I. PURPOSE

The purpose of this policy is to provide general information applicable to the review and appropriateness of Radiation Therapy External Beam/Teletherapy 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.

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

External beam radiation is the most widely used type of radiation therapy and uses photon beams. External beam radiation can be used to treat large areas of the body. It can treat more than one area, such as the main tumor and nearby lymph nodes. External radiation is usually given daily over several weeks. External beam radiation therapy may be used independently as the sole treatment or as an adjunctive treatment in combination with other radiation modalities, surgery, chemotherapy and/or others. External beam radiation can be delivered as standard fraction therapy (usually 180-200 cGy daily) or as hypofractionated care at doses of 210-400 cGy each day. Extreme hypofractionated radiation refers to the use of greater than 400cGy daily and is also called Stereotactic Body Radiation Therapy (SBRT) or Stereotactic Radiosurgery (SRS).

Radiation Therapy Treatment Process:

1. Consultation
2. Simulation
3. Treatment Planning
4. Treatment Delivery

III. 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.

**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.

**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. [1]

**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:**

**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.

**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:** The use of a simulator, or other means, to determine the various treatment portal outlines and orientation to be used in the course of radiation therapy.

**Simulator:** A radiation generator operating in the diagnostic x-ray range. A simulator has the mechanical
capability to orient a radiation beam toward a patient with parameters imitating the geometry of the proposed therapy while affording direct x-ray fluoroscopic visualization and roentgenographic images of the area. This machine is not capable of delivering radiation therapy.

**Stent:** A splint-restraining device generally used in the oral cavity. The device is usually constructed of acrylic or some other dental material but may incorporate lead or other energy absorbing material to protect some portion of the cavity from direct dose deposition.

**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.

### IV. POLICY

1. **Medicare** – For Medicare and Medicare Advantage enrollees, the coverage policies of CMS (Centers for Medicare and Medicaid Services) may take precedence over Company’s guidelines.

2. External Beam Radiation Therapy meets the definition of medical necessity for the following indications:

3. External Beam Radiation Therapy is considered **medically necessary for Basal Cell and Squamous Cell Skin Cancers** when the following criteria are met:
   a. Definitive treatment for a cancer in a cosmetically significant location in which surgery would be disfiguring
   b. Adequate surgical margins have not been achieved and further resection is not possible
   c. Definitive management of large cancers as an alternative to major resection requiring significant plastic repair
   d. Definitive management of large cancers that are considered inoperable
   e. Definitive, preoperative, or postoperative adjuvant therapy for cancers at risk for local or regional recurrence due to perineural, lymphovascular invasion, and/or metastatic adenopathy
   f. Definitive management for non-surgical candidates

4. External Beam Radiation Therapy is considered **medically necessary for Bladder cancer** when the following criteria are met:
   a. Definitively in an individual undergoing bladder preservation with T2-T4, node positive or recurrent disease
   b. Postoperatively in an individual with T3-T4 disease, node positive, or positive surgical margins
   c. Palliation
5. External Beam Radiation Therapy is considered **medically necessary** for Bone metastases.

6. External Beam Radiation Therapy is considered **medically necessary** for Brain metastases.

7. External Beam Radiation Therapy is considered **medically necessary** for Breast cancer when the following criteria are met:
   a. Status post mastectomy, post-mastectomy radiation therapy is medically necessary when any of the following are present:
      i. Positive axillary lymph node(s) **OR**
      ii. Primary tumor > 5 cm **OR**
      iii. Positive or narrow (< 1 mm) margins **OR**
   b. Status post local excision (lumpectomy, breast conservation surgery) adjuvant partial or whole breast radiotherapy is medically necessary

8. External Beam Radiation Therapy is considered **medically necessary** for Gastrointestinal cancers (Anal, Esophageal, Gastric, Gastroesophageal junction, Pancreas, Rectal, and Hepatobiliary) when any of the following criteria are met:
   a. **Neo-adjuvant treatment**
      i. Stage T1b node-positive **OR**
      ii. any Stage T2-T4a
   b. **Adjuvant treatment (if no preoperative or prior irradiation given)**
   c. **Definitive treatment**
      i. Inoperable and/or stage T4b **OR**
      ii. Definitive treatment for tumors located in the cervical esophagus
   d. **Local Recurrence or Palliation**

9. External Beam Radiation Therapy is considered **medically necessary** in malignant Gynecologic tumors (Uterus, Cervix, Ovary, and Fallopian tube), and primary pelvic Sarcomas.

10. External Beam Radiation Therapy is considered **medically necessary** in malignant Lung tumors (both Small Cell and Non-Small Cell), in both the primary and post-operative settings when coverage of the mediastinal lymph node is needed.

11. External Beam Radiation Therapy is considered **medically necessary for any cancer type for Palliation** such as for respiratory distress, severe pain or compromised critical structures.

12. External Beam Radiation Therapy is considered **medically necessary** in malignant Prostate tumors, both in the primary care of the intact prostate and in the post-operative setting.

13. All other indications not listed above may be considered experimental or investigational, as there may be insufficient evidence to support conclusions regarding the effect of on health outcomes. Indications not listed will be evaluated on a case by case basis at the clinical reviewer level.

V. **PROCEDURE**

The following documentation is necessary for reviewing an External Beam Radiation Therapy Request:

1. Physician history and physical including prior radiographic reports IE: MRI, CT and prior PET/CT scan if applicable.

2. Attending Radiation Oncologist Consult or Progress note
3. Radiation treatment plan or completed CTR

VI. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

None

VIII. REFERENCES

1. The American Society of Therapeutic Radiology and Oncology (ASTRO)/American College of Radiology (ACR), Guide to Radiation Oncology Coding 2019 and individual communications with representatives of ASTRO
2. American Society of Therapeutic Radiology and Oncology (ASTRO)/American College of Radiology (ACR)
4. Radiation Oncologists across the country
5. Contractor Medical Consultants
6. Other contractors’ policies
7. Noridian Carrier Advisory Committee Members