MEDICAL POLICY

POLICY TITLE	URINE DRUG TESTING IN PAIN MANAGEMENT AND SUBSTANCE ABUSE TREATMENT SETTINGS
POLICY NUMBER	MP-2.327

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Effective Date:	**June 1, 2014**

I. POLICY

In the outpatient pain management setting, qualitative (i.e., immunoassay) urine drug testing may be considered **medically necessary** for:

- Baseline screening before initiating treatment or at the time treatment is initiated, when the following conditions are met:
  - An adequate clinical assessment of patient history and risk of substance abuse is performed;
  - Clinicians have knowledge of test interpretation;
  - There is a plan in place regarding how to use test findings clinically:

- Subsequent monitoring of treatment at a frequency appropriate for the risk-level of the individual patient (see Policy Guidelines).

In the outpatient substance abuse treatment setting, in-office or point-of-care qualitative (i.e., immunoassay) urine drug testing may be considered **medically necessary** under the following conditions:

-Baseline screening before initiating treatment or at the time treatment is initiated (i.e., induction phase), one time per program entry, when the following conditions are met:

- An adequate clinical assessment of patient history and risk of substance abuse is performed
- Clinicians have knowledge of test interpretation
- There is a plan in place regarding how to use test findings clinically
  - Stabilization phase - targeted weekly qualitative screening for a maximum of 4 weeks (see Policy Guidelines)

- Maintenance phase – targeted qualitative screening once every 1 to 3 months (see Policy Guidelines)

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Quantitative (i.e., confirmatory) urine drug testing, in the pain management or substance abuse setting, may be considered **medically necessary** under the following circumstances:

- When immunoassays for the relevant drug(s) are not commercially available.
- In specific situations for which quantitative drug levels are required for clinical decision making (see Policy Guidelines)

In the outpatient pain management setting and outpatient substance abuse setting, urine drug testing is considered **not medically necessary** when the above criteria are not met including but not limited to routine qualitative or quantitative urine drug testing (eg testing at every visit, without consideration for specific patient risk factors or without consideration for whether quantitative testing is required for clinical decision-making).

Policy Guidelines

Pain management

The risk-level for an individual patient should include a global assessment of risk factors, and monitoring for the presence of aberrant behavior. Standardized risk assessment tools are available, such as the 5 item opioid risk tool (ORT). Another screening instrument is the Screener and Opioid Assessment for Patients with Pain- Revisited (SOAPP-R), a 24-item tool. (Available at http://painedu.org/soapp.asp?gclid=CPvLjOeFl7oCFY1FMgodzQ4ANA)

Aberrant behavior is defined by one or more of the following:

- multiple lost prescriptions,
- multiple requests for early refill,
- obtained opioids from multiple provider,
- unauthorized dose escalation,
- apparent intoxication during previous visits.

Opinions vary on the optimal frequency of urine drug screening to monitor patients on opioid therapy for chronic pain. Frequency of screening using a risk-based approach, as recommended by the Washington State Inter-Agency Guideline (6) is as follows:

- Low risk by Opioid Risk Tool (ORT): Up to 1 per year
- Moderate risk by ORT: Up to 2 per year
- High risk or opioid dose >120 MED/d: Up to 3-4 per year
- Recent history of aberrant behavior each visit

Note that the ORT is a copyrighted instrument. (7)

The Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain does not include specific screening frequencies but states that an individual patient's risk for opioid misuse and addiction should be considered when deciding when to order a urine drug screen. (4)

Substance abuse

Stabilization phase: Most patients are expected to be on a stable dose of opioid medication within 4 weeks of initiating treatment. In some complicated patients, the stabilization phase may last longer than 4 weeks.

Maintenance phase: For most patients, targeted qualitative screening once every 1 to 3 months is sufficient during the maintenance phase of treatment. More frequent testing may be appropriate for some complicated patients.

Guidance regarding quantitative i.e., confirmatory testing

Specific situations for quantitative drug testing may include, but are not limited to the following:

- Unexpected positive test inadequately explained by the patient
- Unexpected negative test (suspected medication diversion)
- Need for quantitative levels to compare with established benchmarks for clinical decision-making

There may not be commercially available tests for certain synthetic or semi-synthetic opioids.

The following information on immunoassay availability and diagnostic capacity is included in the Washington State Inter-Agency Guideline (6):

Natural opioids e.g., codeine, morphine

"Immunoassays for "opiates" are responsive for morphine and codeine but do not distinguish which is present. Confirmatory testing is required to reliably identify drug(s) present. Since codeine is metabolized to morphine and small quantities to hydrocodone, these drugs may be found in the urine. Also, morphine may metabolize to produce a small amount (<10%) of hydromorphone."

Semisynthetic opioids e.g., hydrocodone, hydromorphone, oxycodone, oxymorphone

"Opiates" immunoassays may also detect semisynthetic opioids depending on their cross-reactivity pattern. However, a negative result does not exclude use of semisynthetic opioids. Confirmatory testing (GC/MS or LC/MS/MS) is required to verify compliance with the prescribed semisynthetic opioid(s).

Since hydrocodone is metabolized in small amounts to hydromorphone, both may be found in the urine. Likewise, oxycodone is metabolized to oxymorphone, so these may both be present in the urine of oxycodone users. However, the reverse is not true. In other words,

hydromorphone and oxymorphone use does not result in positive screens for hydrocodone and oxycodone, respectively."

Synthetic opioids e.g., fentanyl, meperidine, methadone, propoxyphene "Current "opiates" immunoassays do not detect synthetic opioids. Thus confirmatory testing (GC/MS or LC/MS/MS) is needed to identify these drugs. If the purpose is to document compliance with treatment, the laboratory can be instructed to remove the cutoff concentration so that the presence of lower concentrations can be identified."

The following table on interpreting unexpected results of urine drug tests was adapted from one developed by the Canadian National Opioid Use Guideline Group (NOUGG) that was cited by ASIPP in their guideline on prescribing opioids for chronic non-cancer pain: (4, 8)

The following table on interpreting unexpected results of urine drug tests was adapted from one developed by the Canadian National Opioid Use Guideline Group that was cited by ASIPP in their guideline on prescribing opioids for chronic noncancer pain(4,8):

Unexpected Result	Possible Explanations	Possible Actions for the Physician
Test is negative for prescribed opioid	• False negative • Noncompliance • Diversion	• Conduct confirmatory testing, specifying the drug of interest (eg, oxycodone often missed by immunoassay) • Take a detailed history of the patient's medication use for the preceding 7 d (eg, could learn that patient ran out several days prior to test) • Ask patient if they've given the drug to others • Monitor compliance with pill counts
Test is positive for nonprescribed opioid or benzodiazepines	• False positive • Patient acquired opioids from other sources (double-doctoring, "street")	• Repeat urine drug testing regularly • Ask patients if they accessed opioids from other sources • Assess for opioid misuse/addiction • Review/revise treatment agreement
UDS positive for illicit drugs (eg, cocaine, cannabis)	• False positive • Patient is occasional user or addicted to the illicit drug • Cannabis is positive for patients taking certain medications (eg, dronabinol)	• Repeat urine drug test regularly • Assess for abuse/addiction and refer for addiction treatment as appropriate

UDS: urine drug screen.

Unexpected Result	Possible Explanations	Possible Actions for the Physician
Test is negative for prescribed opioid.	• False negative. • Non-compliance. • Diversion.	• Conduct confirmatory testing, specifying the drug of interest (e.g.,

		oxycodone often missed by immunoassay). • Take a detailed history of the patient's medication use for the preceding 7 days (e.g., could learn that patient ran out several days prior to test) • Ask patient if they've given the drug to others. • Monitor compliance with pill counts.
Test is positive for non-prescribed opioid or benzodiazepines.	• False positive. • Patient acquired opioids from other sources (double-doctoring, "street").	• Repeat urine drug testing regularly. • Ask the patient if they accessed opioids from other sources. • Assess for opioid misuse/addiction • Review/revise treatment agreement
UDS positive for illicit drugs (e.g., cocaine, cannabis).	• False positive. • Patient is occasional user or addicted to the illicit drug. • Cannabis is positive for patients taking	• Repeat urine drug test regularly. • Assess for abuse/addiction and refer for addiction treatment as appropriate

	certain medications e.g., dronabinol	

Cross-reference:

MP-2.064 Biofeedback and Neurofeedback Therapy
MP-2.303 Opioid Antagonists Under Heavy Sedation or General Anesthesia as a Technique of Opioid Detoxification
MP-2.167 Intravenous Anesthetics for the Treatment of Chronic Pain

II. PRODUCT VARIATIONS

TOP

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N]	Capital Cares 4 Kids	[N]	Indemnity
[N]	PPO	[N]	SpecialCare
[N]	HMO	[N]	POS
[Y]	SeniorBlue HMO*	[N]	FEP PPO
[Y]	SeniorBlue PPO*		

* Refer to Novitas Solutions Local Coverage Determination (LCD) L32050 Qualitative Drug Testing.

III. DESCRIPTION/BACKGROUND

TOP

Patients in pain management programs and substance abuse treatment may misuse prescribed opioids and/or may use non-prescribed drugs. Thus, patients in these settings are often assessed prior to treatment and monitored while they are receiving treatment. Urine drug screening is one monitoring strategy; it is most often used as part of a multi-faceted intervention that includes other components such as patient contracts.

According to an evidence assessment by the American Society of Interventional Pain Physicians (ASIPP), approximately one-third of chronic pain patients do not use opioids as prescribed or may abuse them. (1) Moreover, studies report that a substantial proportion of

chronic pain patients inaccurately report non-adherence to prescribed medications and use of illicit drugs. (2)

Various strategies are available to monitor patients in pain management and substance abuse treatment settings and multi-component interventions are often used. Many settings require patients to sign a contract before they are given a prescription for opioids. The contracts generally involve obtaining patients' agreement on behaviors they will engage in during the treatment period (e.g. taking medication as prescribed) and not engage in (e.g. selling prescribed medication and/or obtaining additional prescriptions from other doctors).

Confirming whether patients follow these behavioral guidelines can be a challenge. Risk-assessment screening instruments, such as the Screener and Opioid Assessment for Patients with Pain-Revisited (SOAPP-R), and the Opioid Risk Tool (ORT), can aid in the assessment of patients' risk for inappropriate drug use. In addition, the presence of "aberrant behaviors" can be used as a marker for patients who are at high risk for deviating from treatment protocols. Aberrant behaviors include multiple lost prescriptions, obtaining prescriptions from other practitioners, and displaying evidence of acute intoxication during office visits.

Another strategy for monitoring patients is testing of biological specimens for the presence or absence of drugs. Currently, urine is the most commonly used biological substance. Advantages of urine sampling are that it is readily available and there are standardized techniques for detecting drugs in urine. Other biological specimens e.g. blood, oral fluids, hair and sweat, can also be tested and may gain in popularity over time as techniques for collecting and analyzing these specimens become more standardized.

Urine drug testing

There are 2 primary categories of urine drug testing:

Immunoassay testing (i.e., qualitative testing, screening): These tests can be performed either in a laboratory or at point of service (POS). Immunoassay tests are based on the principle of competitive binding and use antibodies to detect a particular drug or drug metabolite in a urine sample. With competitive binding, a fixed amount of a labeled drug is added to the urine sample, and the drug or metabolite in the sample competes with the labeled drug for binding sites on the antibody. The amount of labeled antigen that binds with the antibody is inversely proportional to the amount of the drug or metabolite in the sample.

Immunoassay tests vary in the type of compounds they can detect. Some of them detect specific drugs and may fail to recognize similarly structured drugs within the same class. Other immunoassays identify only classes of drugs and thus results cannot be used to determine which drug a patient is taking. For example, a positive result to an opiate immunoassay can be due to morphine or hydromorphone. The degree of cross-reactivity, i.e., an antibody's reactivity with a compound other than the target of the test, varies widely among immunoassays.

Immunoassay findings are generally reported qualitatively as either positive (drug level above a pre-specified threshold) or negative (drug level below a pre-specified threshold). Raising or lowering the threshold thus changes the proportion of positive tests. A negative test is interpreted as a level below the threshold, and does not necessarily mean that the drug or metabolite is absent.

Immunoassays generally have a rapid turnaround time, within minutes for on-site tests in 1-4 hours for laboratory-based tests. (3)

4) Specific drug identification (i.e. quantitative testing, confirmatory testing): Confirmatory tests are always performed in a laboratory. Gas chromatography/mass spectrometry (GC/MS) is considered to be the "gold standard" for confirmatory testing. This technique involves using GC to separate the analytes in a specimen and MS to identify the specific molecular structures of the drug and its metabolites. The tests are able to quantify the amount of drug or metabolite present in the urine sample. Quantitative tests can be used to confirm the presence of a specific drug identified by a screening test and can identify drugs that cannot be isolated by currently available immunoassays. Results are reported as the specific levels of substances detected in the urine. GC/MS generally requires specification of the drug or drugs to be identified. Alternatively, "broad spectrum screens" can be conducted. There is a several day turnaround time for GC/MS testing. (

An issue with both types of urine drug testing is the possibility of sample tampering to mask the presence of illegal drugs. A variety of products and techniques are available to patients, and can be as simple as drinking a large amount of water to dilute the sample. There are also commercial dilution and cleaning products, additives and urine substitutes. Some of these techniques can be detected by visual inspection of the sample e.g. color, or by on-site testing of sample characteristics including urine temperature, creatinine concentration and specific gravity.

In addition, correct interpretation of urine drug testing results is very important. Knowledge of drug metabolites is essential for accurate interpretation. Accurate interpretation of test results also requires knowledge of the drug manufacturing process. For example, due to manufacturing impurities, a small amount of hydrocodone may be present in urine samples from patients prescribed oxycodone. Thus, it would be acceptable to have this degree of hydrocodone if high amounts of oxycodone were also present.

There are various approaches to incorporating urine drug screening into pain management and substance abuse treatment settings. Most commonly, patients undergo urine drug screening before beginning treatment to verify current drug use. Some clinicians believe that urine drug screening should be used routinely to establish baseline information about substance use, but the optimal frequency and interval of testing remains uncertain. A universal approach to screening may uncover more inappropriate use, and may reduce patients' sense that testing is being performed due to a lack of trust. However, routine universal screening may place an unnecessary burden on the health care system and on the

doctor-patient relationship. An alternative approach is selective testing of patients who are judged to be at increased risk for drug misuse

Existing protocols vary for use of qualitative versus quantitative tests. Some settings conduct routine confirmation of positive qualitative tests with quantitative testing. Others use selective confirmation of positive qualitative tests, such as when an unexpected immunoassay result is not adequately explained by the patient. There is also a mixed approach, with routine conformation of qualitative tests only for drugs with poor-performing immunoassays.

Full informed consent is a requirement prior to urine drug testing. Patients should be informed of the specific drug testing protocol prior to treatment, and should provide written agreement with the plan for monitoring. As stated in a joint U.S. Veteran's Affairs (VA)/Department of Defense (DOD) guideline, patients' refusal to consent to urine testing should be considered as one factor in the overall assessment of patients' ability to adhere to treatment. (5)

Regulatory Status

Gas chromatography/mass spectrometry tests and some immunoassays are performed in laboratory settings. Clinical laboratories may develop and validate in house (i.e. laboratory-developed) tests and market them as a service. Laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Act (CLIA).

A CLIA waiver is available for use of certain point-of-care immunoassays. Tests eligible for a CLIA waiver are those considered to be simple, with low risk of error and low potential for harm. The Food and Drug Administration (FDA) is tasked with approving manufacturers' applications for test system waivers. There are commercially available CLIA-waived tests for drugs such as cocaine, methadone, morphine/opiates and oxycodone.

IV. RATIONALE

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The policy was created with a search of the MEDLINE database through January 21, 2014. The policy addresses urine drug testing as a component of pain management and substance abuse treatment. For each of these settings, the literature search focused on the accuracy of testing and on the clinical utility of testing (i.e., the impact of test results on patient management and/or on health outcomes). When published studies were not identified, relevant national and regional clinical practice guidelines were sought.

Accuracy of urine drug tests for detecting prescribed opioids and/or illicit drugs

Few studies have evaluated the accuracy of urine drug testing in a real-world setting. One example of a study of this type was published in 2011 by Manchikanti and colleagues. (9) The investigators evaluated in-office immunoassay testing and used gas

chromatography/mass spectrometry as the "gold standard" comparison. The study was prospective and included consecutive patients recruited from a single pain management practice. Urine samples were tested for opioids and for illicit drugs. A total of 1000 patients had both the immunoassay and confirmatory tests; both tests were performed on the same urine sample. Personnel analyzing the tests were blinded to the results of the other test and to patient demographics. Primary findings for the diagnostic accuracy of in-office immunoassays for detecting opioids compared with the reference standard are summarized below:

Patients prescribed morphine, hydrocodone, codeine or hydromorphone (n=748)

Sensitivity: 92.5% (95% confidence interval [CI]: 90-94%)
Specificity: 89.6% (95% CI: 82-95%.

Patients prescribed oxycodone (n=134)

Sensitivity: 80.0% (95% CI: 71-87%)
Specificity: 84.2% (95% CI: 60-96%)

Patients prescribed methodone (n=46)

Sensitivity: 97.8% (95% CI: 88-99%)
Specificity: 100% (95% CI: 2-100%)

The most commonly identified illicit drugs were marijuana and amphetamines. The sensitivity and specificity of the immunoassay for detecting marijuana were 90.9% and 98.0%, respectively. Similar statistics for amphetamines were 47.0% and 99.1%, respectively. There were too few data to reliably report diagnostic accuracy of other illicit drugs.

Clinical utility (i.e. impact on patient management decisions and/or health outcomes)

Pain management setting

Managing patients with urine drug testing compared to without urine drug testing

The preferred study design is a randomized controlled trial (RCT) comparing treatment decisions and/or health outcomes in patients managed with and without use of urine drug testing. When multifaceted interventions are used, it may be difficult to isolate the impact of drug testing from that of other components of the intervention. In that case, the preferred study design would include one arm with the full intervention and another arm with the same intervention but without urine drug testing missing. In the absence of RCTs, the next most preferred study design is a non-randomized controlled trial that adjusts findings for potential confounding factors.

No RCTs or non-randomized controlled studies adjusting for potential confounders were identified. A systematic review of the available literature on urine drug screening in the chronic pain management setting, alone or as part of a treatment agreement, was published in 2010 by Starrels and colleagues (10) Studies were considered eligible for inclusion in the review if they included patients with chronic non-cancer pain who were treated in an outpatient setting and measured opioid misuse outcomes after intervention implementation. Eleven studies met the eligibility criteria; none were RCTs. Eight studies addressed urine drug testing, 7 of the 8 interventions also involved treatment agreements. Studies used different protocols for urine testing, for example some used random screening and others screened on a regular basis. Three studies stated that drug screening was done at a minimum frequency (i.e., at enrollment and/or annually), with additional testing if deemed necessary by the physician. Five studies described the type of testing used; 4 of the 5 included confirmatory GC/MS testing.

The review authors reported that 4 of 11 studies included a control or comparison group. (11-14) On closer inspection, 2 of the 4 studies labeled as controlled these used historical comparison groups and 1 was a prospective single-arm study. Starrels et al. did not pool findings of the 4 studies. In the individual studies, opioid misuse was reduced after intervention initiation from 7% to 23% compared to pre-intervention or historical controls.

Only 1 of the studies included in the systematic review used a concurrent comparison group. The study, by Goldberg and colleagues, retrospectively reviewed data from a medical center database on 91 patients with a documented pain management contract. (11) By signing the contract, the patient agreed to 8 provisions, 1 of which was "lab tests may be used to check opioid use". Among the other 7 provisions was an agreement not to use illegal drugs and not to share or sell any medication and an agreement that the patient would receive opioid medication only from a single primary care or pain clinic doctor. The comparison group consisted of 224 similar patients without pain management contracts. Consumption of opioids was significantly higher in the intervention group than the comparison group. For example, the intervention group consumed an average of 91 units of opioids quarterly and the comparison group consumed an average of 81 units, $p<0.05$. (An opioid unit was defined as equivalent to 1 systematic administration of 10mg morphine sulfate). Some of the data presented in the article were contradictory. For example, a table showed significantly greater number of emergency room visits among patients in the pain contract group than the comparison group, but the text stated that there not more emergency department visits among patients in the pain contract group.

In the uncontrolled studies included in the systematic review, the proportion of patients with opioid misuse after intervention implementation ranged from 3% to 43%. There were 8 studies that included drug testing as a component of the intervention. The protocol and frequency of drug testing varied in these studies. In 3 studies, there was a minimum baseline frequency, at the time of enrollment, annually, or both, with additional testing performed according to the judgment of the treating clinician. One study performed testing

at baseline and on a monthly basis. In the remaining 4 studies, the frequency was not specified explicitly, but was described as "regular" or "random".

Managing patients with routine urine drug testing versus selective urine drug testing

No studies were identified that compared patient management decisions or health outcomes in patients managed using routine urine testing compared with selective urine drug testing.

Managing patients with routine confirmation of positive qualitative tests versus selective confirmation of positive qualitative tests

No studies were identified that compared patient management decisions or health outcomes in patients managed using routine confirmation of positive qualitative tests versus selective confirmation of positive qualitative tests.

Substance abuse treatment setting

Managing patients with urine drug testing compared to without urine drug testing

One RCT was identified that suggests that urine testing increases treatment compliance when receiving take-home methadone compared to no urine testing. In 2001, Chutuape and colleagues published finding of a study that included patients in a methadone treatment program who had submitted fewer than 80% positive opiate and/or cocaine-positive urine samples during a 5-week baseline period. (15) These patients then participated in a methadone take-home program and were randomized to 1 of 3 groups: 1) continued permission to take-home methadone was contingent on 1 negative urine sample, randomly selected each week; 2) continued permission to take-home methadone was contingent on 1 negative urine sample, randomly selected each month; or 3) Permission to take-home methadone was not based on results of urine testing (control group). After participating in in the intervention, the rate of sustained (8 or more weeks) opiate and cocaine abstinence was significantly higher in the control group. The percentage of patients with sustained (8 or more weeks) opiate and cocaine abstinence was 56.6%, 38.9% and 10.5% in the weekly, monthly and control groups, respectively ($p<0.002$).

Managing patients with routine urine drug testing versus selective urine drug testing

No studies were identified.

Managing patients with routine confirmation of positive qualitative tests versus selective confirmation of positive qualitative tests

No studies were identified.

Clinical Input Received through Physician Medical Societies and Academic Medical Centers

In response to requests, input was received through 5 Physician Specialty Societies and 8 Academic Medical Centers while this policy was under review in 2014. While the various Physician Specialty Societies and Academic Medical Centers may collaborate with and

make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the Physician Specialty Societies or Academic Medical Centers, unless otherwise noted. There was near consensus among reviewers that, in the outpatient pain management setting, qualitative urine drug testing may be considered medically necessary for patients who meet the stated criteria and that the frequency of repeat drug testing should be dependent on the risk level of the individual. There was also near consensus among reviewers that, in the substance abuse treatment setting, baseline qualitative drug testing may be considered medically necessary for patients who meet the stated criteria and that targeted weekly qualitative screening for a maximum of 4 weeks may be considered medically necessary during the stabilization phase. There was mixed input on the frequency of qualitative drug testing that may be considered medically necessary during the maintenance phase of substance abuse treatment. In addition, clinical input was mixed on confirmatory quantitative drug testing and particularly on the issue of whether or not quantitative drug testing should only be performed on a drug-specific basis.

Summary

There is limited published evidence on the diagnostic accuracy and clinical utility of urine drug testing in the pain management and substance abuse treatment settings. There are no randomized controlled trials that isolate the potential effect of urine drug testing on patient management/health outcomes in the pain management setting. One RCT was identified on urine drug testing of patients in substance abuse treatment; that trial focused on the specific situation of testing to determine eligibility for take-home methadone. Based on the available evidence and clinical input, urine drug testing may be considered medically necessary under specific conditions listed in the policy statements.

Practice Guidelines and Position Statements

Pain management setting

In 2013, Nuckols and colleagues published a systematic review of guidelines that addressed management opioid use for chronic pain. (16) The authors included guidelines from national organizations and specialty societies, as well as guidelines from state agencies and specific health systems. The authors identified 9 guidelines with recommendations regarding urine drug testing. Recommendations varied widely; 2 guidelines recommended mandatory testing for all patients, 1 recommended testing only patients at increased risk of medication abuse and 2 stated that testing patients at low-risk of abuse is not cost-effective. If urine drug testing is used, the recommended frequency of follow-up testing was at least quarterly in 1 guideline, at least yearly in 1 guideline and randomly in 2 guidelines. Key guidelines relevant to this policy are described in more detail below.

American Society of Interventional Pain Physicians (ASIPP): In 2012, they issued guidelines on responsible opioid prescribing for chronic non-cancer pain. (8). The guidelines include the following recommendations on urine drug testing:

- "Comprehensive assessment and documentation is recommended before initiating opioid therapy..." (Evidence: good)
- "Despite limited evidence for reliability and accuracy, screening for opioid use is recommended, as it will identify opioid abusers and reduce opioid abuse." (Evidence: limited)
- 'Urine drug testing must be implemented from initiation along with subsequent adherence monitoring, in an in-office setting with immunoassay and confirmation for accuracy with chromatography in select cases, to identify patients who are non-compliant or abusing prescription drugs or illicit drugs, and urine drug testing may decrease prescription drug abuse or illicit drug use when patients are in chronic pain management therapy. (Evidence: good)'

The evidence behind the above recommendations was not clearly described in either the guidance document or the accompanying evidence assessment document. (1)

American Pain Society and American Academy of Pain Medicine Opioids Guidelines Panel: In 2009, they jointly published clinical guidelines on use of opioid therapy in chronic non-cancer pain. (17) The guidelines do not address urine drug testing or other forms of monitoring adherence.

American College of Occupational and Environmental Medicine (ACOEM): In 2011, they issued guidelines on the chronic use of opioids which contained the following recommendations on urine drug testing: (18)

"Routine use of urine drug screening for patients on chronic opioids is recommended as there is evidence that urine drug screens can identify aberrant opioid use and other substance use that otherwise is not apparent to the treating physician." Evidence (C): "The intervention is recommended for appropriate patients. There is limited evidence that the intervention may improve important health and functional benefits."

Screening is recommended for all patients at baseline and then randomly at least twice and up to 4 times a year and at termination. Screening should also be performed if the provider suspects abuse of prescribed medication.

Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain: Guidelines were issued in 2010 and they include the following recommendation on urine drug screening: (4)

"When using urine drug screening (UDS) to establish a baseline measure of risk or to monitor compliance, be aware of benefits and limitations, appropriate test ordering and interpretation, and have a plan to use results. (Grade C)."

The guideline also states:

"There is no compelling evidence to guide physicians on identifying CNCP patients who should have UDS or how often." The document states that the following factors should be considered when deciding whether to order a urine drug screen:

- patient's risk for opioid misuse and addiction
- aberrant drug-related behaviors
- testing availability (note: this may be a Canadian-specific issue)

Veteran's Affairs (VA) and Department of Defense (DoD) Management of Opioid Therapy for Chronic Pain Working Group: In 2010, these federal agencies issued clinical practice guidelines for managing opioid therapy for chronic pain treatment. (5)

The recommendations on assessing adherence to prescribed opioids includes, with patient consent. obtaining a urine drug test before initiating opioid therapy and randomly at follow-up to confirm appropriate use. Other strategies recommended include clinical assessment and screening aids such as random pill counts, adherence checklists and standardized instruments such as the Screener and Opioid Assessment for Patients with Pain (SOAPP).

The guideline included the following specific recommendations regarding urine drug testing:

1. Inform patients that drug testing is a routine procedure for all patients starting or on opioid therapy, and is an important tool for monitoring the safety of their treatment.
2. With patient consent, obtain a UDT in all patients prior to initiation of OT.
3. With patient consent monitor all patients on OT with periodic random UDTs to confirm adherence to the treatment plan. Increase the frequency of UDTs based on risk level for aberrant drug-related behaviors and following each dose increase.
4. Take into consideration a patient's refusal to take a UDT as part of the ongoing assessment of the patient's ability to adhere to the treatment plan and the level of risk for adverse outcomes.
5. When interpreting UDT results take into account other clinical information (e.g., past SUD, other risk factors, aberrant drug-related behaviors, and other conditions indicating risk.)
6. Understanding of lab methods for drug testing and reporting are necessary to interpret UDT results (i.e., screen versus confirmatory test, substances tested, cut-off levels for tests). Maintain a close working relationship with the clinical laboratory to answer any questions about the UDT or for confirming the results.

Washington State Agency Medical Directors' Group: (6) In 2010, this group issued inter-agency guidelines on opioid dosing for chronic non-cancer pain. The guideline included recommendations on urine drug testing. Recommendations on testing frequency differed depending on patient risk of opioid addiction and opioid dosage, and are summarized below (also see Policy Guidelines):

- Low risk: Periodic screening (up to once per year)
- Moderate risk: Regular screening (up to twice per year)
- High risk or opioid dose over 120mg MED/d
- Aberrant behavior: Each visit

Substance abuse treatment setting

American Society of Addiction Medicine (ASAM): In 2010, they issued a statement on drug testing in the substance abuse treatment setting. (19) As stated in this document, the policy of the ASAM is: "Urine drug testing is a key diagnostic and therapeutic tool that is useful for patient care and in monitoring the ongoing status of a person who has been treated for addiction. As such, it is a part of medical care, and should not face undue restrictions."

V. DEFINITIONS

TOP

N/A

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

TOP

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will

govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
80100	80101	80102	80103	80104				

HCPCS Code	Description
G0431	Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter
G0434	Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter

ICD-9-CM Diagnosis Code*	Description
304.00	Opioid type dependence, unspecified
304.01	Opioid type dependence, continuous
304.02	Opioid type dependence, episodic
304.03	Opioid type dependence, in remission
304.1	Sedative, hypnotic or anxiolytic dependence
304.10	Sedative, hypnotic or anxiolytic dependence, unspecified
304.11	Sedative, hypnotic or anxiolytic dependence, continuous
304.12	Sedative, hypnotic or anxiolytic dependence, episodic
304.13	Sedative, hypnotic or anxiolytic dependence, in remission
304.2	Cocaine dependence
304.20	Cocaine dependence, unspecified
304.21	Cocaine dependence, continuous
304.22	Cocaine dependence, episodic

POLICY TITLE	URINE DRUG TESTING IN PAIN MANAGEMENT AND SUBSTANCE ABUSE TREATMENT SETTINGS
POLICY NUMBER	MP-2.327

ICD-9-CM Diagnosis Code*	Description
304.23	Cocaine dependence, in remission
304.3	Cannabis dependence
304.30	Cannabis dependence, unspecified
304.31	Cannabis dependence, continuous
304.32	Cannabis dependence, episodic
304.33	Cannabis dependence, in remission
304.40	Amphetamine and other psychostimulant dependence, unspecified
304.41	Amphetamine and other psychostimulant dependence, continuous
304.42	Amphetamine and other psychostimulant dependence, episodic
304.43	Amphetamine and other psychostimulant dependence, in remission
304.5	Hallucinogen dependence
304.50	Hallucinogen dependence, unspecified
304.51	Hallucinogen dependence, continuous
304.52	Hallucinogen dependence, episodic
304.53	Hallucinogen dependence, in remission
304.6	Other specified drug dependence
304.60	Other specified drug dependence, unspecified
304.61	Other specified drug dependence, continuous
304.62	Other specified drug dependence, episodic
304.63	Other specified drug dependence, in remission
304.7	Combinations of opioid type drug with any other
304.70	Combinations of opioid type drug with any other drug dependence, unspecified
304.71	Combinations of opioid type drug with any other drug dependence, continuous
304.72	Combinations of opioid type drug with any other drug dependence, episodic
304.73	Combinations of opioid type drug with any other drug dependence, in remission
304.8	Combinations of drug dependence excluding opioid type drug
304.80	Combinations of drug dependence excluding opioid type drug, unspecified
304.81	Combinations of drug dependence excluding opioid type drug, continuous
304.82	Combinations of drug dependence excluding opioid type drug, episodic
304.83	Combinations of drug dependence excluding opioid type drug, in remission
304.9	Unspecified drug dependence
304.90	Unspecified drug dependence, unspecified
304.91	Unspecified drug dependence, continuous
304.92	Unspecified drug dependence, episodic
304.93	Unspecified drug dependence, in remission

POLICY TITLE	URINE DRUG TESTING IN PAIN MANAGEMENT AND SUBSTANCE ABUSE TREATMENT SETTINGS
POLICY NUMBER	MP-2.327

ICD-9-CM Diagnosis Code*	Description

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	Description
F11.20	Opioid dependence, uncomplicated
F11.220	Opioid dependence with intoxication, uncomplicated
F11.221	Opioid dependence with intoxication delirium
F11.222	Opioid dependence with intoxication with perceptual disturbance
F11.229	Opioid dependence with intoxication, unspecified
F11.23	Opioid dependence with withdrawal
F11.24	Opioid dependence with opioid-induced mood disorder
F11.250	Opioid dependence with opioid-induced psychotic disorder with delusions
F11.251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
F11.259	Opioid dependence with opioid-induced psychotic disorder, unspecified
F11.281	Opioid dependence with opioid-induced sexual dysfunction
F11.282	Opioid dependence with opioid-induced sleep disorder
F11.288	Opioid dependence with other opioid-induced disorder
F11.29	Opioid dependence with unspecified opioid-induced disorder
F12.20	Cannabis dependence, uncomplicated
F12.220	Cannabis dependence with intoxication, uncomplicated
F12.221	Cannabis dependence with intoxication delirium
F12.222	Cannabis dependence with intoxication with perceptual disturbance
F12.229	Cannabis dependence with intoxication, unspecified
F12.250	Cannabis dependence with psychotic disorder with delusions
F12.251	Cannabis dependence with psychotic disorder with hallucinations
F12.259	Cannabis dependence with psychotic disorder, unspecified
F12.280	Cannabis dependence with cannabis-induced anxiety disorder
F12.288	Cannabis dependence with other cannabis-induced disorder
F12.29	Cannabis dependence with unspecified cannabis-induced disorder
F13.20	Sedative, hypnotic or anxiolytic dependence, uncomplicated
F13.220	Sedative, hypnotic or anxiolytic dependence with intoxication, uncomplicated
F13.221	Sedative, hypnotic or anxiolytic dependence with intoxication delirium

POLICY TITLE	URINE DRUG TESTING IN PAIN MANAGEMENT AND SUBSTANCE ABUSE TREATMENT SETTINGS
POLICY NUMBER	MP-2.327

ICD-10-CM Diagnosis Code*	Description
F13.229	Sedative, hypnotic or anxiolytic dependence with intoxication, unspecified
F13.230	Sedative, hypnotic or anxiolytic dependence with withdrawal, uncomplicated
F13.231	Sedative, hypnotic or anxiolytic dependence with withdrawal delirium
F13.232	Sedative, hypnotic or anxiolytic dependence with withdrawal with perceptual disturbance
F13.239	Sedative, hypnotic or anxiolytic dependence with withdrawal, unspecified
F13.24	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced mood disorder
F13.250	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced psychotic disorder with delusions
F13.251	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced psychotic disorder with hallucinations
F13.259	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced psychotic disorder, unspecified
F13.26	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced persisting amnestic disorder
F13.27	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced persisting dementia
F13.280	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced anxiety disorder
F13.281	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced sexual dysfunction
F13.282	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced sleep disorder
F13.288	Sedative, hypnotic or anxiolytic dependence with other sedative, hypnotic or anxiolytic-induced disorder
F13.29	Sedative, hypnotic or anxiolytic dependence with unspecified sedative, hypnotic or anxiolytic-induced disorder
F14.20	Cocaine dependence, uncomplicated
F14.220	Cocaine dependence with intoxication, uncomplicated
F14.221	Cocaine dependence with intoxication delirium
F14.222	Cocaine dependence with intoxication with perceptual disturbance
F14.229	Cocaine dependence with intoxication, unspecified
F14.23	Cocaine dependence with withdrawal
F14.24	Cocaine dependence with cocaine-induced mood disorder
F14.250	Cocaine dependence with cocaine-induced psychotic disorder with delusions
F14.251	Cocaine dependence with cocaine-induced psychotic
F14.259	Cocaine dependence with cocaine-induced psychotic disorder, unspecified
F14.280	Cocaine dependence with cocaine-induced anxiety disorder
F14.281	Cocaine dependence with cocaine-induced sexual dysfunction
F14.282	Cocaine dependence with cocaine-induced sleep disorder
F14.288	Cocaine dependence with other cocaine-induced disorder

POLICY TITLE	URINE DRUG TESTING IN PAIN MANAGEMENT AND SUBSTANCE ABUSE TREATMENT SETTINGS
POLICY NUMBER	MP-2.327

ICD-10-CM Diagnosis Code*	Description
F14.29	Cocaine dependence with unspecified cocaine-induced disorder

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES

TOP

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X. POLICY HISTORY

TOP

MP 2.327	**CAC 3/25/14** New policy. BCBSA adopted. Policy outlines indications when urinary drug testing is considered medically necessary. Medicare variation added.

POLICY TITLE	URINE DRUG TESTING IN PAIN MANAGEMENT AND SUBSTANCE ABUSE TREATMENT SETTINGS
POLICY NUMBER	MP-2.327

Top