

SECTION 2
LABORATORY SERVICES

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1 GENERAL POLICY

Definition of Laboratory Services

Laboratory services are primarily specialized diagnostic tests essential to the detection, diagnosis and treatment of pathologic patient conditions. CPT/HCPCS codes for laboratory services encompass a great number of laboratory techniques, e.g. chemistry, hematology, molecular genetics, surgical pathology and a variety of immunological studies.

Medical Necessity

It is imperative that the physician requesting laboratory services document the order in either the shared medical record or the request for services. 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.

Reimbursement for Laboratory Services

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.

Professional Technical Split

Laboratory services are by definition not 100% professional. Many laboratory services are performed with the aid of automated machinery and through the expertise of the laboratory technician. Most laboratories employ or contract with a physician or group of physicians who are usually board certified as Pathologists. 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. Pathologists can also be called on to render a professional interpretation and written report on samples that are plated, sliced, dyed or split into their molecular or genetic components.

Technical Component (Facility Portion)

A facility that performs laboratory services incurs the cost of credentialing, equipment, pay roll for technicians, and the administrative services of the provider.

Services considered 100% technical are found on the CMS laboratory fee schedule. These are traditionally services where there is no need for professional intervention. An example would be an automated chemistry test where serum is injected into a machine. After automated analysis the results are printed noting findings that lie outside the established physiological normal ranges.

This provides the ordering provider diagnostic information with regards to whether the chemistry readings are within normal limits. The results are obtained passively and sent to the provider at the bedside who gathers this information in the course of making a medical decision regarding the patient's wellbeing.

A HCPCS modifier TC is appended to the CPT procedure code for the service to show the technical component.

Professional Component

The professional portion of a laboratory study refers to the reading, interpretation, and identification of any pathology in the specimen under review. This portion of the service is appended with a modifier 26 on the CPT code for the procedure to describe the physician component.

Clinical Laboratory Improvement Amendments (CLIA)

Laboratory certification for Medicare reimbursement is based on the Clinical Laboratory Improvement Act. 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.

Laboratory services are authorized by Sections 1861(e) and (j), the sentence following Section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and Section 353 of the Public Health Service Act.

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

Bureau of Laboratory Improvement
4431 South 2700 West
Taylorsville, Utah 84119

Telephone number: (801) 965-2531

1 - 1 Clients Enrolled in a Managed Care Plan

A Medicaid client enrolled in a managed care plan (MCP) or Prepaid Mental Health Plan (PMHP) must receive all health care services through that plan. Refer to SECTION 1, Chapter 5, Verifying Eligibility, for information about how to verify a client's enrollment in a plan. For more information about managed health care plans, please refer to SECTION 1, Chapter 4, Managed Care Plans. Each plan may offer more benefits and/or fewer restrictions than the Medicaid scope of benefits explained in this section of the provider manual. Each plan specifies

which services are covered, those which require prior authorization, the process to request authorization and the conditions for authorization.

All questions concerning services covered by or payment from a managed care plan must be directed to the appropriate plan. Medicaid does NOT process prior authorization requests for services to be provided to a Medicaid client who is enrolled in a capitated managed care plan when the services are included in the contract with the plan. Providers requesting prior authorization for services for a client enrolled in a managed care plan will be referred to that plan.

A list of MCPs and PMHPs with which Medicaid has a contract to provide health care services is included as an attachment to this provider manual. Please note that Medicaid staff makes every effort to provide complete and accurate information on all inquiries as to a client's enrollment in a managed care plan. Because eligibility information as to which plan the patient must use is available to providers, a fee-for-service claim will not be paid even when information is given in error by Medicaid staff.

1 - 2 Clients NOT Enrolled in a Managed Care Plan (Fee-for-Service Clients)

Medicaid clients who are *not* enrolled in a managed care plan may receive services from any provider who accepts Medicaid. This provider manual explains the conditions of coverage for Medicaid fee-for-service clients.

1 - 3 Definition of Terms

Definitions of terms used in multiple Medicaid programs are in SECTION 1, Chapter 13, and Definitions. Definitions particular to laboratory services are 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.

Bundling

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

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.

PPM Procedures must meet the following specifications:

1. The examination must be personally performed by one of the following practitioners:
 - a. 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.
 - b. 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.
 - c. 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:

1. All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.
2. All potassium hydroxide (KOH) preparations.
3. Pinworm examinations.
4. Fern tests.
5. Post-coital direct, qualitative examinations of vaginal or cervical mucous.
6. Urine sediment examinations.
7. Nasal smears for granulocytes.

8. Fecal leukocyte examinations.
9. Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

Laboratories eligible to perform PPM examinations must—

1. Meet the applicable requirements set forth by CLIA.
2. Be subject to inspection as specified in [60 FR 20044, Apr. 24, 1995; 68 FR 50723, Aug. 22, 2003].

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.

Clinical Laboratory Improvement Amendments (CLIA)

The federal Centers for Medicare and Medicaid Services program which limits reimbursement for laboratory services based on the equipment and capability of the physician or laboratory to provide an appropriate, competent level of laboratory service.

Tests for certificate of waiver must meet the descriptive criteria specified below.

Test systems are simple laboratory examinations and procedures which—

- a. Are cleared by FDA for home use;
- b. Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- c. 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) will determine whether a laboratory test meets the criteria listed for a waived test. Revisions to the list of waived tests approved by HHS will be published in the Federal Register in a notice with opportunity for comment.

Laboratories eligible for a certificate of waiver must:

1. Follow manufacturers' instructions for performing the test; and
2. Meet the requirements for Certificate of Waiver

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993]

Diagnostic Related Group (DRG)

The system established to recognize and reimburse for the resources used to treat a hospital inpatient under a prospective payment system. This is based on an identified principal diagnosis, associated comorbidities and/or complications and any qualifying inpatient procedures. The DRG weight, average length of stay (ALOS), and outlier threshold days are extracted from Utah Medicaid paid claims history files or from the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS).

Grouping – A methodology used to arrive at a grouper (prospective payment system) that drives either a DRG or an APC. The methodology used to define a grouper is based on the ICD9 CM principal diagnosis, ICD 9CM co existing diagnoses and ICD9CM volume III procedures performed. Laboratory data collected in the course of an outpatient or inpatient hospital encounter is usually bundled up into the grouper. In the OPSS fee schedule services with a status of N are designated as integral to the APC grouper. DRG systems are required, per CMS and Utah Medicaid, to group all services provided within 3 calendar days of admission.

Inpatient

An individual admitted to a hospital designated by their physician as inpatient status to receive diagnostic, therapeutic, surgical and/or professional services. All services provided in the hospital, with the exception of professional services, are bundled under the DRG payment made for the service.

Commercial Kit

Some diagnostic laboratory tests are commercially packaged for use in the office or clinic. All components of a test that are packaged together should be 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 that is licensed by the Utah Bureau of Health Facility Licensing and is an approved Medicare provider.

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

Midlevel Practitioner

A nurse practitioner, physician assistant or nurse midwife licensed to practice within the State of Utah.

Outpatient

An individual who receives professional services at a hospital outpatient facility or in the Emergency department.

Physician

An individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State of Utah to practice medicine, or osteopathy or podiatry within the state where the laboratory is located.

Professional Component

That part of a laboratory or radiology service that is rendered solely by a physician credentialed to review the results of a laboratory study, render an interpretation and provide a written report. This portion of the service is usually appended with a modifier 26 on the CPT code for the procedure to describe the physician component.

Services

The types of medical laboratory assistance specified in Sections 1905(a)(1) through 25 of the Social Security Act and interpreted in 42 Code of Federal Regulations, Section 440.

Other laboratory and X-ray services means professional and technical laboratory and radiological services—

- a. Ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law or ordered by a physician but provided by referral laboratory;
- b. Provided in an office or similar facility other than a hospital outpatient department or clinic; and
- c. Furnished by a laboratory that meets the requirements of part 493 of this chapter.

[46 FR 42672, Aug. 24, 1981, as amended at 57 FR 7135, Feb. 28, 1992]

Technical Component

That part of laboratory service necessary to process a specimen and prepare it for analysis by the physician. Many laboratory CPT codes are considered 100% technical. The technical portion of the laboratory service refers to the facility's overhead when services are rendered at a place of service other than the provider office, place of service 11.

2 LABORATORY CODING OVERVIEW

The following information is intended to be informational and does not guarantee reimbursement.

The following information is necessary to select the most specific / correct CPT procedure code(s) for laboratory services:

1. Identify the analyte or substance tested - The analyte refers to the substance undergoing testing. The testing can be chemical, molecular, genetic or morphologic to name a few.
2. Identify the source of the analyte – When you are looking at a bodily fluid or tissue you need to know where it originated e.g. the uterus or the intestine and/or is it urine, blood, sputum or tissue?
3. Identify the methodology employed in the analysis of the analyte. This can drive selection of the appropriate laboratory CPT code. In many instances where there is not a specific CPT code assigned to an analyte under study then it is acceptable to code to the method of testing.
 - a. Further specification can be necessary to determine if the laboratory method was manual or automated.

4. Is the study qualitative e.g. is the analyte you are looking for present in the specimen?
 OR
 Is the study quantitative e.g. how much of the analyte is present in the specimen.
5. Are you looking for an antigen (any substance that can induce an immune system response in the body)? OR Are you looking for an antibody (One or more of the numerous Y-shaped gamma globulin proteins found in the blood or lymph, and produced by B cells as an immune defense against foreign agents also called antigens)?
6. Special Note: If there is a CPT laboratory code specific to the analyte and methodology under study then payment will only be made to the specific code and not the generic code for the methodology.
 - a. If the CPT codes billed are included in a panel, they will be rebundled to the panel.

IMPORTANT - 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.

SSA 1905 Section 440.30 (a) Ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law or ordered by a physician but provided by referral laboratory;...

7. Evocative/suppression testing requires the administration of pharmaceutical agents to determine a patient's response to those agents. CPT codes 80400-80440 describe the laboratory components of the testing. Administration of the pharmaceutical agent may be reported with CPT codes 96365-96376. In the facility setting, these codes may be reported by the facility, but not the physician. In the non-facility setting, these codes may be reported by the physician. While supplies necessary to perform the testing are included in the testing CPT codes, the appropriate HCPCS level II J code for the pharmacologic agent may be reported separately. Separate evaluation and management services including prolonged services (e.g., prolonged infusion) **should not be reported separately** unless a significant, separately identifiable service medically reasonable and necessary E&M is provided and documented.

Modifiers Applicable to Laboratory Services

Modifier	Descriptor	Comments
26	Professional component	Use with CMS identified codes with separate professional and technical components
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 must be billed by adding the modifier 'QW' to the appropriate HCPCS code.

Modifiers Applicable to Laboratory Services

Modifier	Descriptor	Comments
TC	Technical component	Use with CMS identified codes with separate professional and technical components.
59	Distinct Procedural Service	Used to show 2 services are separate and Identifiable. Not paid in the Medicaid system, may ask for review upon denial.
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. Do NOT use when test is repeated due to specimen mishandling, insufficient sampling or re-confirmation.

Modifier Usage in Laboratory Medicine

Modifier - 59 is often misused. To avoid misuse adhere to these guidelines.

Use modifier -59:

- Only if there is not a more descriptive modifier available.
- For separate sessions or patient encounters, or different procedure.
- 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

When a test is ordered and performed and additional related procedures are necessary to provide or confirm the result. These would be considered part of the ordered test.

Example – A patient has an abnormal test result and repeat performance of the test is done to verify the result. Only one unit of service of the test may be reported.

Use modifier -91:

- -91 is used to identify repeat performance of the same laboratory test on the same day to obtain subsequent (multiple) test results.

Example – If a second culture is performed from the same wound site on the same day, append modifier -91.

Do NOT use modifier -91 when:

- Tests are re-run to confirm initial results due to testing problems when a normal, one-time reportable result is all that is required.
- Other CPT codes are available to describe series of results (e.g. glucose tolerance tests, evocative/suppression testing).

3 COVERED SERVICES

Covered services are medically necessary diagnostic and therapeutic services, appropriate for the adequate diagnosis or treatment of a patients' illness, ordered and supervised by a physician or other credentialed / licensed midlevel provider per the Utah Department of Professional Licensing.

Services must be consistent with principles of efficiency, economy and quality of care. Some limitations apply.

Dialysis Patients

1. 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.

The routinely covered regimen includes the following tests:

Each Dialysis Session

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

<u>Weekly</u>	<u>Monthly</u>	<u>Every Three Months</u>
<ul style="list-style-type: none"> - Prothrombin time for patients on anticoagulant therapy - Serum Creatinine - BUN (Limited to 13 per quarter) 	<ul style="list-style-type: none"> - CBC Serum Calcium - Serum Potassium - Serum Chloride - Serum Bicarbonate - Serum Phosphorous - Total Protein - Serum Albumin - Alkaline Phosphatase - AST, SGOT - LDH 	<ul style="list-style-type: none"> - Serum Aluminum - Serum Ferritin

2. 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		
Vaccination and Serologic Status	HbsAG Patients	Anti-HBs Patients
Unvaccinated		
Susceptible	Monthly	Semiannually
HbsAg Carrier	Annually	Non
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 will be rebundled into the acute hepatitis panel code 80074 for payment. Note - Per CPT guidelines for 80074 all 4 tests must be done to bill or rebundle to an 80074.

Helicobacter Pylori Testing:

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

- Serologic helicobacter pylori antibody test 86677 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 antigen test 87338 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.

4 LIMITATIONS (UPDATED 1/1/14)

- 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 100% technical. As such there is not a separate payment to “read”, interpret and write a report on these laboratory codes. The reading and interpretation of these services is considered bundled into the ordering physician’s evaluation and management service (hence E/M service) for the patient. Reading data from laboratory tests that are considered 100% technical is counted toward a level of service in the medical decision making portion of the E/M service. Laboratory tests paid from the physician fee schedule from CMS are the only laboratory services with a separate physician / professional component.
3. Clinical diagnostic laboratory tests sent by a physician from his office to an outside laboratory must be billed by the laboratory completing the service. The laboratory cannot look to the physician for payment. Billing and payment must be direct to the patient and/or payer from the reference laboratory performing the test.
4. 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 in conjunction with these tests unless there is an unrelated problem or the patient experiences an untoward reaction to a study substrate.
5. Laboratory tests must be billed using the appropriate “panel” designation. There are chemistry panels. (80047 – 80076) that are home to a prescribed group of CPT codes/services. When all the codes in the description are performed for a patient in a single encounter then only the panel may be billed. 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. Coding and billing for the components of a laboratory panel separately when all the components are performed for the panel in question is considered unbundling and this is a form of upcoding. Inappropriately billed codes will either be denied or rebundled to the appropriate panel.
6. A specimen collection fee 99000 is limited only to specimens drawn in a physician’s office under the supervision of a physician to be sent outside of the office for processing and only to specimens collected by venipuncture or catheterization. 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 will not be 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. (Such service is not covered for adults)
8. By federal regulation, Medicaid is prohibited from paying more for clinical diagnostic laboratory tests than allowed for the same tests by the Medicare fee schedule. The Medicare fee schedule is based on the HCPCS coding system.
9. CPT code 36415, used for obtaining blood by needle stick through a vein, is covered by Medicaid for the physician obtaining a specimen in the office. The service remains non-covered in the hospital or laboratory setting as per Medicare status X exclusion.
10. Per the Medicare provider fee schedule CPT code 99000 is a status B. This indicates the service is a Bundled Code and as such payment for covered services is always bundled into payment for other services not specified. As such, Medicaid considers this service non-covered under the laboratory services reimbursement.
11. Individuals who do not meet United States residency requirements (undocumented), but who meet all other Medicaid eligibility criteria, are eligible only for “Emergency Services”. (Information about the Emergency Services Program can be found in the Utah Medicaid Provider Manual, SECTION 1, GENERAL INFORMATION.)
12. Laboratory codes are now searchable on the Utah Medicaid web site. To determine if one of the new Laboratory CPT codes for 2013 is covered, requires a PA or manual review please see the Coverage and Reimbursement Code Look-Up tool. See <http://health.utah.gov/medicaid/stplan/lookup/CoverageLookup.php>.
13. Cytogenetics studies 88230 through 88299 are not covered services.
14. Testing for specific organisms by isolating a portion of the genome is best achieved by using the nucleic acid probes. There is an Attachment B with an updated policy. If there is a code for the organism of concern then that CPT code should be utilized. If there is not a specific test/CPT code assigned for an organism in need of identification then 87797 can be used. At this point documentation will be required for manual adjudication of the claim.
15. DNA probe testing by the amplification method is not covered for most organisms (87481, 87801).

16. 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. Examples of this policy include:

- The code 87797 - Infectious agent not otherwise specified; direct probe technique, will no longer be accepted when the test completed is *Trichomonas vaginalis*, direct probe, code 87660. *Trichomonas vaginalis* DNA probe testing by the amplification method (87798) is not covered.
- *Chlamydia trachomatis*, direct probe, codes to 87490 and as such CPT code 87800 - Infectious agent detection, direct probe technique will no longer be accepted when testing is done for *Chlamydia*.

17. 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).

18. 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 will be denied. The need for microscopic examination must be supported based on provider documentation regarding the inference the patient's condition.
- Urine culture must be justified as medically necessary in the medical record.
 - a. Patients' urinalysis is abnormal suggesting urinary tract infection (UTI). A urine culture is not always needed for female patients presenting with acute onset symptoms of cystitis and abnormal urinalyses. 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.
 - b. A urine culture is being done to follow up on a previously treated UTI to confirm effectiveness of therapy.
 - c. 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.
 - d. 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.

- e. 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.
 - a. Only one test is allowed on the same day unless documentation supports the medical reasonableness and necessity for additional testing or cultures.
 - b. As per CCI guidelines, urinalyses by reagent strip (81000+ 81002) are not separately payable from an office visit or consult.
 - c. Codes 87086 or 87088 are the usual urine culture codes submitted. Submission of additional codes must have documentation supporting the reasonableness and necessity of the test.
 - d. There is not a valid ICD-9-CM code for Urosepsis, query the provider to obtain an appropriate diagnosis for the laboratory study.
19. CPT codes 80100 or 80101, used for drug testing, require submission of the laboratory results of all drug classes tested. 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. CPT code 80104 is open for urine drug class testing using a kit.
20. HCPCS code S3854, gene expression profile panel for use in management of breast cancer treatment, will be used for Oncotype DX testing. Oncotype DX testing in women and men with breast cancer may be used to determine recurrence risk for deciding whether or not to undergo adjuvant chemotherapy. 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, documentation must be submitted for medical review.
21. BRCA1/BRCA2 is covered when the client meets criteria for using the covered codes 81211 through 81217, and the client can best be served by having a screening panel customized to follow panels completed on other family members. For reimbursement of the service, documentation must be submitted for medical review and approval of the testing prior to testing.
22. For BRCA1/BRCA2 testing consideration, documentation the client meets either of the two requirements (a or b) below is required:
- A cancer affected client with one of the following:
 - a. Women who are 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.

- b. 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
 - c. Men affected with breast cancer at any age.
- An unaffected adult may be considered under one of the following circumstances:
 - a. Unaffected individuals (male or female) from families with a known BRCA1 or BRCA2 mutation.
 - b. 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.
 - c. 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).
23. Manual review is required prior to testing for colon cancer. Less than 3% of colon cancers are linked as hereditary. 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 codes submitted for coverage include 81292, 81293, 81298, and 81299. Submit supportive medical record documentation for manual review prior to testing.
24. 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, codes 88380 and 88381) should be reported separately.
- All analyses are qualitative unless otherwise noted.
 - For microbial identification, see 87149-87153 and 87470-87801, and 87900-87904.
 - For in situ hybridization analyses, see 88271-88275 and 88365-88368.
25. 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.

5 NON-COVERED SERVICES

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

- A. Services rendered during a period the recipient was ineligible for Medicaid.
- B. Services medically unnecessary or unreasonable.
- C. Services which fail to meet existing standards of professional practice, which are currently professionally unacceptable, or which are investigational or experimental in nature.
- D. Services requiring prior authorization, but for which such authorization was not requested, was not obtained, or was denied.
- E. Services, elective in nature, and requested or provided only because of the recipient's personal preference and irrespective of a medically necessary finding or complaint. This does not mean the patient can't have the test. It will require the patient pay for the study.
- F. 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.
- G. Services fraudulently claimed.
- H. Services which represent abuse or overuse.
- I. Services rejected or disallowed by Medicare when the rejection was based on any of the reasons set forth above.
- J. "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.
- K. 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.
- L. Paternity testing.
- M. A drawing fee is not covered for specimens collected at the laboratory. The collection of the specimen is considered an inherent part of processing the specimen and the resultant payment.
- N. 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.)

- O. Billing for additional automated hemogram indices by use of codes 85029 and 85030 is excluded. Modern automated equipment provides a complete hemogram profile including indices as a matter of routine. Additional billing for indices is not necessary.
- P. Anatomic pathology (postmortem examination) and all associated services are non-covered Medicaid services.
- Q. 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 (78267, 78268, 83013, 83014, and 83009) and antigen blood test (87339) are not covered services.
- R. Results that are extrapolated or calculated from automated findings are not separately payable.

6 BILLING

For billing information refer to Section I, General Information, Section 11 – Billing Claims.

6 - 1 CLIA Certification Number

The CLIA certification number must be included on each CMS-1500 (08/05) Form, whether paper or electronic format, for any laboratory performing a test covered by CLIA.

6 - 2 Laboratory Services Billed Separately

Laboratory services must be billed separately from all other services billed on a CMS-1500 (08/05) Form for both Primary Care Network (PCN) and Medicaid clients.

6 - 3 Billing for a Reference Laboratory

Payment may be made only to the person or entity which performed or supervised the performance of such test; except that— (see SSA §1866)

- If a physician performed or supervised the performance of such test, payment may be made to another physician, with whom he shares his practice,
- In the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—
 - a. The referring laboratory is located in, or is part of, a rural hospital,
 - b. The referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both

- the referring laboratory and the entity performing such test are wholly-owned by a third entity, or
- c. Not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II)), receives requests for testing during the year in which the test is performed are performed by another laboratory, and
 - In the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in SSA §1861(w)(1)) made by a hospital, critical access hospital or skilled nursing facility.

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