INTRODUCTION:

Lung cancer is the leading cause of cancer-related deaths of both men and women in the United States. The World Health Organization divides lung cancer into two types: non-small cell lung cancer (NSCLC) as discussed in this guideline and small cell lung cancer (SCLC). The most common lung cancer, NSCLC, includes various histologies: squamous carcinoma, adenocarcinoma, and large cell carcinoma. Surgery alone has been the standard treatment for patients with resectable NSCLC for many years. However, patients with completely resected disease have disappointing survival rates. In some cases, relapse occurs at distant sites which suggest that NSCLC may be a systemic disease when diagnosed. Chemotherapy and radiation therapy are now treatment considerations in both the preoperative and postoperative settings.

Prognosis and treatment of NSCLC are based on the staging of the cancer which documents the extent of cancer growth and spread. The initial goal of staging is to determine if the tumor is surgically resectable. Some patients with resectable disease may be cured by surgery while others, due to contraindications to surgery, may be candidates for radiation therapy for curative intent or for local control.

This guideline outlines several methods suitable for the delivery of radiation therapy to treat lung cancer. These include the use of external beam radiation therapy such as: three-dimensional conformal radiation therapy (3D-CRT), endobronchial brachytherapy, postoperative radiation therapy (PORT) and stereotactic body radiation (SBRT). Endobronchial brachytherapy and SBRT are aggressive approaches justified, in part, for non-resectable tumors. While these advances in treatment offer a range of regimens, the goal of this guideline is to guide diagnosis and treatment to the most efficient, comparatively effective, diagnostic and treatment pathway. With the exception of medically inoperable tumors and extreme palliative circumstances, radiation treatment is performed, in most cases, in conjunction with surgical intervention.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR RADIATION THERAPY

1. Three-dimensional conformal radiation therapy (3D-CRT) is considered medically necessary for the following clinical indications:
- Post Operative Radiation Therapy
  - Positive Nodes (N 1-3) or Positive or close margins
  **Dosage Guidelines:**
  - Extracapsular nodal extension or positive margins: 54-60 Gy up to 33 fractions
  - Gross Residual Tumor: 60-70 Gy up to 39 fractions
  - Negative margins: 50-54 Gy up to 30 fractions

- Pre Operative Radiation Therapy
  - T3-4, N0-N1 or Resectable Superior Sulcus Tumors or N2 disease (Stage IIIA ,T 1-3, N2)
  **Dosage Guidelines:**
  - 45-54 Gy up to 30 fractions

- Inoperable – Definitive
  - Stage I disease (T1-2a,N0,M0) or Stage II and Stage III disease (T2b-T4,N0,M0 or T1-4,N1-3,M0) or Surgery Refused
  **Dosage Guidelines:**
  - 60-70 Gy up to 39 fractions

- Palliative Radiation Therapy is considered medically necessary for Stage IV (M1) disease to relieve pain, airway or endobronchial obstruction, and other symptoms

*Unless otherwise indicated standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day.*

2. **Stereotactic body radiation therapy (SBRT)** is considered medically necessary for patients with inoperable Stage I or II disease or patients who refuse to have surgery.
  **Dosage Guidelines:**
  - Delivered at 5 fractions or less

3. **Endobronchial Brachytherapy** is considered medically necessary for the following clinical indications:
  - Patients with primary tumors who are not otherwise candidates for surgical resection or external-beam radiation therapy due to co-morbidities or location of the tumor
  - Palliative therapy for airway obstruction or severe hemoptysis in patients with primary, metastatic, or recurrent tumors.

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW**

**Intensity Modulated Radiation Therapy (IMRT)**
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for non small cell lung cancer. IMRT may be appropriate
for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D3D-CRT treatment planning and delivery will need to:

- Demonstrate how 2D-3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

**Proton Beam Radiation Therapy (PBT)**

Proton Beam is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for non small cell lung cancer.

**Stereotactic Body Radiation Therapy**

Stereotactic Body Radiation Therapy (SBRT) is not considered a standard form of treatment for NSCLC except for inoperable Stage I and II disease. Other requests for SBRT will require a peer review to make a medical necessity determination. Documentation from the radiation oncologist must include the clinical rationale for performing SBRT rather than 3-D conformal treatment.

**THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:**

*For Proton Beam Radiation refer to Local Coverage Determination (LCD), if applicable.*
REFERENCES


Reviewed / Approved by Caroline Carney, MD, Chief Medical Officer