moda HEALTH	Reimbursement Policy Manual	Policy #:	RPM016
Policy Title:	Clinical Drug Screening and/or Drug Testing		
Section:	Laboratory & Pathology	Subsection:	None

Scope: This policy applies to the following Medical (including Pharmacy/Vision) plans:

Companies:	☒ All Companies: Moda Partners, Inc. and its subsidiaries & affiliates ☐ Moda Health Plan ☐ Moda Assurance Company ☐ Summit Health Plan ☐ Eastern Oregon Coordinated Care Organization (EOCCO) ☐ OHSU Health IDS
Types of Business:	☒ All Types ☐ Commercial Group ☐ Commercial Individual ☐ Commercial Marketplace/Exchange ☐ Commercial Self-funded ☐ Medicaid ☐ Medicare Advantage ☐ Short Term ☐ Other: _____
States:	☒ All States ☐ Alaska ☐ Idaho ☐ Oregon ☐ Texas ☐ Washington
Claim forms:	☒ CMS1500 ☒ CMS1450/UB (or the electronic equivalent or successor forms)
Date:	☒ All dates ☐ Specific date(s): _____ ☐ Date of Service; For Facilities: ☐ n/a ☐ Facility admission ☐ Facility discharge ☐ Date of processing
Provider Contract Status:	☒ Contracted directly, any/all networks ☒ Contracted with a secondary network ☒ Out of Network

Originally Effective:	10/26/2011	Initially Published:	9/27/2012
Last Updated:	8/14/2024	Last Reviewed:	8/14/2024
Last update includes payment policy changes, subject to 28 TAC §3.3703(a)(20)(D)? No			
Last Update Effective Date for Texas:		8/14/2024	

Reimbursement Guidelines

A. General Policy Statement

Drug testing and drug screening tests are allowed, subject to:

1. Medical necessity criteria (see "Therapeutic Drug Monitoring," Moda Health Medical Necessity Criteria).
2. The coding and reimbursement guidelines listed in this policy.
3. Medically Unlikely Edits (MUE) quantity limits will be applied.
4. Drug confirmation testing is not separately eligible for reimbursement. Please see guidelines below.

B. Documentation Requirements

1. Documentation of physician order for testing is required.
   Supporting documentation to show a request from the treating physician asking for clinical drug screening and/or testing services is a key element of required documentation to support the billing of diagnostic services. Copies of the test results alone without documentation of the

treating physician's request for the test(s) <u>are not sufficient documentation</u> to support a claim for the testing services. [B]

a. The physician order must specifically match the number, level, and complexity of the testing panel components performed.
b. Lab test orders for "custom profile" or "conduct additional testing as needed" are not a sufficiently detailed order which can be used to verify the specific tests the ordering physician intended to be performed.

2. Requirements when requisition form is unsigned.
   a. Documentation that the treating physician ordered the test(s) must be available upon request.[9] The clinical lab/pathologist has choices about which form or type of documentation they maintain or utilize to fulfill this requirement.
      i. A requisition form signed and dated by the treating physician is one acceptable method of documenting the physician order.
      ii. Instead of a signed and dated requisition form, the billing office may provide medical documentation by the treating physician showing that he/she intended the clinical diagnostic test be performed.
         1) (Examples include progress note, office visit note, operative report noting specimens submitted and tests requested.)
         2) Specific tests requested must be identified, not just "labs sent," "custom profile," etc.
         3) This alternative documentation from the treating physician's medical records must be signed and dated. [B]
   b. **"Note:** There are some circumstances for which an order does not need to be signed. As an example, orders for clinical diagnostic lab tests are not required to be signed. The rules in 42 CFR 410 and IOM Medicare Benefit Policy Manual, Publication 100-02, Chapter 15, Section 80.6.1, state that if the order for the clinical diagnostic test is unsigned, there must be medical documentation by the treating physician (e.g., a progress note) that he/she intended the clinical diagnostic test be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature."[9, 10, 13, 11]

      Comments to clarify terms in quote above:

      ["orders for clinical diagnostic lab tests" is equivalent to a requisition form.]

      ["must be authenticated by the author via a handwritten or electronic signature" means these documents must be signed and dated.]
   c. "Documentation and recordkeeping requirements… We clarified that we do not require the signature of the ordering physician on a requisition for laboratory tests. However, documentation that the physician ordered the test must be available upon our request." [9], see page 4

3. When sufficient documentation is not provided.
   a. Testing line items will be denied as not documented or for incomplete and/or insufficient documentation when:
      i. The supporting medical record documentation submitted showing the treating physician's request for clinical drug screening and/or testing:
         1) Is not signed by the treating/requesting physician.
         2) The signature of the treating/requesting physician is not dated.
      ii. Test results were submitted, but without documentation of the treating physician's request for the test(s).

b. Line items will be denied with an explanation code indicating the documentation is incomplete and/or insufficient, and the requirements to support billing the procedure code have not been met. This denial for insufficient documentation is not intended to communicate that the test was not performed, nor does it necessarily indicate that copies of the test results themselves have not been received for review. The denial simply indicates that at least one of the key documentation requirements was not met.

C. For dates of service January 1, 2017 and following:

1. Follow CMS coding guidelines for drug testing procedures.
   Claims processing and adjudication follows CMS coding guidelines for reporting drug testing procedures, as outlined in the CMS Calendar Year (CY) 2017 Clinical Laboratory Fee Schedule (CLFS) Final Determinations document posted on the CMS website. [12]
   a. Submit claims for drug testing services for all Commercial and Medicare Advantage lines of business using CPT codes 80305 – 80307 and HCPCS codes G0480 – G0483, G0659 as appropriate.
      i. Only one of the three presumptive codes (80305, 80306, 80307) may be billed per day. Select the most appropriate code for the method of testing performed.
      ii. Only one of the five definitive codes (G0480, G0481, G0482, G0483, G0659) may be billed per day. Select the most appropriate code for the testing performed.
         1) For definitive testing, the selection of the correct definitive G code to bill is based on two factors:
            a) The use or absence of specific:
               i) Calibration controls,
               ii) Quality controls
               iii) Internal standards. [12]
            b) The number of drug classes documented as tested.
               i) The available drug classes are specified by CMS [8].
               ii) The AMA CPT Manual may be consulted for examples of individual drugs within each drug class.
         2) Report a code from range G0480 – G0483 if the drug testing method utilized "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 "method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift)" [12]
         3) G0659 must be reported if the definitive drug testing method was performed:
            a) Without method or drug-specific calibration,
            b) Without matrix-matched quality control material, or
            c) Without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen.

            If *any one* of these requirements is missing, G0659 must be used instead of G0480 – G0483, regardless of the number of drug classes tested. [12]
      iii. A maximum of one service unit per procedure code per date of service may be billed when submitting 80305 – 80307, G0480 – G0483, and/or G0659.
      iv. Effective July 1, 2023, CMS implemented NCCI PTP edits between Column One codes 80305, 80306, and 80307 for presumptive test(s), and Column Two codes G0480 – G0483, and G0659 for definitive test(s).[14] CMS subsequently reversed and withdrew

these edits, retroactive to July 1, 2023.[16] We have adjusted any claims where these edits applied to allow the definitive test.

b. For drug confirmation tests see below for guidelines.
c. Specimen validity testing is not eligible to be separately billed under any procedure codes (e.g., 81000, 81001, 81002, 81003, 81005, 81099, 82570, 83986, or any other code). This is because for all codes in range 80305 – 80307 & G0480 – G0483, G0659, the code description indicates that this testing is included if it was performed.[15]
d. CPT codes 80150, 80162, 80163, 80165, 80171, and 80299 are expected to be used only when the patient is on a prescription of the drug in question.
    i. These codes should not be used to report urine drug testing for illicit use of these drugs. Use 80305 – 80307, G0480 – G0483, G0659 instead.
    ii. For unlisted code 80299, a description must be provided on the claim describing the therapeutic drug which is being quantified. (CPT guidelines for unlisted code reporting)
e. CPT code 80299 *Quantitation of therapeutic drug, not elsewhere specified* is considered included in 80305 – 80307, G0480 – G0483, and G0659 when submitted in combination with these codes.
f. CPT codes 80320 – 80377 are not accepted for processing.
    i. These services should be reported with G0480 – G0483, G0659.
    ii. CPT codes 80320 – 80377 will be denied to provider liability as follows:

Code	Description
EX code 53B	*This procedure code is not accepted for processing by Moda Health for this type of plan and/or line of business.*
CARC 181	*Procedure code was invalid on the date of service.*
RARC N657	*This should be billed with the appropriate code for these services.*

g. For Medicaid claims, follow Oregon Medicaid guidelines.

2. Drug Confirmation Tests
    a. Per CMS guidelines, drug confirmation tests are not eligible to be separately reported under 82570, 83935, 83986, nor any other procedure code, unlisted codes or otherwise.
    b. Drug confirmation testing is considered included in CPT codes 80305 – 80307 and HCPCS codes G0480 – G0483, G0659, and is not eligible for separate reimbursement.
    c. If records review determines that confirmation testing has been submitted and inadvertently allowed, the provider will not be allowed to retain reimbursement. The claim will be adjusted to deny the confirmation testing as included in the primary drug testing service, and a refund request will be generated.

D. For dates of service prior to January 1, 2017:

Information for dates of service in 2016, 2015, 2014, and prior years has been archived. If this information is needed, please provide the relevant claim number and date of service and request the archived policy information. A 2016 version of this policy containing the archived information applicable to this time span will be obtained and provided to you.

Codes, Terms, and Definitions

Acronyms & Abbreviations Defined

Acronym or Abbreviation	Definition
AMA	American Medical Association
CCI	Correct Coding Initiative (see "NCCI")
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
DRG	Diagnosis Related Group (also known as/see also MS DRG)
HCPCS	Healthcare Common Procedure Coding System (acronym often pronounced as "hick picks")
HIPAA	Health Insurance Portability and Accountability Act
MS DRG	Medicare Severity Diagnosis Related Group (also known as/see also DRG)
MUE	Medically Unlikely Edits
NCCI	National Correct Coding Initiative (aka "CCI")
PTP	Procedure-To-Procedure (a type of CCI edit)
RPM	Reimbursement Policy Manual (e.g., in context of "RPM052" policy number, etc.)
UB	Uniform Bill

Definition of Terms

Term	Definition
Definitive Drug Class testing	AMA definition: Definitive Drug Class testing are qualitative or quantitative tests to identify possible use or non-use of a drug. These tests identify specific drugs and associated metabolites, if performed. A presumptive test is not required prior to a definitive drug test.[4] CMS definition: "Quantitative testing" = "definitive testing." Definitive drug testing identifies the specific drug and quantity in the patient.[8]
Drug Assays	Lab tests performed to identify possible use or non-use of a drug that is not a known, prescribed medication (therapeutic drug assay).
Drug confirmation	AMA definition: Drug confirmation is a repeat of the test to reduce the risk of a false positive or false negative result. Confirmation tests can be performed on qualitative and/or quantitative testing.[4] CMS definition: Confirmation drug tests confirm the results of the screening drug tests. (Note: For dates of service 1/1/2016 and following, CMS no longer recognizes a separate procedure code for drug confirmation testing.) [8]

Term	Definition
Qualitative drug testing	AMA definition[4]: Qualitative drug testing determines the presence or absence of drug or drug metabolite in the sample. The test result is expressed in non-numerical terms. • *Negative test result*: A test result which states that either no drug or metabolite is present or drug or metabolite is not present in an amount greater than the cutoff concentration. • *Positive test result*: A test result which states that a drug or metabolite is present. CMS definition: CMS considers that "qualitative testing", "screening testing", and "presumptive testing" all mean the same thing.[8]
Quantitative drug testing	AMA definition[4]: Quantitative drug testing determines the specific quantity of drug or drug metabolite present in the sample. The test result is expressed in numerical terms. CMS definition: "Quantitative testing" = "definitive testing." "…quantitative or "definitive" testing…identifies the specific drug and quantity in the patient." [8]
Specimen Validity Testing	Tests performed on urine specimens used for drug testing to confirm that the urine specimen is not altered or contaminated. This may occur with hopes of changing or affect the test results. A partial list of examples includes testing for: urinary pH, specific gravity, creatinine, nitrates, oxidants. This testing is not to be separately billed.[15]
Therapeutic Drug Assays	Therapeutic Drug Assays are performed to monitor clinical responses to a known, prescribed medication. Therapeutic Drug Assay (TDA) procedures are typically quantitative tests and the specimen type is whole blood, serum, plasma, or cerebrospinal fluid.[5]

Procedure codes (CPT & HCPCS) - (list not all-inclusive):

Procedure Code	Procedure Code Description	Valid for Dates of Service:
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 (eg, 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.	1/1/2017 to current (Description change for 2017)

Procedure Code	Procedure Code Description	Valid for Dates of Service:
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 (eg, 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.	1/1/2017 to current (Description change for 2017)
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 (eg, 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.	1/1/2017 to current (Description change for 2017)
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 (eg, 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.	1/1/2017 to current (Description change for 2017)

Procedure Code	Procedure Code Description	Valid for Dates of Service:
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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, 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.	1/1/2017 to current
80163	Digoxin; free	1/1/2015 to current
80165	Valproic acid (dipropylacetic acid); free	1/1/2015 to current
80299	Quantitation of therapeutic drug, not elsewhere specified (Note, for 2014, description only stated "quantitation of drug…" For 2015, description now specifies **"**quantitation of **therapeutic** drug…**"**)	1/1/2015 to current (Code description changed in 2015)
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	1/1/2017 to current
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	1/1/2017 to current
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	1/1/2017 to current
80320	Alcohols	1/1/2015 to current
80321	Alcohol biomarkers; 1 or 2	1/1/2015 to current
80322	Alcohol biomarkers; 3 or more	1/1/2015 to current
80323	Alkaloids, not otherwise specified	1/1/2015 to current
80324	Amphetamines; 1 or 2	1/1/2015 to current
80325	Amphetamines; 3 or 4	1/1/2015 to current
80326	Amphetamines; 5 or more	1/1/2015 to current
80327	Anabolic steroids; 1 or 2	1/1/2015 to current
80328	Anabolic steroids; 3 or more	1/1/2015 to current

Procedure Code	Procedure Code Description	Valid for Dates of Service:
80329	Analgesics, non-opioid; 1 or 2	1/1/2015 to current
80330	Analgesics, non-opioid; 3-5	1/1/2015 to current
80331	Analgesics, non-opioid; 6 or more	1/1/2015 to current
80332	Antidepressants, serotonergic class; 1 or 2	1/1/2015 to current
80333	Antidepressants, serotonergic class; 3-5	1/1/2015 to current
80334	Antidepressants, serotonergic class; 6 or more	1/1/2015 to current
80335	Antidepressants, tricyclic and other cyclicals; 1 or 2	1/1/2015 to current
80336	Antidepressants, tricyclic and other cyclicals; 3-5	1/1/2015 to current
80337	Antidepressants, tricyclic and other cyclicals; 6 or more	1/1/2015 to current
80338	Antidepressants, not otherwise specified	1/1/2015 to current
80339	Antiepileptics, not otherwise specified; 1-3	1/1/2015 to current
80340	Antiepileptics, not otherwise specified; 4-6	1/1/2015 to current
80341	Antiepileptics, not otherwise specified; 7 or more	1/1/2015 to current
80342	Antipsychotics, not otherwise specified; 1-3	1/1/2015 to current
80343	Antipsychotics, not otherwise specified; 4-6	1/1/2015 to current
80344	Antipsychotics, not otherwise specified; 7 or more	1/1/2015 to current
80345	Barbiturates	1/1/2015 to current
80346	Benzodiazepines; 1-12	1/1/2015 to current
80347	Benzodiazepines; 13 or more	1/1/2015 to current
80348	Buprenorphine	1/1/2015 to current
80349	Cannabinoids, natural	1/1/2015 to current
80350	Cannabinoids, synthetic; 1-3	1/1/2015 to current
80351	Cannabinoids, synthetic; 4-6	1/1/2015 to current
80352	Cannabinoids, synthetic; 7 or more	1/1/2015 to current
80353	Cocaine	1/1/2015 to current
80354	Fentanyl	1/1/2015 to current
80355	Gabapentin, non-blood	1/1/2015 to current
80356	Heroin metabolite	1/1/2015 to current
80357	Ketamine and norketamine	1/1/2015 to current
80358	Methadone	1/1/2015 to current
80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)	1/1/2015 to current
80360	Methylphenidate	1/1/2015 to current
80361	Opiates, 1 or more	1/1/2015 to current
80362	Opioids and opiate analogs; 1 or 2	1/1/2015 to current
80363	Opioids and opiate analogs; 3 or 4	1/1/2015 to current
80364	Opioids and opiate analogs; 5 or more	1/1/2015 to current
80365	Oxycodone	1/1/2015 to current
80366	Pregabalin	1/1/2015 to current
80367	Propoxyphene	1/1/2015 to current
80368	Sedative hypnotics (non-benzodiazepines)	1/1/2015 to current
80369	Skeletal muscle relaxants; 1 or 2	1/1/2015 to current
80370	Skeletal muscle relaxants; 3 or more	1/1/2015 to current

Procedure Code	Procedure Code Description	Valid for Dates of Service:
80371	Stimulants, synthetic	1/1/2015 to current
80372	Tapentadol	1/1/2015 to current
80373	Tramadol	1/1/2015 to current
80374	Stereoisomer (enantiomer) analysis, single drug class	1/1/2015 to current
80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3	1/1/2015 to current
80376	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6	1/1/2015 to current
80377	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more	1/1/2015 to current
81000	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy	All
81001	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy	All
81002	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy	All
81003	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, without microscopy	All
81005	Urinalysis; qualitative or semiquantitative, except immunoassays	All
81099	Unlisted urinalysis procedure	All
82570	Creatinine; other source	All
83935	Osmolality; urine	All
83986	pH; body fluid, not otherwise specified	All
83992	Phencyclidine (PCP)	All
84311	Spectrophotometry, analyte not elsewhere specified	All

Diagnosis codes (ICD-10):

Common Related ICD-10-CM Diagnosis Codes
(list not all-inclusive)

Code	Code Description
Z79.3	Long term (current) use of hormonal contraceptives
Z79.891	Long term (current) use of opiate analgesic
Z79.899	Other long term (current) drug therapy

Coding Guidelines & Sources - (Key quotes, not all-inclusive)

"Documentation and recordkeeping requirements… We clarified that we do not require the signature of the ordering physician on a requisition for laboratory tests. However, documentation that the physician ordered the test must be available upon our request." [9, see page 4]

"*Response [to public comments of proposed rule]:* Regulations set forth at § 410.32(a) require that diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Some have interpreted this regulation to require a physician's signature on the requisition as documentation of the physician's order. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the test, it is not the only permissible way of documenting that the test has been ordered. For example, the physician may document the ordering of specific tests in the patient's medical record. As stated in the preamble to the March 10, 2000 proposed rule, we will publish an instruction to Medicare contractors clarifying that the signature of the ordering physician is not required for Medicare purposes on a requisition for a clinical diagnostic laboratory test…. Authorization does not equate to physician signature; the CLIA regulations provide, for example, that the patient's chart or medical record may be used as the test requisition. The CLIA regulations address this written authorization as a means of ensuring that laboratories are not performing tests that were not authorized. They do not address or conflict with the requirement that there be documentation of the physician's order available upon request of the Medicare contractor. Of course, if the physician signs the requisition himself, it would satisfy both the requirement in § 410.32(a) and § 405.1105." [9]

"Clarification the signature is not required on requisition as contained in section III.D.3 of the proposed rule." [9]

"**NOTE**: No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services; … While a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed." [10]

"If the order is communicated via telephone, both the treating physician/practitioner or his/her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records." [10]

"**Q18. If a lab requisition form is dated and includes a valid legible provider signature, is that considered a valid order?**
A18. Yes, it would be considered valid for the signature requirement; however, the test is subject to medical necessity by the provider's intent that the clinical diagnostic test should be performed.

Q19. To clarify clinical lab reports and the signature requirements, should the reports be signed by the ordering provider or the lab director?

A19. The order should be authenticated by the provider via a handwritten or electronic signature. **Note:** There are some circumstances for which an order does not need to be signed. As an example, orders for clinical diagnostic lab tests are not required to be signed. The rules in 42 CFR 410 and IOM Medicare Benefit Policy Manual, Publication 100-02, Chapter 15, Section 80.6.1, state that if the order for the clinical diagnostic test is unsigned, there must be medical documentation by the treating physician (e.g. a progress note) that he/she intended the clinical diagnostic test be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature." [11, 13]

Both G0431 and G0434 are reported *once per patient encounter.* These codes are reported with one (1) unit of service (UOS) unit, regardless of the number of drug classes tested and irrespective of the use or presence of the QW modifier on claim lines.

- The vast majority of the time, no more than one (1) Unit of Service (UOS) unit per day should be billed.
- There could be rare instances where a patient has more than one patient encounter in a single day resulting in multiple, medically necessary screening tests for drugs performed on the same single day.
    - For instance, a patient seen in an outpatient pain clinic who requires a drug screening test as a part of his/her care is later admitted to an emergency department after an automobile accident and requires another medically necessary drug screening test.
    - The second screening test from the second, separate and distinct patient encounter should be reported with modifier 59 attached.
- Medically Unlikely Edits (MUE) quantity limits exist for many codes billed for these services. These edits define the maximum number of units of service (UOS) under most circumstances allowable by the same provider for the same beneficiary on the same date of service.
- Modifier 59 does not necessarily bypass a quantity limit such as an MUE. These denials may need to be appealed with supporting medical records documentation

"Presumptive Drug Class procedures are used to identify possible use or non-use of a drug or drug class."[5]

"Definitive Drug Class procedures are qualitative or quantitative tests to identify possible use or non-use of a drug. These tests identify specific drugs and associated metabolites, if performed." [5]

"A presumptive test may be followed by a definitive test in order to specifically identify drugs or metabolites…A presumptive test is not required prior to a definitive test." [5]

"All drug class immunoassays are considered presumptive, whether qualitative, semi-quantitative, or quantitative." [5]

"Methods that cannot distinguish between structural isomers (such as morphine and hydromorphone or methamphetamine and phentermine) are also considered presumptive." [5]

"Therapeutic Drug Assays are performed to monitor clinical response to a known, prescribed medication."[6]

"After further consideration of public comments on this issue, we are [CMS is] implementing the following changes for drug testing for Calendar Year (CY) 2016:

1. Delete the following G-codes:
    a. G0431, G0434

b. HCPCS codes G6030 through G6058

2. Continue to not recognize the AMA CPT codes 80300 – 80377
3. For presumptive testing, create three G codes. Only one of the three presumptive G codes may be billed per day.
4. For definitive testing, create four G codes. Only one of the four definitive G codes may be billed per day.
5. For definitive testing, the unit used to determine the appropriate definitive G code to bill is "drug class."
6. Each drug class may only be used once per day in determining the appropriate definitive G code to bill.
7. Drug classes are listed below and are consistent with their usage in the AMA CPT Manual. The AMA CPT Manual may be consulted for examples of individual drugs within each class.
    - Alcohol(s)
    - Alcohol Biomarkers
    - Alkaloids, not otherwise Specified
    - Amphetamines
    - Anabolic steroids
    - Analgesics, non-opioid
    - Antidepressants, serotonergic class
    - Antidepressants, Tricyclic and other cyclicals
    - Antidepressants, not otherwise specified
    - Antiepileptics, not otherwise specified
    - Antipsychotics, not otherwise specified
    - Barbiturates
    - Benzodiazepines
    - Buprenorphine
    - Cannabinoids, natural
    - Cannabinoids, synthetic
    - Cocaine
    - Fentanyls
    - Gabapentin, non-blood
    - Heroin metabolite
    - Ketamine and Norketamine
    - Methadone
    - Methylenedioxyamphetamines
    - Methylphenidate
    - Opiates
    - Opioids and opiate analogs
    - Oxycodone
    - Phencyclidine
    - Pregabalin
    - Propoxyphene
    - Sedative Hypnotics (nonbenzodiazepines)
    - Skeletal muscle relaxants
    - Stereoisomer (enantiomer) analysis
    - Stimulants, synthetic
    - Tapentadol

- Tramadol
- Drug(s) or substance(s), definitive, or quantitative, not otherwise specified;" [8]

"Effective July 1, 2023, CMS implemented NCCI PTP edits between Column One codes 80305, 80306, and 80307 for presumptive test(s), and Column Two codes G0480 – G0483, and G0659 for definitive test(s). Currently, these edits cannot be bypassed using an NCCI modifier; however, CMS will change these edits to a CCMI of 1, which will allow for the use of a modifier to bypass the edits in those circumstances when billing these codes together is allowable. These circumstances are generally defined by the Medicare Administrative Contractors (MACs) in Local Coverage Determinations. This change to allow the use of a modifier will be retroactive to July 1, 2023; the Medicare claims processing systems will implement this change in the next quarterly update effective on October 1, 2023." [14]

"Sep 14, 2023 Replacement Files (4th quarter of 2023) – CMS issued replacement files for NCCI Procedure to Procedure (PTP) edits for the October 1, 2023 files (PRA and OPH). Effective July 1, 2023, CMS implemented NCCI PTP edits between Column One codes 80305, 80306, and 80307 for presumptive test(s), and Column Two codes G0480 – G0483, and G0659 for definitive test(s). CMS will withdraw these edits retroactive to July 1, 2023 in a replacement file for the 4th quarter of 2023. The MACs will adjust those claims with dates of service between July 1, 2023 and October 1, 2023 to allow payment as appropriate under existing payment and coverage policies. Alternatively, a laboratory may also choose to use the MAC appeals process if it does not wish to wait for the automatic adjustment to occur, or it can wait to submit its claims until CMS implements the change." [16]

"Providers performing validity testing on urine specimens used for drug testing shall not separately bill the validity testing. For example, if a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed." [15]

Cross References

A. "Therapeutic Drug Monitoring" Moda Health Medical Necessity Criteria.

B. "Medical Records Documentation Standards." Moda Health Reimbursement Policy Manual, RPM039.

References & Resources

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6. American Medical Association. "Therapeutic Drug Assays." *2015 CPT Book, Professional Edition.* Chicago: AMA Press, 2014, p. 476.
7. CMS. "Clinical Laboratory Fee Schedule (CLFS) Final Determinations." Published November 24, 2014. Accessed January 13, 2015, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2015-CLFS-Codes-Final-Determinations.pdf* .
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12. CMS. "Calendar Year (CY) 2017 Clinical Laboratory Fee Schedule (CLFS) Final Determinations." Accessed January 9, 2017. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2017-CLFS-Codes-Final-Determinations.pdf
13. CMS. "Signature Requirements." *Medicare Program Integrity Manual*. Publication 100-08, chapter 3, § 3.3.2.4.
14. CMS. "Medicare National Correct Coding Initiative (NCCI) Edits Replacement Files." https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare . Last updated (page): July 25, 2023; Last accessed August 7, 2023.
15. CMS. "Drug Testing." *National Correct Coding Initiative Policy Manual*. Chapter 10 Pathology and Laboratory Services, § E.2.
16. CMS. "Sep 14, 2023 Replacement Files (4th quarter of 2023)." https://www.cms.gov/medicare/coding-billing/ncci-medicare . Last updated (page): 10/11/2023; Last accessed December 6, 2023.

Background Information

Clinical drug testing is used in pain management and in substance abuse screening and treatment programs. The testing may be used to detect prescribed, therapeutic drugs, prescription drugs of abuse, illicit drugs, and/or other substances such as nicotine.

Currently, there are no real clinical guidelines or consensus on who to test, how often, and for what drugs. As a result, this testing has become an area ripe for the submission of fraudulent and abusive claims for reimbursement. (Bolen[3]) Issues of severe overutilization, upcoding, unbundling, and inadequate documentation from the ordering practitioner have resulted in increased government and payor scrutiny of these tests.

Procedure codes changed for clinical drug testing in 2015 2016, and again in 2017. CMS and CPT (AMA) have different codes and coding guidelines for the same testing services during these changes. This policy has been updated to address these changes and clarify our policy and requirements, which will vary based on the date the testing services were rendered.

IMPORTANT STATEMENT

The purpose of this Reimbursement Policy is to document our payment guidelines for those services covered by a member's medical benefit plan. Healthcare providers (facilities, physicians, and other professionals) are expected to exercise independent medical judgment in providing care to members. Our Reimbursement Policy is not intended to impact care decisions or medical practice.

Providers are responsible for submission of accurate claims using valid codes from HIPAA-approved code sets and for accurately, completely, and legibly documenting the services performed. Billed codes shall be fully supported in the medical record and/or office notes. Claims are to be coded appropriately according to industry standard coding guidelines (including but not limited to UB Editor, AMA, CPT, CPT Assistant, HCPCS, DRG guidelines, CMS' National Correct Coding Initiative [CCI] Policy Manual, CCI table edits and other CMS guidelines).

Benefit determinations will be based on the member's medical benefit plan. Should there be any conflicts between our Reimbursement Policy and the member's medical benefit plan, the member's medical benefit plan will prevail. Fee determinations will be based on the applicable provider fee schedule, whether out of network or participating provider's agreement, and our Reimbursement Policy.

Policies may not be implemented identically on every claim due to variations in routing requirements, dates of processing, or other constraints; we strive to minimize these variations.

***** The most current version of our reimbursement policies can be found on our provider website. If you are using a printed or saved electronic version of this policy, please verify the information by going to https://www.modahealth.com/medical/policies_reimburse.shtml *****

Policy History

Date	Summary of Update
8/14/2024	Formatting updates. No policy changes.
12/12/2023	Updated to match CMS 2023 Q4 CCI PTP reversal of Q3 changes for 80305-80307, G0480 – G0483, and G0659. Updated Coding Guidelines & Sources and References & Resources.
8/9/2023	Updated to match CMS 2023 Q3 CCI PTP edit changes for 80305-80307, G0480 – G0483, and G0659. Updated Acronyms, Definitions, Procedure Code Table, Coding Guidelines & Sources, References & Resources.
11/9/2022	Idaho added to Scope. Updated References & Resources. Formatting updates. No policy changes.
9/27/2012	Policy initially approved by the Reimbursement Administrative Policy Review Committee & initial publication.
10/26/2011	Original Effective Date (with or without formal documentation). Policy based on code definitions, medical director research, & administrative decisions.