Section 2

Laboratory Services

Attachments

CLIA Certification for Laboratory Services Detection of Microorganisms Using Nucleic Acid Probes Utilization Guidelines

1 General Information

This manual is designed to be used in conjunction with other sections of the Utah Medicaid Provider Manual, such as *Section I: General Information of the Utah Medicaid Provider Manual* (*Section I: General Information*) and the *Physician Services Utah Medicaid Provider Manual*. Access provider manuals at: https://medicaid.utah.gov

The information in this manual represents available services when medically necessary. Services may be more limited or may be expanded if the proposed services are medically appropriate and are more cost effective than alternative services.

1-1 General Policy

The laboratory services ordered should be medically necessary and relevant to the patient's current care and/or condition. Medical necessity must be supported by the documentation in the medical record. It is imperative that the physician requesting laboratory services document the order in either the shared medical record or the request for services.

In this manual, the terms member and patient are interchangeable.

Professional Technical Split

Technical laboratory services are found on the CMS laboratory fee schedule. These are traditionally services where there is no need for professional intervention. Many laboratory services are performed with the aid of automated machinery and through the expertise of the laboratory technician. After automated analysis the results are printed noting findings that lie outside the established physiological normal ranges. The physician in the laboratory has many responsibilities some of which include validation and calibration of testing machinery, verifying normal ranges for test outcomes, in addition to many other non-billable administrative roles. A facility that performs laboratory services incurs the cost of credentialing, equipment, staff pay roll, and the administrative services receives the technical portion. The technical portion of a laboratory study may use the "TC" modifier.

The professional portion of a laboratory study refers to the reading, interpretation, and identification of any pathology in the specimen under review. The professional portion of the service is appended with a modifier 26

Clinical Laboratory Improvement Amendments (CLIA)

Laboratory certification for Medicare reimbursement is based on the Clinical Laboratory Improvement Act (CLIA). Medicaid of Utah has adopted the CLIA certification model. The level of CLIA certification awarded dictates the type of laboratory services that can be performed and billed to Medicaid. The CLIA certification number must be submitted on all claims as this determines whether or not the claim is eligible for payment.

The Department of Health must approve a facility to operate as a laboratory, and laboratories must satisfy the requirements of the federal Clinical Laboratory Improvement Amendments (CLIA) to participate in the

Medicare and Medicaid program. The purpose of CLIA is to uniformly ensure the quality and reliability of medical tests performed by all laboratories which test human specimens. CLIA as codified in 42 CFR Part 493 provides authority for review and monitoring of facilities operating as laboratories.

For information on obtaining CLIA certification, review material at http://health.utah.gov/lab/clinical-lab-certification/index.html or contact your state laboratory licensing agency. In Utah, contact the Bureau of Laboratory Improvement.

Bureau of Laboratory Operations
4431 South 2700 West
Taylorsville, Utah 84129-8600

Telephone number: (801) 965-2400

1-2 Fee-For-Service or Managed Care

This manual provides information regarding Medicaid policy and procedures for fee-for-service Medicaid members. This manual is not intended to provide guidance to providers for Medicaid members enrolled in a managed care plan (MCP). A Medicaid member enrolled in an MCP (health, behavioral health or dental plan) must receive services through that plan with some exceptions called "carve-out services," which may be billed directly to Medicaid.

Refer to the provider manual, *Section I: General Information,* for information regarding MCPs and how to verify if a Medicaid member is enrolled in an MCP. Medicaid members enrolled in MCPs are entitled to the same Medicaid benefits as fee-for-service members. However, plans may offer more benefits than the Medicaid scope of benefits explained in this section of the provider manual. Medicaid does not process prior authorization requests for services to be provided to a Medicaid member enrolled in an MCP when the services are the responsibility of the plan. Providers requesting prior authorization for services for a member enrolled in an MCP will be referred to that plan.

Medicaid makes every effort to provide complete and accurate information regarding a member's enrollment in a managed care plan. However, it is the provider's responsibility to verify eligibility and plan enrollment for a member before providing services. *Therefore, if a Medicaid member is enrolled in a MCP, a fee-for-service claim will not be paid unless the claim is for a "carve-out service."*

Eligibility and plan enrollment information for each member is available to providers from these sources:

- The Eligibility Lookup Tool: https://medicaid.utah.gov/eligibility
- AccessNow: (800) 662-9651
- Member Services hotline at (844) 238-3091

1-3 Definitions

Definitions of terms used in all Medicaid programs are available in the provider manual, *Section I: General Information*. Definitions specific to the content of this manual are provided below.

Approved State Laboratory Program

Refers to a licensure or other regulatory credential for laboratories in Utah, the requirements of which are imposed under State law. The Utah State Laboratory program has received Centers for Medicare and Medicaid Services (CMS) approval.

Authorized Person

An individual authorized under State law to order tests or receive test results.

Bundle

Bundling refers to a group of services that when performed together constitute a complete service by the definition of the service, the CPT code definition or prospective payment system grouping of services.

CLIA Certificate of Compliance

A certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance based on meeting all applicable condition level requirements.

CLIA Certificate of Provider Performed Microscopy (PPMP) Procedures

A certificate issued to a laboratory in which a physician, midlevel practitioner, or dentist performs no tests other than PPMP procedures, and if desired, waiver tests.

To be categorized as a PPM procedure, the procedure must meet the criteria specified below.

1. The examination must be personally performed by one of the following practitioners:
    - A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.
    - A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.
    - A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.
2. The procedure must be categorized as moderately complex.
3. The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.
4. The specimen is labile or delay in performing the test could compromise the accuracy of the test result.
5. Control materials are not available to monitor the entire testing process.
6. Limited specimen handling or processing is required.

A laboratory may qualify to perform microscopy tests if it restricts PPM examinations to one or more of the following procedures waived tests and no others:

- All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.
- All potassium hydroxide (KOH) preparations.
- Pinworm examinations.

- Fern tests.
- Post-coital direct, qualitative examinations of vaginal or cervical mucous.
- Urine sediment examinations.
- Nasal smears for granulocytes.
- Fecal leukocyte examinations.
- Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

Laboratories eligible to perform PPM examinations must fulfill these requirements.

- Meet the applicable requirements set forth by CLIA.
- Be subject to inspection as specified in 79 FR Doc No: 2014-06512, March 25, 2014

CLIA Certificate of Registration (Registration Certificate)

A certificate issued that enables the entity to conduct moderate and/or high complexity laboratory testing until the entity is determined to be in compliance through a survey by CMS or its agent.

Certificate of Waiver

A certificate issued to a laboratory to perform only those tests waived by CLIA for the physician office. Tests for certificate of waiver must meet the descriptive criteria specified below.

Test systems are simple laboratory examinations and procedures which:

- Are cleared by FDA for home use.
- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible.
- Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (this list is updated annually) and no others:

1. Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:
    - Bilirubin
    - Glucose
    - Hemoglobin
    - Ketone
    - Leukocytes
    - Nitrite
    - pH
    - Protein
    - Specific gravity
    - Urobilinogen
2. Fecal occult blood
3. Ovulation tests—visual color comparison tests for human luteinizing hormone
4. Urine pregnancy tests—visual color comparison tests
5. Erythrocyte sedimentation rate—non-automated
6. Hemoglobin—copper sulfate—non-automated
7. Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use
8. Spun microhematocrit
9. Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout

Utah Department Health (with guidance from CMS) determines whether a laboratory test meets the criteria listed for a waived test. Revisions to the list of waived tests approved by United States Department of Health and Human Services (HHS) are published in the Federal Register in a notice with opportunity for comment.

Laboratories eligible for a certificate of waiver must:

- Follow manufacturers' instructions for performing the test and
- Meet the requirements for Certificate of Waiver

Commercial Kit

Commercially packaged diagnostic laboratory tests for use in the office or clinic. All components of a test that are packaged together are billed as a single testing unit or supply.

Laboratory

An approved facility that conducts the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological or other examination of materials derived from the patient for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Hospital Laboratory - A clinical laboratory that is owned and operated by a hospital and licensed by that is an approved Medicare provider and is licensed by CLIA.

Independent Clinical Laboratory - A freestanding clinical laboratory not affiliated with a hospital.

2 Provider Participation Requirements

2-1 Provider Enrollment

Refer to provider manual, *Section I: General Information* for provider enrollment information.

3 Member Eligibility

A Medicaid member is required to present the Medicaid Member Card before each service, and every provider must verify each member's eligibility each time before rendering services. For more information regarding verifying eligibility, refer to provider manual, *Section I: General Information*, *Verifying Medicaid Eligibility* or to the Eligibility Lookup Tool located at https://medicaid.utah.gov/eligibility.

4 Program Coverage

Procedure Codes

With some exceptions, procedure codes with accompanying criteria and limitations have been removed from the provider manual and are now found on the Medicaid website Coverage and Reimbursement Lookup Tool. Laboratory codes are searchable on this web site. To determine if a laboratory code is covered, requires a PA, or

manual review go to the Lookup Tool [http://health.utah.gov/medicaid/stplan/lookup/CoverageLookup.php] and search under provider type 01 (general hospital) or 70 (independent laboratory and/or x-ray).

4-1 Covered Services

Covered services are medically necessary diagnostic and therapeutic services, appropriate for the adequate diagnosis or treatment of a patient's illness

Services must be consistent with principles of efficacy (evidence-based), economy and quality of care. Some limitations apply.

Dialysis Patients

Laboratory tests are essential to monitor the progress of dialysis patients. The following list of tests and frequencies constitute the level and types of routine laboratory tests that are covered under the Composite Payment Rate. Other tests are considered non-routine and can be billed separately. Routine tests at greater frequencies must include medical justification.

This schedule is based upon recommendations from CMS for Medicare patients eligible for ESRD services.

- **Routine tests:**

  Each Dialysis Session

  All hematocrit or hemoglobin and clotting time tests furnished incident to the dialysis treatment should NOT be separately billed.

Weekly	Monthly	Every Three Months
- Prothrombin time for patients on anticoagulant therapy - Serum Creatinine - BUN (Limited to 13 per quarter)	- CBC Serum Calcium - Serum Potassium - Serum Chloride - Serum Bicarbonate - Serum Phosphorous - Total Protein - Serum Albumin - Alkaline Phosphatase - AST, SGOT - LDH	- Serum Aluminum - Serum Ferritin

- **Hepatitis**

  Hepatitis B Surface Antigen (HbsAg) and Anti-HBs for hepatitis B are covered when patients first enter a dialysis facility. Coverage of future testing in these patients depends on their serologic status and on whether they have been successfully immunized against hepatitis B virus.

The following table summarizes the frequency of serologic surveillance for hepatitis B. Tests furnished according to this table do not require additional documentation and are paid separately because payment for maintenance dialysis treatments does not take them into account.

Frequency of Screening (Hepatitis)		
Vaccination and Serologic Status	**HbsAG Patients**	**Anti-HBs Patients**
Unvaccinated		
Susceptible	Monthly	Semiannually
HbsAg Carrier	Annually	None
Anti-Hbs - positive[1]	None	Annually
Vaccinated		
Anti-BHs - positive	None	Annually
Low Level or No Anti-HBs	Monthly	Semiannually

[1]At least 10 sample ration units by radioimmunoassay or positive by enzyme immunoassays

CPT code 80074, acute hepatitis panel, includes four other codes: 86709, 86705, 87340, and 86803. When three of the four codes are billed, they are rebundled into the acute hepatitis panel code 80074 for payment.

Note: Per CPT guidelines to bill or rebundle to an 80074, all four tests must be done, however in this case the panel is the least costly alternative when the three tests are billed separately.

- **Helicobacter Pylori Testing**

  The diagnosis must support laboratory testing or a denial will occur.

  - Serologic helicobacter pylori antibody test may indicate either past or present infection. It may be appropriate in the initial work-up of the symptomatic patient with documented history of chronic/recurrent duodenal ulcer, gastric ulcer, or chronic gastritis. H.Pylori testing in children under ten is an inaccurate test and will not be paid.
  - The stool helicobacter pylori antigen test may be recommended for patients who do not respond to therapy or those who have a history of ulcer complications or cancer. The gold standard for diagnosis of active H. Pylori infection in these patients is performance of endoscopy with biopsy and culture.
  - Typically, culturing is completed using code 87081, culture presumptive pathogen.

5 Non-Covered Services and Limitations

See also the Coverage and Reimbursement Lookup Tool at the Medicaid website at: http://health.utah.gov/medicaid/stplan/lookup/CoverageLookup.php.

5-1 Non-Covered Services

The services listed in this section are not covered by the Utah Medicaid Program.

1. Services rendered during a period the patient was ineligible for Medicaid.

2. Services medically unnecessary or unreasonable.
3. Services which fail to meet existing standards of professional practice, which are currently professionally unacceptable, or which are investigational or experimental in nature.
4. Services requiring prior authorization, but for which such authorization was not requested, was not obtained, or was denied.
5. Services, elective in nature, and requested or provided only because of the patient's personal preference and irrespective of a medically necessary finding or complaint. This does not mean the patient cannot have the test. It will require the patient pay for the study.
6. Services for which third party payers are primarily responsible, e.g., Medicare, private health insurance, liability insurance. Medicaid may make a partial payment up to the Medicaid maximum if limit has not been reached by third party.
7. Services fraudulently claimed.
8. Services which represent abuse or overuse.
9. Services rejected or disallowed by Medicare when the rejection was based on any of the reasons set forth above.
10. "Stat charges", based on after hours or emergency parameters are not covered. Any facility which is open and offers a 24 hour service would need to have appropriate services, including laboratory, available without additional billing.
11. Laboratory studies related to infertility services are excluded:
    - Infertility studies
    - In-vitro fertilization
    - Artificial insemination
    - Tests, services, and related charges for surrogate motherhood.
    - Tests related to abortion, except as exclusively provided by federal regulation.
12. Paternity testing.
13. A phlebotomy fee is not covered for specimens collected at the laboratory. The collection of the specimen is an inherent part of processing the specimen and the resultant payment.
14. A travel allowance is not covered by Medicaid for a technician to go to a nursing facility or to the home of a homebound patient to collect a specimen. (The Deficit Reduction Act of 1984 allowed this exclusion.)
15. Billing for additional automated hemogram indices is not covered. Modern automated equipment provides a complete hemogram profile including indices as a matter of routine. Additional billing for indices is not necessary.
16. Anatomic pathology (postmortem examination) and all associated services are non-covered Medicaid services.
17. Helicobacter Pylori Testing:
    - Testing for H.Pylori is not considered medically necessary under the following conditions:
        - Testing for eradication of H.Pylori in patients whose symptoms have resolved.

  - New onset dyspepsia responsive to conservative treatment (i.e. withdrawal of non-steroidal anti-inflammatory drugs and/or use of antisecretory agents.)
  - A dyspeptic patient who requires upper GI endoscopy or patients with documented normal upper GI endoscopy.
  - For monitoring response to treatment of H.Pylori infection.
- Helicobacter Pylori breath tests and antigen blood test (87339) are not covered services.

18. Results that are extrapolated or calculated from automated findings are not separately payable.
19. Cytogenetics studies are not covered services, Tier 2 Molecular Pathology procedures are not covered services.

5-2 Limitations

1. Laboratory services are limited to those tests identified by Centers for Medicare and Medicaid Services (CMS) for which the individual provider or laboratory is CLIA certified to provide, bill and receive Medicaid payment.
2. Certain laboratory tests are paid by CMS out of a separate Laboratory fee schedule. The laboratory tests on the Laboratory fee schedule are considered technical services. The reading and interpretation of these services is considered bundled into the ordering physician's medical decision portion of the evaluation and management service (E/M service). Laboratory tests with a professional component within the CMS laboratory fee schedule are the only laboratory services with a separate physician / professional component.

   Clinical diagnostic laboratory tests sent to a laboratory must be billed by the laboratory completing the service.
3. Evocative Suppression Testing often requires a prolonged period of patient observation in order to administer specific drugs, obtain sequential specimens, and monitor patient wellbeing. It is not appropriate to code for observation care or prolonged service in conjunction with these tests unless there is an unrelated problem or the patient experiences an untoward reaction to a study substrate. Evocative suppression testing requires the administration of pharmaceutical agents to determine a patient's response to those agents. Administration of the pharmaceutical agent may be reported with the drug administration code and the J-code for the pharmacological agent. In the facility setting, these codes may be reported by the facility, but not the physician.
4. When all the codes in the description are performed for a patient in a single encounter the panel shall be billed. Unbundling means all components of a panel are performed and the codes are billed separately. Unbundled billed codes will be denied.
5. When CPT codes listed for the substances under examination in a laboratory panel are not all performed together then each service may be billed separately, with the exception of the hepatitis panel.
6. Specimens collected by venipuncture or catheterization in a physician's office under the supervision of a physician and sent to the laboratory for processing are covered. Venipuncture or catheterization services performed in the laboratory or hospital setting are excluded from payment (Medicare X status). Drawing Laboratory serum studies from an existing line at the same time as infusion therapy or dialysis hook up is bundled into the larger infusion or dialysis service and is not separately reimbursed.

7. Finger, heel, or ear sticks are limited, for Medicaid reimbursement purposes only, to infants under the age of two years by use of CPT code 36416. (This service is not covered for adults.)
8. Testing for specific organisms by isolating a portion of the genome is best achieved by using the nucleic acid probes. See attachment titled, Identification of Microorganisms Using Nucleic Acid Probes. If there is a code for the organism of concern then that CPT code must be used. If there is not a specific test/CPT code assigned for an organism in need of identification then 87797 or 87798 can be used. However, documentation is required for manual adjudication of the claim.
9. DNA probe testing by the amplification method is not covered for most organisms (such as 87481).
10. Laboratory services can be categorized by the technique used to analyze the specimen and arrive at a result. Most codes are defined by the technique employed. These specific codes for a specific analyte should always be employed when available. Unspecified laboratory codes will no longer be accepted when there is a specific test available. The specific test must be ordered for reimbursement.
11. Medicaid follows the recommendations of in house editing programs which include payment recommendations from the American Society of Microbiology. (I.e. code 87621 allowed once).
12. Urinalysis Testing:
    - One urinalysis, when initially caring for women in the antenatal period, is allowed as part of prenatal care.
    - Two services during a 30-day period for the diagnosis of urinary tract infection are allowed. More frequent service requires additional documentation for the medical record.
    - When the chemical analysis is sufficient to diagnose or treat the patient, and a microscopic evaluation would provide no additional information needed for decision making, the microscopic examination is denied. The need for microscopic examination must be supported based on provider documentation.
    - Urine culture must be justified as medically necessary in the medical record.
        - Patients' urinalysis is abnormal suggesting urinary tract infection (UTI). These patients usually respond to presumptive antimicrobial therapy. Non-responders or those patients who relapse after therapy should have a definitive urine culture with sensitivity.
        - A urine culture to follow up on a previously treated UTI to confirm effectiveness of therapy.
        - Follow up cultures within a week or two of therapy may be indicated for patients who have complicated infections (urinary tract abnormality, foreign body) or who are known to be at risk for relapse.
        - Patient is being evaluated for fever of unknown origin or suspected septicemia. When obtaining a urine specimen by straight catheterization, medical record documentation must support medical necessity.
        - Patients with indwelling urinary catheters are not usually candidates for urinary cultures unless the culture is done in anticipation of catheter removal or the patient becomes symptomatic and treatment is contemplated.
    - When billing for urinalysis and urine cultures, coding should not be fragmented if a single test will provide the necessary information.
        - Only one test is allowed on the same day unless documentation supports the medical reasonableness and necessity for additional testing or cultures.

- As per CCI guidelines, urinalyses by reagent strip without microscopy are not separately payable from an office visit or consult.
- Codes 87086 or 87088 are the usual urine culture codes submitted. Diagnosis must support the medical necessity of cultures. Submission of additional codes must have documentation supporting the reasonableness and necessity of the test.

13. G0431 and G0434 used for drug class testing, are covered services based on CLIA certification. Urine and serum tests which are for the same class are considered duplicative, and therefore, not reimbursed. The medical necessity of completing additional tests beyond those of abuse must be well documented by the diagnoses submitted. For more detail refer to the Coverage and Reimbursement Lookup tool (http://health.utah.gov/medicaid/stplan/lookup/CoverageLookup.php)

14. HCPCS code S3854, gene expression profile panel for use in management of breast cancer treatment, is used for Oncotype DX testing. Oncotype DX testing in women and men with breast cancer is to establish recurrence risk to determine if adjuvant chemotherapy would be beneficial. Current guidelines consider medical necessity to include newly diagnosed patients whose breast cancer is stage I or II, node-negative, and estrogen receptor positive. For reimbursement of the service, prior to testing, submit documentation for medical review and approval.

15. BRCA1/BRCA2 are covered when the client meets criteria for the covered codes and a screening panel customized to follow panels completed on other family members is advised. For reimbursement of the service, submit documentation for medical review and approval of the testing prior to testing. Documentation must meet either of the following two requirements:

    A client affected with one of the following:

    - Women affected with breast cancer, ovarian cancer, cancer of the fallopian tube, or primary peritoneal cancer, and are from families with a high risk of BRCA1 or BRCA2 mutation as defined in the policy guidelines.
    - Women who at 50 years of age or less (regardless of family history), are affected with one of the following:
        - Early onset breast or ovarian cancer
        - Multiple primary breast or ovarian cancers
        - bilateral breast, ovarian, or fallopian tube cancers
        - breast with ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
    - Men affected with breast cancer at any age.

    An unaffected adult may be considered under one of the following circumstances:

    - Unaffected individuals (male or female) from families with a known BRCA1 or BRCA2 mutation
    - Unaffected individuals from families with a high risk of BRCA1 or BRCA2 mutation based on a family history where it is not possible to test an affected family member for a mutation
    - Unaffected individuals in populations at risk for specific founder mutations due to ethnic background (e.g., Ashkenazi Jewish descent, Norwegians, Dutch, and Icelanders with one or more relatives with breast or ovarian cancer at any age)

16. Prior to testing for colon cancer, submit supportive documentation for approval of the appropriate Medicaid covered code. Less than 3% of colon cancers are linked as hereditary. Testing may be supported under one of the following conditions:

- Results from code 81301, microsatellite instability analysis, support the need for further testing, because the result may affect treatment.
- Genetic testing may be considered when there are family members with Lynch Syndrome (data suggests that there is a 50% risk of Lynch Syndrome when a first-degree relative has the disease).
- Testing for hereditary non-polyposis colon cancer requires at least three family members with a history of this, one of which must be a first-degree relative.
- The molecular pathology codes include all analytical services performed in the test (e.g., cell lysis, nucleic acid stabilization, extraction, digestion, amplification, and detection). Any procedures required prior to cell lysis (e.g., microdissection,) is reported separately.
    - All analyses are qualitative unless otherwise noted
    - Microbial identification
    - In situ hybridization analyses

17. Additional cytoplasmic or nuclear markers, add-on code 88185, is limited to 24 markers. Documentation supporting medical necessity must be submitted for manual review when limits are exceeded.

6 Billing

Refer to the provider manual, *Section I: General Information*, for general billing information.

Laboratory Coding Overview

There must be an order citing what test, how many units of the test or analyte(s), a preferred methodology, and a medically necessary reason for all testing. Documentation in the patient record must support the codes on the claim. Diagnose(s) must support the laboratory testing on the claim.

Diagnoses Related Payment

A specific diagnosis is required for reimbursement.

Laboratory Services Reimbursement

The reimbursement for laboratory services per CPT and CMS is first divided into services that are 100% technical, 100% professional or have a technical / professional split. Medicaid of Utah pays for laboratory services at a percentage of either the CMS laboratory fee schedule or the CMS physician fee schedule.

CLIA Certification Number

The CLIA certification number must be included on each claim. This is required on the CMS-1500 form for providers and the UB-04 for hospitals (e.g paper or electronic format) for any laboratory test.

Billing for a Reference Laboratory

Payment may be made only to the person or entity that performed or supervised the performance of such test. See Social Security Act §1833 (5)(A) for exceptions.

Modifiers Applicable to Laboratory Services

Modifier - Descriptor

QW - Qualified Waiver

Signifies that a test kit was used, which requires a Waiver CLIA certificate and is reimbursed at a lower fee. The kit is billed by adding the modifier 'QW' to the appropriate HCPCS code.

TC - Technical component

Use with CMS identified codes with separate professional and technical components.

26 - Professional component

Use with CMS identified codes with separate professional and technical components

59 - Distinct Procedural Service

Modifier 59 and subset modifiers (X{EPSU})

- XE Separate encounter: A service that is distinct because it occurred during a separate encounter
- XP Separate practitioner: A service that is distinct because it was performed by a different practitioner
- XS Separate structure: A service that is distinct because it was performed on a separate organ/structure
- XU Unusual non-overlapping service: The use of a service that is distinct because it does not overlap usual components of the main service

Do not use modifier 59 when a more descriptive modifier is available. The -X{EPSU} modifiers are more selective versions of the 59 modifier so it would be incorrect to include both modifiers on the same line.

Use modifier 59 and subsets to show two services are separate and Identifiable. The claim is processed and denied based on Medicaid's editing program. The provider may submit medical records supporting the distinct or independent identifiable nature of the service.

Examples:

Use modifier 59 and subsets X{EPSU}:

- Only if there is not a more descriptive modifier available
- For separate sessions or patient encounters, or different procedures
- If the same procedure using the same procedure code is used for testing a different specimen (e.g. aerobic culture of two independent wound site specimens)

Do not use modifier 59 and subsets X{EPSU}:

- To append to an E/M service
- When a test is ordered and performed and additional related procedures are necessary to provide or confirm the result. These are part of the ordered test.

Refer to the Physician Services Utah Medicaid Provider Manual https://medicaid.utah.gov for further information on modifier 59 and subsets.

91- Repeat clinical laboratory diagnostic test

Use to report laboratory tests performed more than once on the same date to obtain subsequent, multiple test results. The claim is suspended by Medicaid's editing program. The provider may submit medical records supporting the claim that separate services were provided for a distinct medical purpose.

Examples:

Do not use when:

- A test is repeated due to specimen mishandling, insufficient sampling, confirmation or laboratory quality control
- Other CPT codes are available to describe a series of results (e.g. glucose tolerance tests, evocative/suppression testing).

6-1 Prior Authorization

Prior authorization or manual review may be required for certain services. Failure to obtain prior authorization can result in payment denial by Medicaid. Providers must determine if prior authorization is necessary and obtain authorization *before* providing services. Exceptions may be made, with appropriate documentation, if the service provided is emergent or the member is retro-eligible for the dates of service requested.

Prior authorization (PA) information is provided in the provider manual, *Section I: General Information.* Code specific coverage and prior authorization requirements are provided on the Medicaid website, Coverage and Reimbursement Lookup Tool at: http://health.utah.gov/medicaid/stplan/lookup/CoverageLookup.php.

7 References

Code of Federal Regulations, Title 42, Public Health:

- Part 493, Laboratory Requirements
- Part 440.30, Other laboratory and X-ray services

Current Procedural Terminology, American Medical Association, current edition

HCPCS Medicare Level II, AAPC, Optumlnsight, Inc., current edition

ICD-9-CM (International Classification of Diseases, 9th Edition, Clinical Modification)

ICD-10-CM (International Classification of Diseases, 10th Edition, Clinical Modification)

Social Security Act §1833 (5)(A)

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