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Related Clinical Coverage Policies
Refer to http://dma.ncdhhs.gov/ for the related coverage policies listed below:
1K-7, *Prior Approval for Imaging Services*

1.0 Description of the Procedure, Product, or Service

Breast imaging is used to detect and evaluate breast abnormalities, such as breast cancer.

1.1 Definitions

1.1.1 Mammography

a. A screening mammogram is a radiologic procedure (film or digital) furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer.

b. A diagnostic mammogram is a radiologic procedure (film or digital) furnished to a man or woman with signs or symptoms of breast disease, a personal history of breast cancer, or a personal history of biopsy-proven benign breast disease.

c. Computer aided detection (CAD) is an add-on process for film or digital mammography. Film mammography is scanned and digitized to create a digital mammogram file. Digital images can be transmitted from the digital mammography acquisition device directly to the CAD processing computer. The CAD computer uses a specialized detection algorithm to identify potentially suspicious areas on the images.

d. Breast tomosynthesis, also known as 3D mammography or digital breast tomosynthesis, is an advanced form of breast imaging that uses computer reconstruction to create a three-dimensional image of the breast.

1.1.2 Breast Ultrasound

Breast ultrasound is sometimes used to evaluate breast problems that are found during a screening or diagnostic mammogram or on physical exam. During breast ultrasound, a handheld instrument placed on the skin transmits high-frequency sound waves through the breast.

1.1.3 Breast Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) uses magnets and radio waves, instead of X-rays, to produce very detailed cross-sectional images of the body. This improves the ability to show breast tissue details.

1.1.4 Ductogram (Galactogram)

A ductogram is a test that is sometimes helpful in determining the cause of nipple discharge. In this X-ray procedure, a thin metal catheter is placed into the opening of a duct in the nipple. A small amount of contrast medium is injected, which outlines the shape of the duct on an X-ray image and shows whether there is a mass inside the duct.

1.1.5 Image-Guided Breast Biopsy

Breast biopsy of a suspicious area in the breast is the most accurate way to confirm the presence of cancer. During a breast biopsy, a sample of cells or tissue is removed and inspected under the microscope by a pathologist. Imaging tests may be done to ensure that the correct area is biopsied.

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. <u>Medicaid</u>
None Apply.

b. <u>NCHC</u>
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 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: http://dma.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

The Division of Medical Assistance (DMA) 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 DMA clinical

coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries 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

3.2.1 Specific criteria covered by both Medicaid and NCHC

a. Mammography

1. Diagnostic Mammography

Medicaid and NCHC consider diagnostic mammography for female and male beneficiaries of all ages to be medically necessary when the beneficiary:

A. has or has had a personal history of malignant neoplasm of the breast; or
B. is diagnosed with benign mammary dysplasia(s); or
C. is diagnosed with other disorders of the breast.

2. Computer Aided Detection

Computer-aided detection (CAD) is used to improve radiologists' ability to identify suspicious areas that may otherwise be overlooked on mammograms (screening or diagnostic).

Note: The radiologist remains the reader and interpreter of the mammogram. CAD assists the radiologist by identifying areas warranting further review.

b. Breast Ultrasound

Medicaid and NCHC cover ultrasounds:

1. to evaluate problems found during a screening or diagnostic mammogram;
2. for use during a biopsy procedure for breast lesions; or
3. to evaluate a clinical abnormality.

c. Breast Magnetic Resonance Imaging

Medicaid and NCHC cover magnetic resonance imaging (MRI) for the detection of:

1. Breast cancer in beneficiaries who are at a high genetic risk for breast cancer:
   A. known BRCA 1 or 2 mutation in beneficiary;
   B. known BRCA 1 or 2 mutation in relatives; or
   C. pattern of breast cancer history in multiple first-degree relatives, often at a young age and bilaterally.
2. Breast cancer in beneficiaries who have breast characteristics limiting the sensitivity of mammography (such as dense breasts, implants, scarring after treatment for breast cancer).
3. A suspected occult breast primary tumor in beneficiaries with axillary nodal adenocarcinoma with negative mammography and clinical breast exam.
4. Breast cancer in beneficiaries with a new diagnosis of breast cancer. It can be used to determine the extent of the known cancer and/or to detect disease in the contralateral breast.
5. To evaluate implant integrity in beneficiaries with breast implants.

Note: This is not an all-inclusive list.

d. Ductogram (Galactogram)

Medicaid and NCHC cover ductogram for the diagnosis of the cause of abnormal nipple discharge.

e. Image-Guided Breast Biopsy

Medicaid and NCHC cover image-guided breast biopsy when radiological supervision and interpretation is required for needle placement and/or for biopsy.

3.2.2 Medicaid Additional Criteria Covered

a. Mammography

1. Screening Mammography

Medicaid covers screening mammography for women as a preventive health measure for the purpose of early detection of breast cancer.

A. For female Medicaid beneficiaries ages 20 through 39 years, one exam annually when the beneficiary has:
   i. a documented positive BRCA mutation;
   ii. personal history of ovarian cancer;
   iii. personal history of chest radiation;
   iv. personal history of atypical/high risk biopsy(ies); or

v. strong family history of breast cancer (first-degree relative: mother, sister, daughter)

Note: This is not an all-inclusive list.

B. For female Medicaid beneficiaries ages 35 through 39 years, one baseline exam within the five years.

C. For female Medicaid beneficiaries ages 40 years and older, one exam annually.

Note: See **Attachment A, Letter B,** for specific diagnosis codes to be used for screening mammograms according to age.

3.2.3 NCHC Additional Criteria Covered

None Apply.

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 Medicaid Beneficiaries 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

None Apply.

4.2.2 Medicaid Additional Criteria Not Covered

In addition to the specific criteria not covered in **Subsection 4.2.1** of this policy**,** Medicaid shall not cover screening mammography for male beneficiaries.

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 screening mammography.
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."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Prior approval is required for Medicaid beneficiaries for Breast Ultrasound and Breast Magnetic Resonance Imaging (MRI). Refer to DMA's clinical coverage policy 1K-7, *Prior Approval for Imaging Services* on Medicaid's website at http://dma.ncdhhs.gov/. A signed physician's order or requisition is required.

Prior approval is not required for NCHC beneficiaries.

5.2 Prior Approval Requirements

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

a. the prior approval request; and
b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.3 Limitations

a. Screening Mammograms

1. For female Medicaid beneficiaries ages 40 and older, screening mammograms are limited to one mammogram per year.
2. For female Medicaid beneficiaries ages 20 through 39 with a high-risk diagnosis, screening mammograms are limited to one mammogram per year.
3. For female Medicaid beneficiaries ages 35 through 39, screening mammograms are limited to one mammogram within a five-year period to establish a baseline.

   Note: At least 11 complete calendar months must elapse between annual mammograms for the Medicaid service to be covered.

b. Frequency of Service

Coverage is limited to one procedure per date of service by the same or different provider, unless appropriate modifier is appended to the procedure code.

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 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

None Apply.

6.2 Provider Certifications

None Apply.

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 DMA'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).

8.0 Policy Implementation/Revision Information

Original Effective Date: September 1, 1992

Revision Information:

Date	Section Revised	Change
6/1/07	Throughout policy	Coverage was expanded to include mammography procedures producing direct digital images.
6/1/07	Section 3.2.1	Coverage was expanded to include annual screenings for women ages 20 through 40 who are considered by their physician to be at high risk for breast cancer.
9/1/07	Attachment A	Streamlined language in letter A, **Claim Type.**
9/1/07	Attachment A	Clarified table headers in letter B, **Diagnosis Codes** (added the word "annual" where it now appears; added "baseline" and "secondary diagnosis" concepts where they now appear); in Diagnostic Mammography table, added range 793.80 through 793.89 as an acceptable ICD-9-CM code.
3/1/08	Attachment A	Corrected CPT procedure codes 77051 and 77052 in letter C.
7/1/2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, **Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."**
3/12/12	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 1K-1 under Session Law 2011-145 § 10.41.(b)
3/12/12	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
6/15/12	Attachment A: C	Corrected code 77645 to 76645
10/01/2015	Subsection 5.3.1.a	Corrected typo: "For female Medicaid beneficiaries ages 20 and older …" changed to "For female Medicaid beneficiaries ages 40 and older …"
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
05/01/2018	Subsection 1.1.1.d	Added definition for breast tomosynthesis: "Breast tomosynthesis, also known as 3D mammography or digital breast tomosynthesis, is an advanced form of breast imaging that uses computer reconstruction to create a three-dimensional image of the breast."

Date	Section Revised	Change
05/01/2018	Attachment A	In letter B, added the following diagnosis codes to the diagnostic mammogram list: N61.0, N61.1, N63.11, N63.12, N63.13, N63.14, N63.21, N63.22, N63.23, N63.24, N63.31, N63.32, N63.41, N63.42. Removed the following diagnosis codes from the diagnostic mammogram list: N61, N63
05/01/2018	Attachment A	In letter C, removed end-dated CPT Codes 77051, 77052, 77055, 77056, 77057, G0202, G0204, G0206 and added CPT Codes 77065, 77066, 77067, and G0279 to the list of mammogram codes. A note was added that breast tomosynthesis may be billed with either a screening or diagnostic mammogram.
05/01/2018	Attachment A	In letter C, removed end-dated CPT codes 77031 and 77032 from the list of “Other Codes”

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide,* Medicaid bulletins, fee schedules, DMA'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)

B. International Classification of Diseases, 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.

Annual Screening Mammography Ages 40 Years and Older (for Medicaid Beneficiaries) Primary Diagnosis Allowed		
ICD-10-CM Code		
Z12.39		
Z12.31		
Screening Mammography Ages 35 through 39 Years (for Medicaid Beneficiaries) (Baseline Once in Five Years) Primary Diagnosis Allowed		
ICD-10-CM Code		
Z12.39		
Z12.31		
Annual Screening Mammography Ages 20 through 39 Years (for Medicaid Beneficiaries) Primary Diagnosis Allowed (Secondary Diagnosis Required—See Below)		
ICD-10-CM Code		
Z12.31		
Annual Screening Mammography Ages 20 through 39 Years (for Medicaid Beneficiaries) Secondary Diagnosis Required		
ICD-10-CM Code		
Z85.3	Z77.123	Z91.89
Z77.110	Z77.128	Z92.89
Z77.111	Z77.21	Z80.3
Z77.112	Z77.22	Z80.8
Z77.118	Z77.9	Z12.39

Diagnostic Mammography—Primary or Secondary Diagnosis Allowed		
ICD-10-CM Code		
Z85.3	C50.612	N61.0
C50.011	C50.619	N61.1
C50.012	C50.621	N62
C50.019	C50.622	N63.11
C50.021	C50.629	N63.12
C50.022	C50.811	N63.13
C50.029	C50.812	N63.14
C50.111	C50.819	N63.21
C50.112	C50.821	N63.22
C50.119	C50.822	N63.23
C50.121	C50.829	N63.24
C50.122	C50.911	N63.31
C50.129	C50.912	N63.32
C50.211	C50.919	N63.41
C50.212	C50.921	N63.42
C50.219	C50.922	N64.0
C50.221	C50.929	N64.1
C50.222	N60.01	N64.2
C50.229	N60.02	N64.3
C50.311	N60.09	N64.4
C50.312	N60.11	N64.51
C50.319	N60.12	N64.52
C50.321	N60.19	N64.53
C50.322	N60.21	N64.59
C50.329	N60.22	N64.81
C50.411	N60.29	N64.82
C50.412	N60.31	N64.89
C50.419	N60.32	N64.9
C50.421	N60.39	R92.0
C50.422	N60.41	R92.1
C50.429	N60.42	R92.2
C50.511	N60.49	R92.8
C50.512	N60.81	
C50.519	N60.82	
C50.521	N60.89	
C50.522	N60.91	
C50.529	N60.92	
C50.611	N60.99	

Annual Screening Mammography Ages 40 Years and Older (for Medicaid Beneficiaries) Primary Diagnosis Allowed
ICD-10-CM Code
Z12.39
Z12.31
Screening Mammography Ages 35 through 39 Years (for Medicaid Beneficiaries) (Baseline Once in Five Years) Primary Diagnosis Allowed
ICD-10-CM Code
Z12.39
Z12.31

Annual Screening Mammography Ages 20 through 39 Years (for Medicaid Beneficiaries) Primary Diagnosis Allowed (Secondary Diagnosis Required—See Below)		
ICD-10-CM Code		
Z12.31		
Annual Screening Mammography Ages 20 through 39 Years (for Medicaid Beneficiaries) Secondary Diagnosis Required		
ICD-10-CM Code		
Z85.3	Z77.123	Z91.89
Z77.110	Z77.128	Z92.89
Z77.111	Z77.21	Z80.3
Z77.112	Z77.22	Z80.8
Z77.118	Z77.9	Z12.39
Diagnostic Mammography—Primary or Secondary Diagnosis Allowed		
ICD-10-CM Code		
Z85.3	C50.612	N60.91
C50.011	C50.619	N60.92
C50.012	C50.621	N60.99
C50.019	C50.622	N61.0
C50.021	C50.629	N61.1
C50.022	C50.811	N62
C50.029	C50.812	N63.11
C50.111	C50.819	N63.12
C50.112	C50.821	N63.13
C50.119	C50.822	N63.14
C50.121	C50.829	N63.21
C50.122	C50.911	N63.22
C50.129	C50.912	N63.23
C50.211	C50.919	N63.24
C50.212	C50.921	N63.31
C50.219	C50.922	N63.32
C50.221	C50.929	N63.41
C50.222	N60.01	N63.42
C50.229	N60.02	N64.0
C50.311	N60.09	N64.1
C50.312	N60.11	N64.2
C50.319	N60.12	N64.3
C50.321	N60.19	N64.4
C50.322	N60.21	N64.51
C50.329	N60.22	N64.52
C50.411	N60.29	N64.53
C50.412	N60.31	N64.59
C50.419	N60.32	N64.81
C50.421	N60.39	N64.82
C50.422	N60.41	N64.89
C50.429	N60.42	N64.9
C50.511	N60.49	R92.0
C50.512	N60.81	R92.1

C50.519 C50.521 C50.522 C50.529 C50.611	N60.82 N60.89	R92.2 R92.8

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.

Mammography
Code(s)
77065
77066
77067
G0279

Note: Providers may bill digital breast tomosynthesis with screening and diagnostic mammograms.

Ductogram (Galactogram)
Code(s)
77053
77054

Magnetic Resonance Imaging (MRI) of the Breast
Code(s)
77058
77059
76377
77021

Note: CPT codes 77058, 77059, and 76377 require prior approval for Medicaid beneficiaries.

Other
Code(s)
76641
76642

Note: CPT code, 76641, 76642 requires prior approval for Medicaid beneficiaries.

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

Coverage is limited to one procedure per date of service by the same or different provider, unless appropriate modifier is appended to the procedure code.

F. Place of Service

Inpatient, Outpatient, Physician's office.

G. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at http://dma.ncdhhs.gov/.
For NCHC refer to G.S. 108A-70.21(d),

H. Reimbursement

Providers shall bill their usual and customary charges.
Providers are required to bill applicable revenue codes.
For a schedule of rates, refer to: http://dma.ncdhhs.gov/