According to the Centers for Disease Control and Prevention (CDC), in 2014, more than 28,000 people died of opioid overdoses, 129 people every day as a result of drug poisoning, and 61 percent are pharmaceutical opioid or heroin related. High-profile deaths from opioid overdose have brought into the headlines obscure words from our world—fentanyl, hydrocodone, buprenorphine, quantitative mass urine assay, genetic dependency analysis and liquid chromatography-mass spectrometry. High complexity urine drug screening (UDS), once limited to specialized laboratories, has found a home in physicians’ office laboratories and at both large and small commercial laboratories specializing in UDS to support pain management and substance abuse treatment. So it is no surprise that carriers, adjusters and patients can be overwhelmed when facing decision making about UDS.

Although further clinical studies are needed to standardize best practice for UDS utilization, we know much more about opioid pharmacology and analysis now than we did 10 years ago because of the growth in pain management UDS.

Some have commented on the conundrum of regulating screening for pain management UDS, as it straddles the divide between medical and legal requirements for management of a workers’ compensation claim. Further complicating the picture, revenues for some UDS laboratories soared in the last decade. This
in part was due to a disconnect between the capability of modern technology to rapidly quantify multiple drugs and metabolites in a single test versus each drug or drug class reported.

This growth in spending on UDS caught the eyes of both regulators and the public. In 2014, The Wall Street Journal reported that Medicare’s spending on 22 “high-tech” tests for drugs of abuse hit $445 million in 2012, up 1,423 percent in 5 years.² In October 2015, the U.S. Department of Justice announced that Millennium Health, one of the largest UDS laboratories in the country, agreed to pay $256 million to resolve alleged violations of the False Claims Act for medically unnecessary urine drug and genetic testing.³

In response, the Centers for Medicare and Medicaid Services (CMS) in the last 2 years made big changes to drug testing codes that are expected to decrease reimbursement.⁴ According to CMS, the agency does not recognize the 2015 American Medical Association current procedural terminology code changes for UDS because of “our concern about the potential for overpayment when billing for each individual drug test rather than a single code that pays the same amount regardless of the number of drugs that are being tested.”⁵ CMS has disallowed billing for multiple, individual, quantitative drug tests/sample using definitive methods (mass spectrometry) and substituted instead just four definitive method G-codes based on the number of drug classes reported either qualitatively or quantitatively.

The CMS recently changed codes for UDS from 80101 to G0431 due to excessive use of UDS and abuse. The new G-code is defined as “drug screen, qualitative; single drug class method (e.g. Immunoassay, enzyme assay) each drug class” and excludes chromatography.⁶ An example of reimbursement by CMS for CPT code G0431 at POC is $160. This may vary for state fee guidelines and/ or geographic location. CMS has revised G0431 such that now it may be billed only once per patient encounter, regardless of the number of drug classes tested.

In March 2016, the Centers for Disease Control and Prevention (CDC) also weighed in on UDS in its Guideline for Prescribing Opioids for Chronic Pain. CDC includes a recommendation for UDS but with an evidence grade 4, the lowest level. Furthermore, the CDC guideline notes that UDS “does not provide accurate information about how much or what dose of opioids or other drugs a patient took. The clinical evidence review did not find studies evaluating the effectiveness of urine drug screening for risk mitigation during opioid prescribing for pain.”⁷ Although further clinical studies are needed to standardize best practice for UDS utilization, we know much more about opioid pharmacology and analysis now than we did 10 years ago because of the growth in pain management UDS. Missing from all this is a consensus guideline on laboratory best practice for pain management UDS.

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now than we did 10 years ago because of the growth in pain management UDS.

Official Disability Guidelines (ODG) indications for UDS include testing at the onset of treatment of a new patient who is already receiving a controlled substance or when chronic opioid management is considered. Urine drug testing is not generally recommended in acute treatment settings; in cases in which the patient asks for a specific drug, particularly if the drug has high abuse potential; the patient refuses other drug treatment and/or changes in scheduled drugs, or refuses generic drug substitution; if the patient has a positive or “at risk” addiction screen on evaluation, including evidence of a history of comorbid psychiatric disorder. ODG recommendations for ongoing monitoring only apply if a patient has evidence of a high risk of addiction, including evidence of a comorbid psychiatric disorder, has a history of aberrant behavior, personal or family history of substance abuse or sexual trauma or if dose increases are not decreasing pain and increasing function, but fails to establish the specific frequency or type of testing necessary for ongoing testing.

Conversely, American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines indicates the initial evaluation and treatment plan will not necessarily require urine drug monitoring to ascertain that the prescribed medication is being used, since the use of opioids should generally be short-term, and supports a focus on risk screening for addiction instead. However, Timeframes for UDS in patient’s considered for long term opiate use are recommended to undergo random urine testing, with frequency of testing being at least yearly or more often as needed.

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Here at Mitchell, in the first two months of 2017, we have averaged at least five reviews a day inclusive of UDS related to opiate use, with more than half being approved. Almost 40 percent of those approvals are driven by adjuster level decisions. However, 40 percent of requests for UDS are on claims that are more than five years old and 60 percent of requests for UDS are on claims that are more than two years old. None were for claims with dates of injury within the last 90 days, the target timeframe to establish expectations and best practices around opiate use.

There remains significant controversy as to whether some well selected and carefully monitored patients with chronic pain experience improved function, meaningful pain relief, and improved quality of life from opioid therapy. For others, opioid treatment may result in misuse, abuse, and may not improve function. Therefore, proper prescribing of controlled substances is critical to patients’ health and to safeguard
society against abuse and diversion. A number of organizations and agencies have developed recommendations and guidelines that include the use of UDS as a tool to assist clinicians to responsibly prescribe opioids when managing chronic pain; for example, clinical practice guidelines for chronic pain management published by the American Pain Society/American Academy of Pain Medicine and the Department of Veterans Affairs/Department of Defense include a provision for UDS. However, neither guideline provides instruction for how UDS should be performed in clinical practice, nor how to interpret UDS results. In addition, many state medical boards/agencies have developed policies or guidelines that require or suggest the use of UDS in certain situations.

Because substance abuse disorders are not uncommon, UDS should be considered a core clinical tool in primary care as part of a comprehensive risk management strategy.

Despite potentially serious outcomes from UDS for pain patients (e.g., dismissal or changes to the treatment plan), clinicians often lack training in the use of UDS, and UDS is often underused or used inappropriately in clinical practice. Before ordering UDS, clinicians should understand methods of testing, the potential benefits and limitations of UDS, and how to interpret results, so that they can rationally employ patient-centered UDS in clinical practice. UDS can be an effective tool for clinicians in the assessment and ongoing management of patients who:

- Will be, or are being, treated over the long term with controlled substances, including opioids for chronic pain.
- Are at increased risk for substance-use disorders.
- Have other relevant medical conditions or diagnoses.

Because substance abuse disorders are not uncommon, UDS should be considered a core clinical tool in primary care as part of a comprehensive risk management strategy. The clinician can use UDS to help motivate patient behavioral changes and maintain healthy changes that have already been made. However, testing without an appropriate strategy for frequency and interpreting results can do significant harm and drive increased cost without significant improvement on the patient or the claim resolution. Repetitive UDS for the sake of monitoring adds little value. Clinicians must be aware of the limitations of UDS, and not rely on test results alone to make irreversible patient care decisions or decisions that have other potentially negative ramifications for the patient. Most importantly, a clinician should strive for a relationship of mutual trust and honesty with the patient when using UDS in his or her clinical practice. Ideally, the use of UDS should be a consensual process between clinician and patient that is designed to assist in managing patient care and empowering better outcomes.

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