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To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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**NC Medicaid
Gene Expression Profiling for Breast
Cancer**

**Medicaid and Health Choice
Clinical Coverage Policy No:1S-7
Amended Date:**

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Related Clinical Coverage Policies

Refer to <https://medicaid.ncdhhs.gov/> for the related coverage policies listed below:
1A-12, Breast Surgeries

1.0 Description of the Procedure, Product, or Service

Gene expression profiling is a genomic test that predicts the probability of a cancer recurrence, the possible benefit from chemotherapy, and the probability of survival in patients with newly diagnosed breast cancer that has not spread to the lymph nodes (node-negative) and is hormone receptor-positive. The assay evaluates the activity of 21 genes from a sample of the patient's cancer to determine the patient's Recurrence Score. The Recurrence Score ranges from 0 to 100, with a higher score indicating a greater risk of recurrence.

1.1 Definitions

1.1.1 Adjuvant Therapy

Chemotherapy or endocrine therapy that is given in addition to the primary, main, or initial therapy to maximize effectiveness of treatment.

1.1.2 Human Epidermal Growth Factor Receptor 2 (HER2)

A growth-promoting protein on the outside of all breast cells. Breast cancer cells with higher than normal levels of HER2 are called HER2-positive. These cancers tend to grow and spread faster than other breast cancers.

1.1.3 Oncotype Dx® Breast Cancer Assay Recurrence Score

Diagnostic assay quantifies the likelihood of breast cancer occurrence with newly diagnosed, early stage, node negative, and estrogen receptor positive (ER+) cancer. For the purposes of this policy, gene expression profiling means Oncotype Dx®.

1.1.4 Recurrence Score

The Oncotype Dx® Breast Recurrence Score is a laboratory developed test that is not subject to FDA approval or clearance. The Oncotype Dx® assay analyzes the expression of 21 genes to provide a Recurrence Score® result unique to each beneficiary. The Recurrence Score result is a number between 0 and 100.

- a. **A score of 17 or smaller** means there is a low risk of cancer returning with hormone treatment, chemotherapy would not be needed to help prevent the disease from coming back.
- b. **A score between 18 and 31** means there is a medium risk of cancer returning. Chemotherapy might help some women in this range.
- c. **A score greater than 31** means there is a higher risk that the disease might come back. For women in this range, both chemotherapy and hormone therapy are likely to be recommended.

1.1.5 Tumor board review

A team of expert physicians who meet to review and discuss treatment options for complex beneficiaries with a diagnosis of cancer. It is a treatment planning approach in which a number of doctors who are experts in different medical

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specialties review and discuss the medical condition and treatment options of a patient. Also called a multidisciplinary opinion.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary’s eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. **Medicaid**
The Oncotype Dx® Breast Recurrence Score is for early stage endocrine receptor positive, HER2 negative, node negative or node positive breast cancer.
- b. **NCHC**
None apply

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

- a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services

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will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

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3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

Medicaid and NCHC shall cover Oncotype Dx® Breast Cancer Assay when the female beneficiary meets all of the following specific criteria:

- a. Diagnosis of early stage (Stage 1 or 2) breast cancer;
- b. Tumor is unilateral non-fixed;
- c. Estrogen- receptor positive (ER+) or progesterone-receptor positive;
- d. Node negative or tumor cells isolated less than 2 millimeters in size. If there is more than one tumor then a specimen with the most aggressive histological characteristics should be submitted;
- e. HER 2 negative;
- f. Tumor cell is greater than 0.5 centimeters;
- g. Results will aid in the decision for or against chemotherapy;
- h. Beneficiary will be treated with adjuvant endocrine therapy such as tamoxifen or aromatase inhibitors;
- i. The gene expression profile is ordered by the treating physician or surgeon; and
- j. The assay must be ordered within six months following diagnosis of Stage 1 or 2 breast cancer

3.2.1 Specific criteria covered by both Medicaid and NCHC

None Apply

3.2.2 Medicaid Additional Criteria Covered

None Apply

3.2.3 NCHC Additional Criteria Covered

None Apply

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4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC shall not cover Oncotype Dx® for the following indications:

- a. To predict response to specific chemotherapy regimens;
- b. Repeat Oncotype Dx® testing or testing of multiple tumor sites in the same beneficiary;
- c. Use of Oncotype Dx® to determine risk in a beneficiary with primary breast cancer who meets the criteria above but who has already made the decision to undergo or forego chemotherapy; or
- d. Adjuvant treatment planning for a male beneficiary.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply

4.2.3 NCHC Additional Criteria Not Covered

- a. In addition to the specific criteria not covered in **Subsection 4.2.1** of this policy, NCHC shall not cover...
- b. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

Note: Subsection 4.2.3(b) applies to NCHC only

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5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall not require prior approval for gene expression profiling for breast cancer, however, all claims are subject to post payment review for medical necessity.

5.2 Prior Approval Requirements

5.2.1 General

None Apply

5.2.2 Specific

None Apply

5.3 Additional Limitations or Requirements

Gene expression profiling assay for breast cancer is limited to once per occurrence in early stage breast cancer to guide adjuvant treatment planning

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet NC Medicaid or NCHC qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

CLIA certified laboratory for Genomic Health in Redwood California.

Note: The Oncotype DX Breast Recurrence Score is a laboratory developed test is provided only by Genomic Health 's CLIA -certified (Clinical Laboratory Improvement Amendments), CAP- accredited (College of American Pathologist).

6.2 Provider Certifications

None Apply

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7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

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8.0 Policy Implementation and History

Original Effective Date:

History:

Date	Section or Subsection Amended	Change
0/0/0000	All Sections and Attachment(s)	New policy 1S-7 to document coverage criteria for a new laboratory Gene Expression Profiling Assay Test

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Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

ICD-10-PCS Code(s)

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

CPT Code(s)
81519

Revenue Code(s)

HCPCS Code(s)

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Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions for Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Outpatient, Office

G. Co-payments

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

For NCHC refer to NCHC State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>