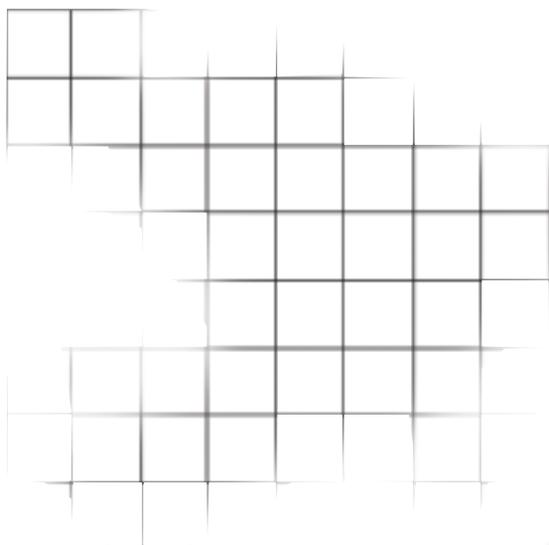


Patient Guide

ASCO

*Information for
People Living
with Cancer*



ADVANCED LUNG CANCER TREATMENT



Recommendations of the American Society of Clinical Oncology

Welcome

The American Society of Clinical Oncology (ASCO) is the world's leading professional society of multidisciplinary medical professionals who treat people with cancer. ASCO's more than 20,000 members from the United States and abroad set the standard for patient care worldwide and lead the fight for more effective cancer treatments, increased funding for clinical and translational research, and, ultimately, cures for the many different cancers that affect 1.3 million Americans every year. ASCO publishes the semi-monthly *Journal of Clinical Oncology* (JCO), the foremost, peer-reviewed journal focusing on clinical cancer research, and produces the award-winning website People Living With Cancer (www.plwc.org), which provides oncologist-vetted cancer information to help patients and families make informed health-care decisions.

To help doctors give their patients the best possible care, ASCO asks its medical experts to review the latest research on issues in cancer care and develop recommendations called clinical practice guidelines.

To help patients understand their cancer care, ASCO created this patient guide, based on the guidelines ASCO's experts developed to help people with lung cancer.

As you read this guide, please keep in mind every person treated for cancer is different. These recommendations are not meant to replace your or your doctors' judgment. The final decisions you and your doctors make will be based on your individual circumstances.



What is lung cancer?

Lung cancer occurs when abnormal cells develop in the lungs and reproduce without the body's normal regulations on cell birth and death. These cells can keep dividing until they form a mass of cells called a tumor. Tumors interfere with normal lung function. Cells can break off from the tumor and can be carried to other parts of the body. This is called metastasis.



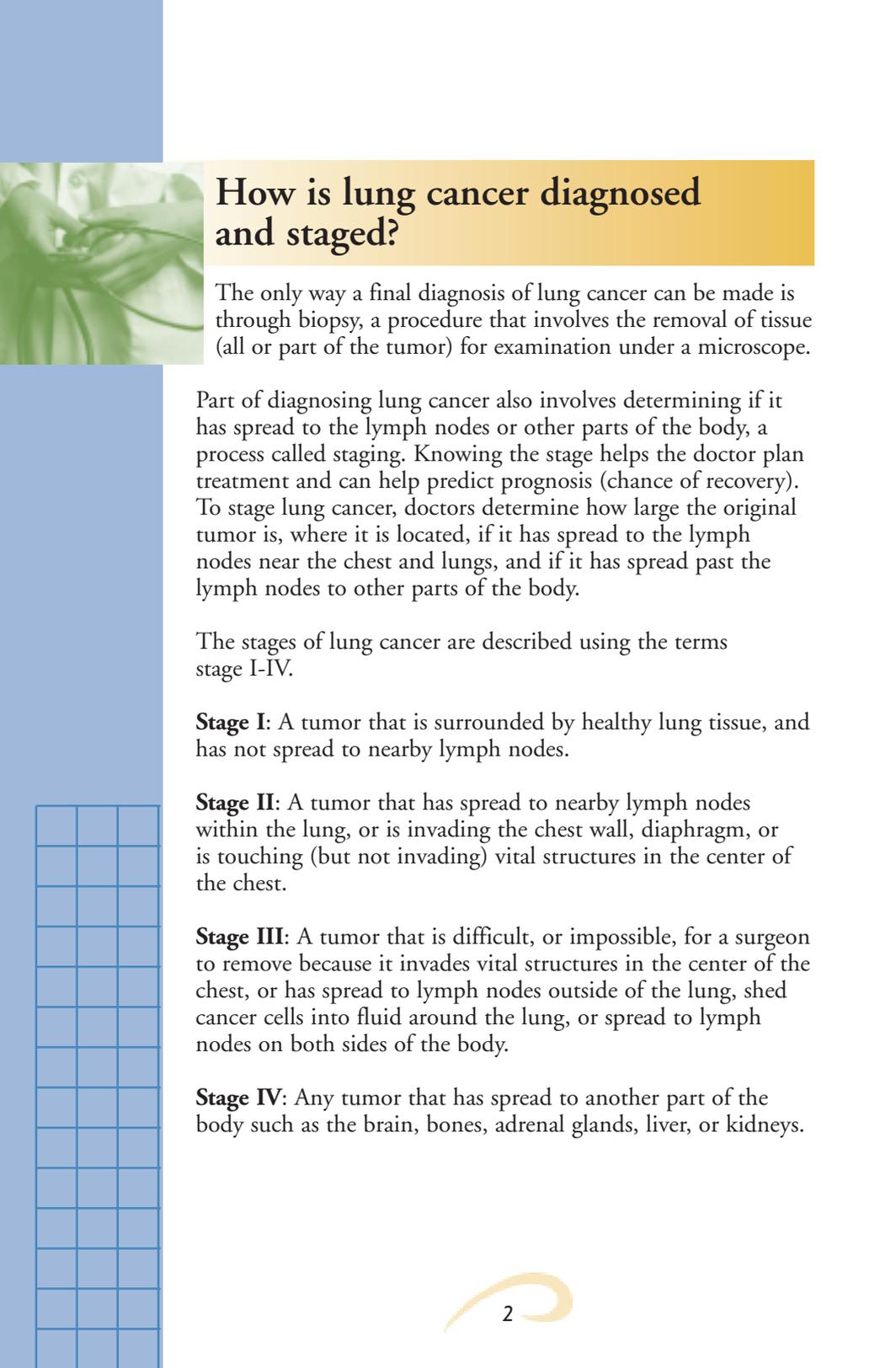
There are two major types of lung cancer: small cell and non-small cell. The terms small cell and non-small cell refer to the types of cells seen under a microscope. About 80% of all lung cancer cases are non-small cell lung cancer (NSCLC). Only non-small cell lung cancer is discussed in this booklet.

Some non-small cell lung cancers can be treated with surgery that removes all or part of the affected lung, but most advanced lung cancers cannot. If surgery is not possible or will not help slow the cancer's growth, the tumor is called unresectable. This can be because of the location or the size of the tumor, or because tests show that the cancer has spread to lymph nodes or other organs in the body.

Lymph nodes are tiny, bean-shaped structures clustered throughout the body—mostly in the areas of the head and neck, chest and abdomen, and groin. The lymph system is an important part of the body's immune system. Its job is to filter out and remove bacteria, viruses, and other foreign substances, and to supply lymphocytes (white blood cells) to the bloodstream.

Information in ASCO's patient information materials is not intended as medical advice or as a substitute for the treating doctor's own professional judgment; nor does it imply ASCO endorsement of any product or company.





How is lung cancer diagnosed and staged?

The only way a final diagnosis of lung cancer can be made is through biopsy, a procedure that involves the removal of tissue (all or part of the tumor) for examination under a microscope.

Part of diagnosing lung cancer also involves determining if it has spread to the lymph nodes or other parts of the body, a process called staging. Knowing the stage helps the doctor plan treatment and can help predict prognosis (chance of recovery). To stage lung cancer, doctors determine how large the original tumor is, where it is located, if it has spread to the lymph nodes near the chest and lungs, and if it has spread past the lymph nodes to other parts of the body.

The stages of lung cancer are described using the terms stage I-IV.

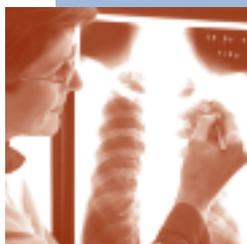
Stage I: A tumor that is surrounded by healthy lung tissue, and has not spread to nearby lymph nodes.

Stage II: A tumor that has spread to nearby lymph nodes within the lung, or is invading the chest wall, diaphragm, or is touching (but not invading) vital structures in the center of the chest.

Stage III: A tumor that is difficult, or impossible, for a surgeon to remove because it invades vital structures in the center of the chest, or has spread to lymph nodes outside of the lung, shed cancer cells into fluid around the lung, or spread to lymph nodes on both sides of the body.

Stage IV: Any tumor that has spread to another part of the body such as the brain, bones, adrenal glands, liver, or kidneys.

In the later stages of lung cancer (stage III and stage IV), surgery to remove all of the cancer is often not possible and the cancer is considered unresectable. This booklet describes guidelines for cancers that are unresectable.



About the Expert Panel

ASCO formed a panel of experts to revise these guidelines. The members included medical, surgical, and radiation oncologists, health services researchers, a pulmonary specialist, and a patient advocate.

The panel worked together using the evidence and their own expertise, and formed their opinions by consensus (agreement from everyone in the group).

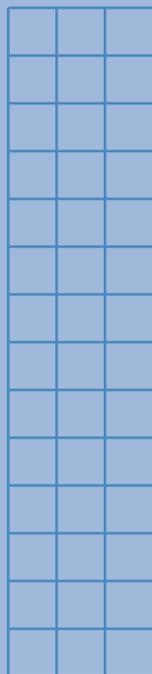
What are the ASCO guidelines on staging lung cancer?

Since knowing the stage of each person's lung cancer is necessary for planning treatment, ASCO has evaluated the available evidence on the use of different tests used to stage lung cancer.

According to ASCO's guidelines:

For staging local or regional lung cancer (usually stage I or stage II), research has shown the following tests to be the most useful:

Chest x-ray. An x-ray of the chest area can help show the location of the primary tumor and help determine if it has grown since a previous x-ray was taken.





Computerized tomography (CT) scan. CT scans use computers to create images of structures inside the body using a series of x-rays. They can show areas of lung cancer and help determine whether surgical removal is possible.

Positron emission tomography (PET) scan. In a PET scan, radioactive sugar molecules are injected into the body. Lung cancer cells absorb sugar more quickly than normal cells, so they light up on the PET scan. PET scans are used to complement information gathered from CT scans, x-rays, and the physical examination. PET scans commonly extend from the patient's neck to their pelvis, and do not evaluate the brain or the legs. The results of a PET scan may affect the need for additional tests.

Biopsy. The final diagnosis of non-small cell lung cancer is made with the results from a biopsy. In a biopsy, a doctor removes a piece of tissue or a sample of cells with a needle (called needle aspiration), and sends it to a laboratory to be checked for cancer cells under a microscope.

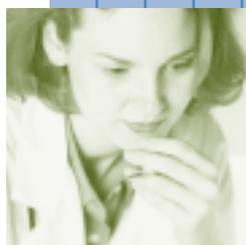
A biopsy may be done during a bronchoscopy, in which doctors examine the tubes that carry air into the lungs (trachea and bronchi) using a slender instrument with a small light at its end called a bronchoscope.

Sometimes, a biopsy is done during an operation to open the chest to examine the lungs and the lymph nodes (called a thoracotomy).

For staging more advanced lung cancers, the following tests may also be useful:

Bone scan. In a bone scan, radioactive molecules are injected into the body to detect abnormal areas within the bone. If patients have symptoms such as bone pain, chest pain, or abnormal blood test results (such as higher than normal levels of calcium or alkaline phosphate in the blood), bone scans can help doctors determine whether cancer has spread to the bone. The result of a prior PET scan may make a bone scan unnecessary.

CT scan of the head or magnetic resonance imaging (MRI) of the brain. Besides using x-rays, another way to create images of structures inside the body is to use magnetic fields and radio waves. This technique is known as magnetic resonance imaging (MRI). If a patient reports symptoms that suggest the cancer has spread to the brain, doctors may order a CT scan or MRI of the brain to confirm. For patients who do not have symptoms (asymptomatic) but whose tumors are larger than 3 cm, or those patients who have cancer in the lymph nodes in the center of the chest, a brain MRI might be recommended.



The CT scan or PET scan may detect masses on the adrenal glands (the small glands that sit on top of the kidneys) or the liver. If there is an abnormality in the liver or adrenal glands, a biopsy is the only definitive way to determine if cancer is present. MRI may be used to examine a mass on the liver. Again, biopsy is the only definitive way to determine if cancer is present.

How is unresectable non-small cell lung cancer treated?

Which treatment is best is based on the individual. The recommendations ASCO provides are based on experts' review of research studies and other evidence, not the results seen in any one person. Treatment decisions should be made through a collaborative effort between patients and their doctors. For people whose cancer is unresectable, doctors usually recommend chemotherapy alone, chemotherapy and radiation therapy (radiotherapy) together, or radiation therapy alone.

Chemotherapy

Chemotherapy is the use of drugs to kill cancer cells by stopping them from growing or dividing. Chemotherapy has been shown to prolong life for patients with advanced (stage III and stage IV) lung cancer. Because cancer cells grow and divide faster than



normal cells, they are more likely than normal cells to be eliminated by chemotherapy drugs.

For most people, chemotherapy is given in an outpatient setting (the patient does not stay overnight in the hospital), and at regular intervals called cycles. Chemotherapy is typically given for a fixed number of cycles over several months.

Many chemotherapy drugs are used to treat lung cancer. Normally, more than one drug is used. ASCO recommends that at least one of the drugs used be either carboplatin (Paraplatin) or cisplatin (Platinol). Other commonly used drugs are docetaxel (Taxotere), gemcitabine (Gemzar), paclitaxel (Taxol), vinorelbine (Navelbine), and vinblastine (Velban). These drugs and others are used in different combinations.

No one treatment or combination of treatments works for everyone. A physical examination, chest x-ray, CT scan, MRI, and/or PET scan may be needed to determine if treatment is effective. If, after several months, the treatment does not appear to be working, the doctor may recommend a change in treatment (called second-line therapy), which may include a drug that is being investigated in a clinical trial. It is important to remember that second-line therapy may also prove to be ineffective.

According to ASCO's guidelines:

- If a patient has non-small cell lung cancer that is unresectable but is still treatable with radiation therapy, then chemotherapy should be added to the radiation therapy. Research shows that chemotherapy plus radiation therapy may prolong survival compared with radiation therapy alone in this setting. The chemotherapy can be delivered either before or during radiation therapy. People who are in overall better health (good performance status) are expected to benefit most from treatment.
- Chemotherapy alone is appropriate for some patients with stage IV non-small cell lung cancer and may prolong survival.

- For advanced non-small cell lung cancer, combination chemotherapy (more than one chemotherapy drug) is recommended. For people whose chemotherapy using platinum-based drugs has stopped working, a drug called docetaxel (Taxotere) has been shown to help as a second-line therapy.



- For people with stage III lung cancer, there is no research to indicate that more than four cycles of chemotherapy is useful. For people with stage IV lung cancer, there is no research to indicate that more than six cycles of chemotherapy is useful.

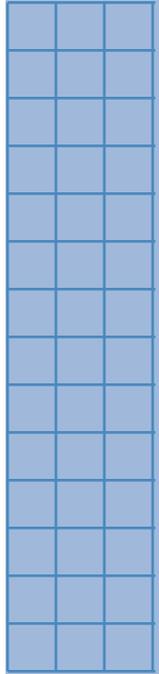
Radiation therapy (Radiotherapy)

Radiation therapy is the use of high-energy x-rays to kill cancer cells in the lungs and shrink small tumors. Radiation of the tumor in the lungs or elsewhere in the body may be recommended in addition to chemotherapy. Radiation therapy is given daily for several weeks, or sometimes more than once a day. Usually, treatment is given in an outpatient setting.

Doctors who specialize in radiation therapy for cancer treatment are called radiation oncologists.

According to ASCO's guidelines:

- Radiation therapy has been shown to successfully treat people whose cancer is locally advanced. It is most likely to be successful in people with overall better health (good performance status) and in those whose cancer has not spread beyond the chest area. Radiation therapy is not recommended for people whose cancer has spread to other parts of the body, or in those who have fluid in their lungs caused by cancer (pleural effusion).
- In people who are having pain or other symptoms caused by lung cancer, radiation therapy may help to relieve symptoms.





Surgery

Surgery to remove a tumor is called resection. Even if the original lung cancer is unresectable, people with lung cancer that has spread to other parts of the body may benefit from surgery.

According to ASCO's guidelines:

- In some cases, research has shown that surgery to remove cancer from the brain may help slow the growth of the cancer.

How are the side effects of cancer and cancer treatment managed?

Many people experience symptoms such as coughing, pain, shortness of breath (dyspnea), or fatigue caused by cancer in the lungs. These symptoms may also occur as a result of lung cancer treatment. There are ways to control symptoms, so it is important to speak with your doctor about all symptoms. Symptoms may also provide the doctor with information about how the cancer is behaving.

While chemotherapy and radiation therapy are designed to kill cancer cells, normal cells can also be damaged by chemotherapy and high doses of radiation therapy. This damage can result in side effects such as nausea, fatigue, and hair loss. These side effects can last for weeks, sometimes longer, but usually go away after treatment is finished. There are methods available to control many of these side effects. If side effects are too severe, treatment may be delayed or stopped.

What are clinical trials?

Scientists continue to look for new and more effective ways to treat lung cancer. A very important method for discovering new information on cancer treatments is through clinical trials.

Clinical trials are conducted to determine the safest doses and methods of administration for a new treatment (phase I clinical trials), how well a new treatment works (phase II clinical trials), and how the new treatment compares with other available treatments (phase III clinical trials).



Clinical trials are research studies that rely on volunteers. Once a doctor tells a patient about an available clinical trial, the patient must volunteer to take part in the trial. There are no guarantees that a new therapy offers an advantage over an existing therapy. Patients who volunteer to participate in a clinical trial may hope for benefits for themselves, such as cure of the disease, longer survival, or a way to resolve symptoms, and often want to contribute to research that may help others.

People in clinical trials are among the first to receive new research treatments before they are widely available. How well a trial will work cannot be known ahead of time. Even standard treatments, although effective for many patients, are not guaranteed to be effective for everyone.

According to ASCO's guidelines:

- For all people with advanced non-small cell lung cancer, ASCO encourages participation in clinical trials of new drugs or treatments. In some cases, clinical trials may offer the best chance for successful treatment. If a person's cancer does not respond to treatment in a clinical trial, standard treatment may be continued.

What happens after lung cancer treatment?

Continued medical care is necessary for people with lung cancer that has been treated to determine if the cancer recurs (comes back), or to evaluate if the tumor continues to grow.



According to ASCO's guidelines:

- ASCO recommends that people who have had treatment to extend their life and have no symptoms or other evidence of cancer should see their doctor every three months for the first two years, then every six months for the next three years, and then once a year.
- In general, research shows that extensive testing is only necessary for patients who have symptoms.
- For patients who are having symptoms after treatment ends, doctors may recommend a CT scan, MRI, or PET scan. Doctors compare the results of tests done after treatment with tests done before treatment to determine if the cancer has progressed. Chest x-rays, bone scans, complete blood cell counts, and other routine tests may be done at follow-up examinations, depending on each patient's symptoms.

What is palliative therapy?

Palliative therapy involves the care of the person with cancer and all of his or her needs, and does not focus only on treating the disease. For people with lung cancer, palliative therapy involves the use of medications, chemotherapy, radiation therapy, and/or other means to relieve the symptoms caused by cancer, such as pain and shortness of breath. The patient's comfort is a priority at every stage of treatment.

When radiation therapy is used as palliative therapy, it is usually given in doses small enough to avoid the side effects that can result at the doses used in curative therapy. If doctors and their patients decide together that treatment will no longer slow or stop the growth of cancer, hospice care for comfort may be suggested.

How can cancer be prevented from recurring?

Since it is known that people with overall better health (good performance status) benefit most from treatment, maintaining the best health possible is important. This includes keeping a balanced, nutritious diet and getting plenty of rest.

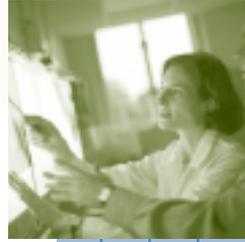
- Research shows that people who smoke can damage their health even after they have lung cancer. It is very important to stop smoking, not to begin smoking, and to avoid being around people who are smoking. Smoking can cause new cancer to develop and can further lung damage. Even in people with advanced lung cancer, stopping smoking can improve breathing.
- No vitamin, antioxidant, or other agent in large doses (more than the recommended daily requirements) has been shown to prevent recurrence or slow the growth of cancer, and some may be harmful. People who are taking these supplements should speak with their doctor.

Where can I get more information?

The revised guidelines are published in ASCO's *Journal of Clinical Oncology* (*J Clin Oncol* Jan 15 2004;22). For a copy of the guidelines, visit www.asco.org, call 703-299-0150, or send an e-mail to: guidelines@asco.org.

For more information about cancer, visit People Living With Cancer at www.plwc.org, ASCO's website for patients, families, and the public.

For more information about advanced lung cancer treatment, patients should speak directly with their doctor.



Resources

Many organizations offer support to people with cancer and their families. Ask your doctor or call your local hospital to find out about such groups in your community. In addition, these organizations can provide information or educational materials about lung cancer.

Alliance for Lung Cancer Advocacy, Support, and Education

500 W. 8th Street, Suite 240
Vancouver, WA 98660
800-298-2436
www.alcase.org

American Cancer Society

1599 Clifton Road, NE
Atlanta, GA 30329
800-ACS-2345 (227-2345)
www.cancer.org

American Lung Association

61 Broadway, 6th Floor
New York, NY 10006
800-LUNG-USA (586-4872)
www.lungusa.org

Cancer Care

275 7th Avenue
New York, NY 10001
800-813-HOPE (4673)
www.cancercare.org

National Cancer Institute

NCI Public Inquiries Office, Suite 3036A
6116 Executive Boulevard, MSC8322
Bethesda, MD 20892-8322
800-4-CANCER (422-6237)
www.cancer.gov

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A Commitment to Service

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Types of Giving

Philanthropic funding of the educational programs is more important than ever. There are a number of ways to provide support for a better understanding and treatment of cancer.

Unrestricted gifts provide the flexibility needed to move quickly in unexpected directions in research and clinical applications, and help to cover the costs of ASCO critical services that are not entirely financed by other support.

Restricted gifts benefit specific programs of the donor's choosing in any of the ASCO initiatives in patient care and education.

Tribute gifts can be made as memorial tributes, remembrance gifts, or as a way of honoring the Society's membership.

For more information, please contact:

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People Living With Cancer

AN ASCO WEBSITE

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