

MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

November 8, 2016

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL
FROM: LYNNE FOSTER, CHIEF OF DIVISION COMPLIANCE
SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 800 – Laboratory Services

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 800 – Laboratory Services are being proposed to add clarification to the coverage guidelines regarding non-covered service limitations on gene expression profiling that only allow for a gene expression profile for a prognostic assay when using *Oncotype DX™* Breast Cancer Assay. Clarification is being added to the coverage guidelines regarding non-covered service limitations on molecular pathology except for BRCA1/BRCA2 testing. Finally, proposed clarification is being added to the coverage guidelines regarding *Oncotype DX™* Breast Cancer Assay. Clarification is being added providing a description of the breast cancer assay, policy, prior authorization and coverage and limitations.

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: Laboratory (PT 43).

Financial Impact on Local Government: Overall impact will be budget neutral.

These changes are effective November 9, 2016.

MATERIAL TRANSMITTED

MTL 23/16
CHAPTER 800 – LABORATORY
SERVICES

MATERIAL SUPERSEDED

MTL 15/14
CHAPTER 800 – LABORATORY
SERVICES

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
803.1A.2.o	Non-Covered Services	Added clarifying language to non-covered laboratory tests for gene expression profiling except for medically

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		<p>necessary, eligible participants with diagnosed breast cancer as a prognostic assay when using <i>Oncotype DX</i>TM Breast Cancer Assay.</p>
803.1A.2.p	Non-Covered Services	<p>Added clarifying language to non-covered laboratory tests for molecular testing except for BRCA1/BRCA 2 testing.</p>
Policy #08-01	Reference	<p>In item number one, spelled out National Comprehensive Cancer Network.</p>
Policy #08-01	Reference	<p>In item number two, updated web address for US Preventive Services Task Force with an access date of August 10, 2016</p>
Policy #08-02	<i>Oncotype DX</i> TM Breast Cancer Assay	<p>New section adding clarifying language to the description, policy, prior authorization and coverage and limitations for <i>Oncotype DX</i>TM.</p>

DIVISION OF HEALTH CARE FINANCING AND POLICY

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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.

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.

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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 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 HIV)
- NRS 442.010 (Serologic testing for syphilis in the first and third trimester of pregnancy)

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802 RESERVED

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803 POLICY

803.1 Nevada Medicaid and Nevada Check Up (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) Human Immunodeficiency Virus (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

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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 Early Periodic Screening, Diagnosis and Treatment (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 Nevada Revised Statute (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 is specified in the DHCFP's/Quality Improvement Organization (QIO)-like vendor billing manual.
 - o. HIV tropism testing, not meeting criteria specified in 803.1A.2.m.
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.

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- b. Reproductive medicine procedures, except as indicated in 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.

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- 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 National Comprehensive Cancer Network (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 Chapter 3600.
2. Have appropriate state licensure or registration from the state where the laboratory is located, as applicable.
3. Have current and appropriate Clinical Laboratory Improvement Amendments (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 Medicaid State Manual policies.

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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 Current Procedural Terminology 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.

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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.

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804 HEARINGS

Reference Nevada Medicaid Services Manual (MSM) Chapters 100 and 3100 for the Medicaid Hearings and Grievance process.

POLICY # 08-01	BRCA1 / BRCA2 GENE ANALYSIS	EFFECTIVE DATE August 1, 2014
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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 National Comprehensive Cancer Network (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;

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POLICY # 08-01	BRCA1 / BRCA2 GENE ANALYSIS	EFFECTIVE DATE August 1, 2014
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- 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.

POLICY # 08-01	BRCA1 / BRCA2 GENE ANALYSIS	EFFECTIVE DATE November 9, 2016
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REFERENCES:

1. The **National Comprehensive Cancer Network (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.

POLICY # 08-02	ONCOTYPE DX™ BREAST CANCER ASSAY	EFFECTIVE DATE November 9, 2016
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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 *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

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PRIOR AUTHORIZATION: YES NO

COVERAGE AND LIMITATIONS:

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- 1.
- 2.
 - a.
 - b.
 - c.
 - d.
 - e.
- 3.
- 4.
- 5.
 - a.

POLICY # 08-02	ONCOTYPE DX™ BREAST CANCER ASSAY	EFFECTIVE DATE November 9, 2016
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Frequency is limited to once in a lifetime.

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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=gAAAABAAAAAAAAA%3d%3d&>