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20 Independent Laboratory

Laboratory services are professional and technical laboratory services in one of the following four categories. Independent lab services are:

- Ordered, provided by, or under the direction of a provider within the scope of their practice as defined by state law
- Ordered by a physician but provided by a referral laboratory
- Provided in an office or similar facility other than a hospital outpatient department or clinic
- Provided by a laboratory that meets the requirements for participation in Medicare

The policy provisions for Independent Laboratory providers can be found in the *Alabama Medicaid Agency Administrative Code,* Chapter 9.

20.1 Enrollment

HP enrolls Independent Laboratory providers and issues provider contracts to applicants who meet the licensure and certification requirements of the state of Alabama, the Code of Federal Regulations, the *Alabama Medicaid Agency Administrative Code*, and the *Alabama Medicaid Provider Manual*.

Refer to Chapter 2, Becoming a Medicaid Provider, for general enrollment instructions and information. Failure to provide accurate and truthful information or intentional misrepresentation might result in action ranging from denial of application to permanent exclusion.

Federal requirements mandate providers re-enroll periodically with the Alabama Medicaid program. Providers will be notified when they are scheduled to re-enroll. Failure to re-enroll and provide appropriate documentation to complete enrollment will result in an end-date being placed on the provider file. Once a provider file has been closed for failure to timely re-enroll, providers will have to submit a new application for enrollment.

National Provider Identifier, Type, and Specialty

A provider who contracts with Alabama Medicaid as an independent laboratory provider is added to the Medicaid system with the National Provider Identifier provided at the time the application is made. Appropriate provider specialty codes are assigned to enable the provider to submit requests and receive reimbursements for laboratory-related claims.

NOTE:
The 10-digit NPI is required when filing a claim.

Independent laboratory providers are assigned a provider type of 28 (Independent Laboratory). The valid specialties for Independent Lab providers include the following:

- Independent Lab (280)
- Department of Public Health Lab (550)

Enrollment Policy for Independent Laboratories

To participate in the Alabama Medicaid Program, Independent Laboratories must meet the following requirements:

- Possess certification as a Medicare provider
- Possess certification as a valid CLIA provider if a clinical lab
- Exist independently of any hospital, clinic, or physician's office
- Possess licensure in the state where located, when it is required by that state

20.2 Benefits and Limitations

This section describes program-specific benefits and limitations. Refer to Chapter 3, Verifying Recipient Eligibility, for general benefit information and limitations.

20.2.1 Covered Services

Medicaid reimburses Independent Labs for services described by procedures that fall between ranges 80049-89399 in the CPT manual. Medicaid also pays for procedures defined in the locally assigned Healthcare Common Procedural Coding System (HCPCS) to supplement the listing in the CPT manual.

Medicaid only pays Independent Lab providers for covered services which they are certified to perform and which they actually perform.

Independent Lab providers may only bill for routine venipuncture for collection of laboratory specimens when sending blood specimens to another site for analysis. Labs may not bill the collection fee if the lab work and specimen collection is performed at the same site. Labs may not bill the collection fee if they perform analysis in a lab owned, operated, or financially associated with the site in which the specimen was drawn.

Qualitative Drug Screening (This policy was effective for dates of service on or after January 1, 2012)

The following drug screens are limited to one specimen every seven days per recipient, per provider (providers within a group are considered a single provider), and may not be billed in any combination: 80100, 80101, 80102, and 80104.

Example: A test that is done on Wednesday cannot be done again until the following Wednesday.

A qualitative drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used; however urine is the best specimen for broad qualitative screening, as blood is relatively insensitive for many common drugs, including psychotropic agents, opioids, and stimulants. Detection of a drug or its metabolite(s) in urine is evidence of prior use. It does not, by itself, indicate that the drug remains in the blood. Current methods of drug analysis include chromatography, immunoassay, chemical (“spot”) tests, and spectrometry. Analysis is comparative, matching the properties or behavior of a substance with that of a valid reference compound (a laboratory must possess a valid reference agent for every substance that it identifies). Drugs or classes of drugs are commonly assayed by qualitative screen followed by confirmation with a second method.

NOTE:

Medicaid will only reimburse one screen (whether the specimen is blood or urine) per recipient, per provider, per seven-day period. A recipient cannot be billed for panels within the specimen.

Drugs or classes of drugs that are commonly assayed by qualitative screen, followed by confirmation with a second method, include the following:

- Alcohols
- Amphetamines
- Barbiturates
- Benzodiazepines
- Cocaine and Metabolites
- Methadones
- Methaqualones
- Opiates
- Phencyclidines
- Phenothiazines
- Propoxyphenes
- Tetrahydrocannabinoids
- Tricyclic Antidepressants

CPT Codes

The following CPT codes are applicable for services under the qualitative drug screening policy (maximum unit limitation per recipient, per provider, per seven-day week):

- 80100-Drug screen, qualitative; multiple drug classes, each procedure-1 unit per specimen
- 80101-Single drug class, each drug class-1 unit per specimen
- 80102-Drug confirmation, each procedure-1 unit per specimen
- 80104-Drug screen, qualitative; multiple drug classes other than chromatographic method-1 unit per specimen

NOTE:

Use of the appropriate chemistry code (82000-84999) for quantitation of drugs screened, and the appropriate therapeutic drug assay code (80150-80299) for therapeutic drug levels.

Drug Screening Test Frequency

Medicaid allows payment of a screening test frequency of once per every seven-day period.

Coverage Criteria

Medicaid will cover medically necessary qualitative drug screens as follows:

1. Suspected drug overdose, **and** one or more of the following conditions:
   - Unexplained coma;
   - Unexplained altered mental status;

- Severe or unexplained cardiovascular instability (cardiotoxicity);
- Unexplained metabolic or respiratory acidosis;
- Unexplained head trauma with neurological signs and symptoms; and/or,
- Seizures with an undetermined history.

2. Beneficiary presents with clinical signs/symptoms of substance abuse.
3. High risk pregnancy only when the documented patient history demonstrates that the procedure is medically necessary. Medicaid does not consider a qualitative drug screen as a routine component of assessment.
4. EPSDT services only when the documented patient history demonstrates that the procedure is medically necessary. Medicaid does **not** consider a qualitative drug screen as a routine component of assessment.

Exclusions

Medicaid will **not** cover qualitative drug screens for the following:

- To screen for the same drug with both a blood and a urine specimen simultaneously.
- For medicolegal purposes, including those listed under ICD-9 code V70.4. (Blood-alcohol tests, paternity testing and blood-drug tests).
- For employment purposes (i.e., as a pre-requisite for employment or as a means for continuation of employment).
- For active treatment of substance abuse, including monitoring for compliance.
- As a component of routine physical/medical examination, including those for subpopulations listed under ICD-9 code V70.5. (Armed forces personnel, Inhabitants of institutions, Occupational health examinations, Pre-employment screening, preschool children, Prisoners, Prostitutes, Refugees, School children and Students).
- As a component of medical examination for administrative purposes, including those listed under ICD-9 code V70.3. (General medical examination for: admission to old age home, adoption, camp, driving license, immigration and naturalization, insurance certification, marriage, prison, school admission and sports competition).

Prior Approval

Prior approval will not be required for qualitative drug screens.

Documentation Requirements

The ordering/referring provider must retain documentation supporting medical necessity in the medical record. Documentation must include the medical necessity for performing the screen. All tests must be ordered in writing, and all drugs/drug classes to be screened must be indicated in the order. A copy of the lab results must be retained in the medical record.

If the provider rendering the service is other than the ordering/referring provider, the provider rendering the service must maintain hard copy documentation of the ordering/referring provider's order for the test and the lab results. The order must include clinical indication/medical necessity in addition to all drugs/drug classes to be screened.

Documentation must be legible and available for review upon request.

Chlamydia and Gonorrhea

Effective for dates of service on or after September 1, 2012, Chlamydia (87491) or gonorrhea (87591), when billed on the same date of service for any one patient will deny. If both procedures are performed on the same date of service, procedure code 87801 (infectious agent antigen detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique) should be billed instead.

ESRD Laboratory Services

Laboratory tests listed in Chapter 35 (Renal Dialysis Facility) are considered routine and are included in the composite rate of reimbursement. When any of these tests are performed at a frequency greater than specified, the additional tests are separately billable and are covered only if they are medically necessary and billed directly by the actual provider of the service. A diagnosis of ESRD alone is not sufficient medical evidence to warrant coverage of additional tests. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of the test(s) must be present on the claim.

20.2.2 Non-Covered Services

Medicaid does not pay packing and handling charges for referred laboratory services.

The referred laboratory receives payment for referred tests only at the normal rate. Medicaid shall monitor this policy through post-payment review.

20.2.3 Clinical Laboratory Improvement Amendments (CLIA)

All laboratory testing sites providing services to Medicaid recipients, either directly by provider, or through contract, must be CLIA certified to provide the level of complexity testing required. The Independent Lab must adhere to all CLIA regulations. As regulations change, Independent Labs must modify practices to comply with the changes. Providers are responsible for providing Medicaid waiver or certification numbers as applicable.

Laboratories which do not meet CLIA certification standards are not eligible to provide services to Medicaid recipients or to participate in Medicaid.

NOTE:

The Health Care Financing Administration (HCFA), now known as CMS, implemented the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), effective for dates of service on or after September 1, 1992. The CLIA regulations were published in the February 28, 1992 Federal Register. More detailed information regarding CLIA can be found at http://www.cms.hhs.gov/clia/

CLIA Certificates

CLIA certificates may limit the holder to performing only certain tests. Medicaid bills must accurately reflect those services authorized by the CLIA program and no other procedures. There are two types of certificates that limit holders to only certain test procedures:

- Waiver certificates – Level 2 certification
- Provider Performed Microscopy Procedure (PPMP) certificates – Level 4 certification

A complete listing of laboratory procedures limited to waived certificates (level 2 certification) and PPMP certificates (level 4 certification) may be accessed via the web at www.cms.hhs.gov/clia/.

20.3 Prior Authorization and Referral Requirements

The Trofile Assay will be a covered service by Medicaid with prior authorization effective December 1, 2008. The procedure code to be billed is 87999 (unlisted microbiology procedure). In order to be reimbursed by Medicaid for the Trofile Assay, the ordering provider must submit a Prior Authorization electronically or by paper on form 342.

Providers requesting a PA should include:

- Any past history of antiretroviral medications prescribed to include date prescribed and the date the drug was discontinued;
- The name and contact information of the HIV clinic that the provider is affiliated with if the requesting provider is not enrolled in Medicaid with specialty of infectious disease, and;
- The result of the most current HIV-1 RNA.

If you need further information, refer to chapter 4, Obtaining Prior Authorization, for general guidelines.

20.4 Cost Sharing (Copayment)

Copayment amount does not apply to services provided for laboratory services.

20.5 Completing the Claim Form

To enhance the effectiveness and efficiency of Medicaid processing, providers should bill Medicaid claims electronically.

Independent Laboratory providers who bill Medicaid claims electronically receive the following benefits:

- Quicker claim processing turnaround
- Immediate claim correction
- Enhanced online adjustment functions
- Improved access to eligibility information

Refer to Appendix B, Electronic Media Claims Guidelines, for more information about electronic filing.

NOTE:

When filing a claim on paper, a CMS-1500 claim form is required. Medicare-related claims must be filed using the Medical Medicaid/Medicare-related Claim Form.

This section describes program-specific claims information. Refer to Chapter 5, Filing Claims, for general claims filing information and instructions.

20.5.1 Time Limit for Filing Claims

Medicaid requires all claims for Independent Laboratory providers to be filed within one year of the date of service. Refer to Section 5.1.4, Filing Limits, for more information regarding timely filing limits and exceptions.

20.5.2 Diagnosis Codes

Claims for lab services must contain a valid diagnosis code. The *International Classification of Diseases - 9th Revision - Clinical Modification* (ICD-9-CM) manual lists required diagnosis codes. These manuals may be obtained by contacting the American Medical Association, P.O. Box 10950, Chicago, IL 60610.

NOTE:

ICD-9 diagnosis codes must be listed to the highest number of digits possible (3, 4, or 5 digits). Do not use decimal points in the diagnosis code field.

20.5.3 Procedure Codes and Modifiers

Medicaid uses the Healthcare Common Procedure Coding System (HCPCS). HCPCS is composed of the following:

- American Medical Association's Current Procedural Terminology (CPT)
- Nationally assigned codes developed for Medicare
- Locally assigned codes issued by Medicaid. Effective for dates of service on or after 01/01/2004, use national codes.

The CPT manual lists most procedure codes required by Medicaid. This manual may be obtained by contacting the Order Department, American Medical Association, 515 North State Street, Chicago, IL 60610-9986.

Medicaid denies claims without procedure codes or with codes that are invalid.

Medicaid also recognizes modifiers when applicable. The (837) Institutional electronic claim and the paper claim have been modified to accept up to four Procedure Code Modifiers.

The following sections describe procedure codes and modifiers that apply when filing claims for independent lab services.

Repeat Laboratory Procedures

Modifier '91' may be utilized to indicate that a laboratory test was performed multiple times on the same date of service for the same recipient. Modifier '91' may not be used when laboratory tests are rerun:

- To confirm initial results
- Due to testing problems encountered with specimens or equipment
- For any other reason when a normal, one-time, reportable result is all that is required.

Distinct Procedural Service

Modifier '59' (distinct procedural service) may be utilized to identify a distinct service. When laboratory services are performed, modifier '59' should be used to report procedures that are distinct or independent, such as performing the same procedure (which uses the same procedure code) for a different specimen. Modifier '59' should not be used when a more descriptive modifier is available.

Blood Specimens

Collection of laboratory specimens may be billed only when sending specimens to another site for analysis if the other site is not owned, operated, or financially associated with the site in which the specimen was collected.

The collection fee may not be billed if the lab work is done at the same site where the specimen was collected or in a lab owned, operated, or financially associated with the site in which the specimen was collected.

Independent laboratory providers will not be paid for and should not submit claims for laboratory work done for them by other independent laboratories or by hospital laboratories.

Providers may submit claims for laboratory work done by them in their own laboratory facilities.

A hospital lab may bill Medicaid on behalf of the reference lab that a specimen is sent to for analysis. It is the responsibility of the referring lab (hospital) to make sure that the reference lab does not bill these services to Medicaid.

Providers who send specimens to another independent laboratory for analysis may bill a collection fee. This fee shall not be paid to any provider who has not actually extracted the specimen from the patient.

NOTE:

Providers should use procedure code 36415-90 for routine venipuncture collection, 36416-90 for collection of capillary blood specimen (eg, finger, heel, ear stick) and Q0091-90 for collection of Pap smear specimen.

Laboratory Paneling and Unbundling

A *panel* is a group of tests performed together or in combination. Medicaid follows the CPT guidelines for panel tests.

The term “unbundling” refers to the practice of using more than one procedure code to bill for a procedure that can more appropriately be described using fewer codes. The use of unbundled codes results in denial of payment, with the exception of organ and disease panels.

All organ and disease oriented panels must include the tests listed with no substitutions. If only part of the tests included in a defined panel is performed, the panel code should not be reported. If additional tests to those indicated in a panel are performed, those tests should be reported separately in addition to the panel code. If two panels overlap, the physician or laboratory will be required to unbundle one of the panels and bill only for the tests that are not duplicative.

Urinalysis – Claims for the same recipient billed by the same provider that contain two or more of the following services (81000, 81001, 81002, 81003, 81005, 81007, 81015, and 81020) for the same date of service will be considered an unbundled service and will be denied.

During post-payment review, Medicaid may recoup payment from providers for claims submitted containing unbundling of laboratory services.

Modifiers

Modifier	***HCPCS-Modifier(s)***	***Description***	***Note***
26	26	Professional Component	Labs providing professional component services include modifier 26 with the procedure code on the claim
59	59	Distinct Procedural Service	To indicate a distinct procedure (using the same procedure code) performed on the same date of service.
77	77	Repeat Procedure by another physician	To indicate that a basic procedure performed by another physician had to be repeated
91	91	Repeat Clinical Diagnostic laboratory Test	To indicate a repeat clinical laboratory test performed on the same date of service for the same recipient.
TC	TC	Technical Component	

NOTE:

Claims submitted for a repeat of the same procedure on the same date of service without modifiers will be denied as duplicate services.

Oncotype DX™

Effective for dates of service, July 1, 2013 and thereafter, Medicaid will cover the Oncotype DX™ genetic profiling lab test if the patient meets Medicaid's prior authorization criteria. Oncotype DX™ is a genetic profiling test developed to classify the risk of recurrence among women treated for early stage breast cancer.

The use of the 21-gene RT-PCR Assay (i.e., Oncotype DX™) to determine recurrence risk for deciding whether or not to undergo adjuvant chemotherapy meets Alabama Medicaid's medical criteria for coverage in women with early stage breast cancer with **ALL** of the following characteristics:

- Newly diagnosed, primary, early stage breast cancer (stage I or stage II) in a female without significant co-morbidities;
- Unilateral, non-fixed tumor;
- Hormone receptor positive (ER-positive or PR-positive);
- HER2-negative;
- Tumor size 0.6-1cm with moderate/poor differentiation or unfavorable features OR tumor size > 1cm;
- Node negative;
- Will be treated with adjuvant endocrine therapy, e.g., tamoxifen or aromatase inhibitors; AND
- When the test result will aid the patient in making the decision regarding chemotherapy (i.e., when chemotherapy is considered a therapeutic option); AND
- When ordered within 6 months following breast cancer diagnosis.

Limitations:

- The 21-gene RT-PCR Assay Oncotype DX™ should only be ordered on a tissue specimen obtained during surgical removal of the tumor and after subsequent pathology examination of the tumor has been completed and determined to meet the above criteria (i.e., the test should not be ordered on a preliminary core biopsy).
- The test should be ordered in the context of a physician-patient discussion regarding risk preferences when the test result will aid in making decisions regarding chemotherapy. This discussion must be documented in the patient's clinical record and a copy of the progress note (signed by the ordering physician) must accompany the PA request (Form 342).
- The Oncotype DX™ test will be limited to one per lifetime, per recipient.
- Repeat tests will not be covered.
- The test will be limited to the following diagnoses: malignant neoplasm of the female breast, carcinoma in situ of breast, and personal history of malignant neoplasm, breast.

Billing providers must bill procedure code S3854 (gene expression profiling panel for use in the management of breast cancer).

The Oncotype DX™ will be exempt from Patient 1st and EPSDT requirements. The Form 342 must be completely filled out, signed by the ordering physician and indicate the name and phone number of the ordering physician. The Form 342 will suffice as the prescription for the test. The test must be performed by an enrolled independent laboratory and ordered by a physician.

Professional and Technical Components

Some procedure codes in the 70000, 80000, 90000, and G series are a combination of a professional component and a technical component. Therefore, these codes may be billed three different ways; (1) as a global, (2) as a professional component, or (3) as a technical component.

- **Global**, the provider must own the equipment, pay the technician, review the results, and provide a written report of the findings. The procedure code is billed with no modifiers.
- **Professional component**, the provider does **not** own the equipment. The provider operates the equipment and/or reviews the results, and provides a written report of the findings. The professional component is billed by adding modifier 26 to the procedure code.
- **Technical component**, the provider must own the equipment, but does not review and document the results. The technical component charges are the facility's charges and are not billed separately by physicians. The technical component is billed by adding modifier TC to the procedure code.

20.5.4 Place of Service Codes

The only valid Place of Service Codes for Independent Laboratory providers is 81.

POS Code	*Description*
81	Independent Laboratory

20.5.5 Required Attachments

To enhance the effectiveness and efficiency of Medicaid processing, your attachments should be limited to Claims with Third Party Denials.

NOTE:

When an attachment is required, a hard copy CMS-1500 claim form must be submitted.

Refer to Section 5.9, Required Attachments, for more information on attachments.

20.6 For More Information

This section contains a cross-reference to other relevant sections in the manual.

Resource	Where to Find It
CMS-1500 Claim Filing Instructions	Section 5.2
Medical Medicaid/Medicare-related Claim Filing Instructions	Section 5.6.1
Electronic Media Claims (EMC) Submission Guidelines	Appendix B
AVRS Quick Reference Guide	Appendix L
Alabama Medicaid Contact Information	Appendix N

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