEY DISCUSSION ITEMS ON MEDICAL NECESSITY: Using Medicare/Medicaid/TriCare Position as a Guide



- Test is ordered by the treating physician
- Test order is individualized to the patient
- Test results must be used promptly by the treating physician
- Proper and complete documentation required

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Medical Necessity:

The Federal Government's Perspective

Case Example:
US ex rel Donna Raush, et al v. Daniel McCollum, et al (US District Court, District of South Carolina, May 2019)(Pending)

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US Enters Whistleblower Lawsuit Against Pain Management Practitioner

- Happened on 5/31/19;
  - Case is pending
- South Carolina
- Reaches back to about 2015
- Medicare/Medicaid Fraud

Multiple causes of action, but focus for lecture is on medically unnecessary drug tests

- Complaint is 115 pages, with many that are fact specific

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6:15-cv-01589-DCC Date Filed 05/31/19 Entry Number 66 Page 1 of 115

UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

UNITED STATES OF AMERICA *ex rel.* DONNA RALCH, MURIEL CALHOUN, BRANDY KNIGHT, KAREN MATHEWSON, AND TRACY HAWKINS

Plaintiffs,

v.

OAKTREE MEDICAL CENTRE, P.C., FIRSTCHOICE HEALTHCARE, P.C., PAIN MANAGEMENT ASSOCIATES OF THE CAROLINAS, LLC, PAIN MANAGEMENT ASSOCIATES OF NORTH CAROLINA, P.C., LABSOURCE, LLC, PROLAB, LLC, PROCARE COUNSELING CENTER, LLC, and DANIEL MCCOLLUM, D.C.

Defendants.

No. 6:15-cv-015

(Conso
No. 6:17- 01190-DCC
No. 8:18- 2932-DCC)

JURY TRIAL DEMAND

Pending Case

UNITED STATES' CONSOLIDATED COMPLAINT IN INTERVENTION

By notice to the Court on March 3, 2019, the United States of America ("United States") intervened, in part, in the above-captioned cases. For its Complaint in Intervention, the United States alleges as follows:

INTRODUCTION

1. The United States brings this action against Defendants pursuant to the False Claims Act, 31 U.S.C. §§ 3729–3733 ("FCA"), seeking treble damages and civil penalties, and under common law and equitable theories of recovery.

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Medical Necessity Requirements in a Medicaid Program (SC Medicaid)

"The service is directed toward the maintenance, improvement, or protection of health (or toward dx and treatment of illness or disability)."

McCollum Complaint at p. 20

76. The Physicians, Laboratories, and Other Medical Professionals Provider Manual for the South Carolina Medicaid program provides, in pertinent part:

> Medicaid will pay for a service when the service is covered under the South Carolina State Plan and is medically necessary. "Medically necessary" means that the service (the provision of which may be limited by specific manual provisions, bulletins, and other directives) is directed toward the maintenance, improvement, or protection of health or toward the diagnosis and treatment of illness or disability. A provider's medical records or other appropriate documentation for each beneficiary must substantiate the need for services, must include all findings and information supporting medical necessity and justification for services, and must detail all treatment provided.

77. State regulations promulgating the South Carolina Medicaid program rules, in defining medical necessity, specify "[t]he fact that a physician prescribed a service or supply does not deem it medically necessary." S.C. Code Ann. Regs. § 126 425.

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VI. Urine Drug Testing Overview

A. Regulatory Requirements for Laboratory Test Services

118. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a, as set forth at 42 C.F.R. Part 493.

119. "Clinical laboratory services involve the . . . examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition." Medicare Benefit Policy Manual ("MBPM"), Pub. 100-02, Ch. 15, § 80.1, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf (last visited May 31, 2019).

120. Medicare regulations make clear that (1) laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury; (2) laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are not covered services; and (3) claims for such laboratory services that do not meet these requirements are ineligible for payment and must be denied. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. *See* 42 C.F.R. § 410.32.

121. In particular, pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." The MPBM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary . . . . [T]he physician must clearly document, in the medical record his or her intent that the test be performed." MPBM, Ch. 15, § 80.6.1.

122. Clinical laboratory services must also be used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a). *See* MPBM, Ch. 15, § 80.1.

123. In order to assess whether those services are reasonable and necessary and whether reimbursement is appropriate, Medicare requires proper and complete documentation of the services rendered to beneficiaries. In particular, the Medicare statute provides that:

> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 1395l(e); *see also* 42 U.S.C. § 1395u(c)(2)(B)(i) ("The term 'clean claim' means a claim that has no defect or impropriety (including any lack of any required substantiating

McCollum Complaint, at pgs. 31-32

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Federal Government's Position in McCollum – Indicators of Medically Unnecessary Drug Tests – Part 1

- No individualized assessment regarding the drug test menu
- No individualized assessment regarding the frequency and timing (random v. planned) of testing
- No test selection option given to the provider – a one-size fits all test menu regardless of whether the patient had a history of problems with a particular drug or whether there was data to show a problem with the drug in the overall patient community
- SOURCE: Pages 71-86, US ex rel Donna Rausch, et al v. Oaktree Medical Centre, . . . , Daniel McCollum et al.

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Federal Government's Position in McCollum – Indicators of Medically Unnecessary Drug Tests – Part 2

- Failure to consider the results of the immunoassay (presumptive) test when determining the test menu for the LCMS (definitive) test
- Seeking LCMS (definitive) testing of negative immunoassay (presumptive) results, even when the negatives were consistent with clinical expectations
- Testing for drugs that have a low risk for abuse/diversion without documented justification as to need in individual patient's case
- SOURCE: Pages 71-86, US ex rel Donna Rausch, et al v. Oaktree Medical Centre, . . . , Daniel McCollum et al.

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Routine Ordering without Individualized Assessment is Medically Unnecessary McCollum Complaint, at pg. 72.

256. McCollum, PMA, and Oaktree caused providers to routinely order excessive UDT for their patients without an individualized assessment of which tests were actually necessary for a given patient by utilizing a default UDT panel established by Oaktree. Although the components of Oaktree's default UDT panel changed periodically between January 1, 2011, and December 31, 2018, Oaktree providers were not given options regarding whether or not to use the default panel or what specific tests to include in the panel. In addition, the default panel included presumptive immunoassay testing. Moreover, the results of a patient's presumptive test (POC and/or immunoassay) were not used in determining whether to run definitive UDT. Rather, Oaktree performed definitive UDT using this default panel on a routine basis, even in situations where the presumptive tests were negative and consistent with clinical expectations. Oaktree's default UDT panel was often comprised of 15 or more different definitive drug tests, including for substances that were not commonly abused by PMA's patient population or had low risk for abuse or diversion. These practices resulted in UDT that was medically unreasonable and unnecessary, which Oaktree billed to Medicare, Medicaid, and TRICARE.

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Drug test menus must be based on the patient's history, risk of abuse, or individual clinical assessment; Default panels are not medically necessary
McCollum Complaint, at pg. 74

263. The determination as to which tests Oaktree and/or Labsource performed on a particular patient's urine specimen was not based on the patient's clinical history, risk of abuse, or individual clinical assessment, but rather driven exclusively by whatever default UDT panel was in effect at that time.

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The Government's Position on Medically Unnecessary Testing:

All drug classes tested must be justified and supported by facts individualized to the Patient's Case.

McCollum Complaint, at pgs. 72-73, 76-77

PCP (pgs. 72-73; without further explanation, immunoassay negative results do not warrant confirmation with LCMS)

Tricyclic Antidepressants (pg. 73; these drugs are low risk for abuse/diversion)

Ordering LCMS Testing off of Expected Presumptive Results (requires further support in the medical record and the treating physician's input)(pgs. 76-77)

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Standing Orders for Custom Profiles May Be Problematic, Depending on Test Menu
McCollum Complaint, at pg. 82

291. Consistent with this direction, when signing up new providers, Labsource sales representatives encouraged each provider to fill out a PPOF. Each physician's standing order was then assigned a code. When the provider wished to order UDT from Labsource, the provider could simply reference the assigned code for his or her standing order, rather than selecting individual tests that were actually reasonable and necessary for a given patient.

292. Through its PPOF protocol, Labsource caused providers to utilize the same standing order of tests for all or most of their patients each and every time they requested UDT for those patients, resulting in frequent, overbroad, and unnecessary testing.

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Routine Ordering of LCMS Testing of Expected Classes off of Presumptive Result May Raise a Medical Necessity Issue without Documentation of Specific Rationale

McCollum Complaint, at pgs. 76-77

268. As another example, PMA Patient S.K., a dual-eligible Medicare and Medicaid beneficiary, was seen on August 24, 2015, by Oaktree physician Dr. Dwight Jacobus. Patient S.K. was an established PMA patient who was being treated for chronic pain. The medical record indicated that Patient S.K. had no history of drug or alcohol abuse and no history of non-compliance or aberrant behavior. On August 24, 2015, presumptive UDT was performed and was positive for oxycodone and benzodiazepines, which was consistent with Patient S.K's prescribed medications. PMA then sent Patient S.K.'s urine specimen to Labsource with a requisition/order form indicating "Automated Panel." The requisition/order form did not specify as to which drugs the laboratory was to perform definitive testing.

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The treating clinician must assess the medical need for definitive testing
McCollum Complaint, at pg. 77

269. Labsource conducted presumptive immunoassay testing and definitive UDT for numerous drugs on Patient S.K.'s urine specimen. The results of Patient S.K.'s presumptive test were not used in determining whether to run definitive UDT. Rather, the definitive UDT panel appeared to be routine and not based on the results of Patient S.K.'s presumptive test or any patient specific risk assessment. There was no indication that the treating clinician assessed the medical need, if any, of those tests. Labsource submitted claims to Medicare for this testing for Patient S.K. and was paid $245. Labsource knew these claims for UDT that were not reasonable and necessary were false.

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The Treating Physician Must Order the Test
McCollum Complaint, at pg. 79

280. As noted above, pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.] Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."

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Testing Profiles Must still meet Medical Necessity Requirements;

Routine use of a default test panel/profile may not meet medical necessity requirements.

McCollum Complaint, at p. 80.

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282. Similar to Oaktree and Labsource, ProLab utilized a default UDT panel established by the laboratory across most, if not all, of its patients without regard to individual need. This default UDT panel was often comprised of numerous different tests, including for substances that were not commonly abused and/or had low risk for abuse or diversion. The determination as to which tests ProLab performed on a particular patient's urine specimen was not based on the patient's clinical history, risk of abuse, or individual clinical assessment, but rather driven exclusively by whatever default UDT panel was in effect at that time.

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Standing Orders are Problematic

McCollum Complaint, at p. 81.

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iii. Medically Unnecessary UDT for Other Patients

288. In addition to serving Oaktree providers, Labsource offered both immunoassay and definitive UDT to other providers throughout the United States. As described below, during the relevant time period, Labsource took proactive steps to encourage providers to routinely order large quantities of medically unreasonable and unnecessary UDT across all or most of their patients—without an individualized assessment of which tests were actually necessary for a given patient—by utilizing standing order forms and the direct bill kickback scheme described in Section II.B., above. This practice resulted in thousands of claims for medically unreasonable and unnecessary UDT that was billed to Medicare, Medicaid and TRICARE.

289. As described above, when processing specimens for Oaktree providers, Labsource used a default UDT panel. When working with non-Oaktree providers, Labsource took a slightly different approach—encouraging medically unreasonable and unnecessary testing through the use of provider standing orders. Labsource obtained these standing orders through the use of its Physician's Preferred Order form ("PPOF"). Labsource created this form as part of its plan to direct providers to establish protocols for UDT to be performed on all of their patients—usually involving, at minimum, dozens of definitive tests—regardless of the patients' individual need.

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Standing Orders are Problematic – 2

McCollum Complaint at p. 82.

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290. Beginning in or around 2013, Labsource directed its sales force to obtain these standing orders from all of its provider clients. The "New Account Form" filled out by sales representatives for each new provider featured a reminder to "COMPLETE PHYSICIAN[']S STANDING ORDER FORM (*EXTREMELY IMPORTANT*)." (Emphasis in original.) A revised version of the "New Account Form," developed in or around December 2014 and used, with some minor modifications, throughout the relevant time period, included the same reminder but referred to the form as "Physician[']s Preferred Order Form," rather than a "Standing Order Form."

291. Consistent with this direction, when signing up new providers, Labsource sales representatives encouraged each provider to fill out a PPOF. Each physician's standing order was then assigned a code. When the provider wished to order UDT from Labsource, the provider could simply reference the assigned code for his or her standing order, rather than selecting individual tests that were actually reasonable and necessary for a given patient.

292. Through its PPOF protocol, Labsource caused providers to utilize the same standing order of tests for all or most of their patients each and every time they requested UDT for those patients, resulting in frequent, overbroad, and unnecessary testing.

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Missing Documentation of Rationale for Definitive Testing and Test Menu is Problematic

McCollum Complaint at p. 83.

referred B.W.'s urine specimen to Labsource for a broad standing order of 37 definitive tests. Medicare paid Labsource $416.79 for this testing alone. Nothing in the patient file supports the need for such definitive testing, and there is no documentation in any follow-up visits of a review of this or any other definitive testing performed by Labsource. Nor is there any indication in the patient file of any modification in treatment based on the results of this or any other definitive testing.

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Pre-set Profiles of ever increasing drugs to test are also problematic if not tied to specific patient –

McCollum Complaint, at p. 84.

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format of the PPOF. Rather than listing each test individually, the revised PPOF grouped Labsource's presumptive and definitive test offerings into "profiles." For example, although these profiles changed to some extent over time, at various points in time during the relevant time period, Labsource offered a "Basic Confirmation Profile," a panel consisting of over 40 individual tests; an "Extended Confirmation Profile," a panel consisting of over 50 individual tests; and an "Extended Confirmation Profile with Pyschotherapeutics," a panel consisting of 70 or more individual tests. Notably, the Labsource-created profiles were all large enough to result in the highest levels of reimbursement from Medicare and TRICARE, even after the 2016 changes to UDT reimbursement. *See supra* Paragraph 148.

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Objective 2

DESCRIBE the Typical Payor Requirement of Individualized Testing and Create a Basic Template for Patient Individualization that can be used in Daily Practice

Individualized Testing

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The Old (and the wrong) Way of "Individualizing" Testing: How to identify Unsophisticated UDT Marketing Platforms

Increase the number of drugs tested via LCMS with each "risk" level	•Fails to recognize the need for a properly structured immunoassay test menu. •Fails to consider individual patient history and drug use patterns. •Fails to recognize that some high risk patients are not at high risk for abuse and diversion. •Often encourages LCMS testing of presumptive negatives – even when no patient history of problems. •Often encourages a "one-size fits all" approach. •Often adds in esoteric drugs or old drugs for which positivity rate data is low or zero. Claims this is what you should do for high risk patients, but then puts the blame on you for "picking" the drugs in the profile. •Largely ignores practice positivity rates and puts the provider at risk for ordering medically unnecessary testing. If an audit is conducted, this further exposes the physician as well as the lab.
Use of "Standing Orders" and "Custom Profiles" and applied to all patient's regardless of individual history (Called many things, but result in checkbox test orders that lack required information)	•Standing Orders are non-covered for UDT by most payors. •Custom Profiles must be set up by the physician and selected based on appropriate criteria and positivity rate data. Exception: Presumptive LCMS test panels offered by an independent lab do not require a test profile. Results are reflexed based on applicable lab rules and payor policies. •Custom Profiles are faulty if they simply increase the drug test menu based on the patient's "risk level"; Results in testing for drugs that have no positivity rate support and no connection to the patient's drug use pattern or other appropriate factors as set forth in policy and applicable licensing board and community standards. •Often fails to account for presumptive results and invites testing of presumptive negatives.

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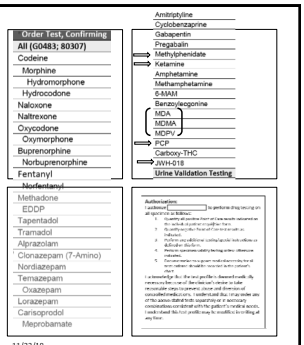
Authorize What?

- A single test profile?
- A standing order unless or until a provider changes it?
- Is this menu missing key analytes typically needed by pain practitioners?
- Am I really authorizing "confirmation" of presumptive negatives?
- How do I change the order?
- What about Ecstasy (MDMA, MDA), MDPV, PCP, JWH-018, Ketamine, and PCP?
  - Do I have patients in my practice using these drugs?
  - Should I be prescribing opioids to people using these drugs? *developing clinical issues with MDMA and Ketamine in certain areas of the country due to clinical use in some patient populations.
- This menu represents 23 drug classes.
- Do you feel fully informed?



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Another Problem in the Making: Test Results on Drugs Relating to Conditions Outside Your Plan of Care with the Patient

- Some laboratories are providing drug test results on drugs that are NOT within your scope of practice.
  - The medication list you provide is being used to generate drug tests for everything and the resulting report becomes confusing with all the "absent but declared" or "present but not declared" comments on these ancillary medications.
  - If you prescribe it or actively monitor it for drug-drug interaction or coordination of care purposes, the results are helpful. If not, talk with your lab and reexamine your needs with your patients.

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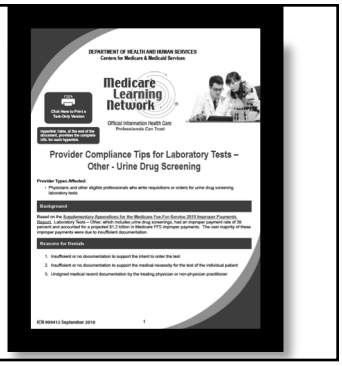
CMS Requirement for Individualized Testing

- CMS Publication 2016 (still good today)
- Available online at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ProviderComplianceTipsforLabTests-Other-ICN909412.pdf


DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Medicare Learning Network

Official Information Health Care Professionals Can Trust

Provider Compliance Tips for Laboratory Tests – Other - Urine Drug Screening

Provider Types Affected:
- Physicians and other eligible professionals who write requisitions or orders for urine drug screening laboratory tests

Background

Reasons for Denials
1. Insufficient or no documentation to support the intent to order the test
2. Insufficient or no documentation to support the medical necessity for the test of the individual patient
3. Unsigned medical record documentation by the treating physician or non-physician practitioner

ICN 909412 September 2016

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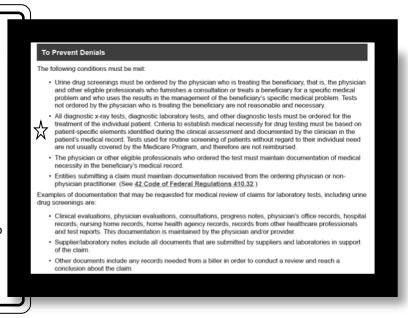
To Prevent Denials

The following conditions must be met:

- Urine drug screenings must be ordered by the physician who is treating the beneficiary, that is, the physician and other eligible professionals who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.
- All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered for the treatment of the individual patient. Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment and documented by the clinician in the patient's medical record. Tests used for routine screening of patients without regard to their individual need are not usually covered by the Medicare Program, and therefore are not reimbursed.
- The physician or other eligible professionals who ordered the test must maintain documentation of medical necessity in the beneficiary's medical record.
- Entities submitting a claim must maintain documentation received from the ordering physician or non-physician practitioner. (See 42 Code of Federal Regulations 410.32.)

Examples of documentation that may be requested for medical review of claims for laboratory tests, including urine drug screenings are:

- Clinical evaluations, physician evaluations, consultations, progress notes, physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation is maintained by the physician and/or provider.
- Supplier/laboratory notes include all documents that are submitted by suppliers and laboratories in support of the claim.
- Other documents include any records needed from a biller in order to conduct a review and reach a conclusion about the claim.

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Today, Individualized Testing is Based On . . .

Basic Checklist

- Proper Patient History
- Patient's Drug Use History (Prescribed); The MEDICATION LIST GIVEN TO THE LAB IS INCREDIBLY IMPORTANT!
- Patient's Drug Use History (Substance Use Disorder or Experimental/Recreational Use)
- PMP Check to Consider Medication Use Patterns
- Prior Drug Test Results
- Proper Comprehensive Risk Evaluation and Stratification that does not simply increase test menu with risk level (it's not an automatic or standing order increase)

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Creating a Physician-Directed Custom Test Profile: Individualization Challenges

- What is a Physician-Directed Custom Test Profile (PD-CTP)?
  - How many physician-directed custom test profiles are needed for the average pain medicine professional?
- Answer: It depends on the practice.
- Examples:
  - New Patient Profile
  - Established Patient Profiles
    - Low, Moderate
    - High Medical
    - High Behavioral

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Creating a Physician-Directed Custom Test Profile: Individualization Challenges

- What are the common elements of a PD-CTP (standard IA to LCMS)?
  - Test UNEXPECTED Presumptive Positives
  - Test UNEXPECTED Presumptive Negatives (Reported Rx Drugs Monitored by the Ordering Provider)
  - Test Presumptive Positives for Rx Medications in the Pain Treatment Plan
  - Test Other Drugs in Patient's Drug Use History or Commonly Abused in Community (as reflected by lab positivity rates for the practice and other appropriate resource); *This is the most problematic area when using a traditional IA to LCMS testing platform*.
  - If using Presumptive LCMS to Tier 1 Definitive LCMS – a PD-CTP might read: Order Presumptive LCMS and have lab reflex unexpected positives and quantify opioid and other controlled drugs prescribed by this practice so quantitative values may be evaluated to determine the patient's compliance with the treatment plan and to evaluate normalized drug values in light of patient's reported medication use patterns and clinical presentation/ongoing complaints of pain. Add in Anti-Psychotics if prescribing them or coordinating care with BH provider. Other add-ins may apply, depending on the number of analytes tested via presumptive LCMS.

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Common Work Flow Challenges Tied to Urine Drug Testing

The Drug Test Order is Connected to the Test Report.

The Test Report is Connected to the Initial and Ongoing Treatment Plan . . . And your license and DEA registration

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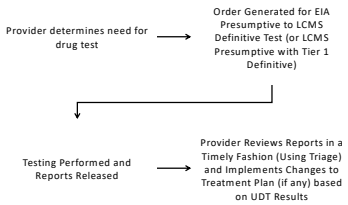
Drafting a Work Flow for Your Practice – If you send orders directly to an Independent Laboratory



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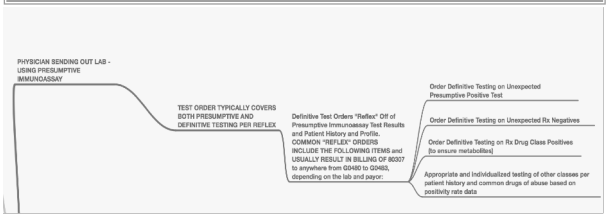
Sample Drug Testing Work Flow – Physician Send Out Immunoassay to LCMS



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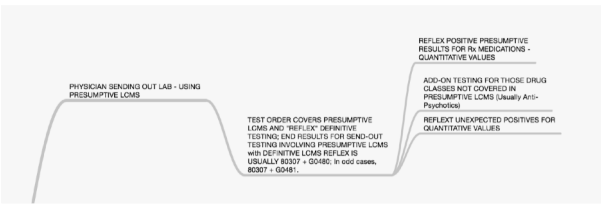
Sample Drug Testing Work Flow – Physician Send Out Presumptive LCMS w/Reflex to Definitive LCMS



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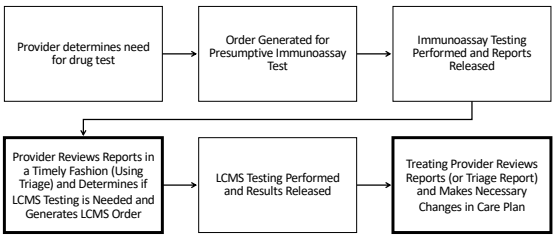
Drafting a Work Flow for Your Practice – If you have a physician office laboratory (IA + LCMS)



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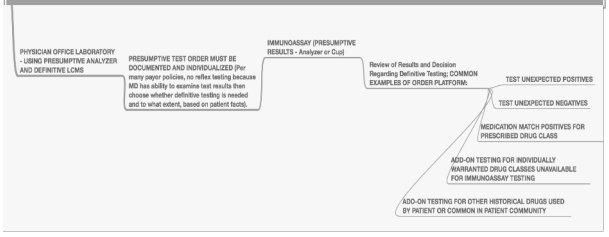
Sample Drug Testing Work Flow – Physician Office Laboratory Using 2019 Policies



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Objective 3

CREATE a Basic Template that Captures the Treating Provider's Rationale for Drug Test Orders and A Basic Triage Plan for Use of/Decision-Making Associated with Drug Test Results.

Capturing Provider Rationale

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REMINDER:

KEY MEDICAL NECESSITY ITEMS:
Using Medicare/Medicaid/TriCare Position as a Guide

- Test is ordered by the treating physician
- Test order is individualized to the patient
- Test results must be used promptly by the treating physician
- Proper and complete documentation required

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Constructing/Evaluating a Drug Testing Plan: The Basics

- Ensure the risk assessment platform is current (beyond the scope of this lecture).
- Develop specific drug testing platform (test methodology and ordering process) and testing protocols (frequency and menu)
- Develop a plan for documenting test orders and provider rationale
- Develop a plan for addressing drug test results, including timely review of results, notification to prescriber and provider response time, and follow-up with the patient
- Develop a plan for annual check-ups for test methods, test menu, test frequency, test order process and related documentation of provider rationale, and utilization of test results and documentation of relevance to patient's ongoing treatment plan

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Checklist

- My risk assessment platform is based on . . . I have verified with appropriate resources and experts that it is current.
- My presumptive test method is _____(immunoassay-cup/cassette/dip), (immunoassay-analyzer), (LCMS-presumptive).
- My test orders are documented (a) in the medical record using more than just an "order UDT" phrase, (b) entered onto an electronic or paper laboratory requisition as authorized by me, and (c) based on individual patient information or a profile that is tailored per payor rules.
- IF POCT OR PHYSICIAN OFFICE LAB - I review presumptive test results before placing orders for definitive testing.
- I review all definitive test results using a triage system, and I act promptly when patient test results indicate the need for a potential change in the plan of care to minimize the potential for patient harm.
- I tie my test order frequency and test menu to the individual patient; I test randomly; I have reviewed my practice positivity rates and considered them in my test ordering.

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Capturing the Treating Physician's Test Order Rationale

- Why is the test being done?
  - New patient? Established Patient?
  - First test? Random Compliance Check According to Risk Level? Targeted testing based on facts or suspicions?
- What type of test is being ordered?
  - Presumptive test (immunoassay or LCMS)?
  - With or without Definitive testing via quantitative LCMS?
  - Why is the definitive test needed? How is the test menu tied to the individual patient?
- What is the patient's risk level?
  - Proper risk assessment performed? If patient will receive an LCMS test order exceeding Tier 1 (1-7 drug classes), explain why you need to test the additional drug classes in light of (a) presumptive results, (b) patient specific history of drug use, and (c) other relevant and specific facts.
- Is the test random?
- Were the results of the patient's last test appropriate?
- Does the patient have a recent (last year) history of aberrant drug test results?
  - REMEMBER: AVOID THE STANDING ORDER AND SAME PROFILE FOR ALL PATIENTS – Under the current AMA-CPT and CMS coding framework, the one-size fits all does not equate to medical necessity. Expect changes in the near future.

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Basic Discussion Points for Developing a Protocol to Guide Medically Necessary Testing – Definitive Testing of Established Patients

Test Method	Established Patient Risk Level (Assuming Properly Evaluated)	Typical Definitive Test Menu (Definitive Testing MUST BE Properly Evaluated and Rationale for Test Menu MUST BE Documented in Medical Record)	Typical Test Frequency* *No universal agreement on frequency	Use of Test Results
LCMS or Similar DEFINITIVE TEST METHOD	Low	Tier 1 (1 to 7 drug classes) or decision to stand on presumptive results in well-established patients	1 to 2 times per year, except in states where required test frequency is greater, such as Georgia.	Medical Necessity DOES NOT WORK UNLESS Test Results are Reviewed and Used PROMPTLY in the treatment of the patient based on the patient's individual risk status and medical needs. Payors look to see whether providers are simply waiting until the next visit to deal with a cocaine positive. If so, medical necessity of the laboratory claim is often called into question. Physician Office Labs under scrutiny here.
	Moderate	Between Tier 1 (1 to 7 drug classes) and Tier 2 (8 to 14 drug classes) if patient history or present behavior supports testing of additional classes.	3 to 4 times per year, except in states where required testing frequency is greater, such as Georgia.	
	High Medical Risk	Tier 1 (1 to 7 classes), except in the most complex MEDICAL cases, then Tier 2 (8-14), if documented appropriately		
	High Behavioral Risk	Often Tier 2 (8-14 drug classes), because patient must also be monitored for compliance with behavioral health medications and may have an individual history of poly-drug abuse. In rare cases, Tier 3 (15-21 drug classes) may apply; Tier 3 is difficult to justify for an established patient.	4 to 6 times per year, and sometimes more frequent presumptive testing is also needed (depends on specific patient facts)	

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Timely Use of Results: What is Timely?

- **Timely use of results means:**

- A. The day the results come in from the lab
- B. At the next office visit
- C. As needed, according to results and patient facts
- D. None of the above

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UDT Results TRIAGE – Create your own template

Routine	Prompt Action Needed	Critical/Urgent Action Needed
• What type of results would you consider as routine? • What type of action do you expect if the results are routine? • How would you train your staff to ensure routine is really routine?	• What type of drug test results would you categorize as needing prompt action? • Does unsanctioned or undisclosed THC fit into this category? • Same questions but benzodiazepines instead of THC? • Other drugs? • How about questionable specimen validity? • What type of action do you consider to be "prompt"? • Who will carry out the interaction with the patient? • How will you make sure a "prompt action" item is called to your attention? • What type of staff training is needed here to ensure success?	• What type of drug test results would you categorize as needing critical action or intervention with the patient? • Who will carry out the interaction/intervention with the patient? • How will you account for your patient's ongoing use of opioids in the face of a "critical" drug test result? • How will you make sure this "critical" item is called to your attention? • What type of staff training is needed here to ensure success?

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Additional Resources on Drug Testing

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CDC and Drug Testing

https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-UrineDrugTesting_FactSheet-508.pdf

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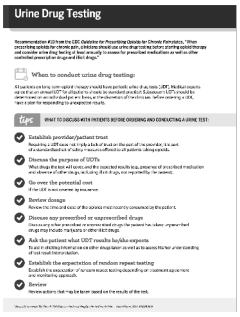
Urine Drug Testing

When to conduct urine drug testing:

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CDC and Drug Testing

https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-UrineDrugTesting_FactSheet-508.pdf

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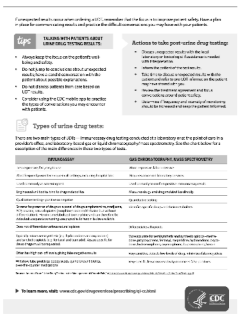

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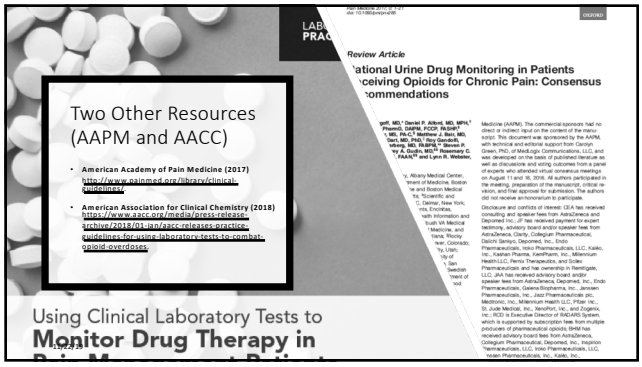
Two Other Resources (AAPM and AACC)

- **American Academy of Pain Medicine (2017)** http://www.painmed.org/library/clinical-guidelines/
- **American Association for Clinical Chemistry (2018)** https://www.aacc.org/media/press-release-archive/2018/01-jan/aacc-releases-practice-guidelines-for-using-laboratory-tests-to-combat-opioid-overdoses



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American Society of Addiction Medicine on Drug Testing

Resource	Position on UDT	Year of Guidance/Policy
American Society of Addiction Medicine	Recent paper on drug testing in the treatment of substance use disorders. https://www.asam.org/resources/guidelines-and-consensus-documents/drug-testing.	2017

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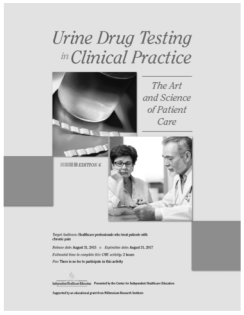
Reading File:
Urine Drug Testing in Clinical Practice

Doug L. Gourlay, MD, Howard A. Heit, MD, and Caplan, Yale H. Caplan, PhD



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Thank you!

Jennifer Bolen, JD

865-755-2369

jbolen@legalsideofpain.com

Questions?

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