MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

July 26, 2018

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: LYNNE FOSTER, CHIEF OF DIVISION COMPLIANCE/*Lynne Foster/*

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 800 – LABORATORY SERVICES

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 800 – are proposed to update language, definitions and limitations for drug screening and testing. Presumptive drug screens are limited to one per day with a maximum of 20 tests per 12-rolling months. Only three definitive drug screens are permitted per recipient per 12-rolling months. Should more than three be needed, a prior authorization is required.

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 August 1, 2018.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
MTL 11/18 MSM Chapter 800 – Laboratory Services	MTL 15/14 MSM Chapter 800 – Laboratory Services

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
803.1A.1.p.1	**Coverage and limitations**	Added language to clarify the requirements of the presence of a drug or drug class for when to conduct a drug screen.
803.1.A.1.p.3	**Coverage and limitations**	Added language to clarify structures of screening of drugs including presumptive and definitive. This includes the maximum number of 20 presumptive and the

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		maximum number of three definitive drugs screens that can be performed in a 12-month rolling period.
803.1.A.1.p.4	**Coverage and limitations**	Added language that standing orders for presumptive drug screens may be utilized.
803.1.A.1.p.5	**Coverage and limitations**	Added language that procedure codes should only be reported with a quantity of one per episode of care.
803.1.A.1.p.6	**Coverage and limitations**	Added language that testing for the same drug with a blood and urine specimen simultaneously is not covered.
803.1.A.1.p.7	**Coverage and limitations**	Added language that drugs screens not meeting medical necessity are not covered.
803.1.A.1.p.8	**Coverage and limitations**	Added language that routine drug screens are not covered unless used in conjunction with an extended course of treatment for substance abuse disorders.
803.1.A.1.p.9	**Coverage and limitations**	Added language that drug confirmation tests are not eligible to be separately reported under any procedure code, unlisted or otherwise.

DIVISION OF HEALTH CARE FINANCING AND POLICY

MEDICAID SERVICES MANUAL
TABLE OF CONTENTS

LABORATORY SERVICES

ATTACHMENT A

800 LABORATORY SERVICES

INTRODUCTION

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.

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

™, as defined in Policy Attachment #08-02.

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 in Policy Attachment #08-01 or as otherwise 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 in Policy Attachment #08-01 or as otherwise 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.

DESCRIPTION

POLICY

BRCA1/BRCA2 testing services for individuals without a personal history of breast and/or ovarian cancer should be provided to high risk individuals as defined below or as otherwise defined by the US Preventive Services Task Force (USPSTF).

BRCA1/BRCA2 testing services for women with a personal history of breast and/or ovarian cancer and for men with a personal history of breast cancer should be provided as defined below or as otherwise defined by the NCCN Clinical Practice Guidelines.

Genetic counseling must precede genetic testing for hereditary cancer.

If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA1 has been identified in a family, a single site mutation analysis for that mutation is covered, while a full sequence BRCA1 and BRCA2 analyses is not. An exception to this can be considered if a Certified Genetic Counselor presents sufficient justifiable need.

PRIOR AUTHORIZATION: YES ☒ NO ☐

COVERAGE AND LIMITATIONS:

1. For individuals without diagnosis of breast or ovarian cancer:

    a. Two first-degree relatives with breast cancer, one of whom was diagnosed at age 50 years or younger;

    b. A combination of three or more first- or second-degree relatives with breast cancer regardless of age at diagnosis;

    c. A combination of both breast and ovarian cancer among first- or second-degree relatives;

    d. A first-degree with bilateral breast cancer;

e. A combination of two or more first- or second-degree relatives with ovarian cancer, regardless of age at diagnosis;

f. A first or second-degree relative with both breast and ovarian cancer at any age;

g. History of breast cancer in a male relative; or

h. For women of Ashkenazi Jewish descent, any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer.

2. A family history of breast or ovarian cancer that includes a relative with a known deleterious BRCA mutation; or

3. A personal history of breast cancer plus one or more of the following:

a. Diagnosed at age ≤ 45 years;

b. Diagnosed at age ≤ 50 years with ≥ 1 close blood relative with breast cancer diagnosed at any age or with a limited family history;

c. Two breast primaries when first breast cancer occurred at age ≤ 50 years;

d. Diagnosed at age ≤ 60 years with a triple negative breast cancer;

e. Diagnosed at age ≤ 50 years with a limited family history;

f. Diagnosed at any age, with ≥ 1 close blood relative with breast cancer diagnosed ≤ 50 years;

g. Diagnosed at any age with ≥ 2 close blood relatives with breast cancer at any age;

h. Diagnosed at any age with ≥ 1 close blood relative with epithelial ovarian cancer;

i. Diagnosed at any age with ≥ 2 close blood relatives with pancreatic cancer or aggressive prostate cancer (Gleason Score ≥ 7) at any age;

j. Close male blood relative with breast cancer; or

k. For an individual of ethnicity associated with higher mutation frequency (e.g. Ashkenazi Jewish) no additional family history may be required.

4. Personal history of epithelial ovarian cancer; or

5. Personal history of male breast cancer; or

6. Personal history of pancreatic cancer or aggressive prostate cancer (Gleason Score ≥ 7) at any age with ≥ 2 close blood relatives with breast and/or ovarian and/or pancreatic cancer or aggressive prostate cancer (Gleason Score ≥ 7) at any age.

REFERENCES:

1. The NCCN Clinical Practice Guidelines in Oncology Breast Cancer (Version 3.2013). 2013 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp. Accessed August 20, 2013.

2. US Preventive Services Task Force. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility recommendation statement. Available at: http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing. Accessed August 10, 2016.

DESCRIPTION

™ predicts the 10-year risk of distant recurrence and the likelihood of chemotherapy benefit in women with ER-positive, HER2-negative, early stage invasive breast cancer. The application of gene expression profiling using Onco*type* DX™ is employed to identify patients who are predicted to obtain the most therapeutic benefit from adjuvant Tamoxifen and may not require adjuvant chemotherapy. The Onco*type* DX™ uses reverse transcription polymerase chain reaction (RT-PCR) to determine the expression of a panel of 21 genes isolated from formalin-fixed, paraffin-embedded tissue (FPET).

POLICY

™

PRIOR AUTHORIZATION: YES ☒ NO ☐

COVERAGE AND LIMITATIONS:

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a.

Frequency is limited to once in a lifetime.

1.

REFERENCES

CMS local coverage determination (LCD) Gene expression profiling panel for use in the management of breast cancer treatment available at:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33586&ver=6&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&CptHcpcsCode=81519&bc=gAAAABAAAAAAAA%3d%3d&