Non-Small Cell Lung Cancer

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INITIAL CLINICAL PRE-TREATMENT EVALUATION

<table>
<thead>
<tr>
<th>STAGE</th>
<th>INITIAL</th>
<th>CLINICAL</th>
<th>PRE-TREATMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-2, N0 (Stage I)</td>
<td>Pathology consistent with non-small cell lung cancer</td>
<td>History and physical</td>
<td>Chest X-ray</td>
</tr>
<tr>
<td>T1-2, N1 (Stage II)</td>
<td>Laboratory studies to include hematological and full chemistry panels</td>
<td>CT chest and upper abdomen</td>
<td>ECG if history of heart disease</td>
</tr>
</tbody>
</table>

The diagram illustrates the staging process, with decision points for medically operable and unresectable cases, and treatment options based on the TNM staging system. The diagram includes options for resection or adjuvant therapy, radiotherapy, and chemoradiation, as well as considerations for metastatic involvement and extracapsular spread.

NOTE: Consider clinical trials as treatment options for eligible patients. This algorithm is based on TNM Staging VI.
Non-Small Cell Lung Cancer

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NOTE: Consider Clinical Trials as treatment options for eligible patients.

CLINICAL STAGE

PRE-TREATMENT EVALUATION

CLINICAL EVALUATION

INITIAL TREATMENT

A

T3, N0 (Stage IIB)

T3, N1 (Stage IIIA) By CT

Brochoscopy
Mediastinoscopy or EBUS\(^1\)
Brain MRI
MRI of spine plus thoracic inlet for superior sulcus lesions (Sup-culcus protocol)
PET scan
Pulmonary Function Tests

Superior sulcus Tumor (T3-4, N0-1)

Resectable

Induction concurrent chemoradiation
Surgery

Definitive chemoradiation\(^2\)

Unresectable

Induction chemotherapy
Surgical Re-evaluation

Surgery

Unresectable

Complete definitive chemoradiation

Resectable

Adjuvant chemoradiation\(^2\)

Surgery

Margins negative

Adjuvant chemotherapy\(^3\)

Margins positive

Post-op adjuvant therapy: radiotherapy\(^4\) followed by chemotherapy\(^3\) or chemotherapy\(^3\) followed by radiotherapy\(^4\)

Unresectable

Surgical Re-evaluation

Resectable

Complete definitive chemoradiation

Unresectable

Note: See page 5, box E

Distant metastasis?

No

Central T3 tumor or Chest wall invasion (i.e. T3 other than Superior sulcus)

Resectable

Margins negative

Adjuvant chemotherapy\(^3\)

Margins positive

Post-op adjuvant therapy: radiotherapy\(^4\) followed by chemotherapy\(^3\) or chemotherapy\(^3\) followed by radiotherapy\(^4\)

Unresectable

Complete definitive chemoradiation

1EBUS Endobronchial Ultrasound
2 Either concurrent radiotherapy followed by 2 cycles of posterior chemotherapy OR cycles of induction chemotherapy followed by concurrent chemoradiation
3 Platinum-based doublet therapy for selected patients
4 cycles of induction chemotherapy followed by concurrent chemoradiation

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Page 2 of 18

Department of Clinical Effectiveness V10
Approved by The Executive Committee of Medical Staff 10/29/2013
Non-Small Cell Lung Cancer

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CLINICAL STAGE

B
T1-3, N2 (Stage IIIA), positive ipsilateral Lymph node (greater than or equal to 1 cm) on CT

PRE-TREATMENT EVALUATION

- Malignant pleural effusion or distant metastasis
- N3 disease
- Clinical N2 disease
- N2, N3 nodes negative
- N2 nodes positive
- Metastasis

INITIAL AND ADJUVANT TREATMENT

- See page 5, box D
- See page 4, box C
- Surgical resection with mediastinal lymph node dissection
- Induction Chemotherapy versus induction Chemoradiation
- Definitive chemoradiation
- See page 5, box E

SURVEILLANCE

N0-1
- Adjuvant chemotherapy
- Surveillance if T1-2, N0

N2-3
- Adjuvant chemotherapy followed by radiotherapy
- Post-op adjuvant therapy: radiotherapy followed by chemotherapy or chemotherapy followed by radiotherapy

Margins positive
- Complete definitive chemoradiation
- Surveillance see page 6

Margins negative
- Surveillance see page 6
Non-Small Cell Lung Cancer

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CLINICAL STAGE

T1-3, N3 (Stage IIIB) mediastinal CT positive contralateral (lymph node greater than or equal to 1 cm) or palpable supraclavicular lymph nodes

T4, N0-1 (Stage IIIB) (see page 5, box D)

PRE-TREATMENT EVALUATION

- PET scan
- Brain MRI
- Pathological confirmation of equivocal N3 disease by:
  - Needle Biopsy
  - Supraclavicular lymph node biopsy
  - Mediastinoscopy
  - Thoracoscopy
  - Mediastinotomy

INITIAL AND ADJUVANT TREATMENT

N3 ruled out → See initial treatment for Stage I-IIIA on Page 1

N3 confirmed → Definitive chemoradiation¹

Distant metastasis or malignant pleural effusion. See page 4, box E

SURVEILLANCE

Resectable

- Surgery
- ▪ Induction concurrent chemoradiation
- ▪ Induction chemotherapy

Unresectable

- Definitive chemoradiation¹

Resectable

- Surgery

Metastasis → See page 5, box E

¹ Either concurrent radiotherapy followed by 2 cycles of posterior chemotherapy OR 2 cycles of induction chemotherapy followed by concurrent chemoradiation

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Non-Small Cell Lung Cancer

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NOTE: Consider Clinical Trials as treatment options for eligible patients.

<table>
<thead>
<tr>
<th>CLINICAL STAGE</th>
<th>PRE-TREATMENT EVALUATION</th>
<th>INITIAL AND ADJUVANT TREATMENT</th>
<th>SURVEILLANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>D Pleural effusion</td>
<td>Thoracentesis or pericardiocentesis, if indicated Thoracoscopy, if thoracentesis indeterminate</td>
<td>Benign Treatment according to T and N stage</td>
<td>Local therapy, if necessary, and treatment for distant metastasis or malignant pleural effusion.</td>
</tr>
<tr>
<td>E Stage IV</td>
<td>Solitary brain metastasis present on MRI?</td>
<td>Yes</td>
<td>Systemic chemotherapy with or without palliative radiotherapy (see principles of radiotherapy and chemotherapy)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>Workup as clinically indicated</td>
</tr>
</tbody>
</table>

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Non-Small Cell Lung Cancer

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NOTE: Consider clinical trials as treatment options for eligible patients.

SURVEILLANCE

Stages I and II
- Physical exam and chest X-ray every 6 months for 5 years
- CT of chest every 6 months for 2 years, then annually

Recurrence or second primary?

Yes
- Physical exam, chest X-ray, and CT chest every 2 – 3 months for 2 years, then every 6 months for 3 years, then annually

Recurrence or second primary?

Yes
- Second primary
- No

TX

 Locoregional recurrence
- Evaluate for surgical resection or Chemoradiation

Yes
- Distant metastasis
- See page 5, box E

Second primary

Yes
- Individualized treatment

No
- Continue with surveillance

Second primary?

Yes
- Individualized treatment

No
- See page 5, box E

No
- Continue with surveillance

Stage IV
- Physical exam, chest X-ray, and scans of involved sites every 2 – 3 months or as clinically indicated

Recurrence or second primary?

Yes
- Second primary

No
- Continue with surveillance

THERAPY FOR RECURRENCE AND METASTASIS
APPENDIX A: Non-Small Cell Lung Cancer Molecular Markers – MD ANDERSON APPROVED¹

<table>
<thead>
<tr>
<th>DISEASE SITE</th>
<th>CELL TYPE</th>
<th>FISH</th>
<th>IMMUNOHISTOCHEMISTRY</th>
<th>MOLECULAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic</td>
<td>Non Small Cell Lung Carcinoma</td>
<td>ALK rearrangement</td>
<td>BRAF V600E</td>
<td>EGFR mutation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ROS1 rearrangement</td>
<td></td>
<td>KRAS mutation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>BRAF mutation</td>
</tr>
</tbody>
</table>

¹ Literature support for MD Anderson approved Biomarkers is available and can be found under Clinical Management Algorithms → “Biomarkers – MD Anderson Approved”
Patients with inoperable stage III disease should be offered definitive concurrent chemoradiation with curative intent, which provides superior survival over XRT alone.

Concurrent chemoradiation should be used only in patients with a suitable performance status who have not had excessive weight loss prior to starting treatment (ie, PS 0-1 and with less than or equal to 5 – 10% weight loss).

Patients in need of immediate XRT for symptom palliation (ie, those with symptomatic bronchial obstruction, SVC obstruction, pain, etc) should begin treatment with concurrent chemoradiation, followed by 2 additional cycles of chemotherapy upon completion of their concurrent chemoradiation.

For patients who do not need immediate XRT for symptom palliation, acceptable sequencing of their chemoradiation is as follows:

- 2 cycles of induction chemotherapy, followed by concurrent chemoradiation
- OR
- concurrent chemoradiation, and followed by 2 additional cycles of chemotherapy upon completion of their concurrent chemoradiation (“posterior chemotherapy”)

Acceptable chemotherapy regimens for induction and/or “posterior” chemotherapy include:

- Paclitaxel 200 mg/m² IV + Carboplatin AUC 6 IV, every 21 days
- Paclitaxel 200 mg/m² IV + Cisplatin 75 mg/m² IV, every 21 days
- Docetaxel 75 mg/m² IV + Carboplatin AUC 6 IV, every 21 days
- Docetaxel 75 mg/m² IV + Cisplatin 75 mg/m² IV, every 21 days
- Cisplatin 60 – 80 mg/m² IV day 1 + Etoposide 80 – 120 mg/m² IV days 1 – 3, every 21 days

Acceptable chemotherapy regimens for the concurrent chemoradiation phase of treatment include:

- Paclitaxel 50 mg/m² IV + Carboplatin AUC 2 IV, weekly during XRT
- Docetaxel 20 – 25 mg/m² IV + Carboplatin AUC 2 IV, weekly during XRT
- Docetaxel 20 – 25 mg/m² IV + Cisplatin 20 – 25 mg/m² IV, weekly during XRT
- Cisplatin 50 mg/m² IV days 1, 8 and days 29, 36 + Etoposide 50 mg/m² IV days 1 – 5 and days 29 – 33

In patients receiving radiation therapy or chemoradiation with curative intent, treatment interruptions or dose reductions for temporary and manageable toxicities, such as esophagitis or myelosuppression, should be avoided. Careful patient monitoring and aggressive supportive care are preferable to treatment breaks in potentially curable patients. Patients should be evaluated at least once per every 5 fractions to monitor weight changes and toxicity.

NOTE: Consider clinical trials as treatment options for eligible patients.
Non-Small Cell Lung Cancer

First-line chemotherapy
- Platinum-based combination chemotherapy prolongs survival and improves symptoms and quality of life compared to best supportive care for patients with acceptable performance status.
- Platinum-based combination chemotherapy should be offered to all patients with Performance Status (PS) of 0 – 1, and to selected patients with PS of 2.
- Patients with PS of 3 – 4 benefit little, if any, from cytotoxic chemotherapy.
- Elderly patients with acceptable PS should be offered chemotherapy, either combination platinum-based therapy or single-agent therapy (depending upon patient’s age and co-morbid conditions).
- Most platinum-based combination regimens yielded similar response rates (25% – 35%) and survival (median: 8 – 10 months; 1-year: 30% – 40%; 2-year: 10% – 15%).
- Acceptable first-line chemotherapy regimens include:
  - Paclitaxel 200 mg/m² IV plus Carboplatin AUC 6 IV, every 21 days
  - Paclitaxel 200 mg/m² IV plus Cisplatin 75 mg/m² IV, every 21 days
  - Docetaxel 75 mg/m² IV plus Carboplatin AUC 6 IV, every 21 days
  - Docetaxel 75 mg/m² IV plus Cisplatin 75 mg/m² IV, every 21 days
  - Gemcitabine 1,000 mg/m² IV days 1, 8 + day 15) plus Cisplatin 75 mg/m² IV day 1, every 21 days (if using day 1/8 gemcitabine schedule) or every 28 days (if using day 1/8/15 gemcitabine schedule)
  - Gemcitabine 1,200 mg/m² IV days 1, 8 plus Carboplatin AUC 5 IV day 1, every 21 days
  - Vinorelbine 25 – 30 mg/m² IV days 1, 8, and 15 plus Cisplatin 80 – 100 mg/m² IV day 1, every 28 days
  - Cisplatin 60 – 80 mg/m² IV day 1 plus Etoposide 80 – 120 mg/m² IV days 1 – 3, every 21 days
  - Pemetrexed 500 mg/m² IV day 1 plus Carboplatin AUC 6 IV day 1, every 21 days
  - Paclitaxel 150 - 200 mg/m² IV plus Carboplatin AUC 6 IV plus Bevacizumab 15 mg/kg IV every 21 days for metastatic NSCLC in patients that have NON-squamous cell histology
  - Crizotinib1 if EML4-ALK positive
  - Erlotinib if EGFR mutation present

- Patients with non-squamous tumors should have their tumor tested for EGFR mutatio, kras mutation, and EML4-ALK translocation. Presence of these mutations is predictive of response to TKIs, and can be used in guiding first-line and second-line chemotherapy in selected patients.

Second-line (and higher) chemotherapy – see next page

1 Formulary restrictions may apply to this agent
PRINCIPLES OF CHEMOTHERAPY FOR PATIENTS WITH STAGES IIIB (EFFUSION) AND IV DISEASE (continued)

Second-line (and higher) chemotherapy
- Second-line chemotherapy prolongs survival and improves symptoms and quality of life compared with best supportive care in patients with acceptable PS.
- Second-line chemotherapy should be offered to all patients with PS of 0 – 1, and to selected patients with PS of 2.
- Patients with PS of 3 – 4 are unlikely to benefit from second-line chemotherapy.
- Elderly patients with acceptable PS should be offered second-line chemotherapy.
- Most single-agents administered in the second-line setting yield similar response rates (10% partial response + 30% stable disease) and survival (median: 8 months; 1-year: 20%).
- Second-line therapy should generally be given as sequential single agents. Acceptable second-line drugs include:
  - Docetaxel 75 mg/m² IV, every 21 days
  - Pemetrexed 500 mg/m² IV, every 21 days
  - Erlotinib 150 mg PO daily
  - Gemcitabine 1,000 mg/m² IV days 1, 8, and 15, every 28 days
  - Vinorelbine 25 – 30 mg/m² IV days 1, 8, and 15, every 28 days
  - Crizotinib¹ if EML4-ALK positive
  - Erlotinib if EGFR mutation present
- If available, patients with non-squamous tumors should have their tumor tested for EGFR mutation, kras mutation, and EML4-ALK translocation. Presence of these mutations is predictive of response to TKIs, and can be used in guiding first-line and second-line chemotherapy in selected patients.

¹ Formulary restrictions may apply to this agent.
Non-Small Cell Lung Cancer

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NOTE: Consider clinical trials as treatment options for eligible patients.

**PRINCIPLES OF RADIATION THERAPY**

- **Treatment of patients with potentially curable NSCLC (ie, stages I – III) should be made after multidisciplinary consultation with a surgical, radiation and medical oncologist.** Decisions about XRT should account for patient’s stage, PS, tumor bulk, underlying pulmonary function, and potential overlap with normal tissue in the proposed radiation field.
- Patients with medically inoperable stage I or II NSCLC, as well as patients with stage III disease who are not candidates for chemoradiation, should be treated with XRT alone with curative intent, to a total dose of 66 – 74 Gy at 200 cGy per fraction. Stereotactic body radiotherapy can be used for medically inoperable Stage I NSCLC patients.
- Patients with inoperable stage III disease should be offered definitive concurrent chemoradiation with curative intent.
  - Concurrent chemoradiation should be used only in patients with a suitable performance status who have not had excessive weight loss prior to starting treatment (ie, PS 0 – 1 and with less than or equal to 5 – 10% weight loss).
  - The dose of XRT for these patients is 60-74 Gy at 180 – 200 cGy per fraction. The V20 for the total lung should be kept below 35% and total mean lung dose should be kept below 20 Gy considered for patients whose volumes exceed 40%.
  - Patients in need of immediate XRT for symptom palliation (ie, those with symptomatic bronchial obstruction, SVC obstruction, pain, etc) should begin treatment with concurrent chemoradiation, followed by 2 additional cycles of chemotherapy upon completion of their concurrent chemoradiation.
  - For patients who do not need immediate XRT for symptom palliation, acceptable sequencing of their chemoradiation is as follows:
    - 2 cycles of induction chemotherapy, followed by concurrent chemoradiation, OR
    - They may begin with concurrent chemoradiation, and then follow that with 2 additional cycles of chemotherapy upon completion of their concurrent chemoradiation
  - See “Non-Small Cell Lung Cancer Principles of Chemotherapy for Patients with Stage III Disease” for details of chemotherapy drugs, dosing and schedule.
  - In patients who are to receive induction chemotherapy prior to beginning radiation or chemoradiation, consideration should be given to obtaining a baseline planning CT prior to starting induction chemotherapy.
- Patients should be well-immobilized for treatment (eg, Vac-Loc bag, wingboard and T-bar). Fusion with PET/CT, if available, may help to elude involved lymph nodes and differentiate atelectasis from tumor involvement.
- **Suggested treatment margins are GTV to CTV of 0.8 cm, and CTV to PTV of 0.5-1.0 cm. However, treatment plans should be individualized using 4 dimensional CT as it may be necessary to modify these suggested margins depending upon the specifics of the case.**
- In general, elective nodal irradiation should be avoided as it may unnecessarily increase the amount of normal lung tissue in the radiated field.
- In patients receiving radiation therapy or chemoradiation with curative intent, treatment interruptions or dose reductions for temporary and manageable toxicities, such as esophagitis or myelosuppression, should be avoided. Careful patient monitoring and aggressive supportive care are preferable to treatment breaks in potentially curable patients. Patients should be evaluated at least once per every 5 fractions to monitor weight changes and toxicity.

Continued on Next Page
Non-Small Cell Lung Cancer

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PRINCIPLES OF RADIATION THERAPY (continued)

- In patients receiving postoperative radiation therapy because of involved mediastinal nodes or resection margins which are close or positive, discussion with the thoracic surgeon and pathologist is helpful in designing appropriate target volumes. Recommended post-operative XRT doses are as follows:
  - N2/N3 nodes 50 Gy
  - T4 primary 50 Gy
  - Extracranial extent 54 Gy
  - Positive margins 60 Gy
  - Gross residual disease 60 – 74 Gy (possibly with concurrent chemotherapy)

- Cobalt and orthovoltage beams are not appropriate for curative treatment due to the possibility of under-dosing, particularly of small tumors or tumor extensions. In addition, it may be preferable to avoid high-energy photons and instead use lower energies (4 – 10 MeV) in most patients. High-energy photons (15MeV, 18MeV, etc) may be preferable when used to treat larger GTVs (gross tumor volumes) surrounded by consolidated and/or atelectic lung tissue, bulky lymphadenopathy or large blood vessels, thus achieving a better dose distribution and also an improved therapeutic ratio.
Non-Small Cell Lung Cancer

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PRINCIPLES OF SURGICAL RESECTION

- It is strongly recommended that determination of resectability be performed by thoracic surgical oncologists who perform lung cancer surgery as a prominent part of their practice.
- All patients should undergo pulmonary function testing if considered for surgical resection.
- Patients with an FEV1 less than 70% of predicted should have xenon function studies.
- Patients with a predicted post resection FEV1 below 35% should have complimentary exercise oxygen consumption testing.
- Patients with enlarged mediastinal nodes by CT scan or PET positive nodes should undergo mediastinal node biopsy prior to thoracotomy either by transthoracic FNA ultrasound guided biopsies via bronchoscopy or esophagoscopy techniques, or mediastinoscopy.
- Patients with co-morbidities require a detailed medical and anesthesia evaluations before surgery.
- All patients need to abstain from smoking a minimum of two weeks prior to thoracotomy. The use of nicotine replacement therapies is encouraged.
- The optimal surgery for non-small cell lung cancer is an anatomical lobectomy or pneumonectomy. In selected patients unable to undergo a lobectomy or pneumonectomy due to physiologic constraints, a more limited resection is an acceptable oncologic alternative.
- N1 and N2 node dissection and mapping should be performed on all patients undergoing a lung cancer resection. Complete node dissection should ideally be performed. When this is not feasible, a minimum of three N2 nodal stations should be sampled.
- Lung-sparing anatomic resections (ie, sleeve lobectomies) are preferred over pneumonectomies, provided that negative margins can be achieved.
- Lobectomies performed by minimal invasive techniques need to adhere to all of the oncologic principles of complete resection with negative margins and full nodal dissection.
Non-Small Cell Lung Cancer

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For further reading/information:

**Staging of Non-Small Cell Lung Cancer**


**Post-Operative Adjuvant Chemotherapy for Resected Non-Small Cell Lung Cancer**


**Stage IIIA Disease:**


**Induction Chemotherapy for Operable Stage III Non-Small Cell Lung Cancer**


Continued on Next Page
Non-Small Cell Lung Cancer

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For further reading/information (continued):

Chemoradiation for Stage III Non-Small Cell Lung Cancer


Chemotherapy for Advanced Non-Small Cell Lung Cancer


Continued on Next Page
Non-Small Cell Lung Cancer

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For further reading/information (continued):

Chemotherapy for Advanced Non-Small Cell Lung Cancer (Continued)

Surgery for Non-Small Cell Lung Cancer
Non-Small Cell Lung Cancer

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NOTE: Consider clinical trials as treatment options for eligible patients.

For further reading/information (continued):

Stereotactic Body Radiation for Non-Small Cell Lung Cancer


Need for CT in Follow-up:


EBUS:

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Development Credits

This practice guideline is based on majority expert opinion of the Thoracic Center faculty at the University of Texas, M D Anderson Cancer Center. It was developed using a multidisciplinary approach that included input from the following medical, radiation and surgical oncologists:

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