MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

August 10, 2010

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL
FROM: MARTA E. STAGLIANO, CHIEF, COMPLIANCE
SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 800 – LABORATORY SERVICES

BACKGROUND AND EXPLANATION

Changes are being made to Medicaid Services Manual (MSM) Chapter 800 – Laboratory Services to:

Add coverage, limitations and prior authorization requirements related to phenotype assay tropism testing. Specified non-covered services.

Throughout the Chapter, grammar, punctuation, and capitalization changes were made, duplications removed, acronyms used and standardized, and language reworded for clarity. Renumbering and re-arranging of sections was necessary.

These policy changes are effective August 11, 2010.

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LABORATORY SERVICES

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800 LABORATORY SERVICES

INTRODUCTION

The Nevada Medicaid Laboratory Services program is designed to provide laboratory services under a Clinical Laboratory Improvement Amendment of 1988 (CLIA) certified provider. These services include microbiology, serology, immunohematology, cytology, histology, chemical, hematology, biophysical, toxicology or other methods of “in-vitro” examination of tissues, secretions, excretions, or other human body parts. Clinical laboratory services are furnished primarily in three distinct settings: independent clinical laboratories, physician office laboratories and hospital-based laboratories. Such services shall maintain a high standard of quality and shall be provided within the limitations and exclusions specified within this chapter.

All providers participating in the Medicaid Program must deliver services in accordance with the rules and regulations of the Medicaid Program. Conditions of participation are available from the Provider Support Services listed in Section 805 of this chapter.

All Medicaid policies and requirements (such as prior authorization, etc.) are the same for Nevada Check Up, with the exception of those listed in the Nevada Check Up Manual, Chapter 1000.
The Centers for Medicare and Medicaid Services (CMS) mandate that necessary and essential laboratory services be available for all Nevada Medicaid recipients. Laboratory services for children are provided under the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program per the Social Security Act of 1905 (a)(3)(1)(B)(iv)(r)(5). The Nevada EPSDT program provides children with services additional to those available to adult recipients.

Laboratory services are available through the Medicaid Program according to the Code of Federal Regulations Title 42, Section 441.17, 440.30, 493, NRS 652 and the Medicaid State Plan; Attachment 1.2-B, 101.9.C and Attachment 4.19-B.3.
802 DEFINITIONS

CLIA PROGRAM (Clinical Laboratory Improvement Amendments)

The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the United States through the CLIA. The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare and Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

CLINICAL LABORATORY

A laboratory which uses microbiological, serological, immunohematological, cytological, histological, chemical, hematological, biophysical, toxicological, or other methods for “in-vitro” examination of tissues, secretions, or excretions of the human body for the diagnosis, prevention or treatment of disease or for the assessment of a medical condition. The term does not include forensic laboratory operated by a law enforcement agency.

INDEPENDENT CLINICAL LABORATORY

A clinical laboratory independent of an attending or consulting physicians’ office or of a hospital that, at least, meets the requirements to qualify as an emergency hospital as defined in 1861 of the Social Security Act.

PHYSICIAN OFFICE LABORATORY

A clinical laboratory set up for the sole purpose of performing diagnostic tests for recipients in connection with the physician’s practice.

REFERENCE LABORATORY

A reference laboratory is an independent clinical laboratory that receives a specimen from another Medicaid approved laboratory for testing.

REFERRING LABORATORY

A referring laboratory is a laboratory that receives a specimen to be tested and refers the specimen to another laboratory for performance of the laboratory test.
803 POLICY

803.1 Nevada Medicaid and Nevada Check Up reimburse for medically necessary, diagnosis related, covered laboratory services provided to all eligible recipients.

Nevada Medicaid and Nevada Check Up provide outpatient clinical laboratory services through one or more independent clinical laboratories serving Nevada and its catchment areas.

A. COVERAGE AND LIMITATIONS

1. Except for specific laboratory tests identified under non-covered services, Medicaid reimburses organ or disease oriented panels, therapeutic drug assays, evocative/suppression testing, clinical pathology consultations, urinalysis, chemistry, hematology and coagulation, immunology, tissue typing, transfusion medicine, microbiology, cytopathology, cytogenic, surgical pathology, total transcutaneous bilirubin, and tests specified under, “Other Procedures” in the most recent version of Current Procedural Terminology. Reference the Nevada Medicaid and Nevada Check Up billing guidelines for Provider Type 43, Laboratory, Pathology/Clinical, for covered CPT codes.

2. Newborns discharged with a hyperbilirubinemia diagnosis are recommended to be followed by the discharging hospital laboratory for testing. If the newborn testing cannot be completed by the discharging hospital, the results need to be coordinated with the discharging hospital and/or newborns physician.

3. Ova and parasite testing are covered for medically appropriate diagnosis.

4. Independent clinical laboratories must have a State License, CLIA certificate, and possess a valid Medicaid provider number.

5. Physicians’ office laboratories must be in compliance with applicable state licensure/registration requirements, have appropriate CLIA certifications, possess a valid Medicaid provider number and only bill tests for which the office laboratory is licensed/registered and certified to perform.

6. In addition, health care providers may continue to bill for Medicaid covered, CLIA waived and Provider Performed Microscopic (PPM) procedures.

7. Physicians and/or respiratory therapists will be reimbursed an arterial blood drawing fee for Arterial Blood Gases (ABG).

8. Specialized or unique testing which cannot be performed within the State and catchment area laboratories may be referred to a reference laboratory.
9. Genotype and Phenotype assay testing for recipients:
   a. With an acute (new or recent) Human Immunodeficiency Virus (HIV) diagnosis upon entry into HIV care and/or prior to the initiation of antiretroviral therapy;
   b. Presenting with documented virologic failure after initiation of antiretroviral therapy; or
   c. Demonstrating documented suboptimal suppression of viral load after initiation of antiretroviral therapy.

10. A physician office laboratory can bill one venipuncture specimen collection fee per patient, per date of service, only when the specimen is sent to an independent clinical laboratory for testing.

11. Laboratory tests associated with the Early Periodic Screening, Diagnosis and Treatment (Healthy Kids Program) screening examination are referenced in MSM Chapter 1500.
   a. Laboratory tests referred out of the office/clinic:
      1. PKU tests are referred to the Oregon State Laboratory
      2. Sickle cell screens may be referred to an independent clinical laboratory.
   b. The associated costs of the hematocrit and urine “dip stick” with the exception of PKU and sickle cell screening fees, are included as part of the fee for EPSDT.

12. Serological or rapid-test HIV testing during the first and/or third trimester of pregnancy or during childbirth performed in accordance with NRS 442.600 – 442.660.

   A HIV rapid test for newborns (including infants in foster care) when the mother has not been tested for HIV prior to or during the delivery or if the mother’s HIV status is unknown post partum.

13. Serologic testing for syphilis in the first and third trimester of pregnancy in accordance with NRS 442.010.
14. The semen analysis, motility and count following a vasectomy procedure, not including Huhner test, is limited to the CPT code specified in Nevada Medicaid’s billing manual.

15. HIV tropism testing requires prior authorization based on established criteria.

B. MEDICAID NON-COVERED SERVICES

1. Laboratory tests listed in the most recent, annually updated Current Procedural Terminology (CPT) publication which are not Medicaid benefits include:
   a. Post mortem examination codes.
   c. Handling/conveyance fees (e.g. urine, stool cultures, pap smears).
   d. Medicaid and Nevada Check Up Managed Care recipients (laboratory tests are the sole responsibility of the managed care provider).
   e. Those services deemed inappropriate to a probable diagnosis are not covered. Services deemed inappropriate will be reviewed for possible recoupments.
   f. All unlisted laboratory codes except for the unlisted microbiology code used to bill phenotype assay tropism testing only.
   g. Routine venipuncture by a provider testing the laboratory specimen or referring the laboratory specimen to an affiliate laboratory.
   h. Collection of a capillary blood specimen (e.g. finger, heel, or ear stick) when it is part of or integral to the test procedure (e.g. a bleeding or clotting time).
   i. Physician services related to deviation from standard blood banking procedures (e.g. use of outdated blood or Rh incompatible units).
   j. Microdissection by laser capture.
   k. Caffeine halothane contracture test.
   l. Routine use (e.g. serial testing) of genotype and/or phenotype testing in individuals without virologic failure or suboptimal viral response or with
viral loads maintained at an undetectable level on a current medication regime.

m. HIV tropism test:
   1. Without prior authorization;
   2. Subsequent to a prior mixed or dual tropism test result; or
   3. Testing performed more than twice in a recipient’s lifetime.

C. PRIOR AUTHORIZATION

The ordering physician must obtain prior authorization for the following services, except for Medicare/Medicaid dual eligible recipients who are still eligible for Medicare benefits:

1. Genotype and phenotype assay testing for recipients with chronic HIV infection prior to initiation of highly active antiretroviral therapy.

2. Laboratory tests referred by a physician office laboratory directly to an out of state laboratory.

3. Tropism testing.

D. PROVIDER RESPONSIBILITY

1. Providers must verify recipients Medicaid eligibility and program benefit. Medicaid fee-for-service will not reimburse for laboratory procedures performed for Medicaid or Nevada Check Up recipients in managed care. Managed care plans may have their own authorization requirements. See Chapter 3600.

2. Must be a valid Nevada Medicaid provider.

3. Obtain the prior authorization number from the treating physician for laboratory test requiring prior authorization specified in 803.1C before performing and billing for these tests.
Reference Nevada Medicaid Services Manual, Chapter 100 and 3100 for the Medicaid Hearings and Grievance process.
805  REFERENCES AND CROSS REFERENCES

805.1  PROVIDER SPECIFIC INFORMATION

1.  Medicaid Service Manual Chapters:

   Chapter 100:  Eligibility, Coverage and Limitations
   Chapter 200:  Hospital Services
   Chapter 300:  Radiology Services
   Chapter 400:  Mental Health and Alcohol/Substance Abuse Services
   Chapter 500:  Nursing Facilities
   Chapter 600:  Physician Services
   Chapter 700:  Rates and Cost Containment
   Chapter 800:  Laboratory Services
   Chapter 900:  Private Duty Nursing
   Chapter 1000:  Dental
   Chapter 1100:  Ocular Services
   Chapter 1200:  Prescribed Drugs
   Chapter 1300:  DME, Disposable Supplies and Supplements
   Chapter 1400:  Home Health Agency
   Chapter 1500:  Healthy Kids Program
   Chapter 1600:  Intermediate Care for the Mentally Retarded
   Chapter 1700:  Therapy
   Chapter 1800:  Adult Day Health Care
   Chapter 1900:  Transportation Services
   Chapter 2400:  Comprehensive Outpatient Rehabilitation (COR) Services
   Chapter 2500:  Case Management
   Chapter 2800:  School Based Child Health Services
   Chapter 2900:  Mental Health
   Chapter 3100:  Hearings
   Chapter 3200:  Hospice
   Chapter 3300:  Program Integrity
   Chapter 3500:  Personal Care Services Program
   Chapter 3600:  Managed Care Organization

2.  Nevada Check Up Manual

   Chapter 1000:  Nevada Check Up Program

805.2  FIRST HEALTH SERVICES CORPORATION

A.  Provider Relations Department
First Health Services Corporation  
PO Box 30042  
Reno, NV 89520-3042  
Toll Free within Nevada (877) NEV-FHSC (638-3472)

B. First Health Services Corporation  
Prior Authorization Department  
Nevada Medicaid and Nevada Check Up  
Health Care Maintenance (HCM)  
4300 Cox Road  
Glen Allen, VA 23060  
Telephone: (800) 525-2395  
Fax: (866) 480-9903

C. Web announcements, billing manuals, billing guidelines, forms, provider enrollment and pharmacy information: [http://nevada.fhsc.com](http://nevada.fhsc.com).