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1.0 Description of the Procedure, Product, or Service

Radiation oncology is the specialty of medicine that utilizes high-energy ionizing radiation in the treatment of malignant neoplasms and certain non-malignant conditions. Radiation therapy is a modality. It is a complex process involving trained personnel who carry out a variety of interrelated activities, including clinical evaluation, establishing treatment goals, treatment planning, simulation of treatment, treatment aids, physics, patient evaluation during treatment, and follow-up evaluation. Radiation *treatment delivery* codes recognize both the technical component and the various energy levels administered. Radiation *therapy management* codes represent the professional services of the physician managing a course of radiation therapy. Radiation oncology may include any of the following:

a. External beam radiotherapy, the most frequently used form of radiotherapy, uses a machine to aim high-energy rays at the cancer from outside of the body.
b. Brachytherapy is a procedure in which small encapsulated radioactive elements ("seeds" or "sources") are placed in or near the tumor or target tissue. They emit a relatively high dose of radiation to the tumor and a considerably lower dose to normal surrounding tissue.
c. Hyperthermia treatments, in which body tissue is exposed to high temperatures to damage and kill cancer cells or to make cancer cells more sensitive to the effects of radiation and certain anticancer drugs, include external (superficial and deep), interstitial, and intracavitary types. Hyperthermia is used only as an adjunct to radiation therapy or chemotherapy.
d. Stereotactic radiosurgery (SRS) is a technique for delivering a dose of radiation to a specific target while delivering a minimal dose to surrounding tissues. SRS refers to treatment of intracranial lesions. Stereotactic body radiation therapy (SBRT) refers to treatment of the spine and other anatomical sites.
e. Intensity Modulated Radiation Therapy (IMRT) is an advanced mode of high-precision radiotherapy that utilizes computer-controlled x-ray accelerators to deliver precise radiation doses to a defined, specific area. IMRT allows the radiation dose to conform to the 3-dimensional shape of the tumor by controlling or modulating the intensity of the beam. This is crucial in terms of normal tissue sparing.
f. Image-Guided Radiation Therapy (IGRT) is a process of using various imaging techniques to locate a tumor target prior to the actual radiation treatment on a daily basis. This process improves treatment accuracy on a day-to-day basis so the need for larger target margins is diminished and therefore spares more normal tissue.
g. 3D Conformal Radiation Therapy (CRT) is radiation therapy that uses computers to create a 3-dimensional picture of the tumor so that more than 2 radiation beams can be shaped or conformed to the contour of the targeted area. This takes less intensive planning than IMRT, but similar, except for the intensity of individual beams.

1.1 Definitions

None Apply.

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://www.ncdhhs.gov/dma/epsdt/

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 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

3.2.1 Specific criteria covered by both Medicaid and NCHC

Medicaid and NCHC cover the following:

a. Local hyperthermia services for a diagnosis of cancer.
b. Brachytherapy services for the following conditions:
    1. Head and neck cancers;
    2. Respiratory and digestive tract cancers;
    3. Genitourinary cancers
    4. Eye tumors;
    5. Brain tumors;
    6. Soft tissue sarcomas; or
    7. Multi-catheter interstitial or balloon brachytherapy (such as MammoSite) for breast cancer is covered.
        A. for the treatment of early-stage breast cancer, in conjunction with external whole-breast radiation therapy following breast-conserving surgery; or
        B. as the sole method of breast radiation therapy for the treatment of breast cancer following breast-conserving surgery, when all of the following medical necessity criteria are met:
            i. Beneficiary is at least 45 years old or is postmenopausal;
            ii. Beneficiary has invasive ductal carcinoma or ductal carcinoma in situ (DCIS);
            iii. Total tumor size (invasive and DCIS) is less than or equal to 3 cm;
            iv. Microscopic surgical margins of excision are negative; and
            v. Axillary/sentinel lymph nodes are negative.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

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 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

Medicaid and NCHC shall not cover the following:

a. Stereotactic radiation oncology procedures for obsessive-compulsive disorder; epilepsy, recurrent seizures, or convulsions; Parkinson's disease; or migraine headaches;
b. Neutron beam procedures;
c. Proton beam procedures;
d. Category III CPT codes;
e. Brachytherapy for breast cancer in any of the following situations, as in these cases it is considered experimental, investigational, or unproven:
    1. When it follows induction chemotherapy as treatment for inoperable locally advanced breast cancer;
    2. When the tumor is located in an area of insufficient tissue (very small breasts, inframammary fold, the Tail of Spence); or
    3. When the tumor is multifocal, has extensive nodal involvement, or is a lobular carcinoma.
f. Electronic/kilovoltage brachytherapy, as it is considered experimental, investigational or unproven;
g. Stereotactic body radiation therapy in conjunction with other radiation treatment delivery procedures; or
h. Stereoscopic x-ray guidance in conjunction with stereotactic radiation treatment management procedures.

4.2.1 Medicaid Additional Criteria Not Covered

None Apply.

4.2.2 NCHC Additional Criteria Not Covered

a. 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

Medicaid and NCHC shall not require prior approval for radiation oncology.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

5.3 Radiation Treatment Management

Radiation treatment management represents the physician's professional services and typically consists of:

a. the review of portal films;
b. the review of dosimetry, dose delivery, and treatment parameters;
c. the review of beneficiary treatment setup; and
d. the examination of the beneficiary for medical evaluation and management to assess the beneficiary's response to treatment.

5.4 Therapeutic Radiology Port Film

Therapeutic radiology port film is limited to one per day, regardless of the number of films required.

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).

7.2 Medical Record Documentation

Medical record documentation must include the planned course of therapy, type and delivery of treatment, level of clinical management involved, and ongoing documentation of any changes in course of treatment. Documentation should be in accordance with the current *American College of Radiology Practice Guideline for Communication: Radiation Oncology* (online at http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/ro/comm_radiation_oncology.aspx).

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 1977

Revision Information:

Date	Section Revised	Change
10/01/2009	Throughout	Initial promulgation of current coverage.
07/01/2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, **Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."**
01/01/2012	4.3	Removed 99185, Updated 99354-99357
01/01/2012	5.2.5	Added "77469 through" and "these codes".
01/01/2012	5.3	Added "77424 through 77425" and added "Requirements and limitations…" statement.
01/01/2012	Attachment A, C.4	Added 77424 and 77425
01/01/2012	Attachment A, C.5	Added 77469
01/01/2012	Attachment A, C.7	Deleted 77781-77784 and deleted the "note" from 77785-77787.
03/01/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
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.

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)

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.

ICD-10-CM Code(s)		
B.1 Stereotactic Radiation Therapy Procedures—Exclusions Stereotactic radiation therapy procedures (CPT 77371, 77372, 77373, and 77435) are not covered for the following diagnoses.		
F60.5	G40.319	G40.A09
G03.0	G40.401	G40.A11
G20	G40.409	G40.A19
G21.11	G40.411	G40.B01
G21.19	G40.419	G40.B09
G21.2	G40.501	G40.B11
G21.3	G40.801	G40.B19
G21.4	G40.802	G43.009
G21.8	G40.803	G43.019
G21.9	G40.804	G43.109
G40.001	G40.811	G43.119
G40.009	G40.812	G43.509
G40.011	G40.813	G43.809
G40.019	G40.814	G43.819
G40.101	G40.821	G43.909
G40.109	G40.822	G43.919
G40.111	G40.823	G43.A0
G40.119	G40.824	G43.B0
G40.201	G40.89	G43.B1
G40.209	G40.901	G43.C0
G40.211	G40.909	G43.C1
G40.219	G40.911	G43.D0
G40.301	G40.919	G43.D1
G40.309	G40.A01	R56.9
G40.311		

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.

C.1 Clinical Treatment Planning

CPT Code(s)	
77261	77285
77262	77290
77263	77295
77280	

C.2 Medical Radiation Physics, Dosimetry, Treatment Devices, and Special Services

CPT Code(s)	
77300	77328
77301	77331
77305	77332
77310	77333
77315	77334
77321	77336
77326	77370
77327	

C.3 Stereotactic Radiation Treatment Delivery

CPT Code(s)
77371
77372
77373

C.4 Radiation Treatment Delivery

CPT Code(s)	
77401	77412
77402	77413
77403	77414
77404	77416
77406	77417
77407	77418
77408	77421
77409	77424
77411	77425

C.5 Radiation Treatment Management

CPT Code(s)
77427
77431
77432
77435
77469
77470

C.6 Hyperthermia

CPT Code(s)
77600
77605
77610
77615
77620

C.7 Clinical Brachytherapy

CPT Code(s)	
77750	77778
77761	77785
77762	77786
77763	77787
77776	77789
77777	77790

C.8 Computed Tomography Guidance

CPT Code(s)
77014

D. Modifiers

Providers 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

Inpatient, Outpatient, Office.

G. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at http://www.ncdhhs.gov/dma/plan/sp.pdf.
For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html

H. Reimbursement

Providers shall bill their usual and customary charges.
For a schedule of rates, see: http://www.ncdhhs.gov/dma/fee/

Attachment B: Billing for Treatment Management and Delivery

A. Treatment Management

Treatment management can include any of the following activities. Payments for the Radiation Oncologist services are bundled with these codes. This is true regardless of which code is billed:

a. Anesthesia
b. Care of infected skin
c. Checking of treatment charts
d. Verification of dosage, as needed
e. Continued patient evaluation, examination, written progress notes, as needed
f. Final physical examination
g. Medical prescription writing
h. Nutritional counseling
i. Pain management
j. Review and revision of treatment plan
k. Routine medical management of unrelated problem
l. Special care of ostomy
m. Written reports, progress notes
n. Follow-up examination and care for 90 days after last treatment

The following CPT codes are included in radiation treatment management during the course of the treatment and for 90 days following completion of the treatment.

CPT Code(s)	
11921	99213
16000	99214
16020	99215
16025	99238
16030	99281
36425	99282
51701	99283
51702	99284
51703	99285
97802	99354
97803	99355
99183	99356
99211	99357
99212	99360

A.1 CPT Code 77427

Requirements and limitations include the following:

a. Report as one unit for every five treatment sessions, regardless of the actual time period in which the services are furnished.
b. “Weekly” is interpreted as five treatments, not a calendar week.
c. The services need not be furnished on consecutive days.

d. Use when there are three or four sessions beyond a multiple of five at the end of a course of treatment.
e. Multiple treatment sessions furnished on the same day may be counted separately, as long as there has been a distinct break in therapy sessions.
f. Twice-daily treatment will require documentation of physician management for every five treatments.
g. Use for external beam treatments only.

A.2 CPT Code 77431

Requirements and limitations include the following:

a. Use when one or two treatments comprise the full course of therapy.
b. Do not use to report the last one or two days of a longer treatment course.
c. Use for external beam treatments only.

A.3 CPT Code 77432

Requirements and limitations include the following:

a. Complete course of treatment consists of one session.
b. This code cannot be reported for the same episode of care as CPT code 77435.
c. The same physician should not report both 77432 and the following stereotactic radiosurgery services:

CPT Code(s)
61796+
61797
61798
+61799
+61800

A.4 CPT Code 77435

Requirements and limitations include the following:

a. Complete course of treatment is one to five fractions.
b. If more than five treatments are given, code 77427 (radiation treatment management, five treatments) should be billed instead of 77435.
c. Code 77435 cannot be reported for the same episode of care as CPT code 77432.
d. The same physician should not report both 77435 and the following stereotactic radiosurgery services:

CPT Coce(s)
61796
+61797
61798
+61799
+61800
63620
+63621

A.5 CPT Codes 77469 through 77470

The use of these codes assumes that the procedure is performed once during the course of therapy, in addition to daily or weekly patient management.

B. Radiation Treatment Delivery

CPT codes include the following:

CPT Code(s)
77371 through 77373
77401 through 77416 and 77418; 77424 through 77425

Requirements and limitations for radiation treatment delivery codes (77401 through 77416 and 77418) include the following:

a. Limit to three treatments per day.

b. When more than one treatment is performed on the same day (for example, hyperfractionation), report each treatment on a separate detail line, with the appropriate number of units indicated.

Requirements and limitations for radiation treatment delivery codes 77424 through 77425 are limited to one time in the operating room.