*National Imaging Associates, Inc.	
Clinical Guideline: **NON-SMALL CELL LUNG CANCER**	**Original Date: March 2011**
Radiation Oncology	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_122	**Implementation Date: January 2024**

GENERAL INFORMATION

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY

Three-dimensional conformal radiation therapy (3D-CRT) is considered medically necessary for the following clinical indications[1]:

- Post-Operative Radiation Therapy[1]:
  - Clinical stage I/II upstaged surgically to N2+
  - Positive Nodes (N 2-3); **or**
  - Positive or close margins

  Dosage Guidelines[1]:
  - 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[1]:
  - T3-4, N0-N1; **or**
  - Resectable Superior Sulcus Tumors; **or**
  - N2 disease (Stage IIIA, T 1-3, N2)

  Dosage Guidelines[1]:
  - 45-54 Gy up to 30 fractions

- Inoperable – Definitive[1]:
    - Stage I disease (T1-2a, N0, M0)
    - Stage II and Stage III disease (T2b-T4, N0, M0 or T1-4, N1-3, M0)

    OR

    - Surgery Refused

  Dosage Guidelines[1]:
    - 60-70 Gy up to 39 fractions

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

- Palliative Radiation Therapy is considered medically necessary for Stage IV (M1) disease to relieve pain, airway or endobronchial obstruction, and other symptoms[1]
    - Shorter courses of RT are preferred for patients with poor performance status and/or shorter life expectancy because they provide similar pain relief as longer courses, although there is a higher potential need for retreatment[2-5]
    - For palliation of thoracic symptoms, higher dose/longer-course thoracic RT (e.g., ≥30 Gy in 10 fractions) is associated with modestly improved survival and symptoms, particularly in patients with good performance status[6, 7]
    - Single-fraction stereotactic RT of 12–16 Gy produced better control of pain response and local control of non-spine bone metastases compared to standard 30 Gy in 10 fractions in a randomized phase II trial and may be promising for patients with longer expected survival[8]

      Dosage Guidelines:
        - 30-45 Gy up to 15 fractions

For hypofractionated palliative radiation, standard radiation fractionation consists of 2.5-3 Gy.

TREATMENT OPTIONS (Will be reviewed on a case-by-case basis)

Endobronchial Brachytherapy is considered medically necessary for the following clinical indications[1]:

- 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.

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.

IMRT – Stage IIIB (any N3, or T3/4N2)[9] , and No-Fly Zone Lesions and/or T3N0 for ablative therapy:

- IMRT is approvable for definitive treatment of stage IIIB/IIIC (any N3, or T3/4N2) NSCLC. A comparative plan is not required.
- IMRT is approvable for No-Fly Zone Lesions for ablative therapy (Up to 15 fractions)

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 or for treatment of previously irradiated field. Other requests for SBRT will be reviewed on a case-by-case basis 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.[10]

Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary for patients with inoperable (including high-risk patients able to tolerate sublobar resection but not lobectomy) Stage I or II disease (including node-negative stage IIB) or patients who refuse to have surgery or for a previously irradiated field[1]

Dosage Guidelines:

- Delivered at 5 fractions or less

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:

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

BACKGROUND

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. Except for medically inoperable tumors and extreme palliative circumstances, radiation treatment is performed, in most cases, in conjunction with surgical intervention.

REFERENCES

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POLICY HISTORY

Date	Summary
May 2023	Added: Post-Operative Radiation Therapy: • Clinical stage I/II upstaged surgically to N2+ • Positive Nodes (N 2-3) (Under Palliative Radiation Therapy) • Shorter courses of RT are preferred for patients with poor performance status and/or shorter life expectancy because they provide similar pain relief as longer courses, although there is a higher potential need for retreatment • For palliation of thoracic symptoms, higher dose/longer-course thoracic RT (e.g., ≥30Gy in 10 fractions) is associated with modestly improved survival and symptoms, particularly in patients with good performance status • Single-fraction stereotactic RT of 12–16Gy produced better control of pain response and local control of non-spine bone metastases compared to standard 30Gy in 10 fractions in a randomized phase II trial and may be promising for patients with longer expected survival • Dosage Guidelines: 30-45Gy up to 15 fractions Added language in parentheses: • **Stereotactic Body Radiation Therapy (SBRT)** is considered medically necessary for patients with inoperable (including high-risk patients able to tolerate sublobar resection but not lobectomy) Stage I or II disease (including node-negative stage IIB) or patients who refuse to have surgery or for a previously irradiated field • Added No-Fly Zone Lesions under IMRT : **IMRT – Stage IIIB (any N3, or T3/4N2) , and No-Fly Zone Lesions and/or T3N0 for ablative therapy:** ○ IMRT is approvable for definitive treatment of stage IIIB/IIIC (any N3, or T3/4N2) NSCLC. A comparative plan is not required. ○ IMRT is approvable for No-Fly Zone Lesions for ablative therapy (Up to 15 fractions) • Deleted Additional Resources • Removed “physician review” language
January 2022	• Within Palliative Radiation Therapy, added “For hypofractionated palliative radiation, standard radiation fractionation consists of 2.5-3Gy.” • Added IMRT – Stage IIIB (any N3, or T3/4N2)

Reviewed / Approved by NIA Clinical Guideline Committee

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