

	MTL 15/14
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 803
MEDICAID SERVICES MANUAL	Subject: POLICY

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

	MTL 15/14
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 803
MEDICAID SERVICES MANUAL	Subject: POLICY

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.

<b>DRAFT</b>	<b>MTL-15/14CL</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 803
MEDICAID SERVICES MANUAL	Subject: POLICY

- 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 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 Addendum #08-02.

<b>DRAFT</b>	<b>MTL-15/14CL</b>
DIVISION OF HEALTH CARE FINANCING AND POLICY	Section: 803
MEDICAID SERVICES MANUAL	Subject: POLICY

- 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 Addendum #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 Addendum #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 Addendum #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.

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

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;

November 1, 2014	LABORATORY SERVICES	Attachment A Page 1
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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  $\leq 45$  years;
    - b. Diagnosed at age  $\leq 50$  years with  $\geq 1$  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  $\leq 50$  years;
    - d. Diagnosed at age  $\leq 60$  years with a triple negative breast cancer;
    - e. Diagnosed at age  $\leq 50$  years with a limited family history;
    - f. Diagnosed at any age, with  $\geq 1$  close blood relative with breast cancer diagnosed  $\leq 50$  years;
    - g. Diagnosed at any age with  $\geq 2$  close blood relatives with breast cancer at any age;
    - h. Diagnosed at any age with  $\geq 1$  close blood relative with epithelial ovarian cancer;
    - i. Diagnosed at any age with  $\geq 2$  close blood relatives with pancreatic cancer or aggressive prostate cancer (Gleason Score  $\geq 7$ ) 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  $\geq 7$ ) at any age with  $\geq 2$  close blood relatives with breast and/or ovarian and/or pancreatic cancer or aggressive prostate cancer (Gleason Score  $\geq 7$ ) at any age.

POLICY # 08-01	BRCA1 / BRCA2 GENE ANALYSIS	EFFECTIVE DATE August 1, 2014
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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](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/uspstf05/breagen/breagenrs.htm>~~  
~~Accessed December 24, 2013.~~  
<http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/bcrarelatedcancer-risk-assessment-genetic-counseling-and-genetic-testing>.  
Accessed August 10, 2016.

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POLICY # 08-02	ONCOTYPE DX™ BREAST CANCER ASSAY	EFFECTIVE DATE TBD
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## 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 6 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.

POLICY # 08-02	ONCOTYPE DX™ BREAST CANCER ASSAY	EFFECTIVE DATE TBD
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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&>

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