# A guide to Invasive Breast Cancer Histopathology Reporting

## Clinical details

<table>
<thead>
<tr>
<th>S1.02</th>
<th>Clinical information provided on request form (complete as narrative or use the structured format below)</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1.03</td>
<td>Pathology accession number</td>
<td>Text</td>
</tr>
<tr>
<td>S1.04</td>
<td>Principal clinician</td>
<td>Text</td>
</tr>
</tbody>
</table>

## Macroscopic findings

<table>
<thead>
<tr>
<th>S2.01</th>
<th>No. of specimens submitted</th>
<th>___</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2.02</td>
<td>Specimen laterality</td>
<td>Left</td>
</tr>
<tr>
<td>S2.03</td>
<td>Specimen type/Lymph tissue</td>
<td>See p3</td>
</tr>
<tr>
<td>S2.04</td>
<td>Specimen orientation</td>
<td>Not oriented</td>
</tr>
<tr>
<td>S2.05</td>
<td>Method of localisation</td>
<td>carbon hook wire</td>
</tr>
<tr>
<td>S2.06</td>
<td>Specimen size</td>
<td><em><strong>x___x</strong></em> mm</td>
</tr>
<tr>
<td>S2.07</td>
<td>Specimen weight</td>
<td>___ g</td>
</tr>
<tr>
<td>S2.08</td>
<td>Macroscopically visible tumours?</td>
<td>Absent</td>
</tr>
</tbody>
</table>

## Macroscopic findings (cont.)

<table>
<thead>
<tr>
<th>S2.09</th>
<th>Gross descrit. of tumour/s (for each tumour record)</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2.10</td>
<td>Skin</td>
<td>Absent</td>
</tr>
<tr>
<td>S2.11</td>
<td>Muscle</td>
<td>Absent</td>
</tr>
<tr>
<td>S2.12</td>
<td>SENTINEL LYMPH NODES (for each node received record...)</td>
<td>Axilla</td>
</tr>
<tr>
<td>S2.13</td>
<td>Block identification key</td>
<td>Text</td>
</tr>
<tr>
<td>S2.14</td>
<td>Other macroscopic findings</td>
<td>Text</td>
</tr>
</tbody>
</table>

## Microscopic findings

<table>
<thead>
<tr>
<th>S3.01</th>
<th>Multiple tumours?</th>
<th>Absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>S3.02</td>
<td>MAX. INVASIVE TUMOUR SIZE</td>
<td>___ mm</td>
</tr>
</tbody>
</table>

For EACH tumour identified above complete S3.02-S3.04 and consider recording G3.01
### Microscopic findings (cont.)

<table>
<thead>
<tr>
<th>S3.01</th>
<th>Other invasive tumour dimensions</th>
<th>__x__mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>S3.03</td>
<td>Histological grade (record for each tumour) (Refer to p3)</td>
<td>3–5 (Grade 1)</td>
</tr>
<tr>
<td>S3.04</td>
<td>Invasive carcinoma subtype</td>
<td>See p4</td>
</tr>
<tr>
<td>S3.05</td>
<td>Peritumoural lymphovascular invasion</td>
<td>Not identified</td>
</tr>
<tr>
<td></td>
<td>If suspicious, record the block</td>
<td>Text</td>
</tr>
<tr>
<td>S3.06</td>
<td>Skin</td>
<td>See p4</td>
</tr>
<tr>
<td>S3.07</td>
<td>Muscle</td>
<td>Not involved</td>
</tr>
<tr>
<td>S3.08</td>
<td>Treatment effect (after neoadjuvant hormonal or chemotherapy) (Refer to p4)</td>
<td>No definite resp.</td>
</tr>
<tr>
<td></td>
<td>If no definite or partial response record the estimate of overall level of cellularity for invasive cancer</td>
<td>___%</td>
</tr>
<tr>
<td></td>
<td>Specify neoadjuvant response classification system used</td>
<td>Text</td>
</tr>
<tr>
<td></td>
<td>Result of treatment</td>
<td>Text</td>
</tr>
<tr>
<td>S3.09</td>
<td>DCIS</td>
<td>See p4</td>
</tr>
<tr>
<td>S3.10</td>
<td>Max. extent of breast involved by DCIS</td>
<td>___mm</td>
</tr>
<tr>
<td>S3.11</td>
<td>Max. dimension pure DCIS</td>
<td>___mm</td>
</tr>
<tr>
<td>S3.12</td>
<td>Highest nuclear grade of DCIS</td>
<td>Low</td>
</tr>
<tr>
<td>G3.02</td>
<td>Nuclear grade heterogeneity of DCIS</td>
<td>Absent</td>
</tr>
<tr>
<td></td>
<td>If present, record, next most prevalent grade</td>
<td>Low</td>
</tr>
<tr>
<td>S3.13</td>
<td>Necrosis in DCIS</td>
<td>Absent</td>
</tr>
<tr>
<td>S3.14</td>
<td>Architecture of DCIS (Select all that apply)</td>
<td>comedo</td>
</tr>
<tr>
<td>S3.15</td>
<td>Microcalcification</td>
<td>Absent</td>
</tr>
<tr>
<td></td>
<td>If present record in which tissue(s):</td>
<td>in DCIS</td>
</tr>
<tr>
<td></td>
<td>Lesion(s) with microcalcification</td>
<td>Text</td>
</tr>
<tr>
<td></td>
<td>Associated with necrosis?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Size and extent of microcalcification (if required, per lesion with microcalcification)</td>
<td>Text</td>
</tr>
</tbody>
</table>

### Ancillary test findings

<table>
<thead>
<tr>
<th>S4.01</th>
<th>Oestrogen receptors</th>
<th>Not performed</th>
<th>Performed</th>
<th>Pending</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If performed, record</td>
<td>___ to ___ %</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>%age nuclei stained</td>
<td>Low</td>
<td>Intermed.</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td>Predominant staining intensity</td>
<td>Text</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ER result</td>
<td>Negative</td>
<td>Positive</td>
<td></td>
</tr>
</tbody>
</table>

### Microscopic findings (cont.)

<table>
<thead>
<tr>
<th>S3.16</th>
<th>Paget disease</th>
<th>Absent</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>S3.17</td>
<td>Margin involvement by invasive carcinoma or DCIS</td>
<td>Not involved</td>
<td>Involved</td>
</tr>
<tr>
<td></td>
<td>If involved, specify for each involved margin:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Type of involvement</td>
<td>DCIS</td>
<td>Invasive ca</td>
</tr>
<tr>
<td></td>
<td>DCIS &amp; invasive ca</td>
<td>Text</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Orientation of margin</td>
<td>Text</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Extent of involvement</td>
<td>___mm OR Focal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Distance of invasive carcinoma to margin</td>
<td>___mm OR &gt;10mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If DCIS is closer to the margin the invasive ca additionally record:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S3.18</td>
<td>Lobular neoplasia</td>
<td>Absent</td>
<td>Present</td>
</tr>
<tr>
<td></td>
<td>If present, record type</td>
<td>Classical</td>
<td>Variant</td>
</tr>
<tr>
<td></td>
<td>Extent</td>
<td>Focal</td>
<td>Extensive</td>
</tr>
<tr>
<td>S3.19</td>
<td>Associated breast changes</td>
<td>See p4</td>
<td></td>
</tr>
<tr>
<td>S3.20</td>
<td>SENTINEL NODES (SN)</td>
<td>Total number of SN</td>
<td>____</td>
</tr>
<tr>
<td></td>
<td>Number of SN with macrometastases</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of SN with micrometastases</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of SN with isolated tumour cells</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td>S3.21</td>
<td>NONSEN'TINEL NODES (NSN)</td>
<td>Total number of NSN</td>
<td>____</td>
</tr>
<tr>
<td></td>
<td>Number of NSN with metastases</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td>S3.22</td>
<td>Extranodal spread</td>
<td>Absent</td>
<td>Present</td>
</tr>
<tr>
<td>S3.23</td>
<td>Treatment effect in LN</td>
<td>See p4</td>
<td></td>
</tr>
<tr>
<td>G3.03</td>
<td>LCIS at the margin</td>
<td>See p4</td>
<td></td>
</tr>
<tr>
<td>G3.04</td>
<td>Other microscopic comments</td>
<td>Text</td>
<td></td>
</tr>
</tbody>
</table>
**Ancillary test findings**

<table>
<thead>
<tr>
<th>Test</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progestrone receptors</td>
<td>Not performed</td>
</tr>
<tr>
<td></td>
<td>Performed</td>
</tr>
<tr>
<td></td>
<td>Pending</td>
</tr>
<tr>
<td><strong>If performed, record</strong></td>
<td></td>
</tr>
<tr>
<td>%age nuclei stained</td>
<td>____ to ____ %</td>
</tr>
<tr>
<td>Predominant staining intensity</td>
<td>1+ Low</td>
</tr>
<tr>
<td></td>
<td>2+ Intermed.</td>
</tr>
<tr>
<td></td>
<td>3+ High</td>
</tr>
<tr>
<td>PR result</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
</tr>
</tbody>
</table>

**S4.03 HER2 (ISH)**

| If performed, record:                     |                             |
| Number of copies of HER2                  | ____                        |
| Number of copies of CEP17 (if assessed)   | ____                        |
| HER2 result                               | Amplified                  |
|                                           | Non-amp diploid            |
|                                           | Non-amp polysomic          |
|                                           | Indeterminate              |

**HER2 IHC (if performed)**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
</tr>
<tr>
<td>1+</td>
<td></td>
</tr>
<tr>
<td>2+</td>
<td></td>
</tr>
<tr>
<td>3+</td>
<td></td>
</tr>
</tbody>
</table>

**S1.02 /S2.03 Specimen type**

Single select from the following:
- diagnostic open biopsy
- wide local excision (partial mastectomy, quadrantectomy or segmentectomy)
- re-excision
- mastectomy
- mastectomy post neoadjuvant therapy
- other (specify)

Lymph tissue - choose all that apply:
- not submitted
- lymph node biopsy - sentinel
- lymph node biopsy - non-sentinel
- axillary sample
- axillary clearance
- other (specify)

**S2.03 Intraoperative consult**

Choose all that apply:
- frozen section
- imprint cytology
- gross examination for margin assessment
- other (specify)

**S3.03 Histological grade**

**Nuclear grade**

Score 1: Size equivalent to normal breast epithelial cells, regular outlines, uniform chromatin; inconspicuous nucleoli, little size variation.

Score 2: Larger nuclei, open vesicular chromatin; visible nucleoli, moderate variability in size and shape.

Score 3: Vesicular nuclei; often with prominent nucleoli; exhibiting marked variation in size and shape, occasionally very large and bizarre forms.

**Tubular differentiation**

Score 1: >75% of invasive carcinoma forming tubular or glandular structures

Score 2: 10–75% of invasive carcinoma forming tubular or glandular structures

Score 3: <10% of invasive carcinoma forming tubular or glandular structures.

Not assessable* (ie microinvasion only (each focus ≤ 1mm))

**Mitotic counts**

Number of mitoses per 10 high-power fields use the tables below. OR Not assessable (ie microinvasion only (each focus ≤ 1mm))

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Invasive carcinoma of No Special Type (Ductal)
- Invasive carcinoma involving dermis or
- Mixed
- Mucinous carcinoma
- Osseous differentiation
- Invasive carcinoma involving dermis or
- Low grade adenosquamous carcinoma
- Others – signet ring, histiocytoid, etc
- Alveolar
- Invasive micropapillary carcinoma
- Present as both pure DCIS and in conjunction with
- lobular neoplasia (ALH/ LCIS)
- sclerosing adenosis
- Not involved
- Carcinomas with Neuroendocrine features
- Paget disease of the nipple (DCIS extending to
- Carcinoma with neuroendocrine differentiation
- Sebaceous carcinoma
- Squamous cell carcinoma
- Mucoepidermoid carcinoma
- Flat epithelial atypia
- Medullary
- Mixed metaplastic carcinoma
- Acinic cell carcinoma
- Carcinoma with signet ring cell differentiation
- Other types of mesenchymal differentiation
- Carcinoma with apocrine differentiation
- Carcinoma with signet ring cell differentiation
- Invasive micropapillary carcinoma
- Metastatic carcinoma
- Low grade adenosquamous carcinoma
- Fibromatosis-like metastatic carcinoma
- Spindle cell carcinoma
- Metastatic carcinoma with mesenchymal differentiation
- Chondroid differentiation
- Osseous differentiation
- Carcinoma with neuroendocrine differentiation
- Secretory carcinoma
- Invasive papillary carcinoma
- Acinic cell carcinoma
- Mucoid carcinoma
- Polymorphous carcinoma
- Oncocytic carcinoma
- Lipid rich carcinoma
- Glycogen rich/Clear cell carcinoma
- Sebaceous carcinoma
- Adenoid gland/adnexal type tumours
- Mixed metaplastic carcinoma
- Myoepithelial carcinoma

Rare Types of Invasive Cancer:
- Carcinomas with Neuroendocrine features
- Neuroendocrine tumour, well differentiated
- Neuroendocrine tumour, poorly differentiated (small cell carcinoma)
- Carcinoma with neuroendocrine differentiation
- Secretory carcinoma
- Invasive papillary carcinoma
- Acinic cell carcinoma
- Mucoid carcinoma
- Polymorphous carcinoma
- Oncocytic carcinoma
- Lipid rich carcinoma
- Glycogen rich/Clear cell carcinoma
- Sebaceous carcinoma
- Adenoid gland/adnexal type tumours
- Carcinomas with apocrine differentiation
- Carcinoma with signet ring cell differentiation
- Invasive micropapillary carcinoma
- Metastatic carcinoma
- Low grade adenosquamous carcinoma
- Fibromatosis-like metastatic carcinoma
- Spindle cell carcinoma
- Metastatic carcinoma with mesenchymal differentiation
- Chondroid differentiation
- Osseous differentiation
- Carcinoma with neuroendocrine differentiation
- Secretory carcinoma
- Invasive papillary carcinoma
- Acinic cell carcinoma
- Mucoid carcinoma
- Polymorphous carcinoma
- Oncocytic carcinoma
- Lipid rich carcinoma
- Glycogen rich/Clear cell carcinoma
- Sebaceous carcinoma
- Adenoid gland/adnexal type tumours
- Mixed metaplastic carcinoma
- Myoepithelial carcinoma

S3.04 Invasive carcinoma subtype
- Invasive carcinoma of No Special Type (Ductal)
- Pleomorphic carcinoma
- Carcinoma with osteoclast like stromal giant cells
- Carcinoma with choriocarcinomatous features
- Carcinoma with melanotic features
- Invasive lobular carcinoma
- Classical
- Tubulolobular
- Alveolar
- Solid
- Pleomorphic
- Mixed
- Others – signet ring, histiocytoid, etc
- Tubular carcinoma
- Cribriform carcinoma
- Mucinous carcinoma
- Carcinoma with medullary features
- Medullary
- Atypical medullary
- Invasive carcinoma NST (ductal) with medullary features
- Carcinoma with apocrine differentiation
- Carcinoma with signet ring cell differentiation
- Invasive micropapillary carcinoma
- Metastatic carcinoma
- Low grade adenosquamous carcinoma
- Fibromatosis-like metastatic carcinoma
- Spindle cell carcinoma
- Metastatic carcinoma with mesenchymal differentiation
- Chondroid differentiation
- Osseous differentiation
- Other types of mesenchymal differentiation
- Mixed metaplastic carcinoma
- Myoepithelial carcinoma

S3.06 Skin
- Not involved
- Paget disease of the nipple (DCIS extending to skin contiguous with lactiferous sinuses)
- Invasive carcinoma involving dermis or epidermis without ulceration
- Invasive carcinoma involving dermis or epidermis with ulceration
- Ipsilateral satellite skin nodules, ie dermal deposits of invasive carcinoma, separate from the main tumour

S3.23 Treatment effect in LN
- nodes negative, no treatment effect
- nodes negative, with treatment effect
- nodes positive, with treatment effect
- nodes positive, no treatment effect
- Not applicable

S3.08 Treatment effect
- No definite response to pre-surgical therapy in the invasive carcinoma
- Partial response to pre-surgical therapy in the invasive carcinoma, residual carcinoma identified.
- Complete pathologic response in breast and lymph nodes: No residual invasive carcinoma is present in the breast or lymph nodes after pre-surgical therapy
- Not applicable

S3.09 DCIS
- Absent
- Present only in conjunction with invasive carcinoma
- Present only as pure DCIS
- Present as both pure DCIS and in conjunction with invasive carcinoma

G3.03 LCIS at the margin
- LCIS with comedo necrosis present
- Pleomorphic LCIS present

S3.19 Assoc. breast changes
- atypical ductal hyperplasia
- flat epithelial atypia
- lobular neoplasia (ALH/ LCIS)
- radial scars
- sclerosing adenosis
- fibrocystic change
- other breast changes (eg calcification) (specify)

S5.01 Tumour stage and group#

Primary Tumour (Invasive Ca) (pT)
TX Primary tumour cannot be assessed
T0 No evidence of primary tumour
Tis (DCIS) Ductal carcinoma in situ
Tis (LCIS) Lobular carcinoma in situ
Tis (Paget’s) Paget disease of the nipple NOT associated with invasive carcinoma and/or carcinoma in situ (DCIS and/or LCIS) in the underlying breast parenchyma. Carcinomas in the breast parenchyma associated with Paget’s disease are categorized based on size and characteristics of the parenchymal disease, although the presence of Paget’s disease should still be noted.
T1 Tumour ≤ 20 mm in greatest dimension
T1mi Tumour ≤ 1 mm in greatest dimension
T1a Tumour >1 mm but ≤ 5 mm in greatest dimension
T1b Tumour >5 mm but ≤10 mm in greatest dimension
T1c Tumour >10 mm but ≤20 mm in greatest dimension
T2 Tumour >20 mm but ≤50 mm in greatest dimension
T3 Tumour >50 mm in greatest dimension
T4 Tumour of any size with direct extension to the chest wall and/or to the skin (ulceration or skin nodules)

Note: Invasion of the dermis alone does not qualify as pT4
T4a Extension to the chest wall, not including only pectoralis muscle adherence/invasion
T4b Ulceration and/or ipsilateral satellite nodules and/or oedema (including peau d’orange) of the skin, which do not meet criteria for inflammatory carcinoma
T4c Both T4a and T4b
T4d Inflammatory carcinoma
Regional Lymph Nodes (pN)*

*Note: Classification is based on axillary lymph node dissection with or without sentinel lymph node biopsy. Classification based solely on sentinel lymph node biopsy without subsequent axillary lymph node dissection is designated (sn) for “sentinel node” for example, pN0(sn)

pN0 Regional lymph nodes cannot be assessed (eg previously removed, or not removed for pathologic study)

pN0 Regional lymph node metastasis identified histologically.

Note: isolated tumour cell clusters (ITC) are defined as small clusters of cells not greater than 0.2mm, or single tumour cells, or a cluster of fewer than 200 cells in a single histologic cross-section. ITCs may be detected by routine histology or by immunohistochemical (IHC) methods. Nodes containing only ITCs are excluded from the total positive node count for purposes of N classification but should be included in the total number of nodes evaluated.

pN0(i-): No regional lymph node metastases histologically, negative IHC

pN0(i+): Malignant cells in regional lymph node(s) no greater than 0.2 mm (detected by H&E or IHC including ITC)

pN0(mol-): No regional lymph node metastases histologically, negative molecular findings (RT-PCR)

pN0(mol+): Positive molecular findings (RT-PCR)**, but no regional lymph node metastases detected by histology or IHC

pN1 Micrometastases; or metastases in 1-3 axillary lymph nodes; and/or in internal mammary nodes with metastases detected by sentinel lymph node biopsy but not clinically detected.***

pN1mi Micrometastases (greater than 0.2 mm and/or more than 200 cells, but none greater than 2.0 mm)

pN1a Metastases in 1-3 axillary lymph nodes, at least 1 metastasis greater than 2.0 mm

pN1b Metastases in internal mammary nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected.***

pN1c Metastases in 1-3 axillary lymph nodes and in internal mammary nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected.

pN2 Metastases in 4-9 axillary lymph nodes; or clinically detected**** in internal mammary lymph nodes in the absence of axillary lymph node metastases

pN2a Metastases in 4-9 axillary lymph nodes (at least one tumour deposit greater than 2.0 mm)

pN2b Metastases in clinically detected**** in internal mammary lymph nodes in the absence of axillary lymph node metastases

pN3 Metastases in ten or more axillary lymph nodes; or in infraclavicular (level III axillary) lymph nodes; or in clinically detected**** ipsilateral internal mammary lymph nodes in the presence of one or more positive level II, III axillary lymph nodes; or in more than three axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected****; or in ipsilateral supraclavicular lymph nodes

pN3a Metastases in 10 or more axillary lymph nodes (at least one tumour deposit greater than 2.0 mm); or metastases to the infraclavicular (level III axillary lymph) nodes

Regional Lymph Nodes (pN)* (cont.)

pN3b Metastases in clinically detected**** ipsilateral internal mammary lymph nodes in the presence of one or more positive axillary lymph nodes; or in more than three axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected****

pN3c Metastases in ipsilateral supraclavicular lymph nodes

Notes:

**RT-PCR: reverse transcriptase/polymerase chain reaction

***Not clinically detected is defined as not detected by imaging studies (excluding lymphoscintigraphy) or not detected by clinical examination

****Clinically detected is defined as detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination and having characteristics highly suspicious for malignancy or a presumed pathologic macrometastasis based on fine needle aspiration biopsy with cytologic examination.

Distant Metastasis (M)

M0 No clinical or radiographic evidence of distant metastases

M0(i+): No clinical or radiographic evidence of distant metastases, but deposits of molecularly or microscopically detected tumour cells in circulating blood, bone marrow, or other nonregional nodal tissue that are no larger than 0.2 mm in a patient without symptoms or signs of metastasis

M1 Distant detectable metastases as determined by classic clinical and radiographic means and/or histologically proven larger than 0.2 mm

Stage Grouping*

Stage T N M
0 Tis N0 M0
IA T1* N0 M0
IB T0 N1mi M0
T1* N1mi M0
T1* N1† M0
T2 N0 M0
T2 N1 M0
T3 N0 M0
T3 N1 M0
T4 NO, N1, N2 M0
IIIC Any T N3 M0
IV Any T Any N M1

* T1 includes T1mic

† T0 and T1 tumours with nodal micrometastases only are excluded from Stage IIA and are classified Stage IB.

Notes:

• M0 includes M0(i+)

• The designation pM0 is not valid; any M0 should be clinical.

• If a patient presents with M1 prior to neoadjuvant systemic therapy, the stage is considered stage IV and remains stage IV regardless of response to neoadjuvant therapy.

• Stage designation may be changed if postsurgical imaging studies reveal the presence of distant metastases, provided that the studies are carried out within 4 months of diagnosis in the absence of disease progression and provided that the patient has not received neoadjuvant therapy.

• Post-neoadjuvant therapy is designated with “yc” or “yp” prefix. No stage group is assigned if there is a complete pathologic response (CR) to neoadjuvant therapy, for example, ypT0ypN0M0.