

DRUG TESTING

Urine drug testing in chronic pain care: what the evidence, the guidelines and the coverage rules support

ABSTRACT

Urine drug testing is a standard monitoring practice in long-term opioid therapy and a closely audited Medicare laboratory service. This review appraises what testing has been shown to accomplish, what its methods detect, what the guidelines recommend and what the Palmetto GBA coverage determination that applies in Tennessee requires. The outcome evidence is weak: a systematic review found no study evaluating whether risk-mitigation strategies improve overdose or addiction outcomes, and the 2022 CDC recommendation carries the lowest evidence grade. Standard opiate immunoassays miss oxycodone, fentanyl and methadone, so interpretation depends on method. Coverage requires individualized, risk-stratified, documented orders and excludes blanket panels. Two Inspector General figures are read against their denominators.

Type Evidence, guideline and coverage review **References** 26 **Reading time** 14 min

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1 A monitoring test with a coverage rule attached

Urine drug testing is a standard monitoring practice in long-term opioid therapy and a laboratory service billed to Medicare, so each test is judged twice: clinically, by what it adds to care, and administratively, by whether the record shows why it was ordered. This paper asks what testing has been shown to accomplish, what its methods can and cannot detect, what the guidelines recommend, and what the Medicare coverage determination that applies in Tennessee requires the record to show.

The outcome evidence is thin: a systematic review of treatment agreements and drug testing judged its evidence relatively weak,^{1,2} a later review found no study that evaluated whether any risk-mitigation strategy improves outcomes related to overdose, addiction, abuse or misuse,³ and the 2022 CDC recommendation on toxicology testing carries the guideline's lowest evidence grade.⁴ The analytic limits are well characterized, and the coverage rule states them: the standard opiate immunoassay does not typically detect oxycodone, and does not detect fentanyl or methadone.⁵ Medicare in Tennessee pays for testing that is individualized, stratified by risk and documented, and not for blanket orders or routine standing orders.⁵

When the benefit of a test depends on what the clinician does with the result, and the meaning of the result depends on what the method could see, the value of the test is decided in the record. The record is also what an auditor reads.

2 The outcome evidence is weak, and the reviews say so

Starrels and colleagues' 2010 systematic review asked whether treatment agreements and urine drug testing reduce opioid misuse in chronic pain.¹ It found 11 prospective or retrospective cohort studies with about 3,155 participants; 4 (1,426 participants) had a control group, 7 were rated fair and 4 poor. Every controlled study showed less misuse with the intervention, with absolute risk reductions from 6.5 percentage points (95% CI 1.3 to 11.7) to 22.9 (95% CI 17.3 to 28.7). The authors concluded that the evidence of effectiveness was relatively weak.

Most studies evaluated treatment agreements with or without urine testing, and only one evaluated urine testing alone, so the review is weak evidence for a bundle rather than for the test. These figures reach this paper through the Centre for Reviews and Dissemination's structured abstract of the review, which judged its conclusions likely to be reliable.²

Five years later, Chou and colleagues reviewed long-term opioid therapy for a National Institutes of Health workshop, drawing on 39 studies.³ Their finding here is flat: no study evaluated the effectiveness of risk mitigation strategies for improving outcomes related to overdose, addiction, abuse or misuse. Drug testing belongs to that category; a 2021 claims analysis describes guidelines as emphasizing “risk mitigation strategies, including urine drug testing”.⁶

An observational study of a hard outcome points the same way. Gaither and colleagues followed 17,044 Veterans Affairs patients, with and without HIV, who began long-term opioid therapy between 2000 and 2010; 1,048 (6%) died within a year.⁷ Receipt of urine drug testing was not associated with all-cause mortality (HR 0.96; 95% CI 0.78 to 1.17; $P = 0.67$). Mortality is a blunt outcome for a monitoring test, and an observational null does not show testing is useless; it shows that benefit has not been demonstrated where it would matter most.

What testing reliably produces is information

In 5,420 tests from patients on chronic opioid therapy in an integrated primary care group practice, Turner and colleagues found 30% aberrant: the prescribed opioid not detected in 12.3%, tetrahydrocannabinol in 11.2%, a non-prescribed opioid in 5.3%, a non-prescribed benzodiazepine in 1.7%, another illicit drug in 0.6%, and a dilute specimen in 4.8%.⁸ The two commonest findings, a missing prescribed drug and cannabis, are the results whose meaning depends most on the method and the context.

What happens next is less studied. Morasco and colleagues reviewed 300 Veterans Affairs patients starting opioids, 100 each with aberrant positive, aberrant negative and expected results.⁹ After an aberrant result, 17.5% of clinicians documented a plan to discontinue or change the opioid dose and 52.5% began another risk-reduction strategy; the response depended on whether the unexpected result was a positive or a negative. Meanwhile use has risen: in a national claims database, annual testing among long-term opioid users doubled from 25.6% in 2012 to 52.2% in 2018, and testing before initiation rose from 3.75% to 11.1%.⁶

WHAT THE OUTCOME GAP DOES NOT ESTABLISH

None of these studies randomized patients to testing, and none separates the test from the clinical response to it. Absent outcome evidence is not evidence that testing does nothing. It means the case for testing rests on its value as information, which is worth what is done with it and whether it was read correctly.

3 What the assays can and cannot see

Clinical drug testing has two tiers. Presumptive testing, usually an immunoassay, indicates the presence or absence of drugs or drug classes; definitive testing identifies specific medications, illicit substances and metabolites, and reports concentrations of specific drugs within a class.¹⁰

The limits of the first tier are written into the coverage rule. An immunoassay's antibody "reacts best with the stimulating drug and reacts to a lesser extent (cross-reactive) or not at all with other drugs in the drug class."⁵ Moeller and colleagues' review for clinicians supplies the pharmacology: cross-reactivity between morphine and the semisynthetic opioids is low, so false negatives are possible, and fentanyl, methadone and buprenorphine differ enough in structure that morphine-specific immunoassays do not react to them at all.¹¹ Applying the 2,000 ng/mL workplace opiate cutoff clinically can itself produce negative results (Table 1).

TABLE 1

What a standard presumptive opiate immunoassay does and does not detect, as stated in the coverage rule and a clinical review.

Substance	Standard opiate immunoassay	Source
Morphine, codeine	Detected; workplace cutoff raised from 300 to 2,000 ng/mL in 1998 to limit positives from poppy seeds and prescribed opiates	Moeller ¹¹
Hydrocodone, hydromorphone	May contribute to a positive result; cross-reactivity low, false negatives possible	LCD; Moeller ^{5,11}
Oxycodone, oxymorphone	"Will not typically be detected even at a 300 ng/mL cutoff"	LCD ⁵
Fentanyl, methadone, meperidine	Not detected by current opiate immunoassays	LCD ⁵
Fentanyl, methadone, buprenorphine	No reactivity in morphine-specific immunoassays; need a specific immunoassay or LC-MS/MS	Moeller ¹¹
Quinolone antibiotics	Widely reported to interfere with opiate immunoassays	Moeller ¹¹

A negative result for a prescribed drug therefore has no fixed meaning. On a screen that cannot see oxycodone, a negative in a patient prescribed oxycodone says nothing about adherence; on a definitive test it may. The LCD recognizes this: definitive confirmation of a negative presumptive result is covered when the result conflicts with the patient's report, presentation, history or prescribed medications; when the clinician suspects a substance the screen detects poorly or not at all; or when an unexpected negative must be resolved and the record says why.⁵

Laboratory medicine reads these limits as an argument for starting at the second tier. The American Association of Clinical Chemistry's practice guideline recommends that "Qualitative definitive tests should be used over immunoassays" in pain management patients (strength A, evidence level II), and that quantitative definitive urine testing not be used to evaluate the dose taken or adherence to a prescribed dosage regimen.¹² A urine concentration identifies a drug; it is not a dose check.

4 Interpretation is where the error concentrates

Given those limits, the value of a result depends on the person reading it, and two surveys that measured that person are discouraging. Reisfield and colleagues gave a seven-question instrument to family physicians at a review course; 60 of 80 completed it, 44 of whom ordered urine drug tests.¹³ None of the 44 answered more than five questions correctly and only 20% answered more than half; the differences between those who ordered testing and those who did not were not statistically significant.

Starrels and colleagues found the same gap among 99 internal medicine residents, with a second finding that matters more for design.¹⁴ The mean knowledge score was 3.0 of 7 (SD 1.2). Fifty-five (56%) felt confident interpreting results, and 40 (73%) of those scored 3 or lower; knowledge was not associated

with confidence. Both are small knowledge surveys, not observations of practice, but they measure the right thing: whether the reader knows what the assay could have seen.

Misreading is not a neutral error, because clinicians act on aberrant results: in the Veterans Affairs sample most responded with a prescribing change or another risk-reduction step, and which one followed depended on whether the result was an unexpected positive or an unexpected negative.⁹ The 2022 CDC guideline describes its recommendations as intended “to support, not supplant, individualized, person-centered care”.⁴

Who gets tested

In a retrospective cohort of 1,612 primary care patients on opioids for chronic non-cancer pain, 62.1% of them Black, Black patients were more often tested than white patients (10.4% against 4.1%).¹⁵ After adjustment the testing difference was not significant (OR 1.41; 95% CI 0.78 to 2.54), while higher odds of regular office visits (OR 1.51) and restricted early refills (OR 1.55) persisted: monitoring intensity differed by race after adjustment for measured clinical factors, including substance abuse and comorbidity, the kind of risk a risk-stratified rule is meant to track.

5 What the guidelines recommend, and what changed in 2022

The 2016 CDC guideline's Recommendation 10 was specific: “When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.”^{16,17}

The 2022 guideline, which updates the 2016 one, rewrote it: “When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances.”⁴ The baseline test and the annual floor are gone; the verb is “consider”, and its object is a weighing of benefit and risk. The recommendation is category B, meaning different choices will be appropriate for different patients, and evidence type 4, the lowest grade: clinical experience and observations, observational studies with important limitations, or randomized trials with several major limitations, indicating “very little confidence in the effect estimate”.

A baseline-plus-annual schedule cited to the CDC is therefore the 2016 statement, not the current one. The 2022 guideline also says its recommendations “should not be used as inflexible standards of care” and are “not intended to be implemented as absolute limits for policy or practice across populations by organizations, health care systems, or government entities.”⁴ A frequency written into a universal order set is the kind of population-wide rule that language addresses.

Laboratory medicine is more prescriptive. An expert-opinion recommendation in the AACC guideline calls for baseline testing before controlled-substance therapy and random testing at least once or twice a year at low risk, more often as risk rises; graded recommendations add pH, temperature, creatinine and oxidant testing on every pain-management specimen.¹² The American Society of Addiction Medicine presents its 2017 consensus document, written for addiction treatment, as addressing the absence of any universal standard for drug testing in addiction care.¹⁸ The guidance converges on testing scaled to risk and read in context; its evidence base is the one section 2 describes.

6 What Palmetto GBA's coverage determination requires in Tennessee

Palmetto GBA is the Medicare contractor for Tennessee in Jurisdiction J (contract 10312 for Part B, 10311 for Part A), and its local coverage determination L35724, *Urine Drug Testing*, applies in seven states: Alabama, Georgia, Tennessee, the Carolinas, Virginia and West Virginia.⁵ First effective 1 October 2015, it was revised through a proposed LCD whose comment period ran from 27 April to 10 June 2023, taking effect on 8 October 2023;¹⁹ the Medicare Coverage Database gives the reason as “Risk Identified by the Office of Inspector General (OIG)”. Later revisions, the latest effective 20 February 2025, corrected bibliography links and formatting; the LCD was in effect in September 2026.⁵

The LCD sorts testing into three groups: symptomatic patients, such as those presenting to emergency or urgent care, patients treated for substance use disorder, and patients on chronic opioid therapy. For the third, medical necessity must rest on patient-specific elements documented by the clinician, at minimum the history, examination and previous laboratory findings, the treatment plan, the prescribed medications and a risk assessment plan. “The patient's risk category must be clearly defined in the medical record and is essential in determining the number of UDTs billed over time and medical necessity.”⁵

TABLE 2

Palmetto GBA LCD L35724, patients on chronic opioid therapy: testing frequency by documented risk category, from the LCD⁵ and Palmetto GBA's 2024 CERT article restating it.²⁰ Score bands are those the LCD gives for its example instrument, the Opioid Risk Tool.

Risk category	Baseline	Presumptive and definitive testing, each
Low (ORT 3 or lower)	Before initiation	Not to exceed 2 in a rolling 365 days
Moderate (ORT 4 to 7)	Before initiation	Not to exceed 2 in a rolling 180 days
High (ORT 8 or higher)	Before initiation	Not to exceed 3 in a rolling 90 days
Beyond these limits	—	Additional definitive testing justified by the clinician: sudden change in response, changed side effects, possible drug–drug interaction, change in condition or behavior, admitted illicit or non-prescribed use

Definitive orders “should be individualized, based on clinical history and risk assessment”, and the clinician's rationale for the definitive test and the tests ordered must be in the record.⁵ A presumptive panel may be billed once per patient encounter regardless of the number of analytes, and direct-to-definitive testing is covered when individualized documentation supports it. Not reasonable and necessary: blanket orders, the same for all patients in a practice; routine standing orders for all patients; point-of-care presumptive testing plus a reference-laboratory immunoassay; immunoassay used to “confirm” a presumptive result; two specimen types on the same date for the same analytes; testing for medico-legal or employment purposes “or to protect a physician from drug diversion charges”; and specimen validity testing.

Beneath the LCD sits the general rule that a diagnostic test must be ordered by the treating physician, who uses the results in managing the patient's specific problem and keeps documentation of medical necessity.²¹ A companion billing article, A54799, lists the diagnosis codes that support medical necessity.²² When a laboratory association commented in 2023 that laboratories struggle to obtain ordering clinicians' records, Palmetto answered that without that documentation payment will be denied.¹⁹ Its 2024 CERT article names the recurring failure: “We are seeing documentation of the risk level but the risk assessment to support the risk level is not included.”²⁰

The risk tier rests on a thin instrument

The LCD offers the Opioid Risk Tool as an example, “used as a suggestion for defining Risk”, and allows other tools accepted by the opioid-treatment community, for instance those accepted by the Substance Abuse and Mental Health Services Administration.⁵ Its original validation enrolled 185 consecutive new patients at one pain clinic.²³ Of 18 scored low risk, 17 (94.4%) showed no aberrant behavior over 12 months; of 44 scored high risk, 40 (90.9%) did. The authors called the study preliminary.

Later work was not reassuring. Chou's review found sensitivity ranging from 0.20 to 0.99 across studies, and no study of whether any risk instrument improves outcomes.³ Clark and colleagues applied the tool to 225 consecutive new patients at an academic pain center and could not replicate the original findings: self-report was no better than chance at predicting aberrant behavior, and the three risk categories were not supported.²⁴ The category that sets how many tests Medicare will pay for is thus derived, in the LCD's own example, from a tool whose original low-risk group numbered 18 patients.

SCOPE OF THIS SECTION

This is one contractor's LCD as published in September 2026; the Inspector General found contractors' requirements inconsistent, including on counting drug classes.¹⁰ Commercial plans and TennCare are not addressed. The billing article was displayed as a draft revision effective 1 June 2026. None of this is advice on a particular claim.

7 Why the rules read like an audit response

Presumptive tests are billed under three codes, 80305 to 80307, that rise with the complexity of the method, from a cup or dipstick read by eye (80305) to a chemical analyzer (80307). Definitive tests use four HCPCS codes tiered by number of drug classes: G0480 for 1 to 7, G0481 for 8 to 14, G0482 for 15 to 21 and G0483 for 22 or more, with 2019 fee schedule amounts of \$114.43, \$156.59, \$198.74 and \$246.92.¹⁰

Three Inspector General audits frame the rules. The first found that Medicare had improperly paid 4,480 laboratories and physician offices \$66.3 million for specimen validity tests billed with urine drug tests from 2014 through 2016; that payment is already included in the drug test codes.²⁵

58.9%

improper payment rate for G0483, the highest-paid drug test code, in 2019 (all Medicare fee-for-service: 7.3%)

89.6% vs 21.2%

definitive tests billed at G0483 by 1,062 "at-risk" providers vs 4,227 others, 2016–2020

\$66.3M

improper payments for specimen validity tests billed with drug tests, 2014–2016

The second, in 2021, reported that Medicare paid about \$180 million in 2019 for drug testing of about 274,000 beneficiaries with substance use disorders.¹⁰ Its headline figure needs its denominator: the 2019 fee-for-service improper payment rate was 7.3%, and the rate for G0483, the drug test with the highest fee, was 58.9%. That is one code's error rate, not drug testing's. Contractors had no clear, consistent rule for counting drug classes: one laboratory counted benzodiazepines as one class, another counted 13 benzodiazepines as 13. CMS did not concur with three of five recommendations, including consistent requirements across contractors and class-counting guidance.

The third, in 2023, is headlined as up to \$216 million in savings.²⁶ Over 2016 to 2020 Medicare paid about \$3 billion for 17.1 million definitive testing services. The 1,062 providers labelled at risk billed 89.6% of their definitive services as G0483, against 21.2% for 4,227 other providers, while testing a similar number

of times per patient (4.2 against 4.7). The Inspector General put \$704.2 million at risk and computed \$215.8 million in savings by assuming the at-risk providers had billed G0483 at the 21.2% rate: a modelled counterfactual on claims not medically reviewed, not a finding of overpayment. CMS declined recovery because the “analysis alone does not provide findings of improper payments, which would have required medical review”, and stated that no clinical evidence supports a single, specific reasonable and necessary standard for drug testing.

Both readings hold. The documentation demands answer a record of overbilling, and the 2023 revision cites OIG risk.⁵ But neither the Inspector General nor CMS defined clinically appropriate testing; the coverage rule fills that gap by requiring the ordering clinician to state it, one patient at a time.

8 What the record has to carry

The evidence, the guidelines and the coverage rule together define properties any record supporting urine drug testing needs, whatever system holds it.

1. **The order is individual and carries its reason.** Blanket and routine standing orders are excluded, and the LCD's standing order is patient-specific and alterable by the clinician.⁵ A default panel attached to every opioid visit, with no individual decision behind it, fits the LCD's definition of a blanket order. The ordering physician must be the treating physician who uses the result.²¹
2. **The risk assessment is stored as an assessment, not a label.** Palmetto's reviewers find the risk level without the assessment behind it.²⁰ The instrument, its items and score, and who completed it when make the tier auditable and, given the tool's validation record, open to clinical challenge.^{23,24}
3. **Expected results derive from the medication list and the method.** A result is interpretable only against what was prescribed and what the assay could detect. An opiate-immunoassay negative for oxycodone is not evidence of non-adherence,^{5,11} and a record that presents it as one invites the error the surveys measured.^{13,14}
4. **Tests are counted by type against rolling windows.** Limits run per risk tier and test type over rolling 90-, 180- and 365-day windows; extra definitive testing needs a listed clinical reason.⁵
5. **The response is documented.** What the clinician did with an unexpected result is the route by which testing could affect outcomes,⁹ and with outcome evidence this weak it is the part most worth recording.^{1,3}

9 What survives

Six statements are supported. Testing often produces findings: 30% of tests were aberrant in one large primary care series.⁸ Its effect on overdose, addiction or misuse has not been shown; the controlled evidence is weak, entangled with treatment agreements, and null on the one hard outcome studied

here.^{1,3,7} Standard opiate immunoassays miss oxycodone, fentanyl and methadone.^{5,11} Clinicians' interpretive knowledge has measured poorly and has not tracked their confidence.^{13,14} The 2022 CDC recommendation asks clinicians to weigh benefit and risk, on the lowest grade of evidence, and no longer states a baseline-plus-annual schedule.^{4,16} And Medicare coverage in Tennessee follows the documented patient, not the practice protocol.⁵

The clinical question would be settled by a trial that randomizes a testing strategy, with its interpretation and response specified, and measures overdose, opioid use disorder and retention in care rather than aberrant results. The coverage rule needs a risk instrument validated in current pain populations, since that category sets how many tests are paid. Until then the defensible position is the one the coverage rule takes: a test ordered for a stated reason, read against what the method could see, and acted on in a way the record shows.

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Entries 1, 3 and 7 carry the outcome argument and entries 23 and 24 the case about the risk instrument; entries 13 and 14 are small knowledge surveys, and entries 8, 9 and 15 are observational. Entries 5, 19, 20 and 22 are Medicare contractor documents and entry 21 is a regulation: they state what is paid for, not what works. Entries 10, 25 and 26 are Inspector General audits, and the savings figure in entry 26 is a modelled estimate, not a finding of overpayment. The figures from entry 1 reach this paper through the structured abstract in entry 2; entry 18 had no abstract available and no number is taken from it; and the 2016 wording is quoted from entry 16 and is reproduced in CDC's own fact sheet, entry 17.

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