PAYMENT GUIDELINE

Guideline No: GL-001

Payment Guideline: Drug Screen

Read First

IMPORTANT INFORMATION CONCERNING WELLFLEET PAYMENT GUIDELINES

This Payment Guideline serves as notice to health care providers of Wellfleet's payment practices. Health providers are advised to consult their own network provider agreement for determining specific payment policies.

Wellfleet may use reasonable discretion in applying these Payment Guidelines to health care services provided to its enrollees. This Payment Guideline does not address all the issues related to reimbursement for health care services. Other factors impacting reimbursement may supplement, modify or, in some cases, supersede this Payment Guideline. These factors may include, but are not limited to, other Payment Guidelines, legislative mandates, the type of provider arrangement and the terms of that agreement, and/or the member's benefit coverage document.

Wellfleet may modify this Payment Guideline at any time to comply with changes in national standards, changes in best practices, or other factors that may impact this payment Guideline. Should this Payment Guideline be revised, Wellfleet shall publish a new version of this Payment Guideline. Wellfleet encourages providers to keep current with any CPT or HCPCS updates as well as industry standards related to the services described in this Payment Guideline.

Providers are responsible for submission of accurate claims. Wellfleet reserves the right to request supporting documentation for claims submitted, including provider records.

Applicable Plans

☒ Student Health Insurance (for policies issued or renewing after May 2019)
- ☒ Fully Insured
  - ☐ Excluding policies issued in the following states: N/A
  - ☐ Excluding Wellfleet Global
- ☒ Self-Funded
  - ☐ Excluding policies issued by the following schools: N/A

☐ Student Sports
- ☐ Fully Insured; for policies issued by the following carriers:

☐ AIG
☐ Wellfleet Insurance Company/Wellfleet New York Insurance Company
☐ Self-Funded
☐ Excluding policies issued by the following schools: N/A
☐ Fully Insured Student Accident; for policies issued by the following carriers:
☐ AIG
☐ Wellfleet Insurance

Purpose

This Payment Guideline addresses drug testing. Drug testing is used as a diagnostic and therapeutic tool for the clinical care and monitoring of an individual who is undergoing treatment for addiction. Testing may be presumptive or definitive. Presumptive drug testing, also referred to as screening, involves qualitative analysis of a sample to determine whether a specific drug, drug metabolite or substance is detectable above a threshold concentration. Definitive or confirmatory testing involves analysis of a sample to determine how much (the quantity) of a drug or metabolite is present. This policy is to assure Wellfleet reimburses for appropriate drug tests performed on our members.

Scope

All drug tests with the following CPT codes:

CPT®* Codes	**Description**
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]) includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service

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
0007U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service
0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites
HCPCS Codes	**Description**
G0480	Drug test(s), definitive, utilizing (1) 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)) (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed

G0481	Drug test(s), definitive, utilizing (1) 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)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed
G0482	Drug test(s), definitive, utilizing (1) 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)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed
G0483	Drug test(s), definitive, utilizing (1) 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)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed

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 drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

Definitions

Presumptive Drug Testing: Presumptive drug testing, also referred to as screening, involves qualitative analysis of a sample to determine whether a specific drug, drug metabolite or substance is detectable above a threshold concentration.

Definitive Drug Testing: Definitive or confirmatory testing involves analysis of a sample to determine how much (the quantity) of a drug or metabolite is present.

Random Drug Testing: Administration of a drug class screening test on different days of the week/different weeks of the month, that is unannounced and unbiased screening.

Guidelines

1. Wellfleet will only pay for appropriate drug tests. The following tests performed under the following circumstances are considered inherently appropriate:
   A. A presumptive drug class screen when performed under the following circumstances:
      (1). During an episode of Emergency Room care (one per episode)
      (2). During an episode of acute inpatient level of care
      (3). Upon admission into a substance abuse rehabilitation program (one screen on admission)
      (4). During an initial pregnancy examination (one per initial exam only)
      (5). Prior to general anaesthesia (one per procedure)
      (6). Random* drug testing for:

(a). Treatment for substance abuse**
(b). Pregnant women with known/documented history of drug abuse**
(c). To assure compliance with an opiate treatment agreement**

*See definition of "Random Drug Testing".
**May require medical record review

B. A definitive drug test under the following circumstances:
(1). A presumptive drug class screen has returned a positive result AND
(2). The results of a definitive drug test will affect the course of the member's treatment

All claims for drug tests may be pended for information supporting the appropriateness.

2. Requirements for information supporting the appropriateness of drug tests:
   A. All documentation must be maintained in the member's record and available to Wellfleet upon request.
   B. Every page of the record must be legible and include appropriate member identification information [e.g., complete name, dates of service(s)]. The record must include the identity of the physician or non-physician practitioner responsible for and providing the care of the member.
   C. If requested for review, the submitted record should support the use of the selected ICD-CM code(s). The submitted CPT/HCPCS code should describe the service performed. Documentation maintained by the ordering provider/treating provider must indicate the reason/requirement for performing the specific drug test on the specified date. All tests must be ordered in writing by the treating provider and all drugs/drug classes to be tested must be indicated in the order. Orders which include statements such as "conduct additional testing as needed or custom profile" will not be accepted by Wellfleet.
   D. If the provider of the service is other than the ordering/referring provider, the service provider must maintain printed copy documentation of the lab results, along with printed copies of the ordering/referring provider's order for the specific drug test.

The ordering provider must include the clinical indication in the order for the specific drug test and the date it was performed

3. A full panel screen should only be considered for initial testing when appropriate or when the member's behavior suggests the use of drugs not identified on the original screening. Documentation must support the justification for conducting a full panel screening. Subsequent testing should only be conducted for those substances identified on the member's initial profile unless medical records identify/support clinical reasons for adding additional substances for a specific test on a specific date
4. The preferred method of drug testing for a member with a history of poly-substance abuse during the monitoring period is by utilization of a multi-drug screening kit with the least amount of drug classes necessary to determine course of treatment.
5. Definitive Testing: Drug confirmation (G0480-G0483) by a second method is indicated when either of the following has occurred:
   A. The result of the screen is positive.
   B. The result is negative, and the negative finding is inconsistent with the patient's medical history and/or treatment plan. For coverage of definitive testing, the test results must be necessary for treatment planning and be requested by the ordering physician. Written orders are required.
6. Wellfleet may cover drug testing for medical conditions, such as those listed below, when appropriate and when treatment planning by the requesting provider is dependent upon the test results.
   A. Altered mental status
   B. Medical or psychiatric condition where drug toxicity may be a contributing factor
   C. Fetal withdrawal syndrome
   D. Possible exposure of the fetus to illicit drugs taken by the mother
   E. To assess and treat Members with substance abuse disorders
   F. To assess adherence to prescribed medications
7. All drug testing should be performed at an appropriate frequency based on clinical needs.

8. Minnesota Plans Only – effective January 1, 2022
   A. There will be no annual or lifetime limit on screenings or urinalysis testing for opioids for an enrolee in an inpatient or outpatient SUD treatment program when testing is ordered by a health care provider AND performed by an accredited clinical laboratory.
   B. Wellfleet may conduct a medical records review if an enrollee in an inpatient or outpatient SUD treatment program exceeds 24 screening or urinalysis tests in any 12-month period.
9. Wellfleet does not cover drug testing in any of the following circumstances:
   A. Testing ordered by third parties, such as school, courts, or employers or requested by a provider for the sole purpose of meeting the requirements of a third party
   B. Testing for routine (non-random) residential monitoring
   C. Routine urinalysis for confirmation of specimen integrity.
      - 81000-81005: Specimen validity testing. Specimen Validity Testing is included in the presumptive and definitive drug testing CPT and HCPCS code descriptions and is considered a quality control which is an integral part of the collection process and is not separately reimbursable. Wellfleet will deny Specimen Validity Testing when performed on the same date of service as a presumptive and/or definitive drug test by the same or different provider. A modifier may be appropriate when a service commonly used for Specimen Validity Testing is performed distinctly separate from the drug test service and the documentation supports the service was not related to the drug testing.

   A. 10.Wellfleet will not separately reimburse the following codesP2031: Hair analysis
   B. utilization review due to potentially inefficient clinical literature

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References

1. Substance Abuse and Mental Health Services Administration. (2012) *Clinical drug testing in primary care*. TAP Series 32, HHS Publication No. SMA 12-4668. Rockville, MD: Substance Abuse and Mental Health Services Administration.

2. Urine Drug Testing. Practice resources. New Hampshire Medical Society. Accessed 08/08/23 @ https://assets-002.noviams.com/novi-file-uploads/nhms/pdfs-and-headshots/Resources/opioid_resources/UrineDrugTestingguide.pdf

3. Center for Substance Abuse Treatment. Substance Abuse: Clinical Issues in Intensive Outpatient Treatment. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2006. (Treatment Improvement Protocol (TIP) Series, No. 47.) Appendix B. Urine Collection and Testing Procedures and Alternative Methods for Monitoring Drug Use. Available from: https://www.ncbi.nlm.nih.gov/books/NBK64092/

4. **U.S. Food and Drug Administration (FDA)**
Numerous point-of-care tests have been cleared for testing drugs of abuse. FDA regulates and reviews drugs of abuse tests before they can be sold to consumers or healthcare professional in the United States. In its review, the FDA evaluates the design and performance of tests and sample collection systems to help ensure that they produce accurate results (FDA, 2023).

5. **American Academy of Pain Medicine (AAPM):** The AAPM published a consensus statement on urine drug monitoring (UDM) in patients with chronic pain who are prescribed opioids (Argoff, et al., 2018). The expert panel recommended that definitive UDM is the most clinically useful method for assessing baseline opioid use and misuse in patients with chronic pain. The panel suggested the following strategies to determine UDM frequency:
   - a physical examination to obtain patient history and behaviors that can be used to predict opioid misuse should be conducted
   - validated tools to assess the risk for aberrant medication-taking behavior, opioid misuse, opioid use disorder, and the potential for respiratory depression/overdose should be used
   - prescription drug monitoring programs (PDMPs) along with previous UDM results should be checked

   Additionally, AAPM recommended that low-risk patients should be tested at least annually, moderate risk patients should be tested two or more times per year, and high risk patients should be tested three or more times per year. Additional monitoring can be performed as frequently as necessary according to clinical judgment.

6. **American Society of Interventional Pain Physicians (ASIPP):** ASIPP Guidelines for Responsible, Safe, and Effective Prescription of Opioids for Chronic Non-Cancer Pain noted that presumptive urine drug testing (UDT) is implemented from initiation along with subsequent adherence monitoring, using in-office point of service testing, followed by confirmation with chromatography/mass spectrometry for accuracy in select cases, to identify patients who are non- compliant or abusing prescription drugs or illicit drugs. Urine drug testing may decrease prescription drug abuse or illicit drug use when patients are in chronic pain management therapy (Manchikanti, et al., 2017)
7. Centers for Disease Control and Prevention (CDC): In 2022 the CDC published a guideline for prescribing opioids for pain. The guideline recommended that when opioids are prescribed 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 (recommendation category: B; evidence type: 4) (Dowell, et al., 2022).
   Toxicology Implementation Considerations:
   · testing should not be punitive
   · clinicians should consider the benefits and risks of testing before starting opioids and at least annually during opioid therapy
   · clinicians should minimize bias and should not use this recommendation differently based on assumptions about patients
   · toxicology screening results can be considered potentially useful data when used in the context of other clinical information
   · discuss with the patient what expected results are and ask whether there may be unexpected results
   · clinicians should know what drugs are included in toxicology screening panels
   · confirmatory/definitive testing should be used when:
   Ø results will guide decisions with major clinical or nonclinical implications for the patient;
   Ø to detect specific opioids or other drugs within a class or those that cannot be identified on standard immunoassays
   Ø to confirm unexpected screening toxicology test results

· restricting confirmatory testing to situations and substances that will affect patient management can reduce costs of toxicology testing
· discuss with unexpected results with patients before specific confirmatory testing may remove the need for confirmatory testing
· if unexpected results from toxicology screening are not explained, a confirmatory test on the same sample using a method selective enough to differentiate specific opioids and metabolites (e.g., gas or liquid chromatography–mass spectrometry) might be warranted
· unexpected results should be used to improve patient safety

Category B recommendations might not apply to all persons in the group addressed in the recommendation; therefore, different choices will be appropriate for different patients, and decisions should be made based on the patient's circumstances. For category B recommendations, clinicians must help patients arrive at a decision consistent with patient values and preferences and specific clinical situations (shared decision-making).

Evidence type 4 include clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations; equivalent to AHRQ low strength of evidence with serious limitations.

8. Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment (SAMHSA): SAMHSA published 'Federal Guidelines for Opioid Treatment Centers' (OTP) (2024) which stated that, "When conducting random drug testing,

OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment, at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year patient, allowing for extenuating circumstances at the individual patient level. This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose."

Regarding point-of-care testing, the SAMHSA (2024) noted that in 2017, the SAMHSA and the CDC published a joint

announcement stating that, "federal funding could be used to purchase rapid fentanyl test strips for drug-checking purposes. 181 In the summer of 2023, the FDA approved a moderate-complexity point-of-care (POC) urine test for detecting fentanyl in human urine samples. OTPs should be familiar with FDA-approved tests for distribution and use in the clinic."

Change History

Version	Effective Date	Next Review Date
1.0	1/1/2019	1/1/2020
1.0 (No changes)	1/1/2019	9/1/2020
2.0	9/1/2020	9/1/2021
3.0	9/1/2021	9/1/2022
4.1	8/1/2022	8/1/2023
5.0	9/1/2023	8/1/2024
6.0	11/1/2025	9/1/2026
6.1	12/15/2025	9/1/2026