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## **7.1 Laboratory and Pathology Services**

### *7.1.1 Description*

These are services ordered and provided by or under the direction of a physician or other licensed health care practitioner within the scope of his/her practice or ordered by a physician or other licensed practitioner and performed by a clinical laboratory.

### *7.1.2 Amount, Duration and Scope*

#### *7.1.2.1 General*

- a) The most current CPT-4 coding manual provides a listing of laboratory codes in the range 80000-89999 for laboratory services on which the Medicaid fee schedule is based.
- b) Only Pathology and laboratory services approved by the Food and Drug Administration (FDA) are covered.
- c) All providers performing clinical laboratory services must have CLIA (Clinical Laboratory Improvement Amendments of 1988) certification to perform the specific tests they intend to provide.

#### *7.1.2.2 CLIA*

The purpose of CLIA is to establish and ensure quality standards for all laboratory testing regardless of where the testing was performed. CLIA is implemented by the Centers for Medicare and Medicaid Services (CMS) formerly known as the Health Care Financing Administration (HCFA). There are four (4) CLIA certifications.

- Certificate of Waiver
  - a) The Certificate of Waiver is issued to a laboratory to perform only waived tests.
  - b) Certificate for Provider-Performed microscopy (PPM) procedures is issued to a laboratory in which a physician, practitioner, or dentist performs no tests other than PPM procedures and waived tests.
- Certificate of Registration

This certificate is issued to a laboratory and enables the entity to conduct moderate and/or high complexity laboratory testing until inspection and certification by CMS agents indicate that the laboratory is in compliance with CLIA regulations.

- Certificate of Compliance

This certification is issued to a laboratory after an inspection that finds the laboratory to be in compliance with CLIA requirements.

- Certificate of Accreditation

This certificate is issued to a laboratory that is accredited by an accreditation organization approved by CMS.

#### *7.1.2.3 Implications of CLIA on Medicaid*

- a) All Medicaid Programs throughout the nation must deny payments to all laboratories for services not covered by a CLIA certificate. Also, Medicaid Programs must deny payments to all laboratories that do not have a CLIA certificate effective for the date(s) of service.

In Hawaii, CLIA applications, enrollment, and certification are delegated to the Department of Health, CLIA Program (contact details are in Appendix 1)

#### *7.1.2.4 Exclusions*

- a) Procedures that are considered experimental, investigational or generally unproven benefit are not covered.
- b) In addition, laboratory procedures related to a non-covered service are not covered.  
Example: Laboratory procedures related to the storing, preparation and transfer of oocytes for in vitro fertilization are not covered.
- c) IgG4 testing for food antigens is not covered.
- d) Chromosomal evaluation is not justified for habitual abortions, gender determination and general screening.
- e) For a complete listing of non-covered procedures, please see Appendix 1.
- f) The collection of specimens for Pap smears is part of the evaluation and management service and NOT a laboratory procedure and thus, not separately covered.
- g) No additional payment is made for “STAT” tests and their delivery and handling.

- h) No additional payment is made for “collection and handling” of samples from the physician or hospital to the laboratory when venipuncture/arterial puncture is performed and billed by the laboratory.
- i) Laboratory procedures occurring on the same day as an ambulatory surgical center (ASC) procedure are considered part of the ASC charge and may not be billed separately.

*7.1.2.5 Limitations*

- a) Claims for laboratory procedures must be submitted by the provider performing the procedure.
- b) Laboratory procedures performed by a provider cannot be billed by another provider.
- c) Reverse billing is not allowed.
- d) Out-of-State providers that participate in the Hawaii Medicaid Program are limited to performing only those laboratory procedures not performed by providers in Hawaii.

*7.1.2.6 Authorization*

As a general statement, most tests that are necessary for a diagnosis do not require prior approval (PA). Those that are confirmatory or are more costly may require PA utilizing the Medical Authorization Form 1144. Testing that require authorizations include but are not limited to:

- Chromosome analysis: Form 1144 is required for the following indications:
  - 1) Myelogenous leukemia, acute or exacerbation;
  - 2) Ambiguous genitalia;
  - 3) Malformations consistent with a chromosome disorder;
  - 4) Primary amenorrhea not attributable to other causes;
  - 5) On fetal cells by amniocentesis between the 16<sup>th</sup> and 20th week of gestation (confirmed by ultrasound) when:
    - a) the mother is 35 or older,
    - b) a parent has a previous child with a known or strongly suspected chromosome abnormality,

- c) either parent has a known chromosome disorder, or
  - d) there is a family history of a hereditary disorder diagnosable by chromosome analysis.
- Other cytogenetic studies such as tissue culture, cryopreservation of cell lines, molecular cytogenetics, DNA probe
  - Radio Allergo Sorbent Test (RAST) tests for immune allergens
  - For a complete listing of laboratory procedures that require authorization, please see Appendix 1.

Prior authorization is not required for amniocentesis. Claims must document the reason(s) for performing the amniocentesis. Amniocentesis alone is covered when:

- An assessment of fetal lung maturity is necessary because pre-term delivery is either imminent or necessary.
- The determination of amniotic fluid bilirubin levels is necessary to assess fetal involvement in hemolytic diseases of the newborn.

#### *7.1.2.7 Coding*

##### a) Laboratory Panels

- CPT-4 groups certain laboratory tests into organ or disease oriented panels. To expedite claims processing, providers should use the panel codes. Additional tests not included in the panel can be reported and billed separately under the CPT-4 codes that identify the tests.

##### b) Miscellaneous codes

- When a code does not exist in CPT-4 for a specific test, a miscellaneous laboratory code may be reported.
- Examples of miscellaneous codes are 80299 “quantitation of drug, not elsewhere specified,” 81099 “unlisted urinalysis procedure,” and 85999 “unlisted hematology and coagulation procedure.”
- When reporting and billing with miscellaneous codes, a description of the procedure must be included.

## 7.2 Radiology and Imaging Services

### 7.2.1 Description

Radiology and imaging services are procedures in the CPT-4 code range 70000 to 79999 and include diagnostic radiology, invasive radiology, diagnostic ultrasound, ultrasonic guidance procedures, radiation oncology, and nuclear medicine.

### 7.2.2 Amount, Duration and Scope

The three (3) modifiers that are appropriate for most diagnostic radiology services are as follows:

- TS Total Service 100% of value
  - TC Technical Component 65% of value
  - 26 Professional Component 35% of value
- a) When there is no specific code for the supervision and interpretation of the radiological service, the modifiers are generally valued according to the percentages listed above.
- b) Usage of the modifiers:
- TS – is applicable in the office or independent laboratory in situations when the physician supervises and provides a written report of the radiologic study and furnishes the imaging equipment and technician services. Applicable places of service (POS) are usually the office or an independent laboratory.
  - TC – is applicable for services provided in the inpatient or outpatient hospital settings and represents the facility’s responsibility—the imaging equipment, supplies related to the radiological study, and technician services. Applicable places of services (POS) are usually facilities such as inpatient acute hospitals, nursing facilities, psychiatric facilities, rehabilitation facilities; outpatient acute hospitals and outpatient rehabilitation facilities, end stage renal disease (ESRD) treatment facilities.
  - 26 – represents the physician component and is applicable when the imaging equipment, supplies and technician services are the responsibility of the facility. The physician is responsible for supervising and interpreting the radiological study and providing the written report that is signed by the interpreting physician and included in the patient’s written medical record. Non-ionic contrasts, should not be billed by the physician. Physicians usually provide these services in facilities such as inpatient acute hospitals, nursing facilities,

psychiatric facilities, rehabilitation facilities; outpatient acute hospitals and rehabilitation facilities, end stage renal disease (ESRD) treatment facilities.

### 7.2.3 *Exclusions*

- a) Supplies and items used in radiology procedures should not be separately coded as they are included in the technical component or total service of the procedure. (Examples are items such as IV start sets, extension tubing, needles, syringes, betadine swabs, tape, intravenous catheters, IV administration sets, IV fluids, ionic contrast materials.)
- b) Ultrasound for the sole purpose of gender determination is not covered. Separate claims for ultrasound performed as an adjunct to amniocentesis, cerclage placement, amnioscopy/fetoscopy or external version should not be submitted as ultrasound is considered an integral part of these procedures.
- c) Prescription and over the counter drugs that are considered part of a diagnostic service are included in the diagnostic services and are not separately covered.

### 7.2.4 *Limitations*

Additional clarification of physician supervision and interpretation

- Certain radiological CPT-4 procedures are described “radiological supervision and interpretation.” (Example: 70010 “Myelography, posterior fossa, radiological supervision and interpretation”). These procedures should not be coded with any of the modifiers listed above.
- Only one physician is allowed to provide “supervision and interpretation” per radiological study. Generally, interpretation of x-rays and other radiological studies in the CPT-4 code range 70000-79999 with or without a modifier 26 are payable only to radiologists. When performed by a treating physician, interpretations of these studies are considered to be part of the E & M service and not separately payable.

### 7.2.5 *Ancillary Supplies and Items*

Ancillary supplies and items should not be separately coded as the supplies and items are included in the technical component. Non-ionic contrasts, diagnostic and therapeutic radiopharmaceuticals can be separately coded using the appropriate HCPC or CPT code.

### 7.2.6 *Radiation Oncology*

Preliminary consultation prior to the decision to treat, should be coded using appropriate E & M codes. Consultation is appropriate when the radiation oncologist is giving advice and/or rendering an opinion and BEFORE the start of the clinical treatment planning process.

*7.2.7 Screening Mammographies and Clinical Breast Exams (CBE)*

Screening mammographies and clinical breast exams are covered as follows:

- Age 40-49: One mammography once every one to two years, CBE annually
- Age 50-69: One mammography every year, CBE annually
- Age 70-74: One mammography once every one to two years, CBE annually
- A woman of any age with a history of breast cancer, or whose mother or sister has a history of breast cancer, is eligible for a screening mammography when authorized by a physician.

*7.2.8 Ultrasound*

The following are indications for maternity and gynecology - related ultrasound. The appropriate reason for the ultrasound must be stated on the claim to facilitate payment. A chart note is an acceptable attachment.

- Estimation of gestational age for patients with uncertain clinical dates, or confirmation of dates for patients who are to undergo scheduled elective repeat cesarean delivery, induction of labor or elective termination of pregnancy.
- Evaluation of fetal growth if the following apply:
  - 1) An abortion is being considered near 20 weeks,
  - 2) A repeat Caesarian section is anticipated,
  - 3) There is established evidence of maternal problems,
  - 4) There is a possibility of delivery complications,
  - 5) When growth of the fetus does not appear to be normal by either method, or
  - 6) The patient is first seen late in her pregnancy and has uncertain dates.
- Pelvic mass
- Suspected hydatidiform mole
- Adjunct to cervical cerclage placement

- Adjunct to amniocentesis
- Adjunct to special procedures
- Suspected uterine abnormality
- Intrauterine contraceptive device localization

7.2.9 *Authorization*

a) Radiological services that require authorization based on a patient's medical needs include but are not limited to the following:

- Magnetic resonance imaging
- Positron emission tomography (PET) scans
- Stereotactic radiation treatment
- Proton beam treatment
- Swallowing studies with or without cineradiography and/or video
- Hystersonography

b) Requests for authorizations for all of the above services are submitted by the requesting physician on the Medical Authorization Form (1144).

c) When any of the above procedures are performed in the acute inpatient acute hospital setting, no authorization is needed for the technical component. However the physician's supervision and interpretation must be authorized.

d) For PET scans to be approved, the form 1144 must be approved. The following PET scans are currently being covered:

- Myocardium for viable myocardium
- Brain for tumor
- Solitary Pulmonary Nodule

### Total Body for Tumor Localization

- Lung Cancer Staging

Physicians should contact the Medical Director of the Hamamatsu PET Center at the Queen's Medical Center (QMC) for assistance in the completion of the Medical Authorization form. In the event that the Medical Director is not available, physicians should contact his/her associate. Phone and fax numbers are located in Appendix 1.

The 1144 Medical Authorization form can be signed by either the Medical Director of the Hamamatsu PET Center, his/her associate or the referring physician.

In the 1144 block "Procedure Code," the specific PET scan being requested should be entered as follows:

Hospital Inpatient – 1 code: one procedure code representing one of the services listed above followed by the modifier 26 (professional component).

Hospital Outpatient – 3 codes: one procedure code representing one of the services listed above followed by modifier 26 (professional component), one procedure code representing one of the services listed above followed by modifier – TC (technical component), and the code assigned to the radiopharmaceutical agent, fluorodeoxyglucose (FDG).