Medicaid Services Manual
Transmittal Letter

November 28, 2023

To: Custodians of Medicaid Services Manual

From: Casey Angres Casey Angres (Dec 13, 2023 13:36 PST)
Chief of Division Compliance

Subject: Medicaid Services Manual Changes
Chapter 800 – Laboratory

Background And Explanation

Revisions to Medicaid Services Manual (MSM) Chapter 800– Laboratory are being proposed include a new section for biomarker testing for cancer as required through the passing of Assembly Bill (AB) 155 of the 82nd Legislative Session and removing the attachment section for Oncotype testing.

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.

Entities Financially Affected: Hospital, Outpatient Provider Type (PT 12) Special Clinics (PT 17), Physician/Osteopath (PT 20), Certified Registered Nurse Practitioner, Nurse (PT 24), Laboratory – Pathology/Clinic (PT 43), School Based Services (PT 60), Nurse Midwife (PT 74), and Physician's Assistant (PT 77).

Financial Impact on Local Government: Unknown at this time.

These changes are effective October 1, 2023.

Material Transmitted	Material Superseded
MTL 17/23 MSM Chapter 800 – Laboratory Services	MTL 11/18, 23/16 MSM Chapter 800 – Laboratory Services

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
803.1A(1)(q)(1)	**Coverage and limitations**	Added language that biomarker testing is covered for the diagnosis, treatment, appropriate management, and ongoing monitoring of cancer.
803.1A(1)(q)(2)		Added language that for Medicaid reimbursement, biomarker testing is analysis of the tissue, blood or other biospecimen of the patient must be in accordance with the requirements of state law.
803.1A(1)(q)(3)		Added language that testing must meet one of the following.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
803.1A(1)(q)(3)(a)		Added language that labeled indications for biomarker test or medication that has been approved for cleared by the United States Food and Drug Administration (USFDA).
803.1A(1)(q)(3)(b)		Added language that indicates tests for a drug that has been approved by the USFDA or the warnings and precautions included on the label of such a drug.
803.1A(1)(q)(3)(c)		Added language of a National coverage determination or local coverage determination, as those terms are defined in 42 C.F.R.
803.1A(1)(q)(3)(d)		Added language of Nationally recognized clinical guidelines or consensus statements including but not limited to NCCN and USPSTF.
803.1A(1)(q)(3)(e)		Added language of National guidelines and recommendations issued by medical professional societies support the indicated use of biomarker test.
803.1A(1)(q)(3)(f)		Added language of biomarker test is supported by evidence in peer-reviewed, scientific studies, biomedical compendia and other medical literature published by nationally recognized medical journals or available through National Library of Medicine at the National Institutes of Health, or Medical Literature Analysis and Retrieval System Online (MEDLARS).
803.1A(1)(q)(4)		Added language for Provider must.
803.1A(1)(q)(4)(a)		Added language that the delivery of biomarker testing services to a recipient in a manner consistent with the standard of care for such services and should avoid unnecessary or excessive biopsies.
803.1A(2)(o)		Removal of language when utilizing Oncotype DX, as defined in Policy Attachment #08-02.
803.1A(2)(p)		Removal of language as defined in Policy Attachment #08-01 or as otherwise defined.
Attachment #08-01	**BRCA1/BRCA2 Gene Analysis**	Remove the entire policy section.
Attachment #08-02	**Oncotype DX™ Breast Cancer Assay**	Remove the entire policy section.

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL
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LABORATORY SERVICES

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.

All Medicaid policies and requirements (such as prior authorization, etc.) are the same for Nevada Check Up (NCU), with the exception of those listed in the NCU Manual Chapter 1000.

801 AUTHORITY

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 (SSA) 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 (CFR):

- 42 CFR 493 Laboratory Requirements
- 42 CFR 410.32 Diagnostic X-Ray and Laboratory Tests
- 42 CFR 440.30 Other Laboratory and X-Ray Services
- 42 CFR 441.17 Laboratory Services

Nevada Revised Statute (NRS) Chapter 652 (Medical Laboratories)

Medicaid State Plan Attachment 1.2-B, 101.9.C and Attachment 4.19-B.3.

Other authorities regarding laboratory services available through the Medicaid Program include:

Social Security Act:

- Section 1902(a)(9)(C) (State Plans for Medical Assistance)
- Section 1905(a)(3), Section 1905(r)(1)(B)(iv) and Section 1905(r)(5) (EPSDT, Provision of Laboratory Services)

42 CFR 482.27 (Conditions of Participation for Hospitals, Laboratory Services)

NRS:

- NRS 442.600- 442.660 (Serologic or rapid test Human Immunodeficiency Virus (HIV))
- NRS 442.010 (Serologic testing for syphilis in the first and third trimester of pregnancy)

802 RESERVED

803 POLICY

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

Nevada Medicaid and NCU provide outpatient clinical laboratory services through one or more independent clinical laboratories, physician office laboratories, clinics and hospital-based laboratories.

803.1A COVERAGE AND LIMITATIONS

1. Covered Services:

   a. Except for specific laboratory tests identified under non-covered services, the Division of Health Care Financing and Policy (DHCFP) 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 (CPT). Reference the Nevada Medicaid and NCU billing guidelines for Provider Type 43, Laboratory, Pathology/Clinical, for covered CPT codes.

   b. Follow-up testing performed by either the discharging hospital laboratory and/or the newborn's physician for newborns discharged with a hyperbilirubinemia diagnosis.

   c. Ova and parasite testing for medically appropriate diagnosis.

   d. An arterial blood drawing fee for Arterial Blood Gases (ABG) performed by physicians and/or respiratory therapists.

   e. Specialized or unique testing which cannot be performed within the State and catchment area laboratories referred to a reference laboratory. Reference Section 803.1C.2 regarding prior authorization requirements.

   f. Genotype and Phenotype assay testing for recipients:

      1. With an acute (new or recent) HIV diagnosis upon entry into HIV care and/or prior to the initiation of antiretroviral therapy;

      2. Presenting with documented virologic failure after initiation of antiretroviral therapy; or

      3. Demonstrating documented suboptimal suppression of viral load after initiation of antiretroviral therapy.

g. One venipuncture specimen collection fee per patient, per date of service, specifically when the specimen is sent directly from a physician's office laboratory or clinic to an independent clinical laboratory for testing.

h. Laboratory tests associated with the EPSDT (Healthy Kids Program) screening examination referenced in Medicaid Services Manual (MSM) Chapter 1500. The associated costs of the hematocrit and urine "dip stick" with the exception of metabolic screening (e.g. Phenylketonuria (PKU)) and sickle cell screening fees, are included as part of the fee for EPSDT.

i. Metabolic screening (e.g. PKU) tests are referred to the Nevada State Public Health Laboratory.

j. Sickle cell screens are referred to an independent clinical laboratory.

k. 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.

l. An 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 postpartum.

m. Serologic testing for syphilis in the first and third trimester of pregnancy in accordance with NRS 442.010.

n. Semen analysis, motility and count following a vasectomy procedure, not including Huhner test, is limited to the CPT code that is specified in the DHCFP's/Quality Improvement Organization (QIO)-like vendor billing manual.

o. HIV tropism testing, not meeting criteria specified in Section 803.1A.2.m.

p. Drug Screening and Testing.

1. Drugs or drug classes for which screening is performed should only reflect those likely to be present based on the recipient's medical history, current clinical presentation or risk potential for abuse and diversion.

2. Each drug or drug class being tested for must be indicated by the referring physician in a written order and reflected in the patient's medical record. This information must be patient-specific and accurately reflect the need for each test and must include the specific drugs being screened including recipient diagnosis.

3. Current coding for testing of drugs relies on a structure of screening (known as presumptive screening) and may be followed by quantitative measurements (known as definitive testing) that identifies the specific drug or drugs and quantity in the recipient.

    a. Only one presumptive test performed by direct observation or instrument assisted direct observation or instrument chemistry analyzers may be billed per recipient per day within a maximum of 20 presumptive test per 12-rolling months.

        1. If the recipient should require more than 20 presumptive tests per 12-rolling month, a prior authorization is required.

    b. Only three definitive drug tests are permitted per recipient per 12-rolling months.

        1. If the recipient requires more than three definitive tests per 12-rolling month, a prior authorization is required, meeting medical necessity.

        2. Definitive testing is only covered to confirm an unexpected result or identify drugs or metabolites that cannot be detected on a presumptive drug screen.

        3. Definitive testing should be based on the recipient's presentation and history and only include what is needed for safe pain management.

4. Standing orders for presumptive drug screens may be utilized, but must be individualized for each member, signed and dated by the treating practitioner and updated every 30 days. Standing orders are not permitted for definitive drug screens.

5. Procedure codes should be reported with a quantity of one per episode of care, regardless of the number of collection/testing items used, the number of procedures and/or the drug classes screened.

6. Testing for the same drug with a blood and urine specimen simultaneously is not covered.

7. Drug screening for pre-employment or employment purposes, medicolegal and/or court ordered that do not meet medical necessity and/or drug screenings for participation in school or military are not covered.

8. Routine drug screening is not covered unless used in conjunction with an extended course of treatment for substance use disorders. Specific intervals, at which recipient test should be performed, based on their individual needs, must be documented in the member's medical record with their treatment plan.

9. Drug confirmation tests are not eligible to be separately reported under any procedure code, unlisted or otherwise.

q. Biomarker testing specific to cancer.

1. Except when biomarker testing is conducted for screening purposes as identified under non-covered services, DHCFP reimburses for medically necessary biomarker testing for the diagnosis, treatment, appropriate management, and monitoring of cancer when supported by medical and scientific evidence as defined below. Please reference the Nevada Medicaid and NCU billing guidelines for Provider Types 12 and 43, Laboratory, Pathology, Clinical, for covered CPT codes.

2. For purposes of Medicaid reimbursement, biomarker testing is the analysis of the tissue, blood or other biospecimen of a patient for the presentation of a biomarker and includes single-analyte tests, multiplex panel tests, and whole genome, whole exome, and whole transcriptome sequencing in accordance with the requirements of state law.

3. Biomarker testing considered as supported by medical and scientific evidence meets one or more of the following:

a. The labeled indications for the biomarker test or medication have been approved or cleared by the United States Food and Drug Administration (USFDA);

b. The indicated tests for the drug have been approved by the USFDA or warnings and precautions included on the label of such a drug;

c. A national coverage determination or local coverage determination, as defined in 42 C.F.R. § 400.202, has been issued for the biomarker test;

d. Nationally recognized clinical practice guidelines or consensus statements, such as those issued by the National Comprehensive Cancer Network (NCCN) and United States Preventive Services Task Force, support the indicated use of the biomarker test;

e. National guidelines and recommendations issued by medical professional societies support the indicated use of the biomarker test; and

f. The biomarker test is supported by evidence in peer-reviewed, scientific studies, biomedical compendia, and other medical literature published by nationally recognized medical journals or available through the National Library of Medicine at the National Institutes of Health, or Medical Literature Analysis and Retrieval System Online (MEDLARS).

4. Providers must:

a. Deliver biomarker testing services to a recipient in a manner consistent with the standard of care for such services and should avoid unnecessary or excessive biopsies, biospecimen sampling, or other delays or disruption in care when rendering biomarker testing.

2. Non-Covered Services

Laboratory tests listed in the most recent, annually updated CPT publication which are not benefits include:

a. Post mortem examination codes.

b. Reproductive medicine procedures, except as indicated in Section 803.1.A.1.m.

c. Handling/conveyance fees (e.g. urine, stool cultures, pap smears).

d. Medicaid and NCU 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. Subsequent to a prior mixed or dual tropism test result; or

2. Testing performed more than twice in a recipient's lifetime.

n. Blood typing for paternity testing.

o. Gene expression profiling, except when it is medically necessary as a prognostic assay to identify recipients diagnosed with breast cancer who are likely to respond to systemic chemotherapy.

p. Molecular testing except for BRCA1/BRCA2 testing services for:

1. Individuals without a personal history of breast and/or ovarian cancers, considered to be high risk as defined by the US Preventive Services Task Force;

2. Women with a personal history of breast and/or ovarian cancer with a personal history of breast cancer as defined in Policy Attachment #08-01 or as otherwise defined by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines; or

3. Men with a personal history of breast cancer as defined by the NCCN Clinical Practice Guidelines.

803.1B PROVIDER RESPONSIBILITY

Providers must:

1. Verify recipients Medicaid eligibility and program benefit. Medicaid Fee-for-Service (FFS) will not reimburse for laboratory procedures performed for Medicaid or NCU recipients in managed care. Managed care plans may have their own authorization requirements. See MSM Chapter 3600.

2. Have appropriate state licensure or registration from the state where the laboratory is located, as applicable.

3. Have current and appropriate CLIA certification for the level of laboratory tests performed.

4. Except in the case of provision of emergency laboratory services, have a valid Provider Contract with the Nevada DHCFP and Nevada Medicaid enrollment number or be an affiliate of an in-state laboratory that has a valid Medicaid enrollment number.

   An out-of-state laboratory providing covered, emergency medical laboratory services to a Medicaid or NCU recipient is exempt from the enrollment process for these services as long as the provider is enrolled as a Medicaid provider and is licensed to provide the laboratory service in the provider's home state.

5. Be in compliance with all applicable federal, state and local laboratory requirements.

6. Be in compliance with all Nevada MSM policies.

7. Be in compliance with claim and billing requirements specified in MSM Chapter 100, the QIO-like vendor/Medicaid and NCU billing manual, and the most recent version of the CPT and the Healthcare Common Procedure Coding System manuals.

8. Include on all claims the highest level of code specificity in accordance with the most current International Classification of Diseases, Clinical Modification manual related to the laboratory test performed. If a diagnosis or narrative diagnosis is not submitted by the prescribing practitioner, a laboratory must request this information from the physician/ practitioner who ordered the service.

9. Specify the current CLIA number of the laboratory performing the test on all claims, except when billing for CLIA exempt tests.

10. Only bill for laboratory services that the laboratory is currently licensed/registered and certified to perform.

11. Ensure each recipient's laboratory record contains the following information:

    a. Identification number of the specimen;

    b. Name or any other means of confidentially identifying the person from whom the specimen was taken;

    c. Name of the prescriber and, if applicable, the referring laboratory that submitted the specimen;

    d. Date the specimen was collected by the prescriber or laboratory;

    e. Date the specimen was received in the laboratory;

f. Condition of unsatisfactory specimens when received (e.g. broken, leaked, hemolyzed or turbid);

g. Test performed;

h. Date the test was performed;

i. Results of the test and the date of reporting; and

j. Name and address of the laboratory where any specimen is referred, if applicable.

12. Ensure that there is a written report on file for laboratory and pathology services that have a professional component requiring physician interpretation, whether or not "with interpretation and report" is stated in the code description of the service provided.

13. Maintain a quality-control program and make results of proficiency testing programs available to Nevada Medicaid or the QIO-like vendor upon request.

803.1C 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.

804 HEARINGS

Reference Nevada MSM Chapters 100 and 3100 for the Medicaid Hearings and Grievance process.