LUNG CANCER TREATMENT REGIMENS (Part 1 of 7)

Clinical Trials: The NCCN recommends cancer patient participation in clinical trials as the gold standard for treatment. Cancer therapy selection, dosing, administration, and the management of related adverse events can be a complex process that should be handled by an experienced healthcare team. Clinicians must choose and verify treatment options based on the individual patient; drug dose modifications and supportive care interventions should be administered accordingly. The cancer treatment regimens below may include both U.S. Food and Drug Administration-approved and unapproved indications/regimens. These regimens are only provided to supplement the latest treatment strategies. These Guidelines are a work in progress that may be refined as often as new significant data becomes available. The NCCN Guidelines® to supplement the latest treatment strategies. The NCCN recommends cancer patient participation in clinical trials as the gold standard for treatment. All recommendations are Category 2A unless otherwise indicated. Non-Small Cell Lung Cancer (NSCLC)

Note: All recommendations are Category 2A unless otherwise indicated.

### Chemotherapy Regimens For Neoadjuvant and Adjuvant Therapy

<table>
<thead>
<tr>
<th>REGIMEN</th>
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<tbody>
<tr>
<td>Cisplatin + vinorelbine</td>
<td>Days 1 and 8: Cisplatin 50mg/m² IV plus Days 1, 8, 15 and 22: Vinorelbine 25mg/m² IV. Repeat cycle every 4 weeks for 4 cycles. OR Day 1: Cisplatin 100mg/m² IV plus Days 1, 8, 15 and 22: Vinorelbine 30mg/m² IV. Repeat cycle every 4 weeks for 4 cycles. OR Day 1: Cisplatin 75–80mg/m² plus Days 1 + 8: Vinorelbine 25–30mg/m² Repeat every 3 weeks for 4 cycles.</td>
</tr>
<tr>
<td>Cisplatin + etoposide</td>
<td>Day 1: Cisplatin 100mg/m² IV plus Days 1–3: Etoposide 100mg/m² IV. Repeat cycle every 4 weeks for 4 cycles.</td>
</tr>
<tr>
<td>Cisplatin + vinblastine</td>
<td>Days 1, 22, 43, 64: Cisplatin 80mg/m² IV. Days 1, 8, 15, 22, 29, and then every 2 weeks after day 43: Vinblastine 4 mg/m². Repeat every 3 weeks for 4 cycles.</td>
</tr>
<tr>
<td>Cisplatin + gemcitabine</td>
<td>Day 1: Cisplatin 75mg/m² IV plus Days 1 and 8: Gemcitabine 1,250mg/m² IV. Repeat cycle every 3 weeks.</td>
</tr>
<tr>
<td>Cisplatin + docetaxel</td>
<td>Day 1: Docetaxel 75mg/m² IV + cisplatin 75mg/m² IV. Repeat every 3 weeks for 4 cycles.</td>
</tr>
<tr>
<td>Cisplatin + pemetrexed</td>
<td>Day 1: Cisplatin 75mg/m² IV + pemetrexed 500mg/m² IV.* Repeat every 3 weeks for 4 cycles.</td>
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</tbody>
</table>

For patients with comorbidities or patients not able to tolerate cisplatin

| Paclitaxel + carboplatin | Day 1: Paclitaxel 200mg/m² IV + carboplatin AUC=6 IV. Repeat every 3 weeks for 4 cycles. |

### Concurrent Chemotherapy/Radiotherapy (RT)

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Cisplatin + etoposide</td>
<td>Days 1, 8, 29 and 36: Cisplatin 50mg/m² IV plus Days 1–5 and 29–33: Etoposide 50mg/m² IV plus Concurrent thoracic radiotherapy 1.8Gy/day for 5 days/week (total dose, 61Gy).</td>
</tr>
<tr>
<td>Cisplatin + vinblastine</td>
<td>Days 1 and 29: Cisplatin 100mg/m² IV plus Days 1, 8, 15, 22 and 29: Vinblastine 5mg/m² IV with concurrent thoracic radiotherapy (total dose, 60Gy).</td>
</tr>
<tr>
<td>Carboplatin + pemetrexed</td>
<td>Day 1: Carboplatin AUC 5 IV plus Day 1: Pemetrexed 500 mg/m² IV with concurrent thoracic radiotherapy. Repeat every 3 weeks for 4 cycles.</td>
</tr>
<tr>
<td>Cisplatin + pemetrexed</td>
<td>Day 1: Cisplatin 75 mg/m² IV. Day 1: Pemetrexed 500 mg/m² IV with concurrent thoracic radiotherapy. Repeat every 3 weeks for 3 cycles.</td>
</tr>
</tbody>
</table>

### Sequential Chemotherapy/ Radiotherapy (RT)

<table>
<thead>
<tr>
<th>REGIMEN</th>
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<tbody>
<tr>
<td>Cisplatin + vinblastine</td>
<td>Days 1 and 29: Cisplatin 100mg/m² IV. Days 1, 8, 15, 22 and 29: Vinblastine 5mg/m² IV; followed by thoracic radiotherapy with 60Gy in 30 fractions beginning on Day 50.</td>
</tr>
<tr>
<td>Paclitaxel + carboplatin</td>
<td>Day 1: Paclitaxel 200mg/m² IV over 3 hours + carboplatin AUC=6 IV over 1 hour. Repeat every 3 weeks for 2 cycles; followed by thoracic radiotherapy 63Gy beginning on Day 42.</td>
</tr>
</tbody>
</table>

continued
Cisplatin + etoposide

Systemic Therapy for Advanced Disease

Continuation maintenance refers to the use of at least one of the agents given in first line, beyond 4 to 6 cycles, in the absence of disease progression. Switch maintenance refers to the initiation of a different agent, not included as part of the first-line regimen, in the absence of disease progression, after 4 to 6 cycles of initial therapy.

- Continuation Maintenance: Bevacizumab and cetuximab given in combination with chemotherapy should be continued until evidence of disease progression or unacceptable toxicity, as per the design of the clinical trials supporting their use.
- Switch Maintenance: Two studies have shown a benefit in progression-free and overall survival with the initiation of pemetrexed or erlotinib after first-line chemotherapy, in patients without disease progression after 4–6 cycles of therapy.
- Initiation of bevacizumab after 4–6 cycles of platinum-doublet chemotherapy and bevacizumab (category 1).
- Initiation of cetuximab after 4–6 cycles of cisplatin, vinorelbine, and cetuximab (category 1).
- Initiation of pemetrexed after 4–6 cycles of cisplatin and pemetrexed chemotherapy, for patients with histologies other than squamous cell carcinoma (category 1).
- Initiation of bevacizumab + pemetrexed after 4–6 cycles of bevacizumab, pemetrexed, cisplatin/carboplatin, for patients with histologies other than squamous cell carcinoma.
- Initiation of gemcitabine after 4–6 cycles of platinum-doublet chemotherapy (category 2B).
- Continuation of gemcitabine after 4–6 cycles of platinum-doublet chemotherapy and bevacizumab (category 1).
- Continuation of docetaxel after 4–6 cycles of first-line platinum-doublet chemotherapy in patients with squamous cell carcinoma (category 2B).
- Continuation of paclitaxel and etoposide (weekly): Paclitaxel 36: Paclitaxel 45-50 mg/m² IV and carboplatin AUC=2 IV.
- Day 1 (weekly): Paclitaxel 200mg/m² IV and carboplatin AUC=6 IV.
- Days 1, 8, 29, and 36: Cisplatin 50mg/m² IV.
- Days 1–5, 29–33: Etoposide 50mg/m² IV with concurrent thoracic radiotherapy; followed by two additional cycles of cisplatin 50mg/m² IV and etoposide 50mg/m² IV.
- Unfit patients of any age (PS 3–4) do not benefit from cytotoxic treatment, except erlotinib for those who are epidermal growth factor receptor (EGFR) mutation-positive.

Principals of Maintenance Therapy

Continuation maintenance refers to the use of at least one of the agents given in first line, beyond 4 to 6 cycles, in the absence of disease progression. Switch maintenance refers to the initiation of a different agent, not included as part of the first-line regimen, in the absence of disease progression, after 4 to 6 cycles of initial therapy.

- Continuation Maintenance: Bevacizumab and cetuximab given in combination with chemotherapy should be continued until evidence of disease progression or unacceptable toxicity, as per the design of the clinical trials supporting their use.
- Switch Maintenance: Two studies have shown a benefit in progression-free and overall survival with the initiation of pemetrexed or erlotinib after first-line chemotherapy, in patients without disease progression after 4–6 cycles of therapy.
- Initiation of bevacizumab after 4–6 cycles of platinum-doublet chemotherapy and bevacizumab (category 1).
- Initiation of cetuximab after 4–6 cycles of cisplatin, vinorelbine, and cetuximab (category 1).
- Initiation of pemetrexed after 4–6 cycles of cisplatin and pemetrexed chemotherapy, for patients with histologies other than squamous cell carcinoma (category 1).
- Initiation of bevacizumab + pemetrexed after 4–6 cycles of bevacizumab, pemetrexed, cisplatin/carboplatin, for patients with histologies other than squamous cell carcinoma.
- Initiation of gemcitabine after 4–6 cycles of platinum-doublet chemotherapy (category 2B).
- Continuation of gemcitabine after 4–6 cycles of platinum-doublet chemotherapy and bevacizumab (category 1).
- Continuation of docetaxel after 4–6 cycles of first-line platinum-doublet chemotherapy in patients with squamous cell carcinoma (category 2B).
- Close surveillance of patients without therapy is a reasonable alternative to maintenance.

Principles of Third-Line Therapy

If not already given, options for patients with PS 0–2 include docetaxel, pemetrexed (nonsquamous), erlotinib, or gemcitabine (category 2B for all options).

Continuation After Disease Progression

With the exception of targeted agents (erlotinib, gefitinib, afatinib, crizotinib, ceritinib) in patients with EGFR-sensitizing mutations or ALK rearrangements who have experienced objective regressions with targeted therapy, no agent should be continued after disease progression has been documented except in selected situations. (refer to discussion section of NCCN Guidelines for Non-Small Cell Lung Cancer v.5.2015)

Systemic Treatment Options for Patients with NSCLC

- Cisplatin
- Carboplatin
- Paclitaxel
- Docetaxel
- Vinorelbine
- Gemcitabine
- Etoposide
- Irinotecan
- Vinblastine
- Mitomycin
- Ifosfamide
- Pemetrexed
- Erlotinib
- Bevacizumab
- Cetuximab
- Albumin-bound paclitaxel
- Crizotinib
- Afatinib
- Ceritinib
- Ramucirumab
- Nivolumab

continued
### First-Line Systemic Therapy for Advanced Disease

<table>
<thead>
<tr>
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| Bevacizumab carboplatin + paclitaxel¹²,³⁶ | **Day 1:** Paclitaxel 200mg/m² IV  
**Day 1:** Carboplatin AUC=6 IV.  
Repeat every 3 weeks for 6 cycles.  
**Day 1:** Bevacizumab 15mg/kg IV every 3 weeks until disease progression. |
| Cetuximab + cisplatin + vinorelbine²⁷||¹¹ | **Day 1:** Cetuximab 400mg/m² IV + cisplatin 80mg/m² IV, **plus**  
**Days 1 and 8:** Vinorelbine 25mg/m² IV, **plus**  
**Day 8:** Cetuximab 250mg/m² IV once weekly.  
Repeat every 3 weeks for 6 cycles. |
| Erlotinib²⁷,³⁸¶ | **Day 1:** Erlotinib 150mg PO once daily; following 4 cycles of platinum-based chemotherapy. |
| Cisplatin + paclitaxel¹⁵ | **Day 1:** Paclitaxel 135mg/m² IV over 24 hours  
**Day 2:** Cisplatin 75mg/m² IV.  
Repeat cycle every 3 weeks. |
| Cisplatin + gemcitabine¹⁹ | **Day 1:** Cisplatin 100mg/m² IV  
**Days 1, 8 and 15:** Gemcitabine 1,000mg/m² IV.  
Repeat cycle every 4 weeks. |
| Cisplatin + docetaxel⁶ | **Day 1:** Cisplatin 75mg/m² IV + docetaxel 75mg/m² IV.  
Repeat cycle every 3 weeks. |
| Cisplatin + vinorelbine⁶ | **Day 1:** Cisplatin 100mg/m² IV  
**Days 1, 8, 15 and 22:** Vinorelbine 25mg/m² IV over 10 minutes.  
Repeat cycle every 4 weeks. |
| Carboplatin + paclitaxel¹⁹ | **Day 1:** Carboplatin AUC=5–6 IV  
**Day 1:** Paclitaxel 225mg/m² IV over 3 hours.  
Repeat cycle every 3 weeks. |
| Pemetrexed + cisplatin²⁴,³⁹ | **Day 1:** Pemetrexed 500mg/m² IV + cisplatin 75mg/m² IV.  
Repeat cycle every 3 weeks. |
| Crizotinib²⁴,⁶⁸ | Crizotinib 250mg PO twice daily.** |
| Afatinib³²¶ | Afatinib 40mg PO once daily. |

#### Principals of First-Line Therapy¹

- Bevacizumab + chemotherapy or chemotherapy alone is indicated in patients with PS 0–1 with advanced or recurrent NSCLC. Bevacizumab should be given until disease progression.
- Cetuximab + vinorelbine/cisplatin is an option for patients with PS 0–1 (category 2B).
- Erlotinib is recommended as a first-line therapy in patients with sensitizing EGFR mutations and should not be given as first-line therapy to patients negative for these EGFR mutations or with unknown EGFR status.
- Afatinib is indicated for select patients with sensitizing EGFR mutations.
- Crizotinib is indicated for select patients with ALK rearrangements.
- There is superior efficacy and reduced toxicity for cisplatin/pemetrexed in patients with nonsquamous histology compared with cisplatin/gemcitabine.
- There is superior efficacy for cisplatin/gemcitabine in patients with squamous histology, in comparison to cisplatin/pemetrexed.
- Two drug regimens are preferred; a third cytotoxic drug increases response rate but not survival.
- Single-agent therapy or platinum-based combinations are a reasonable alternative in PS 2 patients or the elderly.
- Cisplatin or carboplatin have been proven effective in combination with any of the following agents: paclitaxel, docetaxel, gemcitabine, etoposide, vinblastine, vinorelbine, pemetrexed, or albumin-bound paclitaxel.
- New agent/non-platinum combinations are reasonable alternatives if available data show activity and tolerable toxicity (e.g., gemcitabine/docetaxel, gemcitabine/vinorelbine).
- Response assessment after 1–2 cycles, then every 2–4 cycles.

### Subsequent Second-Line Systemic Therapy for Advanced Disease¹

| Docetaxel²³ | **Day 1:** Docetaxel 75mg/m² IV.  
Repeat cycle every 3 weeks. |
| Pemetrexed⁷ | **Day 1:** Pemetrexed 500mg/m² IV.  
Repeat cycle every 3 weeks. |
| Erlotinib²⁵ | Erlotinib 150mg PO once daily. |
| Ceritinib³³a | Ceritinib 750mg PO once daily. |
| Ramucirumab + docetaxel²⁴ | **Day 1:** Ramucirumab 10mg/kg IV + docetaxel 75mg/m² IV.  
Repeat cycle every 3 weeks. |
| Afatinib²²⁴ | Afatinib 40mg PO once daily. |
| Nivolumab²⁶ | Nivolumab 3mg/kg IV over 60 minutes every 2 weeks. |
Subsequent Systemic Therapy for Advanced Disease

Principles of Subsequent Therapy

- In patients who have experienced disease progression either during or after first-line therapy, single-agent docetaxel, pemetrexed, or erlotinib are established second-line agents.
  - Docetaxel is superior to vinorelbine or ifosfamide.
  - Pemetrexed is considered equivalent to docetaxel with less toxicity in patients with adenocarcinoma and large cell carcinoma.
  - Ramucirumab + docetaxel improves survival when compared to docetaxel alone.
  - Erlotinib is superior to best supportive care.
  - Afatinib is indicated for select patients with sensitizing EGFR mutations.
  - Ceritinib is indicated for patients with ALK rearrangements who have disease progression on or are intolerant to crizotinib.
- If not already given, options for patients with PS 0–2 include docetaxel, pemetrexed (nonsquamous), erlotinib, or gemcitabine (category 2B for all options).

Continuation After Disease Progression

- With the exception of targeted agents (erlotinib, gefitinib, afatinib, crizotinib) in patients with EGFR-sensitizing mutations or ALK rearrangements who have experienced objective regressions with targeted therapy, no agent should be continued after disease progression has been documented except in selected situations (refer to discussion section of NCCN Guidelines for Non-Small Cell Lung Cancer v.5.2015).

Small Cell Lung Cancer (SCLC)

Chemotherapy as Primary or Adjuvant Therapy

Limited Stage (maximum of 4–6 cycles)

<table>
<thead>
<tr>
<th>REGIMEN</th>
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<tbody>
<tr>
<td>Cisplatin + etoposide</td>
<td>Day 1: Cisplatin 60mg/m² IV plus Days 1–3: Etoposide 120mg/m² IV. Repeat cycle every 3 weeks for at least 4 cycles. OR Day 1: Cisplatin 80mg/m² IV plus Days 1–3: Etoposide 100mg/m² IV. Repeat every 4 weeks for 4–6 cycles.</td>
</tr>
<tr>
<td>Carboplatin + etoposide</td>
<td>Day 1: Carboplatin AUC=5–6 IV plus Days 1–3: Etoposide 100mg/m² IV. Repeat every 3 weeks for 4–6 cycles.</td>
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</tbody>
</table>

Extensive Stage (maximum of 4–6 cycles)

<table>
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<tr>
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<tbody>
<tr>
<td>Cisplatin + etoposide</td>
<td>Day 1: Cisplatin 75–80mg/m² IV Days 1–3: Etoposide 80–100mg/m² IV. Repeat every 3 weeks for 4–6 cycles. OR Days 1–3: Cisplatin 25mg/m² IV + etoposide 100mg/m² IV. Repeat cycle every 3 weeks for 4–6 cycles.</td>
</tr>
<tr>
<td>Cisplatin + irinotecan</td>
<td>Day 1: Cisplatin 60mg/m² IV Days 1, 8 and 15: Irinotecan 60mg/m² IV. Repeat cycle every 4 weeks for 4 cycles. OR Day 1 and 8: Cisplatin 30mg/m² IV Day 1 and 8: Irinotecan 65mg/m² IV. Repeat every 3 weeks for 4–6 cycles.</td>
</tr>
<tr>
<td>Carboplatin + irinotecan</td>
<td>Day 1: Carboplatin AUC=5 IV plus Days 1, 8 and 15: Irinotecan 50mg/m² IV. Repeat cycle every 4 weeks for 4–6 cycles.</td>
</tr>
<tr>
<td>Carboplatin + etoposide</td>
<td>Day 1: Carboplatin AUC=5–6 IV. Days 1–3: Etoposide 100mg/m² IV. Repeat every 4 weeks for 4–6 cycles.</td>
</tr>
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</table>

Subsequent Chemotherapy

Relapse <2–3 months, PS 0–2

<table>
<thead>
<tr>
<th>Paclitaxel</th>
<th>Day 1: Paclitaxel 175mg/m² IV over 3 hours plus Day 1: Cisplatin 80mg/m² IV. Repeat every 3 weeks for at least 2 cycles. OR Day 1: Paclitaxel 80mg/m² IV over 1 hour. Repeat every week for 6 weeks, followed by a 2-week break.</th>
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continued
### Small Cell Lung Cancer (SCLC) (continued)

#### Subsequent Chemotherapy (continued)

<table>
<thead>
<tr>
<th>REGIMEN</th>
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<tbody>
<tr>
<td><strong>Docetaxel</strong></td>
<td><strong>Day 1:</strong> Docetaxel 100mg/m² IV over 1 hour. Repeat every 21 days.</td>
</tr>
<tr>
<td><strong>Topotecan</strong></td>
<td><strong>Days 1–5:</strong> Topotecan 1.5mg/m² IV once daily over 30 minutes. Repeat every 3 weeks. <strong>OR</strong> <strong>Days 1–5:</strong> Topotecan 2.3mg/m² PO once daily. Repeat every 3 weeks.</td>
</tr>
<tr>
<td><strong>Irinotecan</strong></td>
<td><strong>Day 1:</strong> Irinotecan 100mg/m² IV over 90 minutes. Repeat every week.</td>
</tr>
<tr>
<td><strong>Temozolomide</strong></td>
<td><strong>Day 1–21:</strong> Temozolomide 75mg/m² PO for a 4-week cycle.</td>
</tr>
<tr>
<td><strong>Gemcitabine</strong></td>
<td><strong>Days 1, 8, and 15:</strong> Gemcitabine 1,000mg/m² IV for a 4-week cycle.</td>
</tr>
<tr>
<td><strong>Ifosfamide</strong></td>
<td><strong>Day 1:</strong> Ifosfamide/mesna 5,000mg/m² IV. Repeat every 3 weeks.</td>
</tr>
</tbody>
</table>

#### Relapse > 2–3 months up to 6 months

| **Topotecan (Category 1)** | **Days 1–5:** Topotecan 1.5mg/m² IV once daily over 30 minutes. Repeat every 3 weeks. **OR** **Days 1–5:** Topotecan 2.3mg/m² PO once daily. Repeat every 3 weeks. |
| **Paclitaxel**            | **Day 1:** Paclitaxel 175mg/m² IV over 3 hours plus **Day 1:** Cisplatin 80mg/m² 2 Repeat every 3 weeks for at least 2 cycles. **OR** **Day 1:** Paclitaxel 80mg/m² IV over 1 hour. Repeat every week for 6 weeks, followed by a 2-week break. |
| **Docetaxel**             | **Day 1:** Docetaxel 100mg/m² IV over 1 hour. Repeat every 21 days.     |
| **Irinotecan**            | **Day 1:** Irinotecan 100mg/m² IV over 90 minutes. Repeat every week.    |
| **Gemcitabine**          | **Days 1, 8, and 15:** Gemcitabine 1,000mg/m² IV for a 4-week cycle.    |
| **Vinorelbine**           | **Day 1:** Vinorelbine 25–30mg/m² IV. Repeat every week                 |
| **Etoposide (PO)**        | **Day 1–21:** Etoposide 50mg/m² PO.                                      |
| **Temozolomide**          | **Day 1–21:** Temozolomide 75mg/m² PO for a 4-week cycle.               |
| **Cyclophosphamide + doxorubicin + vincristine (CAV)** | **Day 1:** Cyclophosphamide 1,000 mg/m² IV plus **Day 1:** Doxorubicin 45mg/m² IV plus **Day 1:** Vincristine 2mg IV. Repeat every 21 days. |

#### Relapse > 6 months

- **Original regimen**
  - For adenocarcinoma, large cell carcinoma, and NSCLC NOS without specific histologic subtype.
  - This regimen can be used as neoadjuvant chemoradiation therapy. Cisplatin and etoposide is the preferred regimen. If weekly carboplatin and paclitaxel is used because the patient is not able to tolerate concurrent full-dose cisplatin and radiotherapy, the treating physician should consider 2 cycles of full-dose platinum therapy after local treatment is completed.
  - Most are used in combination, while others are used as monotherapy (e.g., maintenance or second-line therapy).
  - Albumin-bound paclitaxel may be substituted for either paclitaxel or docetaxel in patients who have experienced hypersensitivity reactions after receiving paclitaxel or docetaxel despite premedication, or for patients where the standard premedications (dexamethasone, H2 blockers, H1 blockers) are contraindicated.
  - Indicated in advanced NSCLC.
  - Indicated for EGFR mutation-positive patients and may be considered as an option for patients who test positive for an EGFR mutation.
  - Indicated for ALK-positive patients.
  - May reduce to 200mg twice daily not tolerated or toxicity occurs. If further reduction is needed, reduce to 250mg once daily.
  - The use of myeloid growth factors is not recommended during concurrent chemotherapy plus radiotherapy.
  - During chemoradiotherapy, cisplatin/etoposide is recommended (Category 1).
  - Consider dose reductions versus growth factors in the poor performance status patient.
References


continued
LUNG CANCER TREATMENT REGIMENS (Part 7 of 7)

References (continued)


48. Natale RB et al. S0124: a randomized phase III trial comparing irinotecan-cisplatin (IP) with etoposide/cisplatin (EP) in patients (pts) with previously untreated extensive stage small-cell lung cancer (E-SCCL) [Abstract 7512], 2008 ASCO annual meeting.


