I. PURPOSE

The purpose of this policy is to provide general information applicable to the review and appropriateness of IMRT 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

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 malignant tumor or specific areas within the tumor. IMRT allows for the radiation dose to conform more precisely to the three – dimensional (3D) shape of the tumor by modulating or controlling the intensity of the radiation beam. IMRT also allows higher radiation doses to be focused to regions within the tumor while minimizing the dose to surrounding normal critical structures. Treatment is planned by using 3D computed tomography (CT) images of the patient in conjunction with computerized dose calculations to determine the dose intensity pattern that will best conform to the tumor shape. IMRT treatment may be delivered using several delivery methods, including, for example multiple static segment treatment (Step–and– shoot), dynamic segment treatment (sliding window), binary–collimator tomotherapy and volumetric modulated arc techniques (VMAT).

Other names used to report intensity modulated radiation therapy (IMRT):

- Compensatory – Based IMRT
- Helical Tomotherapy IMRT Tomotherapy
- Inverse Treatment Planning Segment Radiation Therapy (RT)
- Sliding Window Technique
- Step – and – Shoot Inverse IMRT
- Volumetric ARC therapy (VMAT)

III. DEFINITIONS

Intensity-modulated radiation therapy (IMRT) - is complex requiring precision and accuracy and involves multiple radiation specialists (e.g., radiation oncologist, medical physicist, radiation therapists, and dosimetrist). IMRT requires multiple or fractionated treatment sessions and different radiation doses. Several factors determine the number of treatment sessions and radiation dose; the type, location and size of the tumor, doses to the critical normal structures and the individual’s health. An IMRT schedule may consist of...
five days a week for five to ten weeks. At the beginning of each treatment, the individual is positioned on the treatment table guided by the marks on the skin, implanted fiducial markers, or through the use of cone beam CT scans (CBCT) defining the treatment area; the individual may be repositioned during the IMRT treatment. Imaging systems on the IMRT treatment delivery systems may be used to check positioning and marker location, molded devices may be used to help the individual maintain proper position. IMRT treatment may take between 3 to 20 minutes.

IV. POLICY

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.

1. IMRT meets the definition of medical necessity for the following indications:
   a. IMRT is considered medically necessary in individuals with Central Nervous System (CNS) lesions (that are either primary or metastatic lesions) with close proximity to critical structures such as the Optic Nerve, Lens, Retina, Optic Chiasm, Cochlea, or Brain Stem.
   b. IMRT is considered medically necessary in the treatment of individuals with Head and Neck cancer with the exception of individuals with early stage Glottic cancer (stage I and II).

2. IMRT is considered medically necessary in the treatment of individuals with Thyroid cancer.

3. IMRT is considered medically necessary for the treatment of Breast cancer when the following criteria are met:
   a. Treatment of left-sided Breast cancer:
      i. IMRT may be indicated when dose to critical organs, such as the heart, and lung, is of concern
      ii. When comparative 3D and IMRT plans demonstrate that a 3D plan does not meet the "Acceptable" normal tissue constraints using standard metrics published by the Radiation Therapy Oncology Group (RTOG)/National Comprehensive Cancer Network (NCCN) OR
   b. In individuals with large Breasts when the treatment planning with 3D-CRT results in hot spots (focal regions with dose variation greater than 10% of target) and the hot spots are able to be avoided with IMRT; OR
   c. In individuals who are to receive internal mammary node irradiation based on any of the following:
      i. Pathologically enlarged (as reported based on imaging technique utilized) internal mammary lymph node(s) by CT, MRI, PET/CT, or CXR OR
      ii. Pathologically involved internal mammary lymph node(s) (based on aspiration cytology or tissue biopsy pathology); OR
      iii. High risk of internal mammary lymph node involvement based on:
         • Greater than or equal to 4 positive axillary lymph nodes; or
         • Medial quadrant tumor with 1 or more positive axillary lymph nodes; or
         • Medial quadrant T3 tumor.

4. IMRT is considered medically necessary for the treatment of Lung cancer when ALL of the following criteria are met:
   a. Disease in the bilateral mediastinum or bilateral Hilar regions
   b. Disease in the Para-Spinal region
c. Superior Sulcus tumors
d. IMRT may be indicated when dose to critical organs, such as the liver, heart, lung, and spinal cord is of concern. When comparative 3D and IMRT plans demonstrate that a 3D plan does not meet the “Acceptable” normal tissue constraints using standard metrics published by the Radiation Therapy Oncology Group (RTOG)/National Comprehensive Cancer Network (NCCN).

5. IMRT is considered **medically necessary** for the treatment of the following abdominal cancers: Gastric, Gastroesophageal junction, Pancreas, and Hepatobiliary cancer when ALL of the following criteria are met:
   a. The disease is primary and non-metastatic, that is, confined regionally to the primary organ (including regional lymph nodes); AND
   b. IMRT may be indicated when dose to critical organs, such as the small bowel, liver, heart, lung, kidneys, and spinal cord is of concern. When comparative 3D and IMRT plans demonstrate that a 3D plan does not meet the “Acceptable” normal tissue constraints using standard metrics published by the Radiation Therapy Oncology Group (RTOG)/National Comprehensive Cancer Network (NCCN).

6. IMRT is considered **medically necessary** for Esophageal cancer.
   a. The disease is primary and non-metastatic, that is, confined regionally to the primary organ (including regional lymph nodes); AND
   b. IMRT may be indicated when dose to critical organs, such as the small bowel, liver, heart, lung, kidneys, and spinal cord is of concern. When comparative 3D and IMRT plans demonstrate that a 3D plan does not meet the “Acceptable” normal tissue constraints using standard metrics published by the Radiation Therapy Oncology Group (RTOG)/National Comprehensive Cancer Network (NCCN).

7. IMRT of the Prostate is considered **medically necessary** in individuals who meet either of the following:
   a. Definitive treatment for localized prostate cancer; **OR**
   b. Post-Prostatectomy:
      • PSA remains detectable after surgery; **OR**
      • PSA is detectable and increases on two or more lab determinations; **OR**
      • The individual has post-operative stage T3 to T4; **OR**
      • Post-operative pathology reveals positive surgical margins.

8. IMRT is considered **medically necessary** in individuals with cancer of the Anus or Anal canal, certain malignant gynecologic tumors (Uterus, Cervix, Ovary, and Fallopian tube), primary pelvic sarcomas, Bladder carcinoma.

9. IMRT is considered **medically necessary** in individuals with Lymphoma when the disease involves the aortic/periaortic lymph nodes.

10. IMRT is considered **medically necessary** in individuals with Retroperitoneal Sarcomas located within the abdominal cavity.

11. IMRT is considered **medically necessary** in individuals who require repeat irradiation of a field that has received prior irradiation.

12. 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 IMRT Request:

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

b. Attending Radiation Oncologist Consult or Progress note.

c. Treatment; in certain circumstances a comparison dose volume histogram (DVH) comparing IMRT to 3D conformal therapy.

VI. APPROVAL AUTHORITY

1. Review – Utilization Management Department

2. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

None

VIII. REFERENCES


43. Thyroid Carcinoma (V1.2019). Revised September 16, 2019.