Medicaid Services Manual
Transmittal Letter

November 28, 2023

To: Custodians of Medicaid Services Manual

From: Casey Angres
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 to update language, definitions, and limitations for biomarker 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) and Laboratory-Pathology/Clinic (PT 43).

Financial Impact on Local Government: Unknown at this time.

These changes are effective October 1, 2023.

Material Transmitted	Material Superseded
MTL OL 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.
803.1A(1)(q)(3)(a)		Added language that labeled indications for biomarker test or medication that has been approved

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		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.

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. ~~when utilizing Oncotype DX™, 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.

DESCRIPTION

Breast Cancer gene 1 (BRCA1) and Breast Cancer gene 2 (BRCA2) are human genes that belong to a class of genes known as tumor suppressors. Mutation of these genes has been linked to hereditary breast and ovarian cancer. A woman's risk of developing breast and/or ovarian cancer is greatly increased if she inherits a deleterious BRCA1 or BRCA2 mutation. Men with these mutations also have an increased risk of breast cancer.

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.

If the individual is of Ashkenazi Jewish descent, test the three common mutations first. Then if negative, consider comprehensive ("Reflex") testing based on assessment of individual and family history as if the individual is of non-Ashkenazi Jewish descent.

PRIOR AUTHORIZATION: YES ☒ NO ☐

COVERAGE AND LIMITATIONS:

Frequency is limited to once in a lifetime.

BRCA1/BRCA2 gene analysis is covered for individuals meeting the following criteria:

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~~

~~Oncotype DX™ 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 Oncotype 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 Oncotype 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~~

~~The Oncotype DX™ is considered medically necessary for eligible participants with diagnosed breast cancer as a prognostic assay to identify who is most likely to respond to systemic chemotherapy. The assay aids in identifying patients who are predicted to obtain the most therapeutic benefit from adjuvant Tamoxifen and may not require adjuvant chemotherapy.~~

~~PRIOR AUTHORIZATION: YES ☒ NO ☐~~

~~COVERAGE AND LIMITATIONS:~~

~~Oncotype DX™ breast cancer assay is covered for individuals meeting the following criteria:~~

~~1. Patient has new diagnosed early stage (Stage 1 or Stage 2) breast cancer; and~~

~~2. The patient's breast cancer meets all of the following criteria:~~

~~a. Unilateral non-fixed; and~~

~~b. Estrogen-receptor (ER) positive OR progesterone-receptor (PR) positive; and~~

~~c. Node-negative (isolated tumor cells and/or micrometastases [less than or equal to 2mm in size] i.e. pNO(i+) and/or pN1(mi), are not considered positive for the purpose of this guideline) or has 1-3 involved ipsilateral axillary lymph nodes; and~~

~~d. Human epidermal growth factor receptor 2 (HER2) negative; and~~

~~e. Tumor size is >.5 cm.~~

~~3. The Gene expression profile is ordered by the physician who will administer the hormonal and chemotherapy, usually the oncologist, or the test is ordered by the treating surgeon after discussing the patient's clinical situation with the oncologist.~~

~~4. The assay is ordered within six months following diagnosis.~~

~~5. The results will be used to aid in making the decision regarding chemotherapy:~~

~~a. The recipient must be a candidate for chemotherapy or be treated with adjuvant endocrine therapy, e.g. Tamoxifen.~~

~~Frequency is limited to once in a lifetime.~~

~~1. May be billed more than once for the same recipient if the provider can prove that the recipient has a new secondary primary breast cancer that meets the criteria listed.~~

~~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&~~