

External Beam/Teletherapy, Brachytherapy, IMRT, SBRT/SRS, IORT, and IGRT

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PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
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CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

The purpose of this policy is to provide general information applicable to the review and appropriateness of Radiation Therapy services. Although a service, supply or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply, or procedure is not covered and the member proceeds to obtain the service, supply or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of members. NCH is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a member. Regarding Medicare cases, the applicable LCD or NCD will determine coverage of the treatment requested. If an LCD or NCD approves coverage of a treatment but does not specify the number of appropriate radiation fractions (treatments), the determination of the number of appropriate fractions will be made according to the guidance in the corresponding section of the NCH policy. In Medicare cases where there is no LCD or NCD, the determination of coverage and the appropriate number of radiation fractions will be made according to the guidance in the corresponding section of the NCH policy.

II. BACKGROUND

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 Oncology uses several distinct therapeutic modalities: Teletherapy or, 2D external beam radiation therapy (EBRT), 3D external beam radiation therapy (EBRT), electron beam therapy, intensity modulated radiation

therapy (IMRT), brachytherapy, hyperthermia, proton beam therapy, carbon ion therapy, neutron beam therapy and stereotactic radiation.

Radiation Therapy Treatment Process:

- A. Consultation
- B. Simulation
- C. Treatment Planning
- D. Treatment Delivery

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IV. DEFINITIONS

Bite Block: A restraining device generally used in the oral cavity often attached to an outside source for patient stability.

Block: A device fabricated of an energy-absorbing material such as lead or Cerrobend (Wood's metal) to shape or delineate the treatment portal to match the configuration of the desired area and to shield or protect normal structures.

Bolus: A tissue equivalent material used to change the surface deposition of a radiation beam.

Boost: The 2nd phase of a course of radiation treatment when the physician narrows down the treatment from a large area (i.e. the whole breast) to a smaller area of the body (i.e. the lumpectomy cavity).

Brachytherapy: A type of radiation therapy that utilizes radioactive isotopes (radioactive metals) for treatment of malignancies or benign conditions by placing the isotope directly on the target surface, into a body cavity (intracavitary), within the body tissues (interstitial) or near the tumor or target tissue.

Breast Separation: The distance between the entrance points of the medial and lateral tangential beams entering at the breast isocenter point plane.

Centigray (cGy): unit of ionizing radiation dose in the International System of Units (SI). A gray is the energy absorption of 1 joule per kg of irradiated material. 1 Gy is equivalent to 100 centigray/or rad. 1 centigray is equivalent to 1 rad (radiation absorbed dose).

Compensator: An irregularly shaped beam-modifying device utilized to reconfigure the beam intensity to match irregular tissue contours.

Collimator: A beam shaping device attached to the head of the treatment machine to define the initial configuration (the length and width) of the treatment portal.

Distant Metastatic: Metastatic spread of cancer to any area outside of the regional lymph nodes. (The regional lymph nodes for each specific cancer type are defined in the AJCC Cancer Staging Manual).

Dosimetry: The calculation of the radiation dose distribution within a treatment beam.

Fiducial Markers: or fiducial is an object placed in the field of view of an imaging system which appears in the image produced, for use as a point of reference or a measure. It may be either something placed into or on the imaging subject, or a mark or set of marks in the reticle of an optical instrument

Fraction: The number of treatment sessions administered. Administration of the total dose of radiation is spread out over time and delivered to the patient in a number of even parts (fractions) or treatment sessions.

Gray (Gy): unit of ionizing radiation dose in the International System of Units (SI). It is defined as the absorption of one joule of radiation energy per kilogram of matter.

Hydrogel: A water based material that is placed within the patient to provide separation and therefore protection of an organ which is adjacent to a target region or planned target volume (PTV).

Hyperfractionation: Radiation therapy delivered more than once per day.

Hypofractionation: Radiation therapy delivered over a shorter period of time (fewer days or weeks) compared to standard radiation therapy.

IMRT (Intensity Modulated Radiation Therapy): Is an advanced, noninvasive radiation treatment that uses a linear accelerator to safely deliver precise radiation to a tumor while minimizing the dose to surrounding normal tissue.

Intraoperative Radiation Therapy (IORT): An intensive radiation treatment that is administered during surgery.

Isodose: A plotting of lines or a series of lines following paths of the same dose distribution within a treatment beam.

Mold: A patient-restraining device usually constructed of plaster or thermosetting plastic that fits to the contour of the patient and restricts the motion of the patient during treatment.

Partial Mastectomy: A lumpectomy

PTV (planned target volume): A region to be targeted with radiation which may consist of gross tumor volume (GTV) or a clinical target volume (CTV) plus a margin of surrounding tissue to account for potential motion.

Port, Portal: These words are synonymous and refer to the site on the skin where the radiation beam enters the body. Field, often used as a synonym for port, will not be used in this policy.

Portal Verification: Any means of verifying the placement and configuration of the treatment portal.

RAD (radiation absorbed dose): unit used to measure the amount of radiation absorbed by an object or person, known as the “absorbed dose,” which reflects the amount of energy that radioactive sources deposit in materials through which they pass. The radiation-absorbed dose (rad) is the amount of energy (from any type of ionizing radiation) deposited in any medium (e.g., water, tissue, air). The related international system unit is the gray (Gy), where 1 Gy is equivalent to 100 rad.

Simulation: Part of the planning process that happens prior to treatment when a simulator, usually a CT, PET/CT, or MRI, is used to acquire images that will be used to plan the radiation treatments.

Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT): are advanced, noninvasive radiation treatments that administer high-dose radiotherapy to discreet tumor foci in cranial or extracranial locations respectively in 1 to 5 treatments.

Teletherapy or External Beam Radiation Therapy (EBRT): The delivery of electromagnetic energy from a treatment machine at some distance from the treatment area. External beam radiation is commonly delivered by a linear accelerator, which can deliver photons (x-rays) or electrons to the targeted area.

Volume of interest: This phrase refers to that volume within the body to which the radiation therapy is directed. In this policy, volume of interest is never synonymous with port and is preferred to other terms with (presumably) the same meaning because it is the phrase most commonly used by radiation oncologists. Treatment volume is accurate but less often used. Area of interest, used in the AMA's CPT manual, suggests a two-dimensional configuration and is, in this geometric sense, inaccurate. Target site seems to point to just the tumor itself and excludes the surrounding volume of tissue that might be of interest and other times to mean port. It should be discarded.

Wedge: A treatment beam modifying device acting to change the intensity of the treatment beam in a graduated fashion across the width or length of the treatment portal.

V. BREAST CANCER (INVASIVE CANCERS AND DCIS)

A. Post-Mastectomy

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** treatment is considered medically necessary for:
 - a. The treatment of the chest wall and regional lymph nodes with up to 33 total fractions total (28 fractions and 5 boost fractions).
 - b. Palliative treatment of the chest wall (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions total.
 - c. Treatment of the chest wall in patients with distant metastatic cancer with up to 15 fractions total.
2. **Intensity Modulated Radiation Therapy (IMRT)*** treatment (with inverse planning only and when the *Required Documentation* is submitted) is considered medically necessary with up to 33 total fractions total (28 fractions and 5 boost fractions) when **ANY** of the following apply:
 - a. The planned treatment area includes the Internal Mammary Lymph Node Chain OR
 - b. The patient's breast separation is 25cm or greater (see Definitions section for "breast separation").

Exclusion Criteria

1. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.
2. **Brachytherapy** is not considered medically necessary
3. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** are not considered medically necessary

B. Post-Lumpectomy and Lymph Node Negative Patients

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** treatment is considered medically necessary for:
 - a. Treatment of the whole breast following a lumpectomy with up to 21 fractions total (16 fractions and 5 boost fractions). Recent studies have demonstrated equivalent tumor control and cosmetic outcome in specific patient populations (i.e., lymph node negative patients) with shorter courses of therapy.^{1,4}
 - b. **3D Accelerated Partial Breast Irradiation (APBI)** with up to 10 fractions total in patients who meet the following criteria:
 - i. **Invasive ductal carcinoma** – in patients that are greater or equal to 50 years of age **AND** have negative margins **AND** have tumors that are less than or equal to 2 cm in size.

- ii. **DCIS** – in patients that have negative margins **AND** have tumors that are less than or equal to 2.5 cm in size **AND** are grade 1 or 2.
 - c. Palliative treatment of the breast (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions total.
 - d. Treatment of the breast in patients with distant metastatic cancer with up to 15 fractions total.
2. **Intensity Modulated Radiation Therapy (IMRT)*** treatment of the whole breast (with invasive planning only and when the *Required Documentation* is submitted) is considered medically necessary with up to 33 total fractions total (28 fractions and 5 boost fractions) when **ANY** of the following apply:
- a. The patient’s breast separation is 25cm or greater (see Definitions section for “breast separation”).
 - b. IMRT Accelerated Partial Breast Irradiation (APBI) with 5 fractions **OR** 10 fractions total are indicated for patients who meet the following criteria:
 - i. **Invasive ductal carcinoma** – in patients that are greater or equal to 50 years of age **AND** have negative margins **AND** have tumors that are less than or equal to 2 cm in size.
 - ii. **DCIS** – in patients that have negative margins **AND** have tumors that are less than or equal to 2.5 cm in size **AND** are grade 1 or 2.
3. **Brachytherapy** treatment is considered medically necessary for:
- a. Accelerated Partial Breast Irradiation (APBI) with brachytherapy with 10 fractions total is indicated for patients who meet the following criteria:
 - i. **Invasive ductal carcinoma** – in patients that are greater or equal to 50 years of age **AND** have negative margins **AND** have tumors that are less than or equal to 2 cm in size.
 - ii. **DCIS** – in patients that have negative margins **AND** have tumors that are less than or equal to 2.5 cm in size **AND** are grade 1 or 2.

(The use of Electronic Brachytherapy³ and AccuBoost® are considered investigational and not medically necessary)
4. **Intra-Operative Radiation Therapy (IORT)³** - Requires Clinical Review by an NCH Physician

Exclusion Criteria

- 1. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** are not considered medically necessary
- 2. **Intensity Modulated Radiation Therapy (IMRT), Brachytherapy and Intra-Operative Radiation Therapy (IORT)** are not considered medically necessary in patients with distant metastatic cancer.

C. Post-Lumpectomy and Lymph Node Positive Patients

Indications for Use/Inclusion Criteria

- 1. **3D External Beam Radiation Therapy** treatment is considered medically necessary for:
 - a. Treatment of the whole breast and the supraclavicular/axillary lymph nodes following a lumpectomy with up to 33 total fractions total (28 fractions and 5 boost fractions) when an additional field is needed to cover the supraclavicular/axillary lymph nodes.⁴
 - b. Palliative treatment of the breast (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions total.

- c. Treatment of the breast in patients with distant metastatic cancer with up to 15 fractions total.
- 2. **Intensity Modulated Radiation Therapy (IMRT)*** treatment of the whole breast (with inverse planning only and when the *Required Documentation* is submitted) is considered medically necessary with up to 33 total fractions total (28 fractions and 5 boost fractions) when **ANY** of the following apply:
 - a. The planned treatment area includes the Internal Mammary Lymph Node Chain **OR**
 - b. The patient's breast separation is 25cm or greater (see Definitions section for "breast separation").

Exclusion Criteria

- 1. **Brachytherapy** is not considered medically necessary
- 2. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** are not considered medically necessary
- 3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

D. Male Breast Cancer

- 1. Indications for radiation treatment after breast surgery in men with breast cancer are the same as for women with breast cancer

VI. CENTRAL NERVOUS SYSTEM TUMORS (CNS)

A. Primary Brain and Spinal Cord Cancers^{5,6}

Indications for Use/Inclusion Criteria

- 1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of CNS tumors including:
 - a. **Low grade glioma** (grades 1 and 2) with up to 30 fractions of 3D or IMRT, includes pilocytic astrocytoma, astrocytoma, oligodendroglioma, and oligoastrocytoma.
 - b. **High grade glioma** (grades 3 and 4) with up to 30 fractions of 3D or IMRT, includes high grade anaplastic astrocytoma, anaplastic oligodendroglioma, anaplastic oligoastrocytoma, and glioblastoma multiforme (GBM).
 - c. **Primary CNS lymphoma** with up to 25 fractions of 3D or IMRT
 - d. **Adult Medulloblastoma** with up to 31 fractions of 3D or IMRT
 - e. **Meningioma** with up to 30 fractions of 3D or IMRT
 - f. **Pituitary tumors** with up to 27 fractions of 3D or IMRT
 - g. **Ependymoma** with up to 33 fractions of 3D or IMRT for intracranial sites
 - h. **Other primary spinal cord tumors** with up to 33 fractions of 3D or IMRT
(*For the treatment of Brain Metastases, see Section XIII Metastatic Cancer, C. Brain Metastases*).
- 2. **Stereotactic Radiosurgery (SRS)** with 1-5 fractions is considered medically necessary:
 - a. For the treatment of meningiomas **OR**
 - b. For the treatment of pituitary tumors

Exclusion Criteria

- 3. **Brachytherapy** is not considered medically necessary

B. Benign Brain Lesions^{7,8,9}

Including Arteriovenous Malformations (AVM), Acoustic Neuromas or Schwannoma, and Trigeminal Neuralgia

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** - Requires Clinical Review by an NCH Physician
2. **Stereotactic Radiosurgery (SRS)** with 1-5 fractions is considered medically necessary for an AVM, Acoustic Neuroma or Schwannoma, and Trigeminal Neuralgia

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary

C. Prophylactic Cranial Irradiation (PCI) of the Brain¹⁰

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** - treatment is considered medically necessary to attempt to prevent brain metastases from small cell lung cancer with up to 10 fractions of whole brain radiation.
2. **Intensity Modulated Radiation Therapy (IMRT)** treatment is considered medically necessary to attempt to prevent brain metastases from small cell lung cancer with up to 10 fractions, only when using a hippocampal sparing whole brain planning technique.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary
2. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** treatment is not considered medically necessary

VII. GASTROINTESTINAL CANCERS

Indications for Use/Inclusion Criteria

- A. **3D External Beam Radiation Therapy** treatment is considered medically necessary in the treatment of gastrointestinal cancers including:
 1. **Rectal cancer**, for pre-operative or post-operative with up to 28 fractions.^{11,12}
 2. **Anal cancer**, for definitive treatment with up to 30 fractions.^{13,14}
 3. **Cholangiocarcinoma/Gallbladder cancer**, for definitive or post-operative treatment with up to 30 fractions.¹⁵
 4. **Esophageal cancer**, for pre-operative, post-operative and definitive treatment with up to 28 fractions.^{16,17}
 5. **Cervical Esophageal cancer**, for pre-operative, post-operative, and definitive treatment with up to 33 fractions.
 6. **Hepatocellular cancer**, with up to 33 fractions.
 7. **Gastric cancer**, for pre-operative and post-operative with up to 28 fractions.¹⁸
 8. **Pancreatic cancer**, for resected cancers with up to 28 fractions and for resectable/borderline resectable cancers with up to 30 fractions.¹⁹
 9. **For palliative treatment** of GI any Gastrointestinal cancers (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
 10. **Colon cancer** - for inoperable and T4 tumors with up to 28 fractions.

- B. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of any Gastrointestinal cancers in patients with distant metastatic cancer with up to 15 fractions total.
- C. **Intensity Modulated Radiation Therapy (IMRT)** – is indicated for the treatment of:
 1. Rectal cancer when lymph node positive with up to 28 fractions
 2. Cervical Esophageal cancer with up to 33 fractions
 3. Upper Third, middle third and lower third Esophageal cancer with up to 28 fractions
 4. Gastric cancer with up to 28 fractions
 5. Pancreatic Cancers for resected cancers with up to 28 fractions and resectable/borderline resectable cancers with up to 30 fractions
 6. Colon cancer when inoperable or T4 disease with up to 28 fractions
- D. **Intensity Modulated Radiation Therapy (IMRT)** is indicated in the treatment for pre-operative rectal cancer with 5 fractions.²⁰
- E. **Intensity Modulated Radiation Therapy (IMRT)** is indicated in the treatment of anal cancers with 30 fractions.²¹
- F. **Intensity Modulated Radiation Therapy (IMRT)** is indicated in the treatment of Cholangiocarcinoma/Gallbladder cancer with 15 to 30 fractions.
- G. **Intensity Modulated Radiation Therapy (IMRT)** is indicated in the treatment of Hepatocellular cancer with 15 to 33 fractions.
- H. **Intra-Operative Radiation Therapy (IORT)** requires Clinical Review by an NCH Physician for Rectal and Pancreatic cancer.
- I. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation therapy** – is indicated for the treatment of:
 1. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** treatment with 1-5 fractions is considered medically necessary for the treatment of Pancreatic Cancer **ONLY** when the pancreatic cancer is surgically inoperable.²²
 2. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** treatment with 1-5 fractions is considered medically necessary for the treatment of Cholangiocarcinoma/Gallbladder cancer.
 3. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** treatment with 1-5 fractions is considered medically necessary for the treatment of Hepatocellular cancer.

Exclusion Criteria

- A. **Brachytherapy** is not considered medically necessary.
- B. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary for the treatment of Rectal, Anal, Esophageal cancer, Gastric cancers.
- C. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

VIII. GENITOURINARY CANCERS

A. Low-Risk Prostate Cancer^{23,24,25}

(Stage T1c-T2a AND Gleason Score \leq 6 AND PSA < 10)

Indications for Use/Inclusion Criteria

1. **Brachytherapy** is considered medically necessary:
 - a. For treatment in low-risk prostate cancer with 1 LDR radiation seed implantation
 - b. For treatment in low-risk prostate cancer with 2 HDR brachytherapy treatments
2. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary:
 - a. For treatment in low-risk prostate cancer with 28 fractions of IMRT (moderate hypofractionation)
 - b. For treatment in low-risk prostate cancer with 40 fractions of IMRT in patients excluded from hypofractionation due to a prostate of 90 grams or larger **OR** a history of inflammatory bowel disease **OR** a history of superficial bladder cancer **OR** when the International Prostate Symptom Score (IPSS) is 15 or greater AND documented in the submitted records (either by submitting the IPSS scoring sheet or by mentioning the IPSS in the physician's clinical notes).
3. **Stereotactic Body Radiation Therapy (SBRT)** is considered medically necessary with 1-5 fractions for treatment of low-risk prostate cancer.

B. Favorable Intermediate-Risk Prostate Cancer^{23,24,25}

(Stage T2b-c OR Gleason Score = 7 OR PSA level between 10 – 20)

*Favorable and Unfavorable Intermediate risk are defined by the treating physician.

Indications for Use/Inclusion Criteria

1. **Brachytherapy** is considered medically necessary:
 - a. For treatment in favorable intermediate-risk with 1 LDR radiation seed implantation
 - b. For treatment in favorable intermediate risk with 2 HDR brachytherapy treatments
2. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary:
 - a. For treatment in favorable intermediate risk prostate cancer with 28 fractions of IMRT (moderate hypofractionation)
 - b. For treatment in favorable intermediate risk prostate cancer with 40 fractions of IMRT in patients excluded from hypofractionation due to a prostate of 90 grams or larger **OR** a history of inflammatory bowel disease **OR** a history of superficial bladder cancer **OR** when the International Prostate Symptom Score (IPSS) is 15 or greater AND documented in the submitted records (either by submitting the IPSS scoring sheet or by mentioning the IPSS in the physician's clinical notes).
3. **Stereotactic Body Radiation Therapy (SBRT)** with 1-5 fractions is considered medically necessary for the treatment of favorable intermediate-risk prostate cancer.

C. Unfavorable Intermediate-Risk Prostate Cancer^{23,24,25}

(Stage T2b-c OR Gleason Score = 7 OR PSA level between 10 – 20)

*Favorable and Unfavorable Intermediate risk are defined by the treating physician.

Indications for Use/Inclusion Criteria

1. **Brachytherapy** is considered medically necessary:

- a. For treatment in unfavorable intermediate-risk with 1 LDR radiation seed implantation when combined with 28 IMRT treatments
- b. For treatment in unfavorable intermediate-risk with 2 HDR brachytherapy treatments when combined with 28 IMRT treatments
2. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary:
 - a. For treatment in unfavorable intermediate risk prostate cancer with 28 fractions of IMRT (moderate hypofractionation)
 - b. For treatment in unfavorable intermediate risk prostate cancer with 40 fractions of IMRT in patients excluded from hypofractionation due to a prostate of 90 grams or larger **OR** a history of inflammatory bowel disease **OR** a history of superficial bladder cancer **OR** when the International Prostate Symptom Score (IPSS) is 15 or greater **AND** documented in the submitted records (either by submitting the IPSS scoring sheet or by mentioning the IPSS in the physician's clinical notes).
3. **Stereotactic Body Radiation Therapy (SBRT)** with 1-5 fractions is considered medically necessary for the treatment of unfavorable intermediate-risk prostate cancer.

D. High-Risk Prostate Cancer^{23,24,25}

(Stage T3 **OR** Gleason Score = 8–10 **OR** PSA level greater than 20)

Indications for Use/Inclusion Criteria

1. **Brachytherapy** is considered medically necessary:
 - a. For treatment in high-risk prostate cancer with 1 LDR radiation seed implantation when combined with 28 IMRT treatments
 - b. For treatment with high-risk prostate cancer with 2 HDR brachytherapy treatments when combined with 28 IMRT treatments
2. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary:
 - a. For treatment in high-risk prostate cancer with 28 fractions of IMRT (moderate hypofractionation)
 - b. For treatment in high-risk prostate cancer with 40 fractions of IMRT in patients excluded from hypofractionation due to a prostate of 90 grams or larger **OR** a history of inflammatory bowel disease **OR** a history of superficial bladder cancer **OR** when the treatment field includes treating the bilateral pelvic lymph nodes **OR** when the International Prostate Symptom Score (IPSS) is 15 or greater **AND** documented in the submitted records (either by submitting the IPSS scoring sheet or by mentioning the IPSS in the physician's clinical notes).
3. **Stereotactic Body Radiation Therapy (SBRT)** with 1-5 fractions is considered medically necessary for the treatment of high-risk prostate cancer.

E. Prostate Cancer with Positive Regional Lymph Nodes (N1)^{23,24,25}

Indications for Use/Inclusion Criteria

1. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary in the treatment of prostate cancer with positive lymph nodes (N1):
 - a. For treatment of lymph node positive prostate cancer with 40 fractions of IMRT

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.

F. Prostate Cancer with Low Volume Metastatic Disease²⁶

Indications for Use/Inclusion Criteria

1. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary in the treatment of the prostate in patients with a low volume of distant metastatic disease with 20 fractions only if **ALL** of the following conditions are met:
 - a. There is a total of 3 or fewer metastatic bone lesions **AND**
 - b. No visceral metastases (i.e., no metastases in the lungs, brain, or liver) **AND**
 - c. Documentation of the extent of the metastatic disease has been provided through a recent full body PET/CT scan report **OR** through reports of recent CT scans of the Chest, Abdomen, and Pelvis.
2. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of prostate cancer in patients with distant metastatic disease who have 4 or more bone lesions or visceral metastases.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary for distant metastatic cancer in patients with 4 or more metastatic bone lesions or in patients with visceral metastases.

G. Post-Prostatectomy Radiation for Prostate Cancer²³

Indications for Use/Inclusion Criteria

1. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary in the treatment of post-prostatectomy prostate cancer with 36 fractions when **ANY** of the following apply:
 - a. Pathological T3 disease
 - b. Seminal vesical invasion
 - c. Positive surgical margin
 - d. PSA that remains detectable after prostatectomy
 - e. PSA that begins rising in 2 post-postprostatectomy measurements

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.

H. Prostate Cancer/Prophylactic Breast Radiation

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** for prophylactic breast radiation in men receiving Androgen Deprivation Therapy (to prevent gynecomastia) is considered medically necessary with up to 3 fractions.

I. Bladder Cancer²⁷

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of bladder cancer:

- a. For definitive treatment (bladder conservation) with up to 33 fractions.
- b. For post-operative treatment with negative margins with up to 25 fractions.
- c. For post-operative treatment with positive margins with up to 30 fractions.
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of bladder cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of the bladder in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

J. Urethral Cancer

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of urethral cancer:
 - a. For definitive treatment (organ conservation) with up to 35 fractions.
 - b. For post-operative treatment with negative margins with up to 25 fractions.
 - c. For post-operative treatment with positive margins with up to 30 fractions.
 - d. For post-operative treatment with positive margins **AND** gross residual disease with up to 35 fractions.
 - e. For recurrent **AND** gross disease with up to 37 fractions.
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of urethral cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of urethral cancer in patients with distant metastatic disease with up to 15 fractions.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

K. Penile Cancer

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of penile cancer:
 - a. For definitive treatment with up to 35 fractions
 - b. For post-operative treatment following a penectomy with positive margins with up to 30 fractions.

2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of penile cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of penile cancer in patients with distant metastatic disease with up to 15 treatments.
4. **Brachytherapy** may be considered medically necessary for definitive treatment **OR** with post-operative treatment following a penectomy (Requires Clinical Review by an NCH Physician)

Exclusion Criteria

1. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

IX. GYNECOLOGICAL CANCERS

A. Cervical Cancer²⁸

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary for non-surgical definitive treatment:
 - a. In combined modality therapy of cervical cancer with 28 fractions **AND** a brachytherapy boost of 2 LDR insertions
 - b. In combined modality therapy of cervical cancer with 28 fractions **AND** a brachytherapy boost of 5 HDR insertions
2. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)²⁸** are considered medically necessary for post-hysterectomy treatment:
 - a. In combined modality therapy of cervical cancer with 28 fractions **AND** a brachytherapy boost of up to 3 HDR vaginal cylinder insertions
3. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of cervical cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
4. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of cervical cancer in patients with distant metastatic disease with up to 15 treatments.
5. **Brachytherapy** is considered medically necessary in combined modality therapy (see above)

Exclusion Criteria

1. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

B. Endometrial Cancer^{29,30}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary for post-hysterectomy treatment of endometrial cancer with:
 - a. 28 fractions of 3D or IMRT
 - b. Combined modality therapy with 28 fractions **AND** a brachytherapy boost with up to 5 HDR vaginal cylinder insertions

2. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary for non-surgical definitive treatment of endometrial cancer with:
 - a. Combined modality therapy with 28 fractions **AND** a brachytherapy boost with up to 3 HDR insertions
3. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary for pre-operative treatment of endometrial cancer with:
 - a. Combined modality therapy with 28 fractions **AND** a brachytherapy boost with up to 2 HDR insertions
4. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of endometrial cancer (to slow progression of the local disease or to palliative symptoms) with up to 15 fractions.
5. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of endometrial cancer in patients with distant metastatic disease with up to 15 treatments.
6. **Brachytherapy** is considered medically necessary:
 - a. When brachytherapy is combined with 3D or IMRT treatments (see above)
 - b. For post-hysterectomy treatment of endometrial cancer with up to 5 HDR insertions as stand-alone radiation treatment
 - c. For non-surgical definitive treatment of endometrial cancer with up to 5 HDR insertions as stand-alone radiation treatment

Exclusion Criteria

1. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

C. Vulvar Cancer³¹

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary for post-operative treatment of vulvar cancer with:
 - a. 28 fractions with 3D or IMRT
 - b. Combined modality therapy with 28 fractions **AND** a brachytherapy boost with up to 5 HDR treatments
2. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary for non-surgical definitive treatment of vulvar cancer with:
 - a. 36 fractions with 3D or IMRT
3. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of vulvar cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
4. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of vulvar cancer in patients with distant metastatic disease with up to 15 treatments.
5. **Brachytherapy** is considered medically necessary:
 - a. When brachytherapy is combined with 3D or IMRT treatments (see above)

Exclusion Criteria

1. **Stereotactic Body Radiation Therapy (SBRT)** is not considered to be medically necessary

2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

D. Vaginal Cancer

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary for post-operative treatment of vaginal cancer with:
 - a. 28 fractions with 3D or IMRT
2. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary for non-surgical definitive treatment of vaginal cancer with:
 - a. 35 fractions with 3D or IMRT
 - b. Combined modality therapy with 35 fractions **AND** a brachytherapy boost with up to 5 HDR treatments
3. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of vaginal cancer (so slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
4. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of vaginal cancer in patients with distant metastatic disease with up to 15 treatments.
5. **Brachytherapy** is considered medically necessary:
 - a. When brachytherapy is combined with 3D or IMRT treatments (see above)

Exclusion Criteria

1. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

X. HEAD AND NECK CANCERS

A. Oral Cavity Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of cancers of the oral cavity:
 - a. For non-surgical definitive treatment with up to 35 fractions
 - b. For post-operative treatment with up to 33 fractions
 - c. In combination with brachytherapy (see below) with up to 25 fractions of 3D or IMRT
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of oral cavity cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of oral cavity cancer in patients with distant metastatic disease with up to 15 treatments.
4. **Brachytherapy** is considered medically necessary in selected patients:
 - a. As a boost of 7 HDR brachytherapy treatments in combination with 25 fractions of 3D or IMRT
 - b. As a boost of 1 LDR brachytherapy treatment in combination with up to 25 fractions 3D or IMRT
 - c. As sole treatment with up of 10 HDR brachytherapy treatments

- d. As sole treatment with 1 LDR brachytherapy treatment

Exclusion Criteria

1. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

B. Oropharynx Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of cancers of the oropharynx:
 - a. For non-surgical definitive treatment with up to 35 fractions
 - b. For post-operative treatment with up to 33 fractions
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of oropharynx cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of oropharynx cancer in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

C. Hypopharynx Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of cancers of the hypopharynx:
 - a. For non-surgical definitive treatment with up to 35 fractions
 - b. For post-operative treatment with up to 33 fractions
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of hypopharynx cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of hypopharynx cancer in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

D. Nasopharynx Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of cancers of the nasopharynx:

- a. For non-surgical definitive treatment with up to 39 fractions
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of nasopharynx cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of nasopharynx cancer in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

E. Supraglottic Larynx Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of cancers of the supraglottic larynx:
 - a. For non-surgical definitive treatment with up to 35 fractions
 - b. For post-operative treatment with up to 33 fractions
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of supraglottic larynx cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of supraglottic larynx cancer in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

F. Glottic Larynx Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of cancers of the glottic larynx:
 - a. For non-surgical definitive treatment of early stage T1N0 with up to 28 fractions with hypofractionation
 - b. For non-surgical definitive treatment of early stage T2N0 with up to 29 fractions with hypofractionation
 - c. For non-surgical definitive treatment of any stage (except metastatic Stage IV patients) with up to 35 treatments
 - d. For post-laryngectomy treatment of any stage (except metastatic Stage IV patients) with up to 33 treatments
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of glottic larynx cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.

3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of glottic larynx cancer in patients with distant metastatic disease with up to 15 treatments.
4. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary in the treatment of cancers of the glottic larynx:
 - a. For non-surgical definitive treatment of only stage III and non-metastatic Stage IVA and Stage IVB patients who do not have distant metastatic disease with up to 35 treatments.
 - b. For post-laryngectomy treatment of any stage, non-metastatic patient with up to 33 treatments.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary for stage I-II glottic larynx cancer and in patients with distant metastatic cancer.

G. Salivary Gland Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of cancers of the salivary glands:
 - a. For non-surgical definitive treatment with up to 35 fractions
 - b. For post-operative treatment with up to 33 fractions
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of salivary gland cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of salivary gland cancer in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

H. Maxillary Sinus Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary in the treatment of non-metastatic cancers of the maxillary sinus:
 - a. For non-surgical definitive treatment with up to 35 fractions
 - b. For post-operative treatment with up to 33 fractions
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of maxillary sinus cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of maxillary sinus cancer in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.

2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

I. Cancers of the Lip^{32,33,34}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of cancers of the lip:
 - a. For non-surgical definitive treatment with up to 35 fractions
 - b. For post-operative treatment with up to 33 fractions
 - c. In combination with brachytherapy (see below) with up to 25 fractions of 3D or IMRT
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of lip cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of lip cancer in patients with distant metastatic disease with up to 15 treatments.
4. **Brachytherapy** is considered medically necessary in selected patients:
 - a. As a boost of 7 HDR brachytherapy treatments in combination with 25 fractions of 3D or IMRT
 - b. As a boost of 1 LDR brachytherapy treatment in combination with up to 25 fractions 3D or IMRT
 - c. As sole treatment with up of 10 HDR brachytherapy treatments
 - d. As sole treatment with 1 LDR brachytherapy treatment

Exclusion Criteria

1. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

J. Occult/Unknown Primary Head and Neck Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of occult/unknown primary cancers:
 - a. For non-surgical definitive treatment with up to 35 fractions
 - b. For post-operative treatment with up to 33 fractions
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of occult/unknown primary head and neck cancer (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of occult/unknown primary head and neck cancer in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary

3. Intensity Modulated Radiation Therapy (IMRT) is not considered medically necessary in patients with distant metastatic cancer.

K. Re-irradiation of a Head and Neck Cancer^{32,33,34}

Indications for Use/Inclusion Criteria

1. 3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT) are considered medically necessary in the re-irradiation treatment of recurrent head and neck cancers:
 - a. For non-surgical definitive treatment with up to 35 fractions
 - b. For post-operative treatment with up to 33 fractions

Exclusion Criteria

1. Brachytherapy is not considered medically necessary.
2. Stereotactic Body Radiation Therapy (SBRT) is not considered medically necessary.

XI. LUNG CANCERS

A. Early Stage I-II Non-Small Cell Lung Cancer (NSCLC - definitive treatment)

Indications for Use/Inclusion Criteria

1. 3D External Beam Radiation Therapy is considered medically necessary with up to 35 fractions
2. Intensity Modulated Radiation Therapy (IMRT) is considered medically necessary with up to 10 fractions
3. Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary with up to 5 fractions in patients that have stage I OR stage IIA (for tumors greater than 5 cm OR tumors with positive lymph nodes, SBRT is not considered medically necessary).

Exclusion Criteria

1. Brachytherapy is not considered medically necessary.
2. Intensity Modulated Radiation Therapy (IMRT) for more than 10 fractions is not considered medically necessary.

2. Stage III NSCLC (definitive and pre-operative treatment)

Indications for Use/Inclusion Criteria

1. 3D External Beam Radiation Therapy is considered medically necessary with up to 35 fractions OR
2. Intensity Modulated Radiation Therapy (IMRT) is considered medically necessary with up to 35 fractions.

Exclusion Criteria

1. Brachytherapy is not considered medically necessary.
2. Stereotactic Body Radiation Therapy (SBRT) is not considered medically necessary.

B. Stage I-III NSCLC (postoperative OR local recurrence)

Indications for Use/Inclusion Criteria

1. 3D External Beam Radiation Therapy is considered medically necessary with up to 35 fractions
2. Intensity Modulated Radiation Therapy (IMRT) is considered medically necessary with up to 35 fractions

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.

C. Palliative Treatment and Treatment of Patients with Distant Metastatic Disease

1. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of NSCLC (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions
2. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of NSCLC in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

1. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

D. Limited Stage Small Cell Lung Cancer (SCLC)

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary with up to 35 fractions given one fraction per day.
2. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary with up to 35 fractions given once per day.
3. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary for 30 fractions given twice per day (BID).
4. **Stereotactic Body Radiation Therapy (SBRT)*** is considered medically necessary with up to 5 fractions in patients that have limited stage SCLC with tumors 5 cm or smaller (for tumors greater than 5 cm **OR** tumors with positive lymph nodes, SBRT is **not** considered medically necessary).

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.

E. Extensive Stage SCLC (Distant Metastatic Disease – Stage IV)

1. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of extensive stage SCLC (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions

Exclusion Criteria

1. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

F. Prophylactic Cranial Irradiation (PCI)^{39,40}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** - treatment is considered medically necessary to attempt to prevent brain metastases from small cell lung cancer with up to 10 fractions of whole brain radiation.
2. **Intensity Modulated Radiation Therapy (IMRT)** treatment is considered medically necessary to attempt to prevent brain metastases from small cell lung cancer with up to 10 fractions, only when using a hippocampal sparing whole brain planning technique.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** treatment is not considered medically necessary.

XII. LYMPHOMAS

A. Hodgkin's Lymphoma^{41,42}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary with 10 to 20 fractions in Hodgkin's lymphoma.
2. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary with 10 to 20 fractions for Hodgkin's lymphoma in the:
 - a. Head & Neck region
 - b. Mediastinal region

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

B. Non-Hodgkin's Lymphoma^{41,43,44}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary with 10 to 20 fractions in Non-Hodgkin's lymphoma.
2. **3D External Beam Radiation Therapy** is considered medically necessary for palliative treatment with 2 fractions.
3. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary with 10 to 20 fractions for Non-Hodgkin's lymphoma in the:
 - a. Head & Neck region
 - b. Mediastinal region

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

XIII. METASTATIC CANCER

A. Body Metastases

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary with up to 15 fractions to any treatment site except bone or brain metastases.
2. **3D External Beam Radiation Therapy** is considered medically necessary for the treatment of metastatic spread to the Bone (i.e., femur, spinal bones, skull, pelvis, etc.) with either 1, 5 or 10 fractions.^{48,49}

3. Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary for the treatment of Oligometastatic (OM) spread or Oligoprogressive (OP) spread with up to 5 fractions of SBRT. All SBRT requests for treatment of Oligometastatic Spread or Oligoprogressive spread require Clinical Review by an NCH Physician.
4. **Oligometastatic Spread (OM)**^{45,46,47} is defined as limited metastatic disease in a patient with a total of 1-3 metastatic tumors present at the time of the initial cancer diagnosis or within 3 months of the initial treatment when:
 - a. The primary tumor is controlled with no progression at the primary site **AND**
 - b. Sufficient documentation of the extent of the metastatic disease has been provided to NCH (either with a PET/CT scan report **OR** with CT scan reports of the Chest, Abdomen, & Pelvis). These scans provide a recent evaluation of the extent of the patient's metastatic disease and therefore must be performed no more than 2 months prior to the Treatment Start Date (TSD).
5. **Oligoprogressive (OP) Spread** is defined as the development of limited metastatic tumor progression, generally but not always limited to 1-5 metastases when:
 - a. These new metastases developed after an initially successful course of systemic therapy was given to a patient with metastatic disease **AND**
 - b. The primary tumor is controlled with no progression at the primary site **AND**
 - c. Sufficient documentation of the extent of the metastatic disease has been provided to NCH (either with a PET/CT scan report **OR** with CT scan reports of the Chest, Abdomen, & Pelvis). These scans provide a recent evaluation of the extent of the patient's metastatic disease and therefore must be performed no more than 2 months prior to the Treatment Start Date (TSD).

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary.

B. Brain Metastases^{50,51,52,53}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** - treatment is considered medically necessary with up to 10 fractions.
2. **Intensity Modulated Radiation Therapy (IMRT)** treatment with up to 10 fractions is considered medically necessary **ONLY**:
 - a. When using a hippocampal sparing whole brain planning technique
3. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** treatment in 1-5 fractions is considered medically necessary when **ALL** of the following apply:
 - a. When the patient has a performance status of 0, 1, or 2
 - b. When all lesions can be treated in a single treatment plan in a single fraction (for SRS) **OR** with 2 to 5 fractions (of SBRT)

Exclusion Criteria

1. **Brachytherapy** is not considered to be medically necessary.

XIV. MYELOMA

A. Solitary Plasmacytoma⁵⁴

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary with up to 25 fractions for solitary plasmacytomas.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary (requests for IMRT will be reviewed and approved when treatment with 3D external beam would exceed the tolerance of organs at risk (OARs)).
3. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.

B. Multiple Myeloma⁵⁴

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary with up to 10 fractions for multiple myeloma.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary.
3. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.

XV. PEDIATRIC MALIGNANCIES

Indications for Use/Inclusion Criteria

- A. NCH recommends that pediatric cancer patients (18 years or younger) who require radiation treatment, should be treated by Radiation Oncologists who have considerable clinical experience treating pediatric patients. Radiation Oncologists who specialize in this patient population will have the discretion to choose the treatment modality **AND** the appropriate number of fractions that are needed to treat pediatric patients (including 3D conformal external beam, Intensity Modulated Radiation Therapy (IMRT), Stereotactic Body Radiation Therapy (SBRT/SRS) or Brachytherapy). Requests for the ancillary CPT codes (i.e., for treatment planning, imaging, immobilization, physics, etc.) that are submitted in each case will require review by a First Level Reviewer (FLR) and only ancillary CPT codes submitted in the appropriate quantities will be approved. Requests for Proton Beam Radiation Therapy (PBRT) treatment will require review by a physician Clinical Reviewer (CR).

XVI. RE-IRRADIATION

Re-irradiation is defined as a request for radiation treatment to an area of the body that has already received prior radiation to that same area. It does not apply to a situation where a patient has received radiation treatment to one area of the body (i.e. the lung) and now requires radiation to a completely separate area of the body (i.e. the femur). In general, treatments such as IMRT and SRS/SBRT in the context of re-irradiation are considered medically necessary since the organs at risk in the previously treated area are usually at or near their maximum tolerance levels. Greater treatment accuracy with IMRT or SRS/SBRT is therefore required.

- A. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary.
- B. **Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)** are considered medically necessary.

XVII. SARCOMA

A. Soft Tissue Sarcoma of an Extremity/Body Wall/Head and Neck (Pre-operative)⁵⁷

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary in the pre-operative treatment of a soft tissue sarcoma with up to 25 fractions.
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of sarcoma (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of sarcoma in patients with distant metastatic disease with up to 15 treatments.
4. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary in the pre-operative treatment of a soft tissue sarcoma with up to 25 fractions as sole treatment

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

B. Soft Tissue Sarcoma of an Extremity/Body Wall/Head and Neck (Post-operative)⁵⁷

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary in the post-operative treatment of a soft tissue sarcoma:
 - a. With up to 25 treatments followed by a brachytherapy boost
 - b. With up to 35 fractions as sole treatment
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of sarcoma (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of sarcoma in patients with distant metastatic disease with up to 15 treatments.
4. **Brachytherapy** is considered medically necessary as a post-operative boost in combination with 3D or IMRT treatments (see above):
 - a. With 1 LDR brachytherapy boost treatment combined with up to 25 treatments of 3D or IMRT radiation
 - b. With 10 HDR brachytherapy boost treatments combined with up to 25 treatments of 3D or IMRT radiation
5. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary in the post-operative treatment of a soft tissue sarcoma with up to 35 fractions as sole treatment

Exclusion Criteria

1. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

C. Retroperitoneal/Abdominal Sarcoma^{58,59}

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary in the pre-operative or post-operative treatment of a retroperitoneal/abdominal sarcoma with up to 25 fractions.
2. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of sarcoma (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions
3. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of sarcoma in patients with distant metastatic disease with up to 15 treatments.
4. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically in the pre-operative or post-operative treatment of a retroperitoneal/abdominal sarcoma with up to 25 fractions as sole treatment

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.
3. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

D. Desmoid Tumors (Aggressive Fibromatosis)

Indications for Use/Inclusion Criteria

1. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of desmoid tumors with up to 25 fractions.

Exclusion Criteria

1. **Brachytherapy** is not considered medically necessary.
2. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary.
3. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary.

XVIII. SKIN CANCERS^{60,61,62,63,64}

Indications for Use/Inclusion Criteria

- A. **2D or 3D External Beam Radiation Therapy** is considered medically necessary in the treatment of:
 1. **Basal Cell and Squamous Cell Carcinoma** – For tumors less than 2 cm with up to 20 fractions
 2. **Basal Cell and Squamous Cell Carcinoma** – For tumors greater than 2 cm with up to 30 fractions
 3. **Melanoma** – with up to 35 fractions
 4. **Merkel Cell Carcinoma** – with up to 30 fractions
 5. **Dematofibrosarcoma Protuberans (DFSP)** – with up to 30 fractions
- B. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of skin cancers (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions
- C. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of skin cancers in patients with distant metastatic disease with up to 15 treatments.

- D. **Brachytherapy** is considered medically necessary for the treatment of Basal Cell and Squamous Cell Carcinomas with up to 10 fractions of HDR (radioisotope based). The use of Electronic Brachytherapy is considered investigational and not medically necessary.
- E. **Intensity Modulated Radiation Therapy (IMRT)** is considered medically necessary in the treatment of Squamous cell, Melanoma, or Merkel cell cancers only when:
 1. Treatment includes treating a **lymph node chain** when lymph node spread is suspected with up to 35 fractions
- F. Superficial Radiation or Orthovoltage Radiation is considered medically necessary for the treatment of Basal Cell and Squamous Cell Carcinomas with up to 18 fractions.

Exclusion Criteria

- A. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
- B. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

XIX. THYMOMA/THYMIC CANCERS^{65,66}

Indications for Use/Inclusion Criteria

- A. **3D External Beam Radiation Therapy OR Intensity Modulated Radiation Therapy (IMRT)** are considered medically necessary in the treatment of thymoma and thymic tumors with up to 35 fractions.
- B. **3D External Beam Radiation Therapy** is considered medically necessary for the palliative treatment of a thymoma or thymic tumor (to slow progression of the local disease or to palliate symptoms) with up to 15 fractions.
- C. **3D External Beam Radiation Therapy** is considered medically necessary in the treatment of thymoma or thymic tumor in patients with distant metastatic disease with up to 15 treatments.

Exclusion Criteria

- A. **Brachytherapy** is not considered medically necessary
- B. **Stereotactic Body Radiation Therapy (SBRT)** is not considered medically necessary
- C. **Intensity Modulated Radiation Therapy (IMRT)** is not considered medically necessary in patients with distant metastatic cancer.

XX. OPTIONAL SERVICES

A. Image-Guided Radiation Therapy (77387, 77014, G6002, G6017)

Indications - IGRT is indicated when **ANY** of the following apply:

1. When Intensity Modulated Radiation Therapy (IMRT) is being utilized
2. When Proton Beam Radiation Therapy (PBRT) is being utilized
3. When the patient has had prior radiation and the current treatment field abuts the previously irradiated treatment area
4. When a left-sided breast cancer is being treated **AND** a deep inspiration breath hold technique (DIBH) is being utilized
5. When 3D accelerated partial breast irradiation (APBI) is being utilized
6. When fiducial markers have been implanted for the purpose of IGRT tracking

7. When the patient is morbidly obese (BMI>35) and there is considerable variation in the daily patient set-up affecting treatment accuracy

B. Respiratory Motion Management (77293)

Indications – Respiratory Motion Management is used for the purpose of precisely tracking the movement of a targeted tumor as it moves during the respiratory cycle.

Respiratory Motion Management is indicated when **ALL** of the following apply:

1. When treating lung, thoracic, liver, biliary, or pancreatic cancers which move significantly as the patient is breathing.
2. A 4D CT simulation must be performed. The 4D CT captures CT images throughout the entire (inspiration, expiration, and neutral breath positions) respiratory cycle. (Note - This service is not used for treating breast cancer with a Deep Inspiration Breath Hold (DIBH) technique).
3. When the patient's respiratory motion is acquired using respiratory sensors and/or external fiducials and then registered to the 4D CT images.
4. When a Radiation Oncologist contours the moving tumor volume and creates an ITV.

C. Special Treatment Procedure (77470)

Indications – The Special Treatment Procedure is indicated when **ANY** of the following apply:

1. When concurrent chemotherapy is being utilized
2. When brachytherapy is being utilized
3. When proton therapy is being utilized
4. When total body irradiation is being utilized
5. When treating a pediatric cancer patient under anesthesia
6. When hyperthermia is being utilized
7. When the patient has had prior radiation and the current treatment field abuts the previously irradiated treatment field
8. When Stereotactic Body Radiation Therapy (SBRT) or when Stereotactic Radiosurgery (SRS) is being utilized

D. Special Physics Consult (77370)

Indications – The Special Physics Consult is indicated when **ANY** of the following apply:

1. When brachytherapy is being utilized
2. When image fusion (with a PET, CT, or MRI) is performed during the planning process by a medical physicist
3. When the patient has had prior radiation and the current treatment field abuts the previously irradiated treatment field
4. When analysis of dose to a fetus is required
5. When analysis of dose to a pacemaker/defibrillator is required
6. When Stereotactic Body Radiation Therapy (SBRT) or when Stereotactic Radiosurgery (SRS) is being utilized

E. Simulation (77263), (77280, 77285 or 77290), (77332 or 77334)

Indications – A simulation (i.e., the process of acquiring the images necessary for radiation treatment planning) occurs at the beginning of the planning process for each patient who will be

receiving radiation treatment. Since a simulation is a required part of the treatment process, NCH automatically approves certain CPT codes when they are appropriately selected during the preauthorization process.

XXI. Cpt coding & the National Correct Coding Initiative

- A. The NCCI (National Correct Coding Initiative) was an initiative taken by CMS. Per the CMS website, “The CMS developed the National Correct Coding Initiative (NCCI) to promote national correct coding methodologies and to control improper coding leading to inappropriate payment in Part B claims. The CMS developed its coding policies based on coding conventions defined in the American Medical Association's CPT Manual, national and local policies and edits, coding guidelines developed by national societies, analysis of standard medical and surgical practices, and a review of current coding practices.” “The purpose of the NCCI Procedure-to-Procedure (PTP) edits is to prevent improper payment when incorrect code combinations are reported.” “The purpose of the NCCI MUE program is to prevent improper payments when services are reported with incorrect units of service.” The CCI and MUE edits are readily available on the CMS website so that providers and hospitals can stay informed and continually update their billing and coding practices to avoid any unnecessary denials. NCH evaluates the CPT codes and quantities of each case submitted for approval. The goal of this process is to improve compliance of the codes submitted with the regulations established by CMS, the NCCI, and the AMA coding manual. Changes by NCH staff to correct any CPT coding errors in a case must only occur after approval is granted by the provider office.
- B. Some physician offices require prior authorization before performing any services (i.e., the simulation). In these cases, we will approve several codes specific to the simulation only (CPT 77290 or 77280, 77332 or 77334 and 77263). These codes should not be submitted again as duplicates when the physician office submits the remainder of the treatment codes for prior authorization.

XXII. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

XXIII. ATTACHMENTS

- A. None

XXIV. REFERENCES

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