

# Protocol for the Examination of Specimens from Patients with Carcinoma of the Vulva

**Protocol applies to all invasive carcinomas of the vulva.**

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**Based on AJCC/UICC TNM, 7th edition, and FIGO 2008 Annual Report**  
Protocol web posting date: October 2009

## **Procedures**

- Excisional Biopsy
- Vulvectomy (With or Without Removal of Other Organs and Tissues)

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## CAP Vulva Protocol Revision History

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### **Version Code**

The definition of the version code can be found at [www.cap.org/cancerprotocols](http://www.cap.org/cancerprotocols).

**Version:** Vulva 3.0.1.0 June 2010

### **Summary of Changes – 3.0.1.0**

Minor (Code C) change:

1. The terminology of the following data element was changed from labia major to labium majus and from labia minor to labium minus, as follows:

#### **Tumor Site (select all that apply)**

Right vulva

\*  Labium majus

\*  Labium minus

Left vulva

\*  Labium majus

\*  Labium minus

Clitoris

Other (specify): \_\_\_\_\_

Not specified

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

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Protocol web posting date: October 2009

### **VULVA: Excisional Biopsy, Resection**

**Select a single response unless otherwise indicated.**

#### **Specimen (select all that apply) (Note A)**

- Vulva  
 Other (specify): \_\_\_\_\_  
 Not specified

#### **Procedure**

- Local excision  
 Wide excision  
 Partial vulvectomy  
 Total vulvectomy  
 Radical vulvectomy  
 Other (specify): \_\_\_\_\_  
 Not specified

#### **Lymph Node Sampling (select all that apply)**

- Not applicable  
 Sentinel lymph node biopsy  
 Inguinal-femoral nodes  
 Pelvic nodes  
 Other (specify): \_\_\_\_\_

#### **Specimen Size**

- Greatest dimension: \_\_\_\_ cm  
 \*Additional dimensions: \_\_\_\_ x \_\_\_\_ cm  
 Cannot be determined (see Comment)

#### **Tumor Site (select all that apply)**

- Right vulva  
     \*  Labium majus  
     \*  Labium minus  
 Left vulva  
     \*  Labium majus  
     \*  Labium minus  
 Clitoris  
 Other (specify): \_\_\_\_\_  
 Not specified

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

**Tumor Size (Note B)**

Greatest dimension: \_\_\_ cm

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

\_\_\_ Cannot be determined (see Comment)

**Tumor Focality**

\_\_\_ Unifocal

\_\_\_ Multifocal

\_\_\_ Cannot be determined (see Comment)

\_\_\_ Not specified

**Histologic Type (select all that apply) (Notes C and D)**

\_\_\_ Squamous cell carcinoma

\* \_\_\_ Keratinizing

\* \_\_\_ Nonkeratinizing

\* \_\_\_ Basaloid

\* \_\_\_ Warty

\* \_\_\_ Verrucous

\* \_\_\_ Other (specify):

\_\_\_ Glandular tumors

\* \_\_\_ Paget disease

\* \_\_\_ Bartholin gland tumors

\* \_\_\_ Adenocarcinoma

\* \_\_\_ Squamous cell carcinoma

\* \_\_\_ Adenoid cystic carcinoma

\* \_\_\_ Adenosquamous carcinoma

\* \_\_\_ Transitional cell carcinoma

\* \_\_\_ Small cell carcinoma

\* \_\_\_ Adenocarcinoma of mammary gland type

\* \_\_\_ Adenocarcinoma of Skene gland origin

\* \_\_\_ Malignant sweat gland tumors

\_\_\_ Other (specify): \_\_\_\_\_

\_\_\_ Carcinoma, type cannot be determined (see Comment)

**Histologic Grade**

\_\_\_ Not applicable

\_\_\_ GX: Cannot be assessed

\_\_\_ G1: Well differentiated

\_\_\_ G2: Moderately differentiated

\_\_\_ G3: Poorly differentiated

\_\_\_ G4: Undifferentiated

\_\_\_ Other (specify): \_\_\_\_\_

**Microscopic Tumor Extension (Note E)**

Depth of invasion: \_\_\_ mm

\_\_\_ Cannot be determined (see Comment)

\_\_\_ Other (specify): \_\_\_\_\_

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

**\*Tumor Border (Note F)**\*  Pushing\*  Infiltrating**Margins (select all that apply)** Cannot be determined (see Comment) Uninvolved by invasive carcinomaDistance of invasive carcinoma from closest margin:  mm

Specify margin, if possible: \_\_\_\_\_

 Carcinoma in situ not identified at margin Carcinoma in situ present at margin Involved by invasive carcinoma

Specify margin(s): \_\_\_\_\_

**Lymph-Vascular Invasion (Note G)** Not identified Present Cannot be determined (see Comment)**Lymph Nodes (Note H)**Number of lymph nodes examined: Number of lymph nodes with metastasis: Number of lymph nodes with metastasis(es) <5 mm: Number of lymph nodes with metastasis(es) ≥5 mm: 

Extranodal extension:

 Present Not identified Cannot be determined (see Comment)

Fixed or ulcerated femoral-inguinal lymph nodes:

 Present Not identified Cannot be determined (see Comment)

Laterality:

 Unilateral Bilateral**Pathologic Staging (pTNM [FIGO]) (Note I)**TNM Descriptors (required only if applicable) (select all that apply) m (multiple primary tumors) r (recurrent) y (post-treatment)

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

Primary Tumor (pT)

- pTX: Primary tumor cannot be assessed
- pT0: No evidence of primary tumor
- pTis: Carcinoma in situ (preinvasive carcinoma)
- pT1a [FIGO IA]: Lesions 2 cm or less in size, confined to the vulva or perineum, and with stromal invasion 1.0 mm or less
- pT1b [FIGO IB]: Lesions more than 2 cm in size or any size with stromal invasion more than 1.0 mm, confined to the vulva or perineum
- pT2 [FIGO II]: Tumor of any size with extension to adjacent perineal structures (lower/distal 1/3 urethra, lower/distal 1/3 vagina, anal involvement)
- pT3 [FIGO IVA]: Tumor of any size with extension to any of the following: upper/proximal 2/3 of urethra, upper/proximal 2/3 vagina, bladder mucosa, rectal mucosa, or fixed to pelvic bone

Regional Lymph Nodes (pN) (select all that apply)

- pNX: Regional lymph nodes cannot be assessed
- pN0: No regional lymph node metastasis
- pN1: One or two regional lymph nodes with the following features
- pN1a [FIGO IIIA]: One or two lymph node metastasis each 5 mm or less
- pN1b [FIGO IIIA]: One lymph node metastasis 5 mm or greater
- pN2 [FIGO IIIB]: Regional lymph node metastasis with the following features
- pN2a [FIGO IIIB]: Three or more lymph node metastases each less than 5 mm
- pN2b [FIGO IIIB]: Two or more lymph node metastases 5 mm or greater
- pN2c [FIGO IIIC]: Lymph node metastasis with extracapsular spread
- pN3 [FIGO IVA]: Fixed or ulcerated regional lymph node metastasis

Distant Metastasis (pM)

- M0: No distant metastasis
- pM1 [FIGO IVB]: Distant metastasis (including pelvic lymph node metastasis)  
\*Specify site(s), if known: \_\_\_\_\_

**\*Additional Pathologic Findings (select all that apply) (Note I)**

- \*  None identified
- \*  Dysplasia
- \*  Condyloma accuminatum
- \*  Vulvar intraepithelial neoplasia (VIN) 3 (severe dysplasia/carcinoma in situ)
- \*  Other (specify): \_\_\_\_\_

**\*Comment(s)**

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

## Explanatory Notes

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### A. Suggestions for Sampling of Tissue Removed for Diagnosis or Treatment of Vulvar Carcinoma

#### Tumor

Sections taken will vary with procedure, as designated by surgeon.<sup>1</sup> Sections to include the following should be taken (if appropriate):

- Tumor, representative sections, including site of deepest invasion and interface of tumor with adjacent epithelium
- Resection margins
- Sections of abnormal epithelium or other tissue remote from tumor
- Sections of areas(s) marked by surgeon
- Sections of prior biopsy or resection site of tumor if no tumor present grossly

#### Lymph Nodes

The femoral and inguinal lymph nodes are the sites of regional spread.<sup>1,2</sup> When inguinal-femoral lymphadenectomy is performed, 6 or more lymph nodes will normally be included.<sup>1,2</sup> One or more sections of all lymph nodes identified should be taken, depending on presence or absence of gross tumor as well as size of lymph node. In addition, sections to confirm presence or absence of extranodal extension should be taken.

#### Other Organs and Tissues

Other organs and tissues may be submitted with the vulva specimen. Sections to include the following should be taken (if appropriate):

- Sections to demonstrate presence or absence of tumor
- Sections to demonstrate its relation, if present, to vulvar tumor (contiguous or metastatic)
- Sections of other lesions, if present
- Resection margins

If frozen section analysis was performed, those tissue fragment(s) should be submitted.

### B. Thickness of Tumor

The thickness of a squamous cell carcinoma is measured in millimeters from the surface of the tumor or, if there is surface keratinization, from the bottom of the granular layer to the deepest point of invasion.<sup>3,4</sup>

### C. Etiology/Pathogenesis<sup>5-7</sup>

Two pathways have been elucidated in the pathogenesis of invasive vulvar carcinoma. The first pathway involves classic vulvar intraepithelial neoplasia (VIN), which is associated with high-grade human papillomavirus (HPV) subtypes (16 >18), and is histologically similar to dysplasia seen in the cervix. It tends to be multifocal and more common in younger women, with a relatively low risk of progression into an invasive squamous cell carcinoma. It is diffusely positive with p16 (reflecting HPV association) and is negative with p53. The associated invasive component is basaloid or warty in morphology. The second pathway is referred to as differentiated VIN (VIN simplex). VIN simplex is not associated with HPV, but instead with vulvar dystrophy such as that seen



in the context of lichen sclerosus or squamous hyperplasia. The morphologic features are more subtle, with atypia noted in the parabasal cells. The associated invasive component is keratinizing and can be associated with p53 mutations. This subtype usually occurs in older women. Most recently, cutaneous HPV subtypes (5,8) were found to be associated with this form.<sup>8</sup> Of note, overlap does exist between the two pathways, with some tumors exhibiting morphologic and/or clinical features of each.

	<b>Keratinizing Squamous Carcinoma</b>	<b>Basaloid Squamous Carcinoma</b>
<b>Prevalence</b>	More common (approximately 80%)	Less common (approximately 20%)
<b>Age</b>	Older females	Younger females
<b>Distribution</b>	Usually unifocal, may be multifocal	Often multifocal
<b>Association with multifocal lower genital tract neoplasia</b>	Rare	Common
<b>Morphology</b>	Keratinizing	Warty
<b>Associated vulvar intraepithelial neoplasia (VIN)</b>	Uncommon: differentiated type	Common: classic type
<b>Association with HPV</b>	Yes, beta (cutaneous) <sup>8</sup> 5,8	Yes, alpha 16>18
<b>Association with vulvar dystrophy</b>	Common	Rare
<b>Immunohistochemistry</b>	p53: Some cases positive p16: Negative or focally positive at stromal interface	p53: Negative p16: Positive

Adapted from McCluggage.<sup>5</sup>

#### **D. Histologic Type**

The following is an abbreviated, slightly modified version of the World Health Organization (WHO) classification of histologic types of malignant and premalignant vulvar epithelial tumors<sup>3,9</sup>:

#### **WHO Classification of Vulvar Epithelial Tumors and Related Lesions**

##### Squamous Lesions

- Intraepithelial neoplasia (VIN)
  - Mild dysplasia (VIN 1)
  - Moderate dysplasia (VIN 2)
  - Severe dysplasia (VIN 3)
  - Carcinoma in situ (VIN 3)
- Squamous cell carcinoma
  - Keratinizing
  - Nonkeratinizing
  - Basaloid

- Warty
- Verrucous
- Keratoacanthoma-like
- Variant with tumor giant cells
- Others

Basal cell carcinoma

Glandular Lesions

Paget disease

Bartholin gland tumors

- Adenocarcinoma
- Squamous cell carcinoma
- Adenoid cystic carcinoma
- Adenosquamous carcinoma
- Transitional cell carcinoma
- Small cell carcinoma

Adenocarcinoma of mammary gland type

Adenocarcinoma of Skene gland origin

Malignant sweat gland tumors

Adenocarcinomas of other types

**E. Depth of Invasion**

The depth of invasion of squamous cell carcinoma is defined as the measurement in millimeters from the epithelial-stromal junction of the adjacent most superficial dermal papilla to the deepest point of invasion.<sup>2-4</sup>

**F. Tumor Growth Pattern**

Vulvar squamous cell carcinomas can generally be separated into those tumors that have a predominately infiltrating (fingerlike) pattern and those that invade with a broad, pushing front (verrucous carcinoma). In some studies, infiltrating invasion is associated with a higher frequency of regional lymph node metastasis and should be noted in the report.<sup>10</sup>

**G. Lymphatic/Blood Vessel Invasion**

Vascular space invasion by squamous cell carcinoma has been associated with a poorer prognosis, including a risk factor for regional lymph node metastasis, and should be noted in the report.<sup>11-13</sup>

**H. Extranodal Extension/Nodal Replacement**

Both extranodal extension as well as the size of lymph node metastasis have been shown to reflect prognosis and should be noted in the report.<sup>2,12,14,15</sup>

**I. TNM and International Federation of Gynecology and Obstetrics (FIGO) Stage Groupings**

The TNM staging system of the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) for carcinoma of the vulva is recommended and is shown below.<sup>2,16</sup> Comparison with FIGO staging is also shown.<sup>17,18</sup>

According to 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 infeasible) 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.

### TNM and FIGO Staging Systems for Vulvar Carcinoma

#### Primary Tumor (T)

TNM Categories	FIGO Stages	
TX		Primary tumor cannot be assessed
T0		No evidence of primary tumor
Tis		Carcinoma in situ (preinvasive carcinoma)
T1a	IA	Lesions 2 cm or less in size, confined to the vulva or perineum and with stromal invasion 1.0 mm or less
T1b	IB	Lesions more than 2 cm in size <b>or</b> any size with stromal invasion more than 1.0 mm, confined to the vulva or perineum
T2	II	Tumor of any size with extension to adjacent perineal structures (lower/distal 1/3 urethra, lower/distal 1/3 vagina, anal involvement)
T3	IVA	Tumor of any size with extension to any of the following: upper/proximal 2/3 of urethra, upper/proximal 2/3 vagina, bladder mucosa, rectal mucosa, or fixed to pelvic bone

*\*Note:* The depth of invasion is defined as the measurement of the tumor from the epithelial-stromal junction of the adjacent most superficial dermal papilla to the deepest point of invasion.

#### Regional Lymph Nodes (N)

NX		Regional lymph nodes cannot be assessed
N0		No regional lymph node metastasis
N1		One or two regional lymph nodes with the following features
N1a	IIIA	One or two lymph node metastasis each 5 mm or less
N1b	IIIA	One lymph node metastasis 5 mm or greater
N2	IIIB	Regional lymph nodes metastasis with the following features
N2a	IIIB	Three or more lymph node metastases each less than 5 mm
N2b	IIIB	Two or more lymph node metastases 5 mm or greater

N2c	IIIC	Lymph node metastasis with extracapsular spread
N3	IVA	Fixed or ulcerated regional lymph node metastasis

An effort should be made to describe the site and laterality of lymph node metastases.

### Distant Metastasis (M)

M0		No distant metastasis
M1	IVB	Distant metastasis (including pelvic lymph node metastasis)

### Anatomic Stage/Prognostic Groups

Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage IA	T1a	N0	M0
Stage IB	T1b	N0	M0
Stage II	T2	N0	M0
Stage IIIA	T1, T2	N1a, N1b	M0
Stage IIIB	T1, T2	N2a, N2b	M0
Stage IIIC	T1, T2	N2c	M0
Stage IVA	T1, T2	N3	M0
	T3	Any N	M0
Stage IVB	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 after initial multimodality 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 before multimodality therapy.

The “r” prefix indicates a recurrent tumor when staged after a 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)

The absence or presence of residual tumor after treatment. In some cases treated with surgery and/or neoadjuvant therapy there will be residual tumor at the primary site after treatment because of incomplete resection or local and regional disease that extends beyond the limit of ability of resection.

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).

#### Lymph-Vascular Invasion

Lymph-vascular invasion (LVI) indicates whether microscopic lymph-vascular invasion is identified. LVI includes lymphatic invasion, vascular invasion, or lymph-vascular invasion. According to AJCC/UICC convention, LVI does not affect the T category indicating local extent of tumor unless specifically included in the definition of a T category.

#### **Sentinel Lymph Nodes**

The sentinel lymph node is the first node to receive drainage from a primary tumor. There may be more than one sentinel node for some tumors. If a sentinel node contains metastatic tumor, it indicates that other more distant nodes may also contain metastatic disease. If sentinel nodes are negative, other regional nodes are less likely to contain metastasis.<sup>1,13</sup>

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