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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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”
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.

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

January 2017
CMS and Metrics for Naloxone Use

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

Medical Coverage Policy

Effective Date: 01/01/2018
Revision Date: 01/01/2018
Review Date: 06/11/2017
Policy Number: HCM-0532-015

Change Summary: Updated Provider Claims Codes

Humana’s documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not use for billing. Refer to the online version at humana.com/manuals.
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

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

80305
1 unit only

Reader-Assisted Immunoassay

80306
1 unit only

Qualified Test Methods (CLIA Registered High Complexity)

80307
1 unit only

DRUG CLASSES USED BY AMA CPT® and CMS

<table>
<thead>
<tr>
<th>Alcohol</th>
<th>Benzodiazepines</th>
<th>Opiates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol Biomarkers</td>
<td>Buprenorphine</td>
<td>Opioids and Opiate Analogs</td>
</tr>
<tr>
<td>Alkaloids</td>
<td>Cannabinoids, Natural</td>
<td>Oxycodone</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>Cannabinoids, Synthetic</td>
<td>Phencyclidine</td>
</tr>
<tr>
<td>Anti-depressants (Serotonergic)</td>
<td>Cocaine</td>
<td>Pregabalin</td>
</tr>
<tr>
<td>Anti-depressants (Tricyclic)</td>
<td>Fentanyl</td>
<td>Propoxyphene</td>
</tr>
<tr>
<td>Anti-depressants (Other)</td>
<td>Gabapentin</td>
<td>Sedative Hypnotics (Non-BZO)</td>
</tr>
<tr>
<td>Anti-epileptics</td>
<td>Heroin</td>
<td>Skeletal Muscle Relaxants</td>
</tr>
<tr>
<td>Anti-psychotics</td>
<td>Ketamine</td>
<td>Stimulants, Synthetic</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>Methadone</td>
<td>Tapentadol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tramadol</td>
</tr>
</tbody>
</table>

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

- **G0480**
  - 1-7 drug classes
  - Definitive test methods only

- **G0481**
  - 8-14 drug classes
  - Definitive test methods only

- **G0482**
  - 15-21 drug classes
  - Definitive test methods only

- **G0483**
  - 22 or more drug classes
  - Definitive test methods only

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**
  - One or more generally recognized medical indication for the use of the controlled substance

- **Usual Course of Professional Practice**
  - According to licensing and professional standards, including consideration of licensing board material

- **Reasonable Steps to Prevent Abuse and Diversion**
  - 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)

**Historical Steps with Patient**
- General medical history
- Pain Specific History
- Risk of Abuse/Addiction
- Risk of Diversion
- Risk of Overdose

**Active Care Plan Steps**
- Opioid Trial
- Exit Strategy
- Treatment Plan for Frequency, Handling MME, PDMP utilization, drug testing, etc.
- Naloxone
- Patient Education
- Documentation and Process of Informed Consent and Treatment Agreement

**Coordination of Care and Consultations/Referrals**
- Scope of Practice Issues
- Exchange of documentation between PCP and Specialty providers engaged in chronic MEDICATION therapy (not just limited to opioids)
- Dealing with Marijuana issues
- Rationale for starting, stopping, changing, etc.

**Individualization: Test Menu**

- Drugs in Patient History (Past and Active Rx and Known Drugs of Abuse (if any))

**Common Drugs of Abuse in Patient population and Community**
Individualization: Test Frequency

New Patient History and Risk Evaluation and Stratification

Established Patient Risk and Treatment Monitoring and Impact on Monitoring Needs

Test Frequency

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

<table>
<thead>
<tr>
<th>Resource</th>
<th>Position on UDT</th>
<th>Year of Guidance/Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSMB Guideline for Chronic Use of Opioid Analgesics</td>
<td>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.</td>
<td>2017</td>
</tr>
<tr>
<td>American Academy of Pain Medicine</td>
<td>Contains more specific guidance on test menu, test frequency, and test method</td>
<td>2017</td>
</tr>
<tr>
<td>American Association for Clinical Chemistry</td>
<td>Contains more specific guidance on test menu, test frequency, and test method</td>
<td>2018</td>
</tr>
</tbody>
</table>
# Medical Necessity for Drug Testing

**Date of Test Order:**

- Patient Name:
- Patient DOB:

**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

**DRUG CLASSES CURRENTLY PRESCRIBED TO THE PATIENT BY THIS OFFICE:**

- Antibiotics
- Antidepressants
- Antipsychotics
- Benzodiazepines
- Barbiturates
- Sedatives
- Narcotics
- Opioids
- Stimulants
- Other

**FOR ALL ORDERS: How Point of Care Testing Performed or Physician Office Laboratory Analyzers Testing Used. RESULTS ENTERED ON PAGE 2 OF FORM:**

- POST – Cassette, Cup, Dipstick
- POC – Chemistry Analyzer, or Testing
- NO POST OR POC, PERFORMED, Outside laboratory testing ordered

**Rationale for Drug Testing:**

- INCREASED PATIENT TESTING: Due to use of Non-Prescribed High Risk Drugs, Certain Opioid Use History or Missed Visit
- IMPERATIVE TESTING NEEDED BECAUSE PATIENT'S CURRENT MEDICATIONS ARE NOT CONVENTIONAL OR AVAILABLE FROM POST OR POC, and drug testing is part of drug management or other therapy
- DEFINITIVE TESTING NEEDED BECAUSE INFLUENT MEDICATIONS/DRUG CLASSES; SIAMUR LUNG AND INHALATIONAL DEPRESSION, USING PRECONCEIVED TESTING IS INSUFFICIENT FOR CLINICAL DECISION MAKING
- PATIENT'S MEDICATIONS ARE NOT CONVENTIONAL OR AVAILABLE FROM POST OR POC, and drug testing is part of drug management or other therapy
- RULE OUT ERROR: caused by POST or POC, unexpected presumptive result
- COMPREHENSIVE, BASELINE REPORTS: complete results are needed for difference assessment, such as drug-regulation interactions or other test documentation of the medical chart

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## Case Study – Samantha Smith

<table>
<thead>
<tr>
<th>Initial Office Visit</th>
<th>UDT Ordered</th>
<th>Date of Lab Results</th>
<th>Date Reviewed</th>
<th>Compliant Results</th>
<th>Aberrant?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/24/16 RX OXYCODONE</td>
<td>Yes</td>
<td>1/28/16</td>
<td>2/24/16</td>
<td>Yes, Gabapentin positive was an undisclosed Rx from another doctor. Continued.</td>
<td></td>
</tr>
<tr>
<td>Patient had prior Rx Tylenol #3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2/24/16 Patient Rx is OXYCODONE; Added in Morphine</td>
<td>Yes</td>
<td>3/1/16</td>
<td>3/24/16</td>
<td>Gabapentin+, TCA+</td>
<td>Yes, Dextromethorphan; Missing Rx Opioid (Oxy)</td>
</tr>
<tr>
<td>3/24/16</td>
<td>Yes</td>
<td>4/2/16</td>
<td>4/24/16</td>
<td>Morphine + Gabapentin+ Oxycodone +</td>
<td>Codeine + 6-MAM-NEG</td>
</tr>
<tr>
<td>4/24/16 reviewed 5/26/16</td>
<td>Yes</td>
<td>5/2/16; Patient died May 31, 2016</td>
<td></td>
<td>Morphine + Oxycodone+</td>
<td>6-MAM positive Patient overdosed and died.</td>
</tr>
</tbody>
</table>
### Treatment Decision Possibilities

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

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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.

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Individualization Data Points

1. Test Menu
2. Test Frequency
3. Utilization of Test Results
4. Documentation of Clinical Decision-making

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

<table>
<thead>
<tr>
<th>Patient Risk Profile Level</th>
<th>Test Menus (Presumptive/Definitive)</th>
<th>Test Frequency</th>
<th>Test Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Patient</td>
<td>Full Presumptive, Definitive Testing of Positives and Unexpected Negatives; Add Practice Profile Drug Classes</td>
<td>1x full then stratify into risk profiles by next visit</td>
<td>Use results (at least presumptive test results) BEFORE prescribing controlled medication</td>
</tr>
<tr>
<td>Low Risk</td>
<td>Low Risk Test Profile (Rx Medication Match; Definitive Testing of Positives and Unexpected Negatives (Generally, Definitive Drug Class Tier 1 or 2)</td>
<td>At least 1x every 6 months</td>
<td>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.</td>
</tr>
<tr>
<td>Moderate/High Risk</td>
<td>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)</td>
<td>At least 2x every 6 months (but varies significantly in applicable literature and state approaches)</td>
<td>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.</td>
</tr>
</tbody>
</table>
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. Carry results forward in the patient’s treatment record.
2. Comment as to whether patient is following the treatment plan.
3. Comment as to unsanctioned drug use (pain) and new evidence of drug abuse (treatment).
4. Discuss whether individual patient facts require variance in the nature and frequency of drug testing.
5. 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

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

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# Questions?

- Thank you!
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- jbolen@legalsideofpain.com