

Protocol for the Examination of Specimens from Patients with Malignant Pleural Mesothelioma

Protocol applies to all malignant mesotheliomas arising from the mesothelial lining of the pleural cavity (parietal, mediastinal, diaphragmatic and visceral pleura). This protocol does not apply to solitary fibrous tumor, peritoneal mesothelioma, lymphoma, or sarcoma.

Based on:

AJCC/UICC TNM, 8th edition
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Revision History:

Addition of TNM Staging criteria

Summary of Changes:

This protocol is revised to the 8th edition of the AJCC Cancer Staging Manual and the current version of the CAP Cancer Protocol Mesothelioma 4.0.0.1.

Procedures Covered in this Protocol:

- Pleurectomy (removal of affected parietal pleura)
- Pleural decortication (removal of affected pleura and fibrous rind from pleural space)
- Extrapleural pneumonectomy (en bloc resection of the lung, pleura, chest wall, pericardium, diaphragm)

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The purpose of the Protocols is to support Laboratory Personnel engaged in the macroscopic examination of cancer resection specimens. The Protocols are based on specified relevant source documents, drafted by pathologists' assistant experts, and supported by information provided by the College of American Pathologists (CAP) and the American Joint Committee on Cancer (AJCC). These Protocols are intended to serve patients by ensuring that the macroscopic examination of cancer resection specimens is compliant with CAP Cancer Protocols, the AJCC Cancer Staging Manual, and provide optimization of the pre-analytic steps necessary to promote appropriate molecular studies.

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Immunohistochemical Considerations:

Immunohistochemistry is required for a definitive diagnosis of malignant mesothelioma. Because there is no uniformly sensitive and specific immunohistochemical marker for malignant mesothelioma, a panel of stains is generally necessary. The immunohistochemical method depends on the mesothelioma morphology and the type of tumors that are considered in the differential diagnosis. The 2015 WHO recommends the combined use of at least two mesothelial markers and two carcinoma markers. Mesothelial markers include calretinin, cytokeratins 5/6, WT-1, and D2-40. Carcinoma markers include BerEP4 or MOC31, B72.3, CEA, and BG8.

These tests can be performed on formalin fixed paraffin embedded tissue sections. The macroscopic description should provide the fixative used. 10% neutral buffered formalin is the preferred fixative. It is recommended that the duration of fixation be provided as well.

Electron Microscopy:

For optimal ultrastructural preservation, fresh tissue should be procured and placed in cold glutaraldehyde or other suitable fixative if electron microscopy is requested.

PROCEDURES AND GENERAL ANATOMIC CONSIDERATIONS:

■ Procedures Covered by this Protocol:

- Pleurectomy/decortication
- Extended pleurectomy/decortication
- Partial pleurectomy
- Extrapleural pneumonectomy
- Other (specify)

■ Specimen Size and Extent of Resection:

- Pleura
 - Specify laterality.
 - Specify parietal versus visceral.
 - Measure in three dimensions including pleural thickness.
- Lung
 - Specify laterality.
 - Weight.
 - Measure in three dimensions.
- Extrapleural pneumonectomy (EPP)
 - Specify laterality.
 - Weight.
 - Overall dimensions.
 - Identify and measure, as appropriate, attached structures.

■ Specimen Integrity and Adequacy:

Provide an assessment of the specimen integrity. Statements should include the precise location of any disruptions, the relationship of the disruption to the tumor, and whether the disruption may hinder the assessment of the final surgical margins.

Pleurectomies are performed for debulking of mesotheliomas if the tumor is unresectable. These specimens consist of multiple fragments of pleura with tumor implants. In this setting, when applicable, consider providing a comment indicating that the status of the final margin cannot be provided.

TUMOR ("T" of TNM)

■ **Tumor Size:**

- Tumor size is not prognostically significant, but three dimensions should be recorded.
- It is most important to describe diffuse or focal disease.
- If multiple nodules are present, then an approximate number of nodules is given along with a range in size of the nodules.
- Since mesotheliomas have a growth pattern extending along the pleural surface, the thickness of the pleura should be recorded.
- Record approximate percentage of pleura involved by tumor.

■ **Tumor Focality:**

- Localized (sharply circumscribed)
- Diffuse (multinodular, plaque-like, confluent)

The majority of malignant mesotheliomas exhibit diffuse growth and may take the form of multiple small nodules, plaque-like masses, or confluent rind-like sheets. However, a small proportion of malignant mesotheliomas are sharply circumscribed, which are designated by the term "localized malignant mesothelioma."

Localized malignant mesotheliomas have a better prognosis than their diffuse counterpart.

■ **Tumor Site(s):**

- Parietal pleura
- Visceral pleura
- Diaphragm
- Other (specify)

■ **Tumor Extent of Involvement / Extension and Relationship to Attached Organs / Structures:**

The most significant pathologic prognostic factors are extent of tumor involvement and nodal status.

- Record the presence, size, and tumor involvement / extension of any other structures:

- Parietal pleura with or without involvement of ipsilateral visceral, mediastinal, or diaphragmatic pleura
- All ipsilateral pleural surfaces (including fissure)
- Mediastinal organ(s) (specify)
- Diaphragmatic muscle
- Pulmonary parenchyma

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- Describe the extent of parenchymal involvement and whether the tumor is pushing into the lung from the pleura or whether there are separate lung nodules (the latter should definitely be sampled since patients may have concomitant lung cancer).

- Endothoracic fascia *
- Mediastinal fat
- Chest wall soft tissues (solitary or diffuse) **
- Pericardium (extending into but not through the pericardium)
- Rib(s)
- Other ***

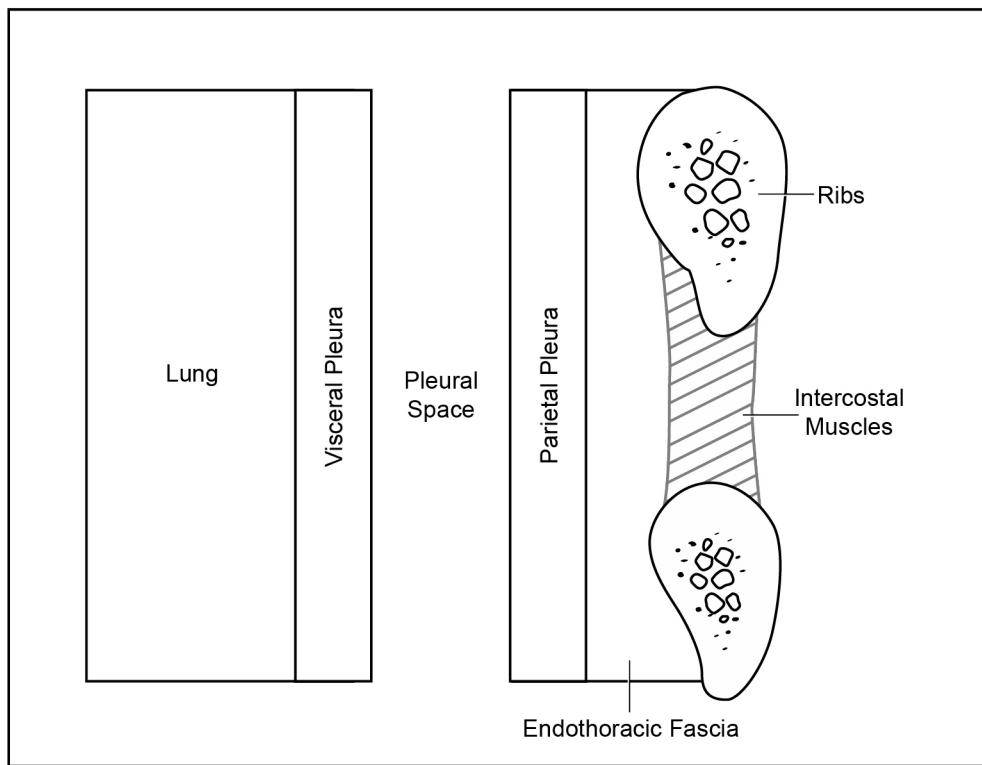


Figure 1: Endothoracic fascia diagram

*Assessment of the endothoracic fascia (located external to the parietal pleura beneath the intercostal muscles and ribs of the chest wall) is best made by the surgeon at the time of operation. Invasion of the endothoracic fascia is categorized as T3. Determining the presence or absence of endothoracic fascial invasion can be difficult on pathologic examination, due to the endothoracic fascia lacking distinctive macroscopic features. (*Figure 1*)

**A solitary focus of tumor invading soft tissues of the chest wall is designated as T3. The elements of the chest wall include the ribs, intercostal muscles, and supporting connective tissues, the latter two representing the chest wall soft tissues. This does not include the layer of adipose tissue (sometimes referred to as extrapleural fat), that lies

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between the chest wall and the parietal pleura. It is recommended that the surgeon designate the locations of these structures to ensure optimal pathologic assessment.

***Radical extrapleural pneumonectomy specimens may incorporate structures directly invaded by tumor that fall under the T4 designation. These should be specified under "other" and include tumor extension to the following:

- Peritoneum (through the diaphragm)
- Contralateral pleura
- Spine
- Internal surface of the pericardium
- Myocardium
- Brachial Plexus

Definition of Primary Tumor (pT) (Figure 2)

pT Category	pT Criteria
pTX	Primary tumor cannot be assessed
pT0	No evidence of primary tumor
pT1	Tumor limited to the ipsilateral parietal pleura with or without involvement of <ul style="list-style-type: none"> • visceral pleura • mediastinal pleura • diaphragmatic pleura
pT2	Tumor involving each of the ipsilateral pleural surfaces (parietal, mediastinal, diaphragmatic, and visceral pleura) with at least one of the following features: <ul style="list-style-type: none"> • involvement of diaphragmatic muscle • extension of tumor from visceral pleura into the underlying pulmonary parenchyma
pT3	Describes locally advanced but potentially resectable tumor. Tumor involving all the ipsilateral pleural surfaces (parietal, mediastinal, diaphragmatic, and visceral pleura) with at least one of the following features: <ul style="list-style-type: none"> • involvement of the endothoracic fascia • extension into the mediastinal fat • solitary completely resectable focus of tumor extending into the soft tissues of the chest wall • nontransmural involvement of the pericardium
pT4	Describes locally advanced technically unresectable tumor. Tumor involving all the ipsilateral pleural surfaces (parietal, mediastinal, diaphragmatic, and visceral pleura) with at least one of the following features: <ul style="list-style-type: none"> • diffuse extension or multifocal masses of tumor in the chest wall, with or without associated rib destruction • direct transdiaphragmatic extension of tumor to the peritoneum • direct extension of tumor to the contralateral pleura • direct extension of tumor to mediastinal organs • direct extension of tumor into the spine • tumor extending through to the internal surface of the pericardium with or without a pericardial effusion; or tumor involving the myocardium

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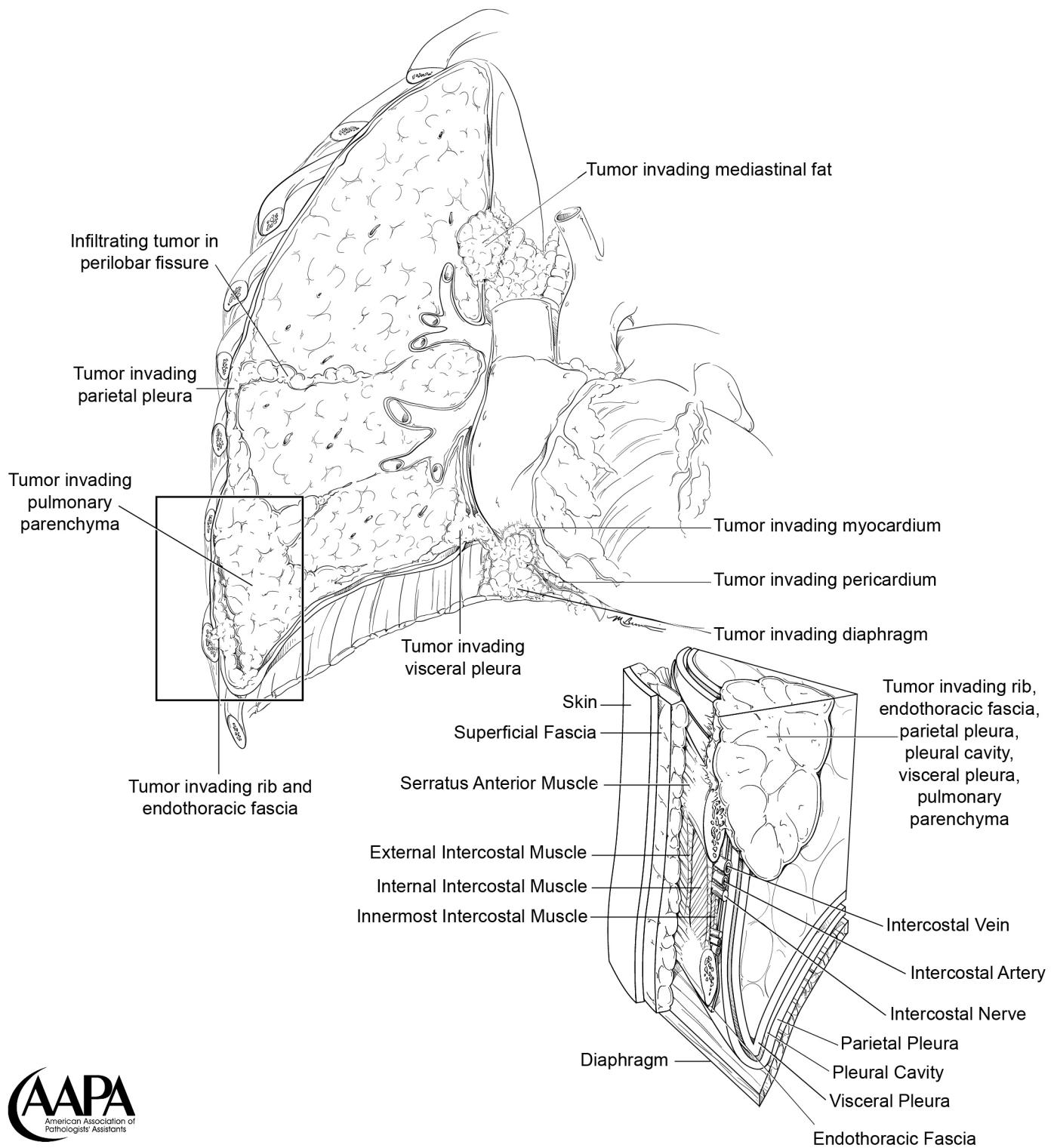


Figure 2: The most significant pathologic prognostic factors are extent of tumor involvement and nodal status

TNM Descriptors:

pT(m)NM: the "m" suffix (multiple primary tumors in a single site) is recorded in parentheses. This is not a descriptor that readily applies to diffuse malignant pleural mesothelioma, which often exhibits a multinodular growth pattern but is best considered a single tumor for staging purposes. A localized malignant pleura mesothelioma may on rare occasion have multiple primary tumors.

ypTNM: the "y" prefix (post treatment) indicates those cases in which classification is performed during or after initial multimodality therapy (i.e., neoadjuvant chemotherapy, radiation therapy, or both chemotherapy and radiation therapy). The "y" categorizes the extent of tumor actually present at the time of that examination and is NOT an estimate of tumor before multimodality therapy (i.e., before initiation of neoadjuvant therapy).

rpTNM: the "r" prefix indicates a recurrent tumor when staged after a documented disease-free interval.

apTNM: the "a" prefix designates stage at autopsy.

Other staging systems for malignant pleural mesothelioma have also been devised, such as the Brigham Staging System, as shown below. Use of this protocol does not preclude reporting of tumor stage as determined by other systems concurrent with TNM designation.

Brigham Staging System for Malignant Pleural Mesothelioma

Stage	Definition
I	Disease confined to within capsule of the parietal pleura: ipsilateral pleura, lung, pericardium, diaphragm, or chest wall disease limited to previous biopsy sites
II	All of stage I with positive intrathoracic (N1 or N2) nodes
III	Local extension of disease into chest wall or mediastinum, heart, or through diaphragm, peritoneum; with or without extrathoracic or contralateral (N3) lymph node involvement
IV	Distant metastatic disease

According to the Brigham Staging System, stage I represents resectable patients with negative nodes, whereas stage II patients are resectable, but have positive nodal status.

■ **Treatment Effect**

Induction chemotherapy prior to extrapleural pneumonectomy is utilized in some centers for locally advanced malignant pleural mesothelioma.

- In applicable specimens:
 - A generalized estimate of the amount of residual viable tumor should be reported in the gross description.
 - Representative sections of viable appearing areas of the tumor should be submitted to ensure adequate sampling.

The threshold of greater than or less than 50% residual viable tumor provides prognostically relevant information.

Residual Tumor (R) Category

The absence or presence of residual tumor at the primary tumor site after treatment is denoted by the symbol R. The R categories for the primary tumor site are as follows:

R	R Definition
RX	Presence of residual tumor cannot be assessed
R0	No residual tumor
R1	Microscopic residual tumor
R2	Macroscopic residual tumor at the primary cancer site or regional nodal sites

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For the surgeon, the R classification may be useful to indicate the known or assumed status of the completeness of a surgical excision. For the pathologist, the R classification is relevant to the status of the margins of a surgical resection specimen. That is, tumor involving the resection margin on pathologic examination may be assumed to correspond to residual tumor in the patient and may be classified as macroscopic or microscopic according to the findings at the specimen margin(s).

■ **Margins:**

Extrapleural pneumonectomy specimens are obtained by dissection of tumor from the thorax with en bloc resection of the lung, pleura, pericardium and diaphragm. Consequently, the entire non-pleural surface of the extrapleural pneumonectomy specimen represents a surgical margin (unless otherwise specified by the surgeon).

- If margins are ***macroscopically involved*** by tumor:
 - Provide anatomic location of involvement.
 - Submit sections for microscopic demonstration.
- If margins are ***macroscopically unininvolved*** by tumor:
 - Provide specific anatomic location and distance of tumor to the closest margins.
 - Submit sections for microscopic demonstration of all included margins as appropriate.
- The distance between the thickened pleura and adjacent lung resection margin should be provided.
- If multiple fragments are received in the setting of debulking pleurectomies, when applicable, consider providing a comment indicating that the status of the final margin cannot be provided.

LYMPH NODES ("N" of TNM)

- **Lymph Nodes:** (if applicable)

Definition of Regional Lymph Node (pN)

pN Category	pN Criteria
pNX	Regional lymph nodes cannot be assessed
pN0	No regional lymph node metastases
pN1	Metastases in the ipsilateral bronchopulmonary, hilar, or mediastinal (including the internal mammary, peridiaphragmatic, pericardial fat pad, or intercostal) lymph nodes
pN2	Metastases in the contralateral mediastinal, ipsilateral, or contralateral supraclavicular lymph nodes

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Regional lymph nodes for mesothelioma include:

- Intrathoracic
 - Internal mammary
 - Peridiaphragmatic
 - Pericardial fat pad
 - Intercostal
- Scalene
- Supraclavicular

Intrathoracic nodes share the same lymph node mapping system as lung cancer.

Some resections may not include lymph nodes. If lymph nodes are encountered, follow the steps below for lymph node sampling.

Lymph Node Sampling:

- Count lymph nodes identified.
- Specify site of lymph nodes identified.
- Measure lymph nodes in three dimensions.
- Describe the cut surface of the identified lymph nodes.
- Submit all lymph nodes for microscopic examination.
 - Submit small lymph nodes in toto.
 - Serially section and entirely submit larger macroscopically negative lymph nodes.
 - Representative sections from macroscopically positive lymph nodes are adequate.
- If possible, submit lymph node sections so that the long axis of the lymph node is demonstrated.
- Take steps to ensure that an accurate lymph node count can be rendered.

- **Explanatory Notes:**

The anatomic location of tumor involvement in lymph nodes is more significant than the number of involved nodes. Any nodal involvement in any location upstages the patient to at least Stage II.

METASTASIS ("M" of TNM)

- **Metastasis:** (if applicable)

Definition of Distant Metastasis (pM) (required only if confirmed pathologically)

pM Category	pM Criteria
M0	No distant metastasis
pM1	Distant metastasis present

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The most common sites of metastatic disease are the peritoneum, contralateral pleura and lung, extrathoracic lymph nodes, bones, and liver. This does not qualify as M1 if the tumor involvement is due to direct extension.

Advanced malignant pleural mesothelioma, often metastasizes to uncommon sites, including the brain, thyroid or prostate.

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