

prescribed or may abuse them.⁵ Moreover, studies have found that a substantial proportion of chronic pain patients inaccurately report non-adherence to prescribed medications and use of illicit drugs.

Various strategies are available to monitor pain management and substance abuse treatment patients, and multicomponent 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 physicians).

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 standardized techniques for detecting drugs in urine exist. Other biological specimens, eg, 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.

UDT

There are two primary categories of UDT.

Immunoassay Testing (i.e., Qualitative/Presumptive Testing, Screening)

These tests can be performed either in a laboratory or at point of service. 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 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, ie, 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 onsite tests and one to four hours for laboratory-based tests.⁷

Specific Drug Identification (ie, Quantitative/Definitive Testing, Confirmatory Testing)

Confirmatory tests are always performed in a laboratory. Gas chromatography/mass spectrometry (GC/MS) is considered to be the criterion 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 UDT 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, eg, color, or by onsite testing of sample characteristics including urine temperature, creatinine concentration, and specific gravity.

In addition, correct interpretation of UDT 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 UDS into pain management and substance abuse treatment settings. Most commonly, patients undergo UDS before beginning treatment to verify current drug use. Some clinicians believe that UDS should be routinely used 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 healthcare 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 of these involve conducting 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 before UDT. Patients should be informed of the specific drug testing protocol before treatment and should provide written agreement with the plan for monitoring. As stated in a joint U.S. Veterans Affairs/Department of Defense 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.⁸

Regulatory Status

Opioid Treatment Programs Screening Guidelines Vermont 2013 and Data 2000 policy

http://www.healthvermont.gov/sites/default/files/documents/2016/12/adap_opioid_treatment_programs_screening_guidelines.pdf

http://www.healthvermont.gov/sites/default/files/documents/2016/12/BMP_Policies_Data%202000%20Policy%20with%20Intro%20and%20Refs%2006062014.pdf

The primary goal of medication assisted therapy is to improve overall individual functioning of the patient. A necessary component in reaching this goal is the monitoring of illicit substance use and ensuring programmatic compliance. Urine toxicology testing is consistent with the reasonable standard of practice and is a requirement for medication assisted therapy programs in the State of Vermont for providers governed by the Medication Assisted Therapy (MAT) rules. Current federal and state regulations, however, are not prescriptive of which substances must be tested for in urine toxicology panels. It is recommended that a comprehensive screening for drugs of abuse shall be done at admission into Opioid Treatment Programs (OTPs) and should reflect the prevailing use patterns in the community.

Guidelines for Opioid Treatment Programs

Under current regulations, individuals receiving MAT in Opioid Treatment Programs (OTP) are required by 42CFR8.12 to receive a minimum of eight urine toxicology tests annually. The results of those urine toxicology tests are part of the "8 factor checklist" required by the Center for Substance Abuse Treatment (CSAT) as a determinant factor in an individual's ability to obtain "take home" medications.

The absence of illicit substances is specified as the goal of doing urine toxicology testing. Evaluation may include opioids (morphine, codeine, heroin, hydrocodone, hydromorphone, oxycodone, methadone, and buprenorphine), cocaine, amphetamine and methamphetamine, barbiturates, benzodiazepines, cannabis, bath salts, ecstasy, PCP, GHB, and ethyl alcohol. Further confirmation shall be performed via testing, primarily in the

urine, but other sources such as saliva, sweat, hair, and breath may be used.

GC/MS tests and some immunoassays are performed in laboratory settings. Clinical laboratories may develop and validate in house (ie, 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 U.S. Food and Drug Administration 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.

Vermont Board of Medical Practice Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain

http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioid_Pain_Treatment_Policy_0.pdf

Rationale

The Blue Cross and Blue Shield Association policy was created in 2014 with a search of the MEDLINE database and updated with a literature review through October 25, 2016. The policy addresses urine drug testing (UDT) as a component of pain management and substance abuse treatment. For each of these settings topics, the literature search focused on the accuracy of testing and on the clinical utility of testing (ie, 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. In January 2016, testing oral fluids and hair was added to the review.

Accuracy of Urine Drug Tests for Detecting Prescribed Opioids and/or Illicit Drugs Few studies have evaluated the accuracy of UDT in a real-world setting. One example of a study of this type was published in 2011 by Manchikanti et al. The investigators evaluated in-office immunoassay testing and used gas chromatography/mass spectrometry (GC/MS) 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. The study's primary findings for the diagnostic accuracy of in-office immunoassays for detecting opioids compared with the reference standard are:

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

Sensitivity: 92.5% (95% confidence interval [CI], 90% to 94%)

Specificity: 89.6% (95% CI, 82 to 95%)

Patients prescribed oxycodone (n=134)

Sensitivity: 80.0% (95% CI, 71% to 87%)

Specificity: 84.2% (95% CI, 60% to 96%)

Patients prescribed methadone (n=46)

Sensitivity: 97.8% (95% CI, 88% to 99%)

Specificity: 100% (95% CI, 2% to 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 (ie, Impact on Patient Management Decisions and/or Health Outcomes)

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 UDT. 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 UDT missing. In the absence of RCTs, the next most preferred study design is a nonrandomized controlled trial that adjusts findings for potential confounding factors.

Pain Management

Managing Patients With Urine Drug Testing Compared to Without Urine Drug Testing

No RCTs or nonrandomized controlled studies adjusting for potential confounders were identified. A systematic review of the available literature on urine drug screening (UDS) in the chronic pain management setting, alone or as part of a treatment agreement, was published in 2010 by Starrels et al. 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 UDT, seven of the eight 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 (ie, at enrollment and/or annually), with additional testing if deemed necessary by the physician. Five studies described the type of testing used; four of the five included confirmatory GC/MS testing.

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

Only one of the studies included in the systematic review used a concurrent comparison

group. The study, by Goldberg et al, retrospectively reviewed data from a medical center database on 91 patients with a documented pain management contract. By signing the contract, the patient agreed to eight provisions, one of which was “lab tests may be used to check opioid use.” Among the other seven 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 physician. 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 one systematic administration of 10-mg morphine sulfate). Some of the data presented in the article were contradictory. For example, a table showed significantly greater number of emergency department 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 eight studies that included drug testing as a component of the intervention. The protocol and frequency of drug testing varied in these studies. In three 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 four studies, the frequency was not specified explicitly, but was described as “regular” or “random.” In 2014, Dupouy et al published a systematic review of literature on the impact of UDS on patient management. All study designs and clinical settings were eligible for inclusion. Other article inclusion criteria were that the urine drug screens were conducted using the enzyme immunoassay technique and, for controlled studies, the comparison arm was patient management in the absence of urine testing. In addition, some type of medical management outcome needed to be reported, eg, reassessment of treatment, referral for specialist visits, hospitalization etc. Eight studies met the review’s inclusion criteria. Five were rated as poor quality and three as fair quality. The studies consisted of one RCT, two quasi-randomized studies, one observational cohort study and 4 cross-sectional studies. The RCT, published in 2000 by Schiller et al, was a study of routine drug screening in a psychiatric emergency center, a setting that is not addressed in this reference policy. Most of the other studies were also conducted in settings that fall outside of the scope of the policy. However two studies evaluated relevant populations: one of these was an uncontrolled evaluation of UDT of opioid-addicted patients and the other was a quasi-randomized study conducted in U.S. pain centers. The latter study, Manchikanti et al 2006, was included in the Starrels et al meta-analysis, previously described. The authors of the 2014 systematic review did not pool study findings.

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 Managing Patients With Urine Drug Testing Compared to Without Urine Drug Testing

One RCT was identified that suggests urine testing increases treatment compliance when receiving take-home methadone compared with no urine testing. In 2001, Chutuape et al published findings 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.¹⁶ These patients then participated in a methadone take-home program and were randomized to one of three groups: (1) continued permission to take-home methadone was contingent on one negative urine sample, randomly selected each week; (2) continued permission to take-home methadone was contingent on one 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 (eight 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.

Managing Patients with using Oral Fluid Drug Testing and Hair Testing Versus Urine Drug Testing

No studies were identified that compared patient management decisions or health outcomes in patients managed using oral fluid drug testing versus UDT or no drug testing.

The limited number of studies on the diagnostic accuracy of oral fluid testing compared with urine testing had variable findings. No studies were identified on the impact of oral fluid testing on health outcomes compared with UDT or no drug testing.

No studies were identified that compared patient management decisions or health outcomes in patients managed using testing of hair versus UDT or no drug testing.

Hair testing cannot detect recent drug use (ie, in the past few days). One study looked at this longer time frame in patients starting psychiatric treatment. It found a higher prevalence of drug use with hair testing versus UDT testing for most drugs; however, the implications of study findings for patients in pain management or substance abuse treatment is unclear. No studies were identified on the diagnostic accuracy of hair testing versus urine testing in patients with chronic pain or substance abuse. In addition, no studies were identified on the clinical utility of hair testing in pain management or substance abuse treatment.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

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.

In response to requests, input was received through five physician specialty societies and eight academic medical centers while this policy was under review in 2014. There was near consensus among reviewers that, in the outpatient pain management, 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 substance abuse treatment, 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 four 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 quantitative drug testing should only be performed on a drug-specific basis.

Summary of Evidence

There is limited published evidence on the diagnostic accuracy and clinical utility of urine drug testing in pain management and substance abuse treatment. For pain management patients, there are no randomized controlled trials (RCTs) that isolate the potential effect of urine drug testing on patient management/health outcomes. 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 special conditions listed in the policy statements.

Supplemental Information

Practice Guidelines and Position Statements

Pain Management In 2014, Nuckols et al published a systematic review of guidelines that addressed management of opioid use for chronic pain. 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 UDT. The recommendations varied widely; two guidelines recommended mandatory testing for all patients, one recommended testing only patients at increased risk of medication

abuse, and two 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 one guideline, at least yearly in one guideline and randomly in two guidelines.

American Society of Interventional Pain Physicians

In 2012, ASIPP issued guidelines on responsible opioid prescribing for chronic non-cancer pain. The guidelines include the following recommendations on UDT:

- “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 these recommendations was not clearly described in either the guidance document or the accompanying evidence assessment document.⁵

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. The guidelines do not address UDT or other forms of monitoring adherence.

American College of Occupational and Environmental Medicine

In 2011, ACOEM issued guidelines on the chronic use of opioids which contained the following recommendations on urine drug testing:

“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 four 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: “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 that there is no “compelling evidence” to guide physicians on identifying patients who should have UDS, or on how often they should be tested. 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)

Veterans Affairs and Department of Defense 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.

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.

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 opioid treatment.
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 substance abuse, 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 (ie, 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’ Group¹

In 2010, this group issued interagency 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 next (also see Policy Guidelines section):

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

Substance Abuse Treatment

American Society of Addiction Medicine

In 2010, ASAM issued a statement on drug testing in the substance abuse treatment programs. As stated in this document, the policy of 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.”

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Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service

to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

06/2015	New Policy
07/2016	Language adopted from BCBSA # 2.04.98. HCPCS codes updated.
06/2017	Aligned to BCBSA MPRM 2.04.98. Updated references. Added investigational language for hair and oral fluid drug testing. Minor grammatical and formatting changes. Added CPT® Codes 80305, 80306, 80307, G0480, G0481, G0482, G0483, G0659. Deleted CPT® Codes 80300, 80301, 80302, 80303, 80304, G6030-G6058, G0477, G0478, G0479.

Eligible Providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

Date Approved

Gabrielle Bercy-Roberson, MD, MPH, MBA
Senior Medical Director
Chair, Health Policy Committee

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Attachment I CPT® and HCPCS Code Table & Instructions

Code Table	Number	Brief Description	Policy Instructions Units beyond those specified will deny
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			not medically necessary, provider liability
The following codes may be considered as medically Necessary when applicable criteria have been met.			
CPT®	80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (eg, immunoassay); capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges) includes sample validation when performed, per date of service	1 unit per date of service
CPT®	80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (eg, immunoassay); read by instrument assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service	1 unit per date of service
CPT®	80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service	1 unit per date of service
	80299	Quantitation of therapeutic drug, not elsewhere specified.	Suspend for medical review
CPT®	80320	Alcohols	1 unit per date of service
CPT®	80321	Alcohol biomarkers; 1 or 2	1 unit per date of service
CPT®	80322	Alcohol biomarkers; 3 or more	1 unit per date of service
CPT®	80323	Alkaloids, not otherwise specified	1 unit per date of service
CPT®	80324	Amphetamines; 1 or 2	1 unit per date of service
CPT®	80325	Amphetamines; 3 or 4	1 unit per date of service
CPT®	80326	Amphetamines; 5 or more	1 unit per date of service

CPT®	80327	Anabolic steroids; 1 or 2	1 unit per date of service
CPT®	80328	Anabolic steroids; 3 or more	1 unit per date of service
CPT®	80329	Analgesics, non-opioid; 1 or 2	1 unit per date of service
CPT®	80330	Analgesics, non-opioid; 3-5	1 unit per date of service
CPT®	80331	Analgesics, non-opioid; 6 or more	1 unit per date of service
CPT®	80332	Antidepressants, serotonergic class; 1 or 2	1 unit per date of service
CPT®	80333	Antidepressants, serotonergic class; 3-5	1 unit per date of service
CPT®	80334	Antidepressants, serotonergic class; 6 or more	1 unit per date of service
CPT®	80335	Antidepressants, tricyclic and other cyclical; 1 or 2	1 unit per date of service
CPT®	80336	Antidepressants, tricyclic and other cyclical; 3-5	1 unit per date of service
CPT®	80337	Antidepressants, tricyclic and other cyclical; 6 or more	1 unit per date of service
CPT®	80338	Antidepressants, not otherwise classified	1 unit per date of service
CPT®	80339	Antiepileptics, not otherwise specified; 1-3	1 unit per date of service
CPT®	80340	Antiepileptics, not otherwise specified; 4-6	1 unit per date of service
CPT®	80341	Antiepileptics, not otherwise specified; 7 or more	1 unit per date of service
CPT®	80342	Antipsychotics, not otherwise specified; 1-3	1 unit per date of service
CPT®	80343	Antipsychotics, not otherwise specified; 4-6	1 unit per date of service
CPT®	80344	Antipsychotics, not otherwise specified; 7 or more	1 unit per date of service
CPT®	80345	Barbiturates or Phenobarbital	1 unit per date of service
CPT®	80346	Benzodiazepines; 1-12	1 unit per date of service
CPT®	80347	Benzodiazepines; 13 or more	1 unit per date of service

CPT [®]	80348	Buprenorphine	1 unit per date of service
CPT [®]	80349	Cannabinoids, natural	1 unit per date of service
CPT [®]	80350	Cannabinoids, synthetic; 1-3	1 unit per date of service
CPT [®]	80351	Cannabinoids, synthetic; 4-6	1 unit per date of service
CPT [®]	80352	Cannabinoids, synthetic; 7 or more	1 unit per date of service
CPT [®]	80353	Cocaine	1 unit per date of service
CPT [®]	80354	Fentanyl	1 unit per date of service
CPT [®]	80355	Gabapentin, non-blood	1 unit per date of service
CPT [®]	80356	Heroin metabolite	1 unit per date of service
CPT [®]	80357	Ketamine and norketamine	1 unit per date of service
CPT [®]	80358	Methadone	1 unit per date of service
CPT [®]	80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)	1 unit per date of service
CPT [®]	80360	Methyphenidate	1 unit per date of service
CPT [®]	80361	Opiates, 1 or more	1 unit per date of service
CPT [®]	80362	Opioids and opiate analogs; 1 or 2	1 unit per date of service
CPT [®]	80363	Opioids and opiate analogs; 3 or 4	1 unit per date of service
CPT [®]	80364	Opioids and opiate analogs; 5 or more	1 unit per date of service
CPT [®]	80365	Oxycodone	1 unit per date of service
CPT [®]	80366	Pregabalin	1 unit per date of service
CPT [®]	80367	Propoxyphene	1 unit per date of service
CPT [®]	80368	Sedative hypnotics (non-benzodiazepines)	1 unit per date of service

CPT®	80369	Skeletal muscle relaxants; 1 or 2	1 unit per date of service
CPT®	80370	Skeletal muscle relaxants; 3 or more	1 unit per date of service
CPT®	80371	Stimulants, synthetic	1 unit per date of service
CPT®	80372	Tapentadol	1 unit per date of service
CPT®	80373	Tramadol	1 unit per date of service
CPT®	80374	Stereoisomer (enantiomer) analysis, single drug class	1 unit per date of service
CPT®	80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3	1 unit per date of service
CPT®	80376	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6	1 unit per date of service
CPT®	80377	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more	1 unit per date of service
CPT®	83992	Phencyclidine (PCP)	1 unit per date of service
HCPCS	G0480	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem) and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.	1 unit per date of service
HCPCS	G0481	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem) and excluding immunoassays (e.g., IA, EIA,	

		ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed	1 unit per date of service
HCPCS	G0482	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem) and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed	1 unit per date of service
HCPCS	G0483	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem) and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed	1 unit per date of service
HCPCS	G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each	1 unit per date of service

		drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes	
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Attachment II
ICD Diagnosis Code Table & Instructions

Code Type	Number	Description
Any of a large number of diagnosis codes might apply to this policy, the following are just examples		
ICD-10	F11.10- F11.99	Opioid related disorders, code range
ICD-10	F14.10- F14.99	Cocaine related disorders, code range
ICD-10	F16.10- F16.99	Hallucinogen related disorders, code range
ICD-10	F45.42	Pain disorder with related psychological factors
ICD-10	G89.21- G89.4	Chronic pain not otherwise specified code range
Type of Service		Laboratory
Place of Service		11 Office, 22 Outpatient Hospital, 52 Psychiatric Facility-Partial Hospitalization, 53 Community Mental Health Center, 55 Residential Substance Abuse Treatment Facility, 56 Psychiatric Residential Treatment Center.