

# **Gallbladder**

**Protocol applies to all invasive carcinomas of the gallbladder, including those showing focal endocrine differentiation.**

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*Protocol revision date: January 2005  
Based on AJCC/UICC TNM, 6<sup>th</sup> edition*

## **Procedures**

- **Cholecystectomy**
- **Cholecystectomy with Partial Hepatectomy**
- **Cholecystectomy with Lymph Node Dissection**

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The College of American Pathologists offers these protocols to assist pathologists in providing clinically useful and relevant information when reporting results of surgical specimen examinations of surgical specimens. The College regards the reporting elements in the "Surgical Pathology Cancer Case Summary (Checklist)" portion of the protocols as essential elements of the pathology report. However, the manner in which these elements are reported is at the discretion of each specific pathologist, taking into account clinician preferences, institutional policies, and individual practice.

The College developed these protocols as an educational tool to assist pathologists in the useful reporting of relevant information. It did not issue the protocols for use in litigation, reimbursement, or other contexts. Nevertheless, the College recognizes that the protocols might be used by hospitals, attorneys, payers, and others. Indeed, effective January 1, 2004, the Commission on Cancer of the American College of Surgeons mandated the use of the checklist elements of the protocols as part of its Cancer Program Standards for Approved Cancer Programs. Therefore, it becomes even more important for pathologists to familiarize themselves with the document. At the same time, the College cautions that use of the protocols other than for their intended educational purpose may involve additional considerations that are beyond the scope of this document.

## **Summary of Changes to Checklist(s)**

*Protocol revision date: January 2005*

No changes have been made to the data elements of the checklist(s) since the January 2004 protocol revision.

**Surgical Pathology Cancer Case Summary (Checklist)**

*Protocol revision date: January 2005  
Applies to invasive carcinomas only  
Based on AJCC/UICC TNM, 6<sup>th</sup> edition*

**GALLBLADDER: Resection/Cholecystectomy**

Patient name:

Surgical pathology number:

<b>Note: Check 1 response unless otherwise indicated.</b>
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**MACROSCOPIC****Specimen Type**

- Cholecystectomy  
 Cholecystectomy with partial hepatectomy  
 Other (specify): \_\_\_\_\_  
 Not specified

**Tumor Site (check all that apply)**

- Fundus  
 Body  
 Neck  
 Indeterminate  
 Not specified

**Tumor Size**

Greatest dimension: \_\_\_ cm

\*Additional dimensions: \_\_\_ x \_\_\_ cm

 Cannot be determined (see Comment)

**MICROSCOPIC****Histologic Type**

- Adenocarcinoma
- Papillary adenocarcinoma
- Adenocarcinoma, intestinal type
- Adenocarcinoma, gastric foveolar type
- Mucinous adenocarcinoma
- Clear cell carcinoma
- Adenosquamous carcinoma
- Small cell carcinoma
- Large cell neuroendocrine carcinoma
- Undifferentiated carcinoma
- Other (specify): \_\_\_\_\_
- Carcinoma, type cannot be determined

**Histologic Grade**

- Not applicable
- GX: Cannot be assessed
- G1: Well differentiated
- G2: Moderately differentiated
- G3: Poorly differentiated
- G4: Undifferentiated
- Other (specify): \_\_\_\_\_

**Pathologic Staging (pTNM)**Primary Tumor (pT)

- pTX: Cannot be assessed
- pT0: No evidence of primary tumor
- pTis: Carcinoma in situ
- pT1: Tumor invades lamina propria or muscle layer
  - pT1a: Tumor invades lamina propria
  - pT1b: Tumor invades muscle layer
- pT2: Tumor invades perimuscular connective tissue; no extension beyond serosa or into liver
- pT3: Tumor perforates serosa (visceral peritoneum) and/or directly invades the liver and/or other adjacent organ or structure, such as the stomach duodenum, colon, or pancreas, omentum or extrahepatic bile ducts
- pT4: Tumor invades main portal vein or hepatic artery or invades two or more extrahepatic organs or structures

\* Data elements **with asterisks** are **not required** for accreditation purposes for the Commission on Cancer. These elements may be clinically important, but are not yet validated or regularly used in patient management. Alternatively, the necessary data may not be available to the pathologist at the time of pathologic assessment of this specimen.

Regional Lymph Nodes (pN)

- pNX: Cannot be assessed
- pN0: No regional lymph node metastasis
- pN1: Regional lymph node metastasis
- Specify: Number examined
- Number involved

Distant Metastasis (pM)

- pMX: Cannot be assessed
- pM1: Distant metastasis
- \*Specify site(s), if known: \_\_\_\_\_

**Margins (check all that apply)**

- Cannot be assessed
- Margins uninvolved by invasive carcinoma
- Distance of invasive carcinoma from closest margin:  mm
- Specify margin: \_\_\_\_\_
- Margins involved by invasive carcinoma
- Specify margin: \_\_\_\_\_
- Cystic duct margin uninvolved by in situ carcinoma
- Cystic duct margin involved by in situ carcinoma

**\*Venous/Lymphatic (Large/Small Vessel) Invasion (V/L)**

- \*  Absent
- \*  Present
- \*  Indeterminate

**\*Perineural Invasion**

- \*  Absent
- \*  Present
- \*  Indeterminate

**\*Additional Pathologic Findings (check all that apply)**

- \*  None identified
- \*  Dysplasia/adenoma
- \*  Acute cholecystitis
- \*  Cholelithiasis
- \*  Chronic cholecystitis
- \*  Other (specify): \_\_\_\_\_

**\*Comment(s)**

6           \* Data elements **with asterisks** are **not required** for accreditation purposes for the Commission on Cancer. These elements may be clinically important, but are not yet validated or regularly used in patient management. Alternatively, the necessary data may not be available to the pathologist at the time of pathologic assessment of this specimen.

## Background Documentation

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Protocol revision date: January 2004

### I. Resection (Cholecystectomy)

#### A. Clinical Information

1. Patient identification
  - a. Name
  - b. Identification number
  - c. Age (birth date)
  - d. Sex
2. Responsible physician(s)
3. Date of procedure
4. Other clinical information
  - a. Relevant history (eg, right upper abdominal pain)
  - b. Relevant findings (eg, ultrasound, other imaging studies)
  - c. Clinical diagnosis (eg, chronic cholecystitis)
  - d. Procedure (eg, abdominal cholecystectomy)
  - e. Operative findings

#### B. Macroscopic Examination

1. Specimen
  - a. Organ(s)/tissue(s) received (Note **A**)
  - b. Unfixed/fixed (specify fixative)
  - c. Previously opened
  - d. Orientation, if indicated by surgeon
  - e. Dimensions (measure attached tissues individually)
  - f. Gallstones (number, type) (Note **B**)
  - g. Results of intraoperative consultation
2. Tumor
  - a. Location (fundus/body/neck)
  - b. Configuration (Note **C**)
  - c. Dimensions (include entire tumor)
  - d. Descriptive features (eg, color, consistency, necrosis)
  - e. Extent of invasion (Note **D**)
3. Margins
  - a. Cystic duct
  - b. Liver bed
  - c. Other(s) (as appropriate)
4. Regional lymph nodes
  - a. Location (if possible)
  - b. Number
5. Additional pathologic findings, if present
6. Tissues submitted for microscopic evaluation
  - a. Tumor, including:
    - (1) point of deepest penetration
    - (2) overlying serosa
    - (3) interface with adjacent tissue
  - b. Gallbladder uninvolved by tumor
  - c. Margin of cystic duct
  - d. Liver, including margin of resection closest to tumor
  - e. All lymph nodes
  - f. Other lesion(s)
  - g. Frozen section tissue fragment(s) (unless saved for special studies)
  - h. Other tissue(s)/organ(s)

7. Special studies (specify) (eg, histochemistry, immunohistochemistry, morphometry, DNA analysis, cytogenetic analysis)

### C. Microscopic Evaluation

1. Tumor (Note **E**)
  - a. Histologic type (Note **F**)
  - b. Histologic grade (Note **G**)
  - c. Depth of invasion (Note **D**)
  - d. Venous/lymphatic vessel invasion (Note **H**)
  - e. Perineural invasion (Note **I**)
2. Margins
  - a. Cystic duct
  - b. Liver bed
  - c. Other(s), as appropriate
3. Additional pathologic findings, if present (Note **J**)
  - a. Dysplasia
  - b. Intestinal metaplasia
  - c. Other(s)
4. Regional lymph nodes (Note **K**)
  - a. Number
  - b. Number involved by tumor (specify location, if possible)
5. Other organ(s) or structure(s) (specify sites) (Note **K**)
  - a. Involvement by tumor by direct extension
  - b. Metastasis involvement
6. Other tissue(s)/organ(s)
7. Results/status of special studies (specify)
8. Comments
  - a. Correlation with intraoperative consultation, as appropriate
  - b. Correlation with other specimens, as appropriate
  - c. Correlation with clinical information, as appropriate

## Explanatory Notes

### A. Application

The protocol applies only to carcinomas of the gallbladder, including those showing endocrine differentiation, but excludes carcinoid tumors. More than 98% of malignant tumors of the gallbladder are carcinomas.

### B. Gallstones

The presence or absence of stones should be reported. Gallbladder cancer occurring in the absence of stones may result from an anomalous choledocho-pancreatic junction or from an association with chronic inflammatory bowel disease.

### C. Configuration

Configuration types include exophytic (fungating/polypoid), endophytic (ulcerating), or diffusely infiltrating. Since papillary carcinomas (usually polypoid) have a favorable prognosis, these lesions should be specifically reported.<sup>1</sup>

### D. TNM and Stage Grouping

The TNM staging system for carcinomas of the gallbladder of the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) is recommended by the protocol and shown below.<sup>2,3</sup> The TNM does not apply to carcinoid tumors or to sarcomas. Carcinomas of the gallbladder are staged according to their depth

of penetration into the wall and extension to adjacent organs, and the extent of invasion correlates inversely with survival.<sup>1</sup>

By AJCC/UICC convention, the designation “T” refers to a primary tumor that has not been previously treated. The symbol “p” refers to the pathologic classification of the TNM, as opposed to the clinical classification, and is based on gross and microscopic examination. pT entails a resection of the primary tumor or biopsy adequate to evaluate the highest pT category, pN entails removal of nodes adequate to validate lymph node metastasis, and pM implies microscopic examination of distant lesions. Clinical classification (cTNM) is usually carried out by the referring physician before treatment during initial evaluation of the patient or when pathologic classification is not possible.

Pathologic staging is usually performed after surgical resection of the primary tumor. Pathologic staging depends on pathologic documentation of the anatomic extent of disease, whether or not the primary tumor has been completely removed. If a biopsied tumor is not resected for any reason (eg, when technically unfeasible) and if the highest T and N categories or the M1 category of the tumor can be confirmed microscopically, the criteria for pathologic classification and staging have been satisfied without total removal of the primary cancer.

#### Primary Tumor (T)

TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma in situ <sup>#</sup>
T1	Tumor invades lamina propria or muscle layer
T1a	Tumor invades lamina propria
T1b	Tumor invades muscle layer
T2	Tumor invades perimuscular connective tissue; no extension beyond serosa or into liver
T3	Tumor perforates serosa (visceral peritoneum) and/or directly invades the liver and/or other adjacent organ or structure, such as the stomach duodenum, colon, or pancreas, omentum or extrahepatic bile ducts
T4:	Tumor invades main portal vein or hepatic artery or invades two or more extrahepatic organs or structures

<sup>#</sup> Because carcinoma in situ may be multifocal, cases of carcinoma in situ should be studied by multiple sections or by the “Swiss role” method in order to exclude invasive cancer in other areas of the gallbladder. Carcinoma in situ is often confused with the epithelial atypia of repair.<sup>4</sup>

#### Regional Lymph Nodes (N)<sup>#</sup>

NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis <sup>##</sup>
N1	Regional lymph node metastasis

<sup>#</sup> The frequency of nodal involvement depends on the depth of invasion into the gallbladder wall by the primary tumor. The regional lymph nodes of the gallbladder include the cystic duct, pericholedochal, hilar (ie, in the hepatoduodenal ligament), peripancreatic (head only), periduodenal, periportal, celiac, and superior mesenteric lymph nodes. The hilar nodes include those along the inferior vena cava, hepatic artery, portal vein and hepatic pedicle. Peripancreatic nodes located along the body and tail of the pancreas are sites of distant metastasis.

## Regional Lymph Nodes (pN0): Isolated Tumor Cells

Isolated tumor cells (ITCs) are single cells or small clusters of cells not more than 0.2 mm in greatest dimension. Lymph nodes or distant sites with ITCs found by either histologic examination, immunohistochemistry, or nonmorphological techniques (eg, flow cytometry, DNA analysis, polymerase chain reaction [PCR] amplification of a specific tumor marker) should be classified as N0 or M0, respectively. Specific denotation of the assigned N category is suggested as follows for cases in which ITCs are the only evidence of possible metastatic disease.<sup>5,6</sup>

pN0	No regional lymph node metastasis histologically, no examination for isolated tumor cells (ITCs)
pN0(i-)	No regional lymph node metastasis histologically, negative morphologic (any morphologic technique, including hemotoxylin-eosin and immunohistochemistry) findings for ITCs
pN0(i+)	No regional lymph node metastasis histologically, positive morphologic (any morphologic technique, including hemotoxylin-eosin and immunohistochemistry) findings for ITCs
pN0(mol-)	No regional lymph node metastasis histologically, negative nonmorphologic (molecular) findings for ITCs
pN0(mol+)	No regional lymph node metastasis histologically, positive nonmorphologic (molecular) findings for ITCs

**Distant Metastasis (M)**

MX	Presence of distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis

**Stage Groupings**

Stage 0	Tis	N0	M0
Stage IA	T1	N0	M0
Stage IB	T2	N0	M0
Stage IIA	T3	N0	M0
Stage IIB	T1	N1	M0
	T2	N1	M0
	T3	N1	M0
Stage III	T4	N0	M0
	T4	N1	M0
Stage IV	Any T	Any N	M1

**TNM Descriptors**

For identification of special cases of TNM or pTNM classifications, the “m” suffix and “y,” “r,” and “a” prefixes are used. Although they do not affect the stage grouping, they indicate cases needing separate analysis.

The “m” suffix indicates the presence of multiple primary tumors in a single site and is recorded in parentheses: pT(m)NM.

The “y” prefix indicates those cases in which classification is performed during or following initial multimodality therapy (ie, neoadjuvant chemotherapy, radiation therapy, or both chemotherapy and radiation therapy). The cTNM or pTNM category is identified by a “y” prefix. The ycTNM or ypTNM categorizes the extent of tumor actually present at the time of that examination. The “y” categorization is not an estimate of tumor prior to multimodality therapy (ie, before initiation of neoadjuvant therapy).

The “r” prefix indicates a recurrent tumor when staged after a documented disease-free interval, and is identified by the “r” prefix: rTNM.

The “a” prefix designates the stage determined at autopsy: aTNM.

### **Additional Descriptors**

#### Residual Tumor (R)

Tumor remaining in a patient after therapy with curative intent (eg, surgical resection for cure) is categorized by a system known as R classification, shown below.<sup>7</sup>

RX	Presence of residual tumor cannot be assessed
R0	No residual tumor
R1	Microscopic residual tumor
R2	Macroscopic residual tumor

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).

#### **Vessel Invasion**

By AJCC/UICC convention, vessel invasion (lymphatic or venous) does not affect the T category indicating local extent of tumor unless specifically included in the definition of a T category. In all other cases, lymphatic and venous invasion by tumor are coded separately as follows.

#### Lymphatic Vessel Invasion (L)

LX	Lymphatic vessel invasion cannot be assessed
L0	No lymphatic vessel invasion
L1	Lymphatic vessel invasion

#### Venous Invasion (V)

VX	Venous invasion cannot be assessed
V0	No venous invasion
V1	Microscopic venous invasion
V2	Macroscopic venous invasion

### **E Occult Carcinomas**

Occasionally carcinoma is found in gallbladders removed by laparoscopic surgery. Not recognized clinically or by imaging techniques, tumor is discovered during pathologic evaluation of the resected specimen. In this setting, tumor spillage with seeding along the endoscopic tract or intra-abdominal dissemination may be a major complication of the procedure. If carcinoma in situ is found in such specimens, multiple sections should be examined to exclude invasive cancer.

To exclude occult carcinoma in gallbladders excised intact, at least 3 sections, 1 from the fundus, 1 from the body, and 1 from the neck should be submitted if no gross lesions are found.

**F. Histologic Type**

For consistency in reporting, the histologic classification proposed by the World Health Organization (WHO), shown below, is recommended.<sup>8</sup> However, this protocol does not preclude use of other systems of classification or histologic types.

**WHO Classification of Gallbladder Carcinomas**

Adenocarcinoma<sup>#</sup>  
 Papillary adenocarcinoma<sup>##</sup>  
 Adenocarcinoma, intestinal type  
 Adenocarcinoma, gastric foveolar type  
 Mucinous adenocarcinoma<sup>###</sup>  
 Clear cell adenocarcinoma<sup>##</sup>  
 Signet-ring cell carcinoma<sup>^</sup>  
 Adenosquamous carcinoma  
 Squamous cell carcinoma  
 Small cell carcinoma<sup>^^</sup>  
 Large cell neuroendocrine carcinoma  
 Undifferentiated carcinoma<sup>^^</sup>  
 Biliary cystadenocarcinoma

<sup>#</sup> Many adenocarcinomas contain neuroendocrine cells. These tumors should not be considered neuroendocrine carcinomas.

<sup>##</sup> These histologic types are not usually graded (see below).

<sup>###</sup> A mucocoele may be mistaken for a mucinous carcinoma. Mucocoeles often contain macrophages that have engulfed mucin (muciphages). Consequently these macrophages may resemble signet-ring cells. Neoplastic signet-ring cells are cytokeratin- and carcinoembryonic antigen (CEA)-positive, whereas muciphages do not stain for these markers.

<sup>^</sup> By convention, signet-ring cell carcinomas are assigned grade 3 (see below).

<sup>^^</sup> Small cell carcinomas and undifferentiated (histologic type) carcinomas are assigned grade 4 (see below). Small cell carcinomas should be specifically reported since they may cause endocrine syndromes. In addition, small cell carcinomas and undifferentiated carcinomas are, by definition, high-grade (grade 4), an adverse prognostic factor.<sup>9</sup>

**G. Histologic Grade**

The following grading system, based on the extent of glandular formation in the tumor, is suggested.

Grade X	Grade cannot be assessed
Grade 1	Well differentiated (greater than 95% of tumor composed of glands)
Grade 2	Moderately differentiated (50% to 95% of tumor composed of glands)
Grade 3	Poorly differentiated (49% or less of tumor composed of glands)

Grade 4 carcinomas are classified as undifferentiated carcinomas (histologic type) by the WHO classification (see above).

Published data indicate that histologic grade is prognostically significant.<sup>1</sup>

**H. Venous/Lymphatic Vessel Invasion**

Published data indicate that blood vessel and/or lymphatic invasion has an adverse effect on outcome and should be specifically recorded.<sup>1</sup>

**I. Perineural Invasion**

Perineural invasion by neoplastic cells is an adverse prognostic factor and should be reported. A diagnostic pitfall may occur in cases of adenomyomatous hyperplasia, since the ductal structures of adenomyomatous hyperplasia may invade perineural spaces.<sup>10</sup>

**J. Additional Pathologic Findings**

Other common lesions include chronic cholecystitis, dysplasia, carcinoma in situ, and various types of metaplasia such as squamous, pyloric gland, and intestinal metaplasia. Occasionally changes consistent with inflammatory bowel disease are found in the gallbladder.

**K. Lymph Node Metastasis**

In general, carcinomas of the gallbladder spread from some focus in the hepatoduodenal ligament toward the nodes around the head of the pancreas. The cystic and pericholedochal nodes are the key stations for spread toward the peripancreatic nodes. Lymph flows through the pericholedochal nodes to these other regional nodes. Most often, the tumor initially metastasizes to the pericholedochal lymph nodes.

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