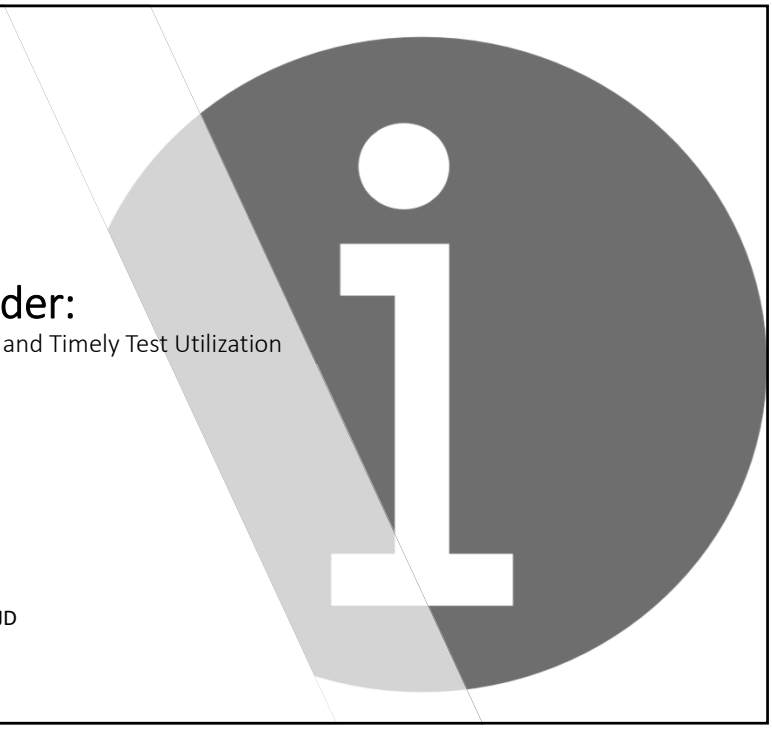
Get Your Specimens in Order:

The Importance of Individualized Test Orders and Timely Test Utilization



Prepared and presented by Jennifer Bolen, JD

PainWeekEnd – Spring –Summer 2018

Disclosures

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- Consultant to Generation Partners
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Course Objectives

01

Examine current fraud and inappropriate controlled substance prescribing investigations, and payer and regulatory focus on drug testing in pain management

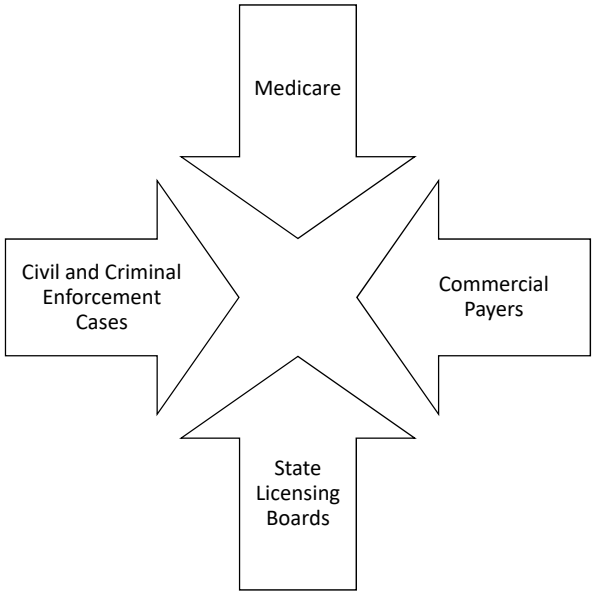
02

Define medical necessity and identify common directives regarding individualization of patient testing and documentation of rationale for testing

03

Identify Action Steps to Improving Test Order and Utilization Process

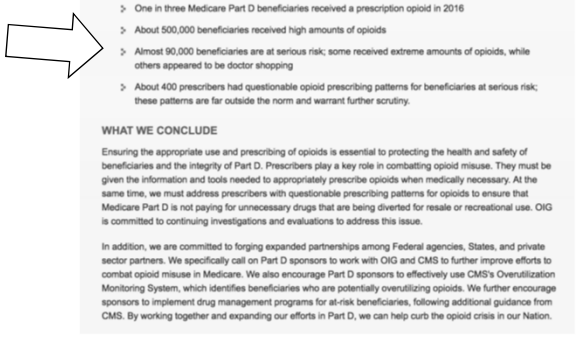
2017-2018 signals: investigations into drug testing tied to fraud and inappropriate prescribing will continue



Medicare Part D Prescribing Investigations

Approach and Tie to Fraud Investigations Related to Drug Testing

Medicare Part D – "Extreme Use and Questionable Prescribing"



https://oig.hhs.gov/oei/reports/oei-02-17-00250.asp

Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing

WHY WE DID THIS STUDY

Opioid abuse and overdose deaths are at epidemic levels in the United States. This data brief is part of a larger strategy by the OIG to fight the opioid crisis and address one of its top priority outcomes-to protect beneficiaries from prescription drug abuse. It provides baseline data on the extent to which beneficiaries receive extreme amounts of opioids and appear to be "doctor shopping." It also identifies prescribers who have questionable opioid prescribing patterns.

HOW WE DID THIS STUDY

We based this data brief on an analysis of prescription drug event records of opioids received in 2016. We determined beneficiaries' morphine equivalent dose (MED), which is a measure that equates all of the various opioids and strengths into one standard value.

WHAT WE FOUND

- One in three Medicare Part D beneficiaries received a prescription opioid in 2016
- About 500,000 beneficiaries received high amounts of opioids
- Almost 90,000 beneficiaries are at serious risk; some received extreme amounts of opioids, while others appeared to be doctor shopping
- About 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk; these patterns are far outside the norm and warrant further scrutiny.

WHAT WE CONCLUDE

Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. Prescribers play a key role in combatting opioid misuse. They must be given the information and tools needed to appropriately prescribe opioids when medically necessary. At the same time, we must address prescribers with questionable prescribing patterns for opioids to ensure that Medicare Part D is not paying for unnecessary drugs that are being diverted for resale or recreational use. OIG is committed to continuing investigations and evaluations to address this issue.

In addition, we are committed to forging expanded partnerships among Federal agencies, States, and private sector partners. We specifically call on Part D sponsors to work with OIG and CMS to further improve efforts to combat opioid misuse in Medicare. We also encourage Part D sponsors to effectively use CMS's Overutilization Monitoring System, which identifies beneficiaries who are potentially overutilizing opioids. We further encourage sponsors to implement drug management programs for at-risk beneficiaries, following additional guidance from CMS. By working together and expanding our efforts in Part D, we can help curb the opioid crisis in our Nation.

CMS and exercise of its expanded regulatory authority

Additionally, CMS is addressing the issue of drug diversion by identifying consistent thresholds across programs to flag providers as "high prescribers" and patients as "high utilizers" who may require additional scrutiny. The NBI MEDIC assists law enforcement and Part D plans in addressing drug diversion through data analysis and the Pill Mill Doctor Project results. For example, in response to requests for information from law enforcement, the NBI MEDIC conducts invoice reconciliations, impact calculations, and reviews of medical records.

Leveraging new authority in the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA), CMS will continue its efforts to link fee-for-service payments to quality and value, and encourage improved prescribing practices. For example, CMS will promote methods to encourage prescribers to consult a PDMP prior to issuing a Schedule II prescription for a course lasting longer than three days, with states tailoring these methods to their existing policies. CMS also plans further development of a new measure in the Hospital Outpatient Prospective Payment System, which will report the rates and sources of concurrent prescriptions for opioids and benzodiazepines, a drug combination that places patients at high risk for respiratory depression.

CMS and Metrics for Opioid Prescribing (Part D)

Metrics

CMS is in the exploratory phase of identifying metrics to quantify and track progress in each priority area. For *priority area 1*, metrics are currently under consideration in the following areas:

For prescribers enrolled in Medicare who prescribe Part D drugs:

- Percentage of opioid prescriptions:
  - Exceeding CDC guideline of 90 morphine milligram equivalents (MME) per day
  - Exceeding 7 days of treatment
  - Written for extended release/long-acting opioids
- Percentage with beneficiaries receiving an opioid prescription without other supportive therapies/treatments

CMS and Metrics for Naloxone Use

Metrics

CMS is in the exploratory phase of identifying metrics to quantify and track progress in each priority area. For *priority area 2*, metrics are currently under consideration in the following areas:

- Percentage of naloxone prescriptions issued for beneficiaries receiving opioid prescriptions:
  - Over a certain period of time (e.g. over 90 days)
  - Over a certain dose (e.g., exceeding CDC recommended guideline), etc.
  - As a co-prescription with medication assisted treatment for opioid use disorder because these people may be vulnerable to overdose if they relapse.

For incidences in which naloxone is administered to beneficiaries, what percentage of those beneficiaries were receiving:

  - Opioid prescriptions exceeding the CDC guideline
  - Extended release/long-acting opioids
  - A concurrent benzodiazepine prescription
- Rate of naloxone administration to beneficiaries
- Institute reporting requirement for opioid-related adverse drug events (ADEs); compare data year-to-year

Commercial Payers

Changes to Medical Necessity Policies

Ongoing financial audits pertaining to drug testing utilization

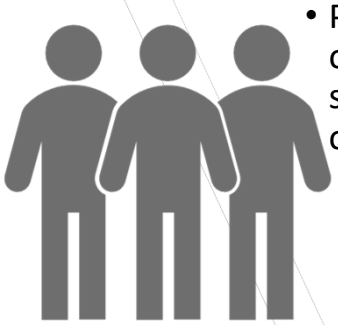
Ongoing financial investigations pertaining to inappropriate business relationships between physicians and independent clinical laboratories and related business entities

Objective 2 –

Medical Necessity and Individualized Drug Testing

Define medical necessity and identify common directives regarding individualization of patient testing and documentation of rationale for testing

Medical Necessity – What is it?



- Private insurance payors may use different definitions of medical necessity that include“ prevailing standards of care” or “generally accepted standards of medical practice.”
  - It is the responsibility of every ordering physician or medical professional to ensure that each test ordered from a laboratory is medically necessary for the treatment of the individual for whom the test is ordered.

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.

Medicare and Medical Necessity

(Medicare Learning Network Item - ICN 909412 September 2016)

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.)

Medicare and Test Utilization

Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a).

Resource:

MPBM, Ch. 15, § 80.1.

HUMANA – 2018 Drug Testing Policy

Drug Testing

Humana.

Medical Coverage Policy

Effective Date: 01/01/2018
Revision Date: 01/01/2018
Review Date: 08/31/2017
Policy Number: HCS-0532-015

Page: 1 of 16

Change Summary: Updated Provider Claims Codes

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do

Humana – 2018 Drug Testing Policy

Coverage Determination

Services provided by a psychiatrist, psychologist or other behavioral health professionals are subject to the provisions of the applicable behavioral health benefit.

State mandates for clinical drug testing take precedence over this clinical policy.

General Criteria for Drug Testing

Humana members may be eligible under the Plan for **drug testing** when the following criteria are met:

- Clinical rationale for all drug testing is clearly documented; **AND**
- Drug testing is performed randomly to avoid preparation for the testing; **AND**
- Drug testing is tailored to the individual and includes drugs that are prescribed or

Humana – 2018 Drug Testing Policy

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **drug testing** for any indications other than those listed above including, but may not be limited to, the following:

Qualitative (screening/presumptive) Testing

- Greater than one qualitative test when performed on the same date of service by one or more providers; **OR**
- Routine, nonspecific standing orders for panel testing; **OR**
- Routine testing for confirmation of negative qualitative results; **OR**
- Testing for employment purposes (ie, as a pre-requisite for a job or continuation of employment); **OR**
- Testing for forensic or medico-legal purposes (ie, court-ordered drug screening); **OR**
- Testing for sociologic determinants (ie, housing); **OR**
- Testing from multiple source specimens on same date of service; **OR**
- Testing in excess of twelve (12) per calendar year; **OR**
- Testing using hair analysis

Presumptive Drug Test Coding Framework

Waived Testing	Reader-Assisted Immunoassay	Qualified Test Methods (CLIA Registered High Complexity)
80305	80306	80307
1 unit only	1 unit only	1 unit only

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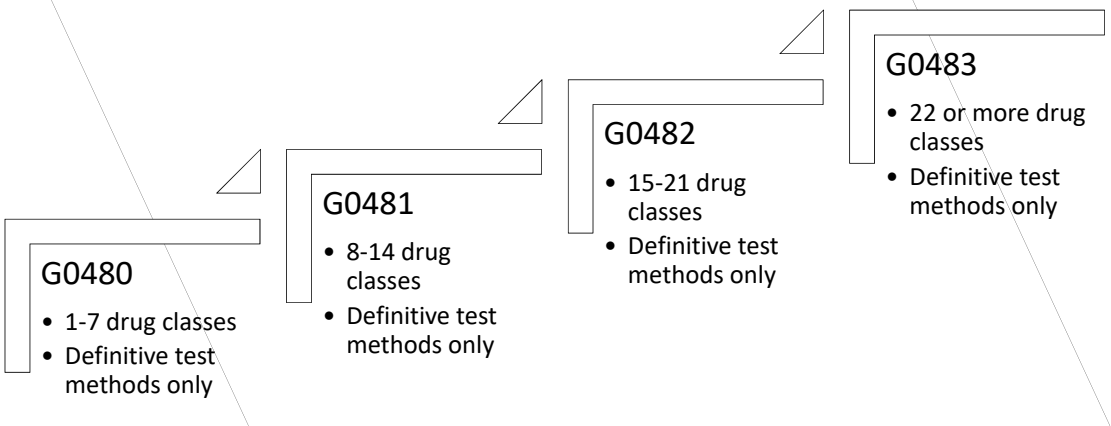
Definitive Drug Testing; Drug Class Descriptors

DRUG CLASSES USED BY AMA CPT® and CMS		
Alcohol	Benzodiazepines	Opiates
Alcohol Biomarkers	Buprenorphine	Opioids and Opiate Analogs
Alkaloids	Cannabinoids, Natural	Oxycodone
Amphetamines	Cannabinoids, Synthetic	Phencyclidine
Anti-depressants (Serotonergic)	Cocaine	Pregabalin
Anti-depressants (Tricyclic)	Fentanyl	Propoxyphene
Anti-depressants (Other)	Gabapentin	Sedative Hypnotics (Non-BZO)
Anti-epileptics	Heroin	Skeletal Muscle Relaxants
Anti-psychotics	Ketamine	Stimulants, Synthetic
Barbiturates	Methadone	Tapentadol
		Tramadol

Medical Necessity: Definitive Drug Testing Tiers (G-Codes)



Medical Necessity Checklist

- Review Carrier Policies
- CMS Documentation Guidelines
- If Physician-Office Laboratory, make sure your laboratory codes are included on your in-network contracts.
- If using an Independent Clinical Laboratory, make sure proper disclosures to the patient regarding the laboratory's status as in-network or out-of-network.
- Review Professional Licensing Board Guidelines and Rules Regarding Opioid Prescribing

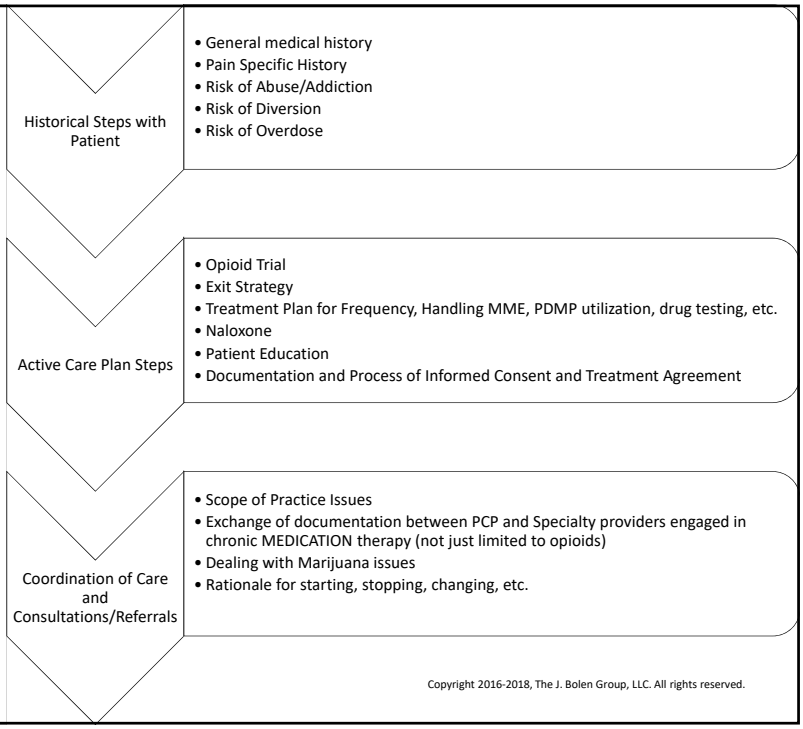
Objective 3 – Action Steps for Providers

Identify Action Steps to Improving Test Order and Utilization Process

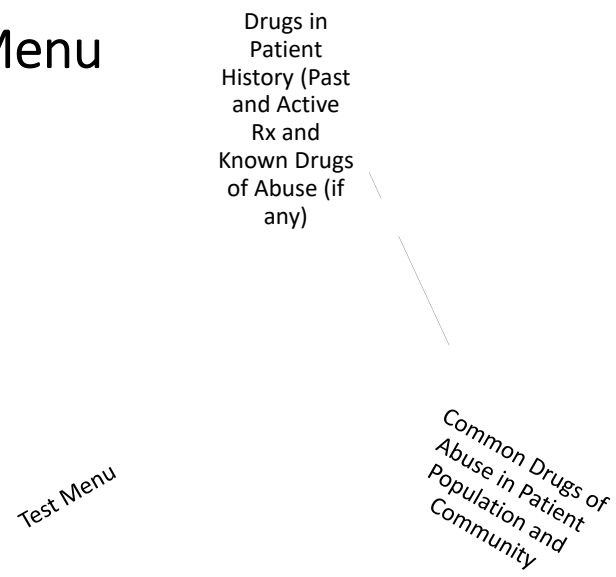
DEA Standards for Registrants

Legitimate Medical Purpose	Usual Course of Professional Practice	Reasonable Steps to Prevent Abuse and Diversion
• One or more generally recognized medical indication for the use of the controlled substance	• According to licensing and professional standards, including consideration of licensing board material	• Proper Risk Evaluation, Stratification, and Monitoring Protocols, including overdose risk evaluation • PDMP • UDT • NALOXONE • Visit Frequency • Many other "reasonable steps"

Licensing Board and Professional Standards (Clinical and Documentation of Same)



Individualization: Test Menu



Individualization: Test Frequency

Sample Resources and Positions
(Test Frequency and Reference to Test Method)

Resource	Position on UDT	Year of Guidance/Policy
FSMB Guideline for Chronic Use of Opioid Analgesics	Periodic and Unannounced (including Chromatography). Clinical judgement trumps recommendations of frequency. Strong recommendation that if patient is in addiction treatment, test as frequently as necessary to ensure treatment adherence.	2017
American Academy of Pain Medicine	Contains more specific guidance on test menu, test frequency, and test method	2017
American Association for Clinical Chemistry	Contains more specific guidance on test menu, test frequency, and test method	2018

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MEDICAL NECESSITY FOR DRUG TESTING

Date of Test Order: | Patient Name: | Patient DOB: | ICD-10 Diagnosis Code(s) supporting drug testing order

Is this a new or established patient?
- ☐ New patient
- ☐ Established patient

What is the patient's risk level as of date of test order?
- ◯ Low Risk ◯ Moderate Risk ◯ High Risk
- ◯ Other

DRUG CLASSES CURRENTLY PRESCRIBED TO THE PATIENT BY THIS OFFICE:

☐ Amphetamines	☐ Antidepressants	☐ Antipsychotics
☐ Barbiturates	☐ Benzodiazepines	☐ Buprenorphine
☐ Cannabinoids, Natural	☐ Fentanyl	☐ Hydrocodone, Hydromorphone
☐ Methadone	☐ Opiates (Codeine, Morphine)	☐ Oxycodone, Oxymorphone
☐ Sedative Hypnotics	☐ Skeletal Muscle Relaxants	☐ Tapentadol
☐ Tramadol		
☐ Other		

FOR ALL ORDERS: Was Point of Care Testing Performed or Physician Office Laboratory Analyzer Testing Used. RESULTS ENTERED ON PAGE 2 of FORM.
- ◯ POCT - Cassette, Cup, Dipstick
- ◯ POL - Chemistry Analyzer, IA Testing
- ◯ NO POCT OR POL PERFORMED, Outside laboratory testing ordered

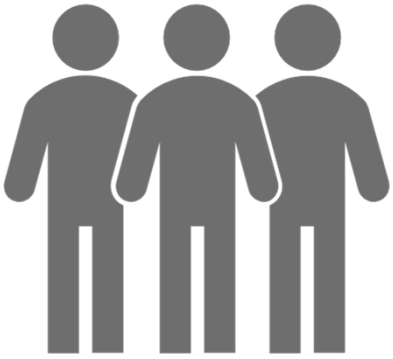
RATIONALE FOR DRUG TESTING:
- ☐ BASELINE/NEW PATIENT TESTING: Rule Out Use of Non-Disclosed High Risk Drugs, Confirm Consistent Use of Rx medication
- ☐ DEFINITIVE TESTING NEEDED BECAUSE RELEVANT DRUG CLASS IS NOT COMMERCIALLY AVAILABLE FOR POCT or POL, and drug class is a high risk drug class based on patient history or practice census or presents a risk for drug-drug interaction
- ☐ DEFINITIVE TESTING NEEDED BECAUSE RELEVANT DRUG CLASS(ES) IS/ARE LARGE and individual detection using presumptive immunoassay testing is inadequate for clinical decision-making
- ☐ MEDICATION MATCH requested, Quantification needed to guide clinical management and assess drug utilization, Quantification not available via POCT or POL
- ☐ POCT or POL RESULTS INCONSISTENT WITH PATIENT's self-report, presentation, medical history, or current medication list
- ☐ RULE OUT ERROR: caused by POCT or POL unexpected presumptive result
- ☐ DIFFERENTIAL ASSESSMENT: Definitive results are needed for differential assessment, such as drug-drug interactions or other item documented in the medical chart

INITIAL OFFICE VISIT	UDT ORDERED	DATE OF LAB RESULTS	Date Reviewed	Compliant RESULTS	Aberrant?
1/24/16 RX OXYCODONE Patient had prior Rx Tylenol #3	Yes	1/28/16	2/24/16		Yes, Gabapentin positive was an undisclosed Rx from another doctor. Continued.
2/24/16 Patient Rx is OXYCODONE; Added in Morphine	Yes	3/1/16	3/24/16	Gabapentin+ TCA+	Yes, Dextromethorphan; Missing Rx Opioid (Oxy)
3/24/16	Yes	4/2/16	4/24/16	Morphine + Gabapentin+ Oxycodone +	Codeine + 6-MAM-NEG
4/24/16	Yes	5/2/16; Reviewed 5/26/16	Patient died May 31, 2016	Morphine+ Oxycodone+	6-MAM positive Patient overdosed and died.

CASE STUDY – SAMANTHA SMITH

Treatment Decision Possibilities		
Discussed the behavior/result	Require increase visits	Require increase PDMP database checks
Require increase UDT	Controls on the Supply of Opioids (fewer dosage units in more frequently issued prescriptions)	Change the medication
Refer for substance abuse treatment	Refer for mental health evaluation	Refer to specialty service
Plan reduction in opioid dose and taper off of medication (Terminate the medication)	Buprenorphine	Terminate the patient
Transition to another medication	Nothing; Allow 3 strikes	Other

Sample Treatment Decisions following Risky Behaviors and Aberrant UDT Results



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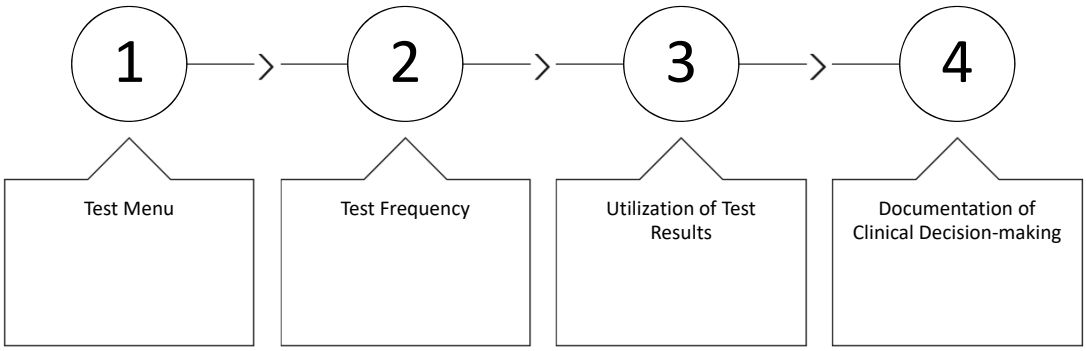
A few "how to" Recommendations on Individualizing Patient Testing

NOTE: This may vary somewhat by payer and state.

Individualization Data Points



Resources for Test Orders (Selecting Drug Classes for Testing and Testing Frequency):

Federation of State Medical Boards

American Academy of Pain Medicine, American Association for Clinical Chemistry

Medical Licensing Boards

CDC Opioid Prescribing Guidelines

FDA Materials (test manufacturer recommendations)

Individualization: Test Orders and Other Issues

Test Orders

Lab Custom Panels v. Physician Custom Profiles

Standing Orders

Patient Consent and Authorized Provider Approval

Individualization: What does it look like?

Example in Chronic Pain

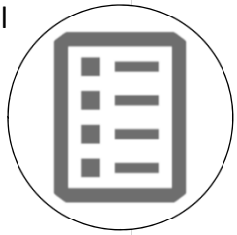
Patient Risk Profile Level	Test Menus (Presumptive/Definitive)	Test Frequency	Test Utilization
New Patient	Full Presumptive, Definitive Testing of Positives and Unexpected Negatives; Add Practice Profile Drug Classes	1x full then stratify into risk profiles by next visit	Use results (at least presumptive test results) BEFORE prescribing controlled medication
Low Risk	Low Risk Test Profile (Rx Medication Match; Definitive Testing of Positives and Unexpected Negatives (Generally, Definitive Drug Class Tier 1 or 2)	At least 1x every 6 months	Use results to determine if another patient encounter and treatment plan adjustment is necessary. Presumptive results should be used prior to ordering definitive testing. Definitive results should be used within 24 hours of report receipt.
Moderate/High Risk	Mod/High Risk Test Profile (Rx Medication Match; Definitive Testing of Positives and Unexpected Negatives; Add Additional Definitive Drug Classes based on Patient and Practice Drugs of Abuse Profile) (Generally, Definitive Drug Class Tier 2)	At least 2x every 6 months (but varies significantly in applicable literature and state approaches)	Use results to determine if another patient encounter and treatment plan adjustment is necessary. Presumptive results should be used prior to ordering definitive testing. Definitive results should be used within 24 hours of report receipt

Use Drug Test Results to Guide Ongoing Treatment

Physician must use the drug test results to guide treatment and future testing

Physician Review of Test Results

- Adopt a plan for when the physician (or someone other medical provider) will review the presumptive and definitive test results.
  - Prompt review
  - Medical decision-making regarding patient's ongoing care



Basic Checklist for Documenting Provider Review of Drug Test Results

1	2	3	4	5
Carry results forward in the patient's treatment record.	Comment as to whether patient is following the treatment plan.	Comment as to unsanctioned drug use (pain) and new evidence of drug abuse (treatment).	Discuss whether individual patient facts require variance in the nature and frequency of drug testing.	Make sure physician reviews and signs off on these clinical comments.

Documentation = "Cheese Trail"

1. Allows your team to understand what's going on with each client.

2. Allows outside auditors to understand and report back that you know what you are doing.

3. Minimizes the potential for a bad outcome on an audit – whether behavioral health or lab.

Checklists

Licensing Board Directives	Professional Society and Basic Regulatory Guidance on Chronic Opioid Therapy	Risk Assessment Tools, Stratification, and Monitoring	Internal Education	Patient and Family Member Education
History and Physical Examination	American Academy of Pain Medicine	Risk of Abuse/Addiction	Current State Requirements	Risks of Opioid Use
Risk Evaluation	American Association for Clinical Chemistry	Risk of Diversion	CDC and Academy Positions	Informed Consent Process
Treatment Plan	Federation of State Medical Boards	Risk of Overdose	Interaction with Pharmacists	Consequences if Treatment Agreement Violation
Informed Consent	Medicare Guidance	Other Behavioral Risks	PDMP Use	Safe Use
Treatment Agreement	CDC Guidelines	Protocols for Scoring and Overall Assessment of Risk and Stratification	Drug Testing	Safe Storage
Periodic Review	SAMHSA Materials	Protocols for Monitoring tied to Risk Stratification	Opioid Trials and Exit Strategies	Safe Disposal
Consultations and Referrals	Other	Protocols for Coordination of Care	Business Relationships	Naloxone
Documentation Requirements		Referral Plan and Overdose Event Plan	Self-Audit	Exit Strategies and Boundaries

Questions?

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- Thank you!

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