BREAST STAGING FORM

CLINICAL *Extent of disease before any treatment*	STAGE CATEGORY DEFINITIONS		PATHOLOGIC *Extent of disease through completion of definitive surgery*
❒ y clinical– staging completed after neoadjuvant therapy but before subsequent surgery	**TUMOR SIZE:** _____	**LATERALITY:** □ left □ right □ bilateral	❒ y pathologic – staging completed after neoadjuvant therapy AND subsequent surgery
	PRIMARY TUMOR (T)		
❑ TX	Primary tumor cannot be assessed		❑ TX
❑ T0	No evidence of primary tumor		❑ T0
❑ Tis	Carcinoma *in situ*		❑ Tis
❑ Tis (DCIS)	Ductal carcinoma *in situ*		❑ Tis (DCIS)
❑ Tis (LCIS)	Lobular carcinoma *in situ*		❑ Tis (LCIS)
❑ Tis (Paget's)	Paget's disease of the nipple is 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 the size and characteristics of the parenchymal disease, although the presence of Paget's disease should still be noted		❑ Tis (Paget's)
❑ T1	Tumor ≤20 mm in greatest dimension		❑ T1
❑ T1mi	Tumor ≤1 mm in greatest dimension		❑ T1mi
❑ T1a	Tumor >1 mm but ≤5 mm in greatest dimension		❑ T1a
❑ T1b	Tumor >5 mm but ≤10 mm in greatest dimension		❑ T1b
❑ T1c	Tumor >10 mm but ≤20 mm in greatest dimension		❑ T1c
❑ T2	Tumor >20 mm but ≤50 mm in greatest dimension		❑ T2
❑ T3	Tumor >50 mm in greatest dimension		❑ T3
❑ T4	Tumor of any size with direct extension to the chest wall and/or to the skin (ulceration or skin nodules)*		❑ T4
❑ T4a	Extension to the chest wall, not including only pectoralis muscle adherence/invasion		❑ T4a
❑ T4b	Ulceration and/or ipsilateral satellite nodules and/or edema (including peau d'orange) of the skin which do not meet the criteria for inflammatory carcinoma		❑ T4b
❑ T4c	Both T4a and T4b		❑ T4c
❑ T4d	Inflammatory carcinoma**		❑ T4d
	*Note: Invasion of the dermis alone does not qualify as T4. **Note: Inflammatory carcinoma is restricted to cases with typical skin changes involving a third or more of the skin of the breast. While the histologic presence of invasive carcinoma invading dermal lymphatics is supportive of the diagnosis, it is not required, nor is dermal lymphatic invasion without typical clinical findings sufficient for a diagnosis of inflammatory breast cancer.		
	REGIONAL LYMPH NODES (N)		
❑ NX pNX	Regional lymph nodes cannot be assessed (e.g., previously removed) Regional lymph nodes cannot be assessed (e.g., previously removed, or not removed for pathologic study)		NX ❑ pNX*
❑ N0	No regional lymph node metastases		N0
pN0	No regional lymph node metastasis identified histologically		❑ pN0
pN0(i-)	No regional lymph node metastases histologically, negative IHC		❑ pN0(i-)
pN0(i+)	Malignant cells in regional lymph node(s) no greater than 0.2 mm (detected by H&E or IHC including ITC)		❑ pN0(i+)
pN0(mol-)	No regional lymph node metastases histologically, negative molecular findings (RT-PCR)		❑ pN0(mol-)
pN0(mol+)	Positive molecular findings (RT-PCR), but no regional lymph node		❑ pN0(mol+)

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		metastases detected by histology or IHC	
❑	N1	Metastases to movable ipsilateral level I, II axillary lymph node(s)	N1
	pN1	Micrometastases; or metastases in 1 to 3 axillary lymph nodes; and/or in internal mammary nodes with metastases detected by sentinel lymph node biopsy but not clinically detected**	❑ pN1
	pN1mi	Micrometastases (greater than 0.2 mm and/or more than 200 cells, but none greater than 2.0 mm)	❑ pN1mi
	pN1a	Metastases in 1 to 3 axillary lymph nodes, at least one metastasis greater than 2.0 mm	❑ pN1a
	pN1b	Metastases in internal mammary nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected**	❑ pN1b
	pN1c	Metastases in 1 to 3 axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected**	❑ pN1c
❑	N2	Metastases in ipsilateral level I, II axillary lymph nodes that are clinically fixed or matted; or in clinically detected* ipsilateral internal mammary nodes in the *absence* of clinically evident axillary lymph node metastases	
	pN2	Metastases in 4 to 9 axillary lymph nodes; or in clinically detected*** internal mammary lymph nodes in the *absence* of axillary lymph node metastases	❑ pN2
❑	N2a	Metastases in ipsilateral axillary lymph nodes fixed to one another (matted) or to other structures	
	pN2a	Metastases in 4 to 9 axillary lymph nodes (at least one tumor deposit greater than 2.0 mm)	❑ pN2a
❑	N2b	Metastases only in clinically detected** ipsilateral internal mammary nodes and in the *absence* of clinically evident axillary lymph node metastases	
	pN2b	Metastases in clinically detected*** internal mammary lymph nodes in the *absence* of axillary lymph node metastases	❑ pN2b
❑	N3	Metastases in ipsilateral infraclavicular (level III axillary) lymph node(s) with or without level I, II axillary lymph node involvement; or in clinically detected* ipsilateral internal mammary lymph node(s) with clinically evident level I, II axillary lymph node metastases; or metastases in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement	
	pN3	Metastases in 10 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 1 or more positive level I, II axillary lymph nodes; or in more than 3 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	❑ pN3
❑	N3a	Metastases in ipsilateral infraclavicular lymph node(s)	
	pN3a	Metastases in 10 or more axillary lymph nodes (at least one tumor deposit greater than 2.0 mm); or metastases to the infraclavicular (level III axillary lymph) nodes	❑ pN3a
❑	N3b	Metastases in ipsilateral internal mammary lymph node(s) and axillary lymph node(s)	
	pN3b	Metastases in clinically detected*** ipsilateral internal mammary lymph nodes in the *presence* of 1 or more positive axillary lymph nodes; or in more than 3 axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph	❑ pN3b

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	node biopsy but not clinically detected**	
❑ N3c pN3c	Metastases in ipsilateral supraclavicular lymph node(s) Metastases in ipsilateral supraclavicular lymph nodes	❑ pN3c
	* 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).	
	**Note: *Not clinically detected* is defined as not detected by imaging studies (excluding lymphoscintigraphy) or not detected by clinical examination.	
	***Note: 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. Confirmation of clinically detected metastatic disease by fine needle aspiration without excision biopsy is designated with an (f) suffix, for example, cN3a(f). Excisional biopsy of a lymph node or biopsy of a sentinel node, in the absence of assignment of a pT, is classified as a clinical N, for example, cN1. Information regarding the confirmation of the nodal status will be designated in site specific factors as clinical, fine needle aspiration, core biopsy or sentinel lymph node biopsy. Pathologic classification (pN) is used for excision or sentinel lymph node biopsy only in conjunction with a pathologic T assignment.	
	Note: Isolated tumor cell clusters (ITC) are defined as small clusters of cells not greater than 0.2 mm, or single tumor 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	
	DISTANT METASTASIS (M)	
❑ M0	No clinical or radiographic evidence of distant metastases (no pathologic M0; use clinical M to complete stage group)	
❑ cM0(i+)	No clinical or radiographic evidence of distant metastases, but deposits of molecularly or microscopically detected tumor cells in circulating blood, bone marrow or other non-regional nodal tissue that are no larger than 0.2 mm in a patient without symptoms or signs of metastases	
❑ M1	Distant detectable metastases as determined by classic clinical and radiographic means and/or histologically proven larger than 0.2 mm	❑ M1

ANATOMIC STAGE • PROGNOSTIC GROUPS

CLINICAL				PATHOLOGIC			
GROUP	T	N	M	GROUP	T	N	M
❑ 0	Tis	N0	M0	❑ 0	Tis	N0	M0
❑ IA	T1*	N0	M0	❑ IA	T1*	N0	M0
❑ IB	T0	N1mi	M0	❑ IB	T0	N1mi	M0
	T1*	N1mi	M0		T1*	N1mi	M0
❑ IIA	T0	N1**	M0	❑ IIA	T0	N1**	M0
	T1*	N1**	M0		T1*	N1**	M0
	T2	N0	M0		T2	N0	M0
❑ IIB	T2	N1	M0	❑ IIB	T2	N1	M0
	T3	N0	M0		T3	N0	M0
❑ IIIA	T0	N2	M0	❑ IIIA	T0	N2	M0
	T1*	N2	M0		T1*	N2	M0
	T2	N2	M0		T2	N2	M0
	T3	N1	M0		T3	N1	M0

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		T3	N2	M0
❑	IIIB	T4	N0	M0
		T4	N1	M0
		T4	N2	M0
❑	Stage IIIC	Any T	N3	M0
❑	Stage IV	Any T	Any N	M1

* T1 includes T1mi
** T0 and T1 tumors with nodal micrometastases only are excluded from Stage IIA and are classified Stage IB.

❑ Stage unknown

		T3	N2	M0
❑	IIIB	T4	N0	M0
		T4	N1	M0
		T4	N2	M0
❑	Stage IIIC	Any T	N3	M0
❑	Stage IV	Any T	Any N	M1

* T1 includes T1mi
** T0 and T1 tumors with nodal micrometastases only are excluded from Stage IIA and are classified Stage IB.

❑ Stage unknown

PROGNOSTIC FACTORS (SITE-SPECIFIC FACTORS)

REQUIRED FOR STAGING: None

CLINICALLY SIGNIFICANT:

Paget's disease: _____

Tumor grade (Scarff-Bloom-Richardson system): _____

Estrogen receptor and test method (IHC, RT-PCR, other): _____

Progesterone receptor and test method (IHC, RT-PCR, other): _____

HER2 status and test method (IHC, FISH, CISH, RT-PCR, other):

_____

Method of lymph node assessment (e.g., clinical, fine needle aspiration; core biopsy;

sentinel lymph node biopsy): _____

IHC of regional lymph nodes: _____

Molecular studies of regional lymph nodes:

_____

Distant metastases method of detection (clinical, radiographic, biopsy): _____

Circulating Tumor Cells (CTC) and method of detection (RT-PCR, immunomagnetic

separation, other): _____

Disseminated Tumor Cells (DTC; bone marrow micrometastases) and method of detection

(RT-PCR, immunohistochemical, other): _____

Multi-gene signature score: _____

Response to neoadjuvant therapy will be collected in the registry but does not affect the

post-neoadjuvant stage:

_____

General Notes:
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.

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

y prefix indicates those cases in which classification is performed during or following 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 prior to multimodality therapy.

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

a prefix designates the stage determined at autopsy: aTNM.

surgical margins is data field recorded by registrars describing the surgical margins of the resected primary site specimen as determined only by the pathology report.

neoadjuvant treatment is radiation therapy or systemic therapy

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Histologic Grade (G) *(also known as overall grade)*

Grading system	*Grade*
❑ 2 grade system	❑ Grade I or 1
❑ 3 grade system	❑ Grade II or 2
❑ 4 grade system	❑ Grade III or 3
❑ No 2, 3, or 4 grade system is available	❑ Grade IV or 4

ADDITIONAL DESCRIPTORS

Lymphatic Vessel Invasion (L) and Venous Invasion (V) have been combined into Lymph-Vascular Invasion (LVI) for collection by cancer registrars. The College of American Pathologists' (CAP) Checklist should be used as the primary source. Other sources may be used in the absence of a Checklist. Priority is given to positive results.

- ❑ Lymph-Vascular Invasion Not Present (absent)/Not Identified
- ❑ Lymph-Vascular Invasion Present/Identified
- ❑ Not Applicable
- ❑ Unknown/Indeterminate

Residual Tumor (R)

The absence or presence of residual tumor after treatment. In some cases treated with surgery and/or with 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

(consisting of chemotherapy, hormone therapy, or immunotherapy) administered prior to a definitive surgical procedure. If the surgical procedure is not performed, the administered therapy no longer meets the definition of neoadjuvant therapy.

❑ Clinical stage was used in treatment planning (describe): _____

❑ National guidelines were used in treatment planning ❑ NCCN ❑ Other (describe):_____

_____

_____

Physician signature Date/Time

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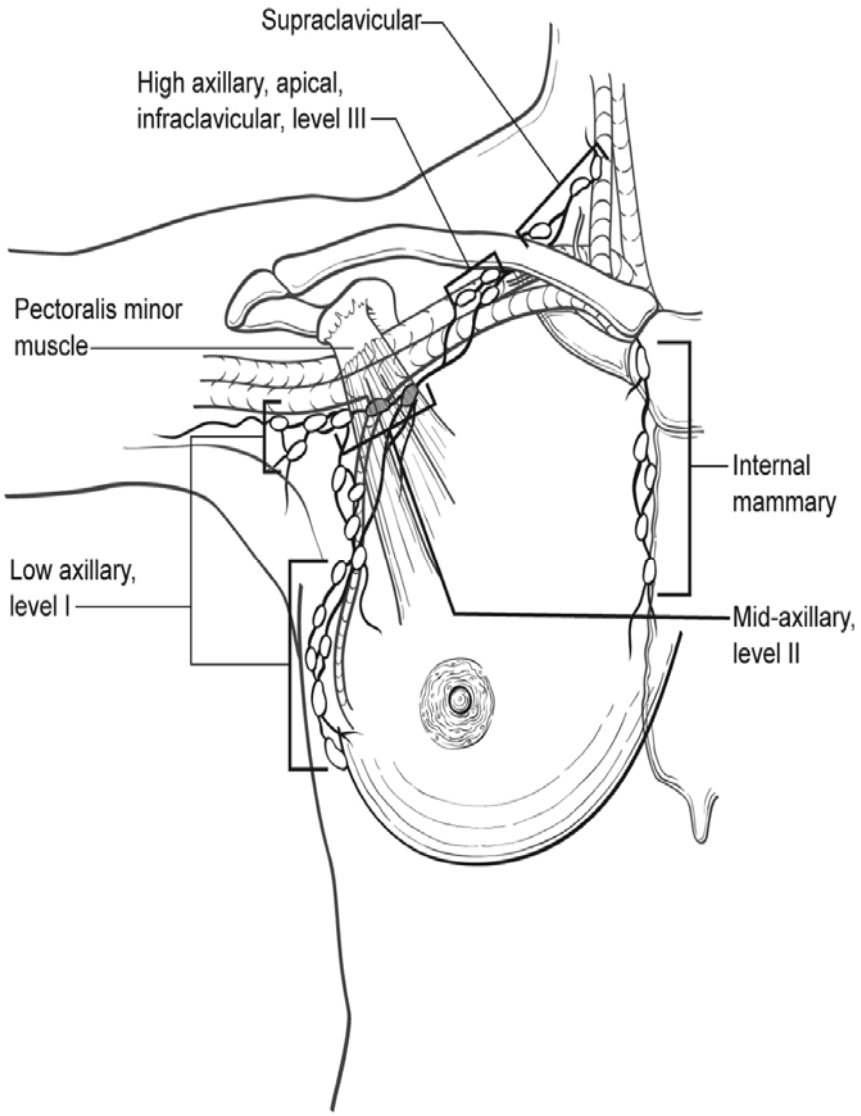
Illustration: Indicate on diagram primary tumor and regional nodes involved.



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