

Vulva

Protocol applies to invasive carcinomas of the vulva.

*Protocol revision date: January 2005
Based on AJCC/UICC TNM, 6th edition
and FIGO 2001 Annual Report*

Procedures

- **Cytology** (No Accompanying Checklist)
- **Incisional Biopsy** (No Accompanying Checklist)
- **Excisional Biopsy**
- **Vulvectomy (With or Without Removal of Other Organs and Tissues)**

Author

Philip A. Branton, MD

Department of Pathology, Inova Fairfax Hospital, Fairfax, Virginia
For the Members of the Cancer Committee, College of American Pathologists

Previous contributors: Edward J. Wilkinson, MD; Robert E. Scully, MD

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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.

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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, 6th edition
and FIGO 2001 Annual Report*

VULVA: Excisional Biopsy, Resection

Patient name:

Surgical pathology number:

Note: Check 1 response unless otherwise indicated.

MACROSCOPIC

Specimen Type

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

Lymphadenectomy

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

Tumor Site (check all that apply)

- Right vulva
 * Labia major
 * Labia minor
 Left vulva
 * Labia major
 * Labia minor
 Clitoris
 Other (specify): _____
 Not specified

4 * 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.

Tumor Size

Greatest dimension: ___ cm

*Additional dimensions: ___ x ___ cm

___ Cannot be determined (see Comment)

MICROSCOPIC**Histologic Type (check all that apply)**

___ Squamous cell carcinoma

* ___ Keratinizing

* ___ Non keratinizing

* ___ Basaloid

* ___ Warty (condylomatous)

* ___ Other (specify): _____

___ Verrucous carcinoma

___ Adenocarcinoma

* ___ Carcinoma resembling breast carcinoma

* ___ Eccrine carcinoma

* ___ Other (specify): _____

___ Paget disease

___ 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): _____

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Pathologic Staging (pTNM [FIGO])

Primary Tumor (pT)

- pTX [--]: Cannot be assessed
- pT0 [--]: No evidence of primary tumor
- pTis [0]: Carcinoma in situ
- pT1 [I]: Tumor confined to vulva or vulva and perineum, 2 cm or less in greatest dimension
- pT1a [IA]: Tumor confined to vulva or vulva and perineum, 2 cm or less in greatest dimension, and with stromal invasion no more than 1 mm
- pT1b [IB]: Tumor confined to vulva or vulva and perineum, 2 cm or less in greatest dimension, and with stromal invasion greater than 1 mm
- pT2 [II]: Tumor confined to vulva or vulva and perineum greater than 2 cm in greatest dimension
- pT3 [III]: Tumor of any size with contiguous spread to the lower urethra and/or vagina or anus
- pT4 [IVA]: Tumor invades any of the following: upper urethra, bladder mucosa, rectal mucosa, or is fixed to pubic bone

Regional Lymph Nodes (pN)

- pNX: Cannot be assessed
 - pN0: No regional lymph node metastasis
 - pN1 [III]: Unilateral regional lymph node metastasis (pT1-pT3)
 - pN1 [IVA]: Unilateral regional lymph node metastasis (pT4)
 - pN1 [IVB]: Unilateral regional lymph node metastasis (pT1-pT4, pM1)
 - pN2 [IVA]: Bilateral regional lymph node metastasis (pT1-pT4)
 - pN2 [IVB]: Bilateral regional lymph node metastasis (pT1-pT4, pM1)
- Specify: Number examined:
- Number involved:

Distant Metastasis (pM)

- pMX: Cannot be assessed
 - pM1 [IVB]: Distant metastasis
- *Specify site(s), if known: _____

Depth of Invasion

- Specify: mm
- Cannot be determined (see Comment)

***Tumor Border**

- * Pushing
- * Infiltrating

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Margins (check all that apply)

- Cannot be assessed
- Uninvolved by invasive carcinoma
 Distance of invasive carcinoma from closest margin: ___ mm
 Specify margin, if possible: _____
- Carcinoma in situ absent at margin
- Carcinoma in situ present at margin
- Involved by invasive carcinoma
 Specify margin(s): _____

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

- * Absent
- * Present
- * Indeterminate

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

- * None identified
- * Dysplasia
- * Condyloma accuminatum
- * Vulvar intraepithelial neoplasia 3 (VIN3: severe dysplasia/carcinoma in situ)
- * Other (specify): _____

***Comment(s)**

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Background Documentation

Protocol revision date: January 2005

I. Cytologic Material

A. Clinical Information

1. Patient identification
 - a. Name
 - b. Identification number
 - c. Age (birth date)
2. Responsible physician(s)
3. Date of procedure
4. Other clinical information
 - a. Relevant history (eg, previous therapy, previous tumors or operations of possible relevance, previous abnormal cytology)
 - b. Relevant findings (eg, appearance of lesion, laboratory data)
 - c. Clinical diagnosis
 - d. Procedure
 - e. Type(s) or site(s) of specimen(s)
 - (1) scraping of vulvar vestibule, lesion or tumor
 - (2) vesicle contents and scraping of vesicle base
 - (3) imprint of lesion
 - (4) fine-needle aspiration

B. Macroscopic Examination

1. Specimen
 - a. Unfixed/fixed (specify fixative)
 - b. Number of slides received, if appropriate
 - c. Quantity and appearance of fluid specimen, if appropriate
 - d. Other (eg, cytologic preparation from tissue)
 - e. Results of intraprocedural consultation
2. Material submitted for microscopic evaluation (eg, smear, cytocentrifuge, touch or filter preparation, cell block)
3. Special studies (specify) (eg, flow cytometry, immunocytochemistry)

C. Microscopic Evaluation (Note A)

1. Adequacy of specimen (if unsatisfactory for evaluation, specify reason)
2. Tumor, if present
 - a. Histologic type, if possible (Note B)
 - b. Other features
3. Additional pathologic findings, if present
4. Results/status of special studies
5. Comments
 - a. Correlation with intraprocedural consultation, as appropriate
 - b. Correlation with other specimens, as appropriate
 - c. Correlation with clinical information, as appropriate

II. Vulvar Biopsy**(Incisional or Excisional)****A. Clinical Information**

1. Patient identification
 - a. Name
 - b. Identification number
 - c. Age (birth date)
2. Responsible physician(s)
3. Date of procedure
4. Other clinical information
 - a. Relevant history (eg, previous therapy, previous tumors or operations of possible relevance, previous abnormal cytology)
 - b. Relevant findings (eg, radiologic studies, laboratory data)
 - c. Clinical diagnosis
 - d. Procedure
 - (1) biopsy with cervical biopsy device
 - (2) punch biopsy
 - (3) shave biopsy
 - (4) incisional biopsy
 - (5) excisional biopsy
 - e. Operative findings
 - f. Anatomic site(s) of specimen(s)
 - (1) vestibule, periurethral
 - (2) perineal body
 - (3) perineum
 - (4) labium minus
 - (5) labium majus
 - (6) clitoris
 - (7) frenulum
 - (8) prepuce
 - (9) mons
 - (10) other
 - g. Location(s) of specimen(s) (eg, right or left, medial or lateral, posterior or anterior)
 - h. Orientation of specimen(s), if necessary

B. Macroscopic Examination

1. Specimen
 - a. Unfixed/fixed (specify fixative)
 - b. Size
 - (1) three dimensions, if single or multiple and separately designated
 - (2) number, aggregate dimensions and size range, if multiple and not separately designated
 - c. Descriptive features
 - d. Orientation, if designated
 - e. Results of intraoperative consultation
3. Tumor, if present
 - a. Size (3 dimensions, including depth)
 - b. Descriptive features
4. Additional pathologic findings, if present
5. Resection margins, if pertinent

6. Other tissue(s) present
 - a. Lesion(s), if present
 - (1) descriptive features
 - (2) location
 - (3) size
 - b. Margin(s) (proximity of lesions to margins, if pertinent)
7. Specimens submitted for microscopic evaluation
8. Special studies (specify) (eg, flow cytometry, immunohistochemistry, human papilloma virus [HPV] typing)

C. Microscopic Evaluation

1. Tumor
 - a. Histologic type (Note **B**)
 - b. Histologic grade
 - c. Extent (measure if appropriate)
 - (1) site(s) of involvement
 - (2) depth of invasion (Note **C**)
 - (3) thickness (Note **D**)
 - (4) pagetoid spread
 - d. Type of invasion (eg, broad-front, tentacular [fingerlike], mixed, indeterminate) (Note **E**)
 - e. Lymphatic/blood vessel invasion (Note **F**)
 - f. Other features of possible prognostic or therapeutic significance
2. Findings at apparent site of prior tumor, if no tumor present
3. Resection margins if applicable and interpretable (if not interpretable, specify reason)
4. Additional pathologic findings, if present; and relation to tumor, if pertinent
 - a. Other tumors (determine if metastatic or separate primary, if possible)
 - b. Precancerous lesions (eg, vulvar intraepithelial neoplasia [VIN]/dysplasia)
 - c. Squamous cell hyperplasia
 - d. Lichen sclerosus
 - e. Condyloma acuminatum
 - f. Nevus
 - g. Other
5. Results/status of special studies (specify)
6. Comments
 - a. Correlation with intraoperative consultation, as appropriate
 - b. Correlation with other specimens, as appropriate
 - c. Correlation with clinical information, as appropriate

III. Therapeutic Local Excision or Vulvectomy

(With or Without Lymph Node Dissection and Resection of Adjacent Tissues or Organs; Separate Lymph Node Dissection)

A. Clinical Information

1. Patient identification
 - a. Name
 - b. Identification number
 - c. Age (birth date)
2. Responsible physician(s)
3. Date of procedure
4. Other clinical information
 - a. Relevant history (eg, previous therapy, previous tumors or operations of possible relevance, previous abnormal cytology)
 - b. Relevant findings (eg, radiologic studies, laboratory data)

- c. Clinical diagnosis
 - d. Procedure (specify depth of excision and dimensions of the excision in the vertical and horizontal axis)
 - e. Operative findings
 - f. Anatomic site(s) of specimen(s)
 - (1) vestibule, periurethral
 - (2) perineal body
 - (3) perineum
 - (4) labium minus
 - (5) labium majus
 - (6) clitoris
 - (7) frenulum
 - (8) prepuce
 - (9) mons
 - (10) other
 - g. Location(s) of specimen(s) (eg, right or left, posterior or anterior)
 - h. Orientation of specimens, if necessary
- B. Macroscopic Examination**
- 1. Specimen
 - a. Organs/tissues received (specify)
 - b. Unfixed/fixed (specify fixative)
 - c. Number of pieces
 - d. Dimensions (measure attached tissues individually)
 - e. Orientation of specimen if indicated by surgeon
 - f. Results of intraoperative consultation
 - 2. Vulva
 - a. Tumor
 - (1) location
 - (2) size (3 dimensions, including depth)
 - (3) descriptive features (ulcerative, nodular, exophytic, verrucoid, other)
 - (4) extent (eg, urethra, vagina, anus) (Note **G**)
 - (5) distances from margins, as appropriate
 - b. Margins (ink as appropriate)
 - c. Findings at apparent site of prior tumor, if no tumor present
 - d. Additional pathologic findings
 - (1) other tumors
 - i. determine whether metastatic or separate primary tumors, if possible
 - ii. describe as for major tumor
 - (2) precancerous lesions (eg, vulvar intraepithelial neoplasia [VIN]/dysplasia)
 - (3) squamous cell hyperplasia
 - (4) lichen sclerosus
 - (5) condyloma acuminatum
 - (6) nevus
 - (7) other
 - e. Lymph nodes
 - (1) location
 - (2) number
 - (3) size
 - (4) tumor, if discernable
 - i. size
 - ii. descriptive features

- f. Lymph nodes submitted separately
 - (1) location, as specified by surgeon
 - i. inguinal-femoral (specify right, left, or both)
 - ii. pelvic (specify right, left, or both)
 - iii. other (specify)
 - (2) number
 - (3) size
 - (4) tumor, if discernable
 - i. size
 - ii. descriptive features
- g. Other tissue(s) (eg, urethra, urethra and bladder, vagina, anus and rectum; see appropriate protocol if second primary tumor present)
 - 1) description
 - (2) tumor, if present
 - i. location
 - ii. extent
 - iii. relation to vulvar tumor
 - (3) resection margins
 - (4) additional pathologic findings, if present
- 3. Specimens submitted for microscopic evaluation (Note H)
- 4. Special studies (specify) (eg, flow cytometry, immunohistochemistry, human papilloma virus typing)

C. Microscopic Evaluation

- 1. Tumor
 - a. Histologic type (Note B)
 - b. Histologic grade
 - c. Extent (Note G)
 - (1) measure, if appropriate (greatest diameter of surface of tumor)
 - (2) anatomic site(s) of involvement
 - (3) depth of invasion (Note C)
 - (4) thickness (Note D)
 - (5) pagetoid spread
 - d. Type of invasion (eg, pushing border, infiltrating border, mixed, indeterminate) (Note E)
 - e. Lymphatic/blood vessel invasion (Note F)
- 2. Other features of possible prognostic or therapeutic significance
 - a. Other tumors (determine if metastatic or separate primary, if possible)
 - b. Precancerous lesions
 - (1) dysplasia/vulvar intraepithelial neoplasia (VIN)
 - (2) junctional nevus
 - c. Related benign lesions
 - (1) squamous cell hyperplasia
 - (2) lichen sclerosus
 - (3) condyloma acuminatum
- 3. Findings at apparent site of primary tumor, if no tumor present
- 4. Resection margins
- 5. Lymph nodes
 - a. Number at each designated site (Note G)
 - b. Number involved by tumor at each designated site
 - c. Presence or absence of extranodal extension (Note I)

6. Other organs and tissues
 - a. Tumor, if present
 - (1) location
 - (2) size
 - (3) extent
 - (4) relation to vulvar tumor
 - b. Resection margins, if applicable
 - c. Additional pathologic findings, if present
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. Cytologic Diagnosis

A modification of the Bethesda System,¹ which has been recommended for the classification of cervical cytologic findings, may also be used for reporting vulvar cytologic findings.

Cervical/Vaginal Cytologic Classification (The Bethesda System 2001 Modified for Vulva)

Negative for Intraepithelial Lesion or Malignancy

Organisms

- *Trichomonas vaginalis*
- Fungal organisms morphologically consistent with *Candida* spp
- Shift in flora suggestive of bacterial vaginosis
- Bacteria morphologically consistent with *Actinomyces* spp.
- Cellular changes associated with Herpes simplex virus

Other non-neoplastic findings (optional to report, list not inclusive)

- Reactive cellular changes associated with
 - inflammation (includes typical repair)
 - irradiation
- Glandular cells status post hysterectomy
- Atrophy

Other

Epithelial Cell Abnormalities

Squamous Cell

- Atypical squamous cells
 - of undetermined significance (ASC-US)
 - cannot exclude HSIL (ASC-H)
- Low grade squamous intraepithelial lesion (LSIL)
 - encompassing: HPV/mild dysplasia/VIN I
- High grade squamous intraepithelial lesion (HSIL)
 - encompassing: moderate and severe dysplasia/ VIN2/VIN3/VCIS
 - with features suspicious for invasion (if invasion suspected)
- Squamous cell carcinoma

Glandular Cell

- Atypical
 - glandular cells (NOS or specify in comment)
 - glandular cells, favor neoplastic
- Adenocarcinoma
 - not otherwise specified (NOS)

Other Malignant Neoplasms

Specify

B. Histologic Type

The following is an abbreviated, slightly modified version of the World Health Organization classification of histologic types of malignant and premalignant vulvar epithelial tumors; melanomas are discussed in the melanoma protocol.²

WHO Classification of Vulvar Epithelial Tumors and Related Lesions

Squamous Lesions

Intraepithelial neoplasia (vulvar 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
- Verrucous
- Warty (condylomatous)
- Others

Basal cell carcinoma

Glandular Lesions

Paget disease

Bartholin gland carcinoma

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

Carcinoma resembling breast carcinoma

Carcinoma of sweat gland origin

Adenocarcinomas of other types

C. 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.³⁻⁵

D. 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 deep border of the granular layer to the deepest point of invasion.^{3,6-10}

E. 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). Infiltrating invasion is associated with a higher frequency of regional lymph node metastasis and should be noted in the report.^{10,11}

F. Lymphatic/Blood Vessel Invasion

Vascular space invasion by squamous cell carcinoma with a depth of invasion greater than 1 mm may be associated with a higher frequency of regional lymph node metastasis – either lymphadenectomy or sentinel lymph node biopsy may be performed – and should be noted in the report.^{3,11-14}

G. TNM and FIGO Stage Groupings

The TNM Staging System for carcinoma of the vulva of the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) is recommended and is shown below.^{15,16} Comparison with International Federation of Gynecology and Obstetrics (FIGO) staging is also shown.¹⁷

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.

TNM and FIGO Staging Systems for Vaginal Carcinoma

Primary Tumor (T)

TNM Category	FIGO Stage	Definition
TX	(--)	Cannot be assessed
T0	(--)	No evidence of primary tumor
Tis	0	Carcinoma in situ
T1	I	Tumor confined to vulva or vulva and perineum, 2 cm or less in greatest dimension
T1a	IA	Tumor confined to vulva or vulva and perineum, 2 cm or less in greatest dimension, and with stromal invasion no more than 1 mm
T1b	IB	Tumor confined to vulva or vulva and perineum, 2 cm or less in greatest dimension, and with stromal invasion greater than 1 mm
T2	II	Tumor confined to vulva or vulva and perineum greater than 2 cm in greatest dimension
T3	III	Tumor of any size with contiguous spread to the lower urethra and/or vagina or anus
T4	IVA	Tumor invades any of the following: bladder mucosa, rectal mucosa, upper urethral mucosa; or is fixed to pubic bone
(M1)	IVB	Distant metastasis (including pelvic lymph node metastasis)

Regional Lymph Nodes (N): TNM

NX	Regional lymph nodes cannot be assessed
N0	No lymph nodes palpable
N1	Unilateral regional lymph node metastasis
N2	Bilateral regional lymph node metastasis

Distant Metastasis (M): TNM

MX	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis (including pelvic lymph node metastasis)

Stage Groupings

AJCC/UICC TNM				FIGO
Stage 0	Tis	N0	M0	
Stage I	T1	N0	M0	Stage I
Stage IA	T1a	N0	M0	
Stage IB	T1b	N0	M0	
Stage II	T2	N0	M0	Stage II
Stage III	T1	N1	M0	Stage III
	T2	N1	M0	
	T3	N0, N1	M0	
Stage IVA	T1	N2	M0	Stage IVA
	T2	N2	M0	
	T3	N2	M0	
	T4	Any N	M0	
Stage IVB	Any T	Any N	M1	Stage IVB

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.

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

Regional Lymph Nodes: Isolated Tumor Cells

Isolated tumor cells (ITC) are single cells or small clusters of cells not more than 0.2 mm in greatest dimension. Lymph nodes or distant sites with ITC found by either histologic examination, immunohistochemical stains (eg, cytokeratin), or nonmorphological techniques (eg, flow cytometry, DNA analysis, polymerase chain reaction [PCR] amplification of a specific tumor marker) should be identified appropriately. There are currently no studies in the literature to guide nodal classification of patients with micrometastatic lymph node deposits found only by ancillary studies. Until further guidance is available, these should be specifically mentioned in the report and provisionally assigned a status of “N1.”

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.

H. Suggestions for Sampling of Tissue Removed for Diagnosis or Treatment of Vulvar Carcinoma**Tumor**

Sections taken will vary with procedure, as designated by surgeon¹⁸

Tumor, representative sections to include (if appropriate):

- site of deepest invasion
- interface of tumor with adjacent epithelium

Resection margins

Sections of abnormal epithelium or other tissue remote from tumor

Sections of area(s) marked by surgeon

Sections of prior biopsy or resection site of tumor if no tumor present grossly

Lymph Nodes

One or more sections of all lymph nodes identified, depending on presence or absence of gross tumor and size of lymph node, including sections to confirm presence or absence of extranodal extension (Note I).

Other Organs and Tissues

Sections to demonstrate presence or absence of tumor, its relation if present to vulvar tumor (continuous or metastatic) and its resection margins.

Sections of other lesions, if present

Frozen section tissue fragment(s)

I. Extranodal Extension

Extranodal extension of tumor metastatic to regional lymph nodes may correlate with an increased risk of recurrence and should be noted in the report.¹²

J. Melanoma

See protocol for Melanoma of the Skin.

References

1. Solomon D, Davey D, Kurman R, Moriarty A, et al The 2001 Bethesda System: terminology for reporting results of cervical cytology. *JAMA*. 2002;287:2114-2119.
2. Scully RE, Bonfiglio TA, Kurman RJ, Silverberg SJ, Wilkinson EJ. *Histological Typing of Female Genital Tract Tumours. World Health Organization. International Histological Classification of Tumours*. Heidelberg: Springer-Verlag; 1993.
3. Kurman RJ, Norris HJ, Wilkinson EJ. *Atlas of Tumor Pathology. Tumors of the Cervix, Vagina, and Vulva*. 3rd Series. Fascicle 4. Washington, DC: Armed Forces Institute of Pathology; 1992.
4. Heaps JM, Fu YS, Montz FJ, Hacker NF, Berek JS. Surgical-pathologic variables predictive of local recurrence in squamous cell carcinoma of the vulva. *Gynecol Oncol*. 1990;38:309-314.
5. Hacker NF, van-der-Velden J. Conservative management of early vulvar cancer. *Cancer*. 1993;71:1673-1677.
6. Dvoretzky PM, Bonfiglio TA, Helmkamp FH, Ramsey G, Chuang C, Beecham JB. The pathology of superficially invasive, thin vulvar squamous cell carcinoma. *Int J Gynecol Pathol*. 1984;3:331-343.
7. Kelley JL, Burke TW, Tornos C, et al. Minimally invasive vulvar carcinoma: an indication for conservative surgical therapy. *Gynecol Oncol*. 1992;44:240-244.
8. Boyce J, Fruchter RG, Kasambilides E, Nicastrì AD, Sedlis A, Remy JC. Prognostic factors in carcinoma of the vulva. *Gynecol Oncol*. 1985; 20:364-377.
9. Hussein-zadeh N, Zaino R, Nahhas WA, Mortel R. The significance of histologic findings in predicting nodal metastasis in invasive squamous cell carcinoma of the vulva. *Gynecol Oncol*. 1983;16:105-111.
10. Sedlis A, Homesley H, Bundy BN, et al. Positive groin lymph nodes in superficial squamous cell vulvar carcinoma. *Am J Obstet Gynecol*. 1987;156:1159-1164.
11. Drew P, Al-Abadi A, Hendricks JB, Kubilis PS, Wilkinson EJ. Prognostic factors in carcinoma of the vulva: a clinicopathologic and DNA flow cytometric study. *Int J Gynecol Pathol*. 1996; 15:235-241.
12. Paladini D, Cross P, Lopes A, Monaghan JM. Prognostic significance of lymph node variables in squamous cell carcinoma of the vulva. *Cancer*. 1994;74:2491-2494.
13. De Hullu JA, Doting E, Piers DA, et al. Sentinel lymph node identification with technitium-99m-labeled noncolloid in squamous cell cancer of the vulva. *J Nucl Med*. 1998;39:1381-1385.
14. Magrina JF, Gonzalez-Bosquet J, Weaver AL. Squamous cell carcinoma of the vulva stage IA: long term results. *Gynecol Oncol*. 2000;76:24-27
15. Greene FL, Page DL, Fleming ID, et al, eds. *AJCC Cancer Staging Manual*. 6th ed. New York: Springer; 2002.
16. Sobin LH, Wittekind C. *UICC TNM Classification of Malignant Tumours*. 6th ed. New York: Wiley-Liss; 2002.
17. Beller U, Sideri M, Maisonneuve P, et al. Carcinoma of the vagina: FIGO Annual Report. *J Epidemiol Biostat*. 2001;6:153-174.
18. Iversen T, Andreasson B, Bryson SCP, et al. Surgical-procedure terminology for the vulva and vagina: a report of an International Society for the Study of Vulvar Disease task force. *J Reprod Med*. 1990;35:1033-1034.

Bibliography

- Kurman RJ, ed. *Blaustein's Pathology of the Female Genital Tract*. New York: Springer-Verlag; 2002:99-150.
- Kurman RJ, Norris HJ, Wilkinson EJ. *Atlas of Tumor Pathology. Tumors of the Cervix, Vagina, and Vulva*. 3rd Series. Fascicle 4. Washington, DC: Armed Forces Institute of Pathology; 1992.