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)

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For the Members of the Cancer Committee, College of American Pathologists

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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, 6th edition
and FIGO 2001 Annual Report

VULVA: Excisional Biopsy, Resection

Patient name:
Surgical pathology number:

Note: Check 1 response unless otherwise indicated.

MACROSCOPIC

<table>
<thead>
<tr>
<th>Specimen Type</th>
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<tbody>
<tr>
<td>___ Local excision</td>
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</tr>
<tr>
<td>___ Wide excision</td>
<td></td>
</tr>
<tr>
<td>___ Partial vulvectomy</td>
<td></td>
</tr>
<tr>
<td>___ Total vulvectomy</td>
<td></td>
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<tr>
<td>___ Radical vulvectomy</td>
<td></td>
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<tr>
<td>___ Other (specify):</td>
<td></td>
</tr>
<tr>
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</table>

Lymphadenectomy

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>___ Not applicable</td>
<td></td>
</tr>
<tr>
<td>___ Sentinel lymph node biopsy</td>
<td></td>
</tr>
<tr>
<td>___ Inguinal-femoral nodes</td>
<td></td>
</tr>
<tr>
<td>___ Pelvic nodes</td>
<td></td>
</tr>
<tr>
<td>___ Other (specify):</td>
<td></td>
</tr>
</tbody>
</table>

Tumor Site (check all that apply)

<table>
<thead>
<tr>
<th>Tumor Site (specify)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>___ Right vulva</td>
<td></td>
</tr>
<tr>
<td>* ___ Labia major</td>
<td></td>
</tr>
<tr>
<td>* ___ Labia minor</td>
<td></td>
</tr>
<tr>
<td>___ Left vulva</td>
<td></td>
</tr>
<tr>
<td>* ___ Labia major</td>
<td></td>
</tr>
<tr>
<td>* ___ Labia minor</td>
<td></td>
</tr>
<tr>
<td>___ Clitoris</td>
<td></td>
</tr>
<tr>
<td>___ Other (specify):</td>
<td></td>
</tr>
<tr>
<td>___ Not specified</td>
<td></td>
</tr>
</tbody>
</table>

* 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): ____________________________

* 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.
**Pathologic Staging (pTNM [FIGO])**

**Primary Tumor (pT)**
- **pTX**: Cannot be assessed
- **pT0**: No evidence of primary tumor
- **pTis**: 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**

*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.
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)

* 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

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
2. Tumor, if present
   a. Size (3 dimensions, including depth)
   b. Descriptive features
3. Additional pathologic findings, if present
4. 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 1
   • 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

¹ Bethesda System for Reporting Cervical/Vaginal Cytology
**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)**

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
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<tbody>
<tr>
<td>NX</td>
<td>Regional lymph nodes cannot be assessed</td>
</tr>
<tr>
<td>N0</td>
<td>No lymph nodes palpable</td>
</tr>
<tr>
<td>N1</td>
<td>Unilateral regional lymph node metastasis</td>
</tr>
<tr>
<td>N2</td>
<td>Bilateral regional lymph node metastasis</td>
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**Distant Metastasis (M): TNM**

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>MX</td>
<td>Distant metastasis cannot be assessed</td>
</tr>
<tr>
<td>M0</td>
<td>No distant metastasis</td>
</tr>
<tr>
<td>M1</td>
<td>Distant metastasis (including pelvic lymph node metastasis)</td>
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</tbody>
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**Stage Groupings**

<table>
<thead>
<tr>
<th>AJCC/UICC TNM</th>
<th>FIGO</th>
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<tbody>
<tr>
<td>Stage 0</td>
<td>Tis</td>
</tr>
<tr>
<td>Stage I</td>
<td>T1</td>
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<tr>
<td>Stage IA</td>
<td>T1a</td>
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<tr>
<td>Stage IB</td>
<td>T1b</td>
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<td>Stage II</td>
<td>T2</td>
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<tr>
<td>Stage III</td>
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<td>T3</td>
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<td>Stage IVA</td>
<td>T1</td>
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<td>Stage IVB</td>
<td>Any T</td>
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**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 surgeon\textsuperscript{18}
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.\textsuperscript{12}

J. Melanoma
See protocol for Melanoma of the Skin.
References

Bibliography