Presentation Outline

- Overview
- Anatomy of Breast
- Multiple Primary and Histology Coding Rules Refresher
- Collaborative Stage Data Collection System (CSv02.03.02)
- 2011 FCDS Required C.S. Site Specific Factors
- NCCN and ASCO Treatment Guidelines by Stage
- Documentation
Breast cancer – 2nd most common

- 2011 estimates - New Cancer Cases – United States
  - 1,596,670 new cancer cases (malignant neoplasms plus in-situ only)
  - 230,480 female breast cancer
  - 2,140 male breast cancer

- 2011 estimates - Cancer Deaths – United States
  - 571,950 cancer deaths
  - 39,970 breast cancer deaths
  - 59,520 female breast cancer deaths
  - 450 male breast cancer deaths

- 2011 estimates – New Cancer Cases and Cancer Deaths – Florida
  - 113,400 new cancer cases (malignant neoplasms plus in-situ only)
  - 15,130 female breast cancer
  - 2,690 female breast cancer deaths
  - Male breast cancer – no published estimates (new cases or deaths)

Source: American Cancer Society Cancer Facts and Figures 2011

Breast Cancer Histology

Adenocarcinoma (ICD-O-3 code 8140/3)

- Ductal (850_/3) most common 70-80%
  - Also known as duct carcinoma

- Medullary (851_/3)

- Mucinous or colloid (848_/3)

- Lobular (852_) frequently bilateral at diagnosis

- Tubular (8211/3)

- Papillary (805_/3)

- Ductular (8521/3) a histologic type distinct from ductal carcinoma

http://training.seer.cancer.gov
<table>
<thead>
<tr>
<th>ICD-O-3</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>C50.0</td>
<td>Nipple Paget disease without underlying tumor</td>
</tr>
<tr>
<td>C50.1</td>
<td>Central portion of breast (subareolar) area extending 1 cm around areolar complex</td>
</tr>
<tr>
<td>C50.2</td>
<td>Upper inner quadrant of breast (UIQ)</td>
</tr>
<tr>
<td>C50.3</td>
<td>Lower inner quadrant (LIQ) of breast</td>
</tr>
<tr>
<td>C50.4</td>
<td>Upper outer quadrant (UOQ) of breast</td>
</tr>
<tr>
<td>C50.5</td>
<td>Lower outer quadrant (LOQ) of breast</td>
</tr>
<tr>
<td>C50.6</td>
<td>Axillary tail of breast</td>
</tr>
<tr>
<td>C50.7</td>
<td>Overlapping lesion of breast</td>
</tr>
</tbody>
</table>

Multifocal Tumors

- Code the specific quadrant for multifocal tumors all within one quadrant
- Do not code C509 (Breast, NOS) in this situation

ICD-O-3 Term

<table>
<thead>
<tr>
<th>C50.9</th>
<th>Breast, NOS Entire breast</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Multiple tumors in different subsites within breast</td>
</tr>
<tr>
<td></td>
<td>Inflammatory without palpable mass</td>
</tr>
<tr>
<td></td>
<td>⅓ or more of breast involved with tumor</td>
</tr>
<tr>
<td></td>
<td>Diffuse (tumor size &lt; 98)</td>
</tr>
</tbody>
</table>


Quadrants of the Breast

Regional Lymph Nodes

- 2. Axillary lymphatic plexus
- 3. Interpectoral lymph nodes
- 4. Subpectoral lymph nodes (pectoral muscle)
- 5. Superficial axillary (low axillary) lymph nodes
- 6. Deep axillary lymph nodes
- 7. Brachial axillary lymph nodes
- 8. Intercostal axillary lymph nodes (Retic nodes)
- 9. Paramammary or intramammary lymph nodes
- 10. Paramammary lymph nodes (internal mammary nodes)

* Note: The cutaneous lymph nodes are not part of the lymph node drainage of the breast.
A blue dye in lumpectomy site
B axillary lymph nodes: levels I
C axillary lymph nodes: levels II
D axillary lymph nodes: levels III
E large lymphatic channels
F small lymphatic channels
G sentinel lymph nodes taking up dye

Source: http://www.breastcancer.org/illustrations/i0050.html

ICD-O-3 Site/Histology table

Multiple Primary and Histology Coding Rules

January 01, 2007

National Cancer Institute
Surveillance Epidemiology and End Results Program
Bethesda, MD
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease</td>
<td>Diagnosis</td>
<td>Code</td>
<td>Code</td>
</tr>
<tr>
<td>Cancer</td>
<td>1:01:01</td>
<td>1:01:01</td>
<td>1:01:01</td>
</tr>
<tr>
<td>Breast</td>
<td>1:01:01</td>
<td>1:01:01</td>
<td>1:01:01</td>
</tr>
<tr>
<td>Colon</td>
<td>1:01:01</td>
<td>1:01:01</td>
<td>1:01:01</td>
</tr>
<tr>
<td>Lung</td>
<td>1:01:01</td>
<td>1:01:01</td>
<td>1:01:01</td>
</tr>
</tbody>
</table>

Note: Code refers to the code used for each disease.
Histology: Breast cancer; nests of malignant ductal carcinoma invading tissue; 10X magnification.
Schema Selection


- Breast

  - Click on Site Specific Schema tab on the left

  - Select the Breast Schema

  - All Florida Cases are coded in Cs02.03.02
CS Tumor Size

- Refer to Notes for each CSv2.02.03 data item
- No new codes
- Priority rules for size (see Part I)
  - Pathology
  - Surgery
  - Imaging
  - Physical exam
- Take largest size found from multiple imaging reports

Collaborative Stage for TNM 7 - Revised 11/11/2010

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td>0.0 - No evidence of disease</td>
</tr>
<tr>
<td>001</td>
<td>0.1 - Microscopic only</td>
</tr>
<tr>
<td>002</td>
<td>0.2 - Less than 1 mm</td>
</tr>
<tr>
<td>003</td>
<td>0.3 - Greater than 1 mm and less than 2 mm</td>
</tr>
<tr>
<td>004</td>
<td>0.4 - Greater than 2 mm and less than 4 mm</td>
</tr>
<tr>
<td>005</td>
<td>0.5 - Greater than 4 mm and less than 10 mm</td>
</tr>
<tr>
<td>006</td>
<td>0.6 - Greater than 10 mm and less than 20 mm</td>
</tr>
<tr>
<td>007</td>
<td>0.7 - Greater than 20 mm and less than 50 mm</td>
</tr>
<tr>
<td>008</td>
<td>0.8 - Greater than 50 mm and less than 100 mm</td>
</tr>
<tr>
<td>009</td>
<td>0.9 - Greater than 100 mm and less than 200 mm</td>
</tr>
<tr>
<td>010</td>
<td>1.0 - Greater than 200 mm</td>
</tr>
<tr>
<td>011</td>
<td>2.0 - Unknown or cannot determine</td>
</tr>
<tr>
<td>012</td>
<td>3.0 - Not available</td>
</tr>
</tbody>
</table>

Note: TNM stage with no other information is considered stage zero.
Collaborative Stage for TNM 7 - Revised 11/11/2010

**Breast**

**CS Tumor Size**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>TNM Stage</th>
<th>TNM Stage</th>
<th>TNM Stage</th>
<th>TNM Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>990</td>
<td>Breast cancer T1a, N0, M0</td>
<td>T3</td>
<td>N0</td>
<td>M0</td>
<td>X</td>
</tr>
<tr>
<td>991</td>
<td>Breast cancer T1b, N0, M0</td>
<td>T2</td>
<td>N0</td>
<td>M0</td>
<td>X</td>
</tr>
</tbody>
</table>

**Notes:**
- Note 1: Changes such as dimpling of the skin, retraction of nipple, and skin ulceration are caused by tension on Cooper's ligament (e.g., by an acute skin retraction). They do not alter the description.

**Collaborative Stage for TNM 7 - Revised 11/11/2010**

**Breast**

**CS Extension**

- Note 1: Changes such as dimpling of the skin, retraction of nipple, and skin ulceration are caused by tension on Cooper's ligament (e.g., by an acute skin retraction). They do not alter the description.

**Collaborative Stage for TNM 7 - Revised 11/11/2010**

**Breast**

**CS Extension**

- Note 1: Changes such as dimpling of the skin, retraction of nipple, and skin ulceration are caused by tension on Cooper's ligament (e.g., by an acute skin retraction). They do not alter the description.
Breast Primary Tumor (T)

- Primary tumor cannot be assessed
- No evidence of primary tumor
- Carcinoma insitu
- Ductal insitu
- Lobular carcinoma insitu
- Paget’s disease of the nipple NOT associated with invasive and/or carcinoma insitu DCIS and/or LCIS in the underlying breast parenchyma
- Extension to the chest wall
- Inflammatory carcinoma

Source: http://www.breastcancer.org/illustrations/3050.html
Breast Regional Lymph Nodes (N)

- Level I (low-axilla): lymph nodes lateral to the lateral border of pectoralis minor muscle
- Level II (mid-axilla): lymph nodes between the medial and lateral borders of the pectoralis minor muscle and the interpectoral (Rotter’s) lymph nodes
- Level III (apical axilla): lymph nodes medial to the medial margin of the pectoralis minor muscle and inferior clavicle (apical or infraclavicular nodes) worse prognosis

Breast: CS Lymph Nodes

- Pathologic Lymph Node Eval
  - Code 050
  - Code 130
  - Code 150
  - Code 155 (NEW v02.03)
  - Code 250
  - Code 258 (NEW v02.03)
  - Code 320
  - Code 620 (NEW v02.03)
  - Code 710
  - Code 720
  - Code 730
  - Code 815
**Breast: CS Lymph Nodes- Clinical**

- Clinical Lymph Node Eval
  - Code 255
  - Code 257 (NEW v02.03)
  - Code 510
  - Code 610
  - Code 735
  - Code 810
Metastatic Sites

- Regional Direct Ext
- Chestwall
  - ribs
  - Intercostal muscles
  - Sternoternal muscle
  - Pectoral muscle doesn’t constitute chest wall invasion
- Lymph nodes
  - Cervical lymph nodes or contralateral internal mammary or contralateral axillary lymph nodes
- Distant Metastasis
  - Bone
  - Lung
  - Brain
  - Liver
- Disseminated tumor cells (DTCs) – Bone Marrow
- Circulating tumor cells (CTCs) – Blood Stream

AJCC, 2010, pg 347-367
Prognostic Factors
(Site-Specific Factors)

Clinically Significant
None are required for staging

FCDS Required SSFs

Paget’s disease
Estrogen receptor
Progesterone receptor
HER2 status

Method of node assessment: radiographic, physical examination

There are no prognostic factors required for staging

AJCC, 2010, pg 347-367

Breast
Site-Specific Factors

FCDS-Required ONLY SSFs for this Presentation

<table>
<thead>
<tr>
<th>Schema Number</th>
<th>Schema Name</th>
<th>FCDS Required</th>
<th>Cut. Additional Required/NCI/SEER</th>
</tr>
</thead>
<tbody>
<tr>
<td>106</td>
<td>Breast</td>
<td>1,2,3,4,5,8,9,10,11,13,14,15,16,21,22,23</td>
<td>6,7</td>
</tr>
</tbody>
</table>

CS Site-Specific Factor 1
Endogenous Estrogen Receptor (ER) Assay

- Code
- Description
- Value
- Measurement
- Indicates percentage of ER positive or negative
- Indicates tumor grade
- Indicates whether the assay was performed
- Indicates whether the ER was determined
- Indicates whether the assay was performed
- Indicates whether the ER was determined
- Indicates whether the assay was performed
- Indicates whether the ER was determined
- Indicates whether the assay was performed
**CS Site-Specific Factor 2**

Progestrone Receptor (PR) Assay

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td>Negative/unknown</td>
</tr>
<tr>
<td>010</td>
<td>Positive/normal</td>
</tr>
<tr>
<td>020</td>
<td>Positive/oncology notes</td>
</tr>
<tr>
<td>030</td>
<td>Positive, results not on chart</td>
</tr>
<tr>
<td>040</td>
<td>Test not done (test was not ordered and not performed)</td>
</tr>
</tbody>
</table>

**Note:**
- In women, PR is expected on more than one tumor specimen (specimens are tested in B and C), record the highest value. If any sample is negative, code 000.
- In women, note testing is not performed in B and C. If the field is not marked, do not code this space.
- For T1a tumors, PR testing is not performed. Do not allow for a 24-hour result. Therefore, code 000 will never be coded. If PR is tested and results are not documented in this space, code 000.
- PR testing is not performed in B and C. If the field is not marked, do not code this space.

**CS Site-Specific Factor 3**

Number of Positive Ipsilateral Level I-II Axillary Lymph Nodes

- Note 1: Include only the number of positive axillary level I and II axillary lymph nodes and intramammary lymph nodes in this field. Intramammary nodes located within the axilla, are not the same as axillary mammary nodes, located along the sternum.
- Note 2: Ignore this field if there has been prophylactic lymph node dissection.
- Note 3: If lymph nodes with metastasis greater than 2 mm in diameter are present, they should be counted as positive. If the pathology report indicates that axillary nodes are present but less than 2 mm in diameter, code 000. If axillary nodes are positive in this field, lymph node staging area is counted as 1 or 2 lymph nodes are found, code 000. If axillary nodes are positive and intramammary nodes are positive, code 000.
- Note 4: Instructions in the OCM General Notes Part II Regional Nodes Positive for Tumor Node in this field list the codes in Regional History.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td>0 total axillary nodes examined/z staged negative</td>
</tr>
<tr>
<td>001-009</td>
<td>1-9 positive nodes</td>
</tr>
<tr>
<td>100</td>
<td>10 or more total axillary nodes positive</td>
</tr>
<tr>
<td>101-109</td>
<td>10-19 positive axillary nodes</td>
</tr>
<tr>
<td>110</td>
<td>20 or more positive axillary nodes</td>
</tr>
<tr>
<td>200</td>
<td>No axillary nodes examined</td>
</tr>
<tr>
<td>201</td>
<td>Intramammary nodes positive, but documented in another space</td>
</tr>
</tbody>
</table>

**Note:** Information not collected for this case.
- If this item is required by your standard set, use code 000 will result in an audit error.

**CS Site-Specific Factor 4**

Immunohistochemistry (IHC) of Regional Lymph Nodes

- Note 1: Included here are TILs (Tumor Infiltrating Lymphocytes) as defined in single cell culture assay, in small clusters not greater than 0.2 millimeter (mm). Usually obtained from lymph nodes/subcutaneous fat. These lymph nodes and fat are also considered for nodal staging of lymph nodes. Tumor Infiltrating Lymphocytes (TILs) and IHC markers are usually performed in cases of IHC markers. If TILs or IHC markers are used, use code 000.
- Note 2: TILs are usually assessed in a case set in the current study, even if not done. TILs are not documented in the current study.
- Note 3: If TILs are not performed, use code 000.
- Note 4: For cases with no further information on regional lymph nodes, use code 000.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td>Regional lymph nodes negative on routine hematoxylin and eosin (H&amp;E), no immunohistochemistry (IHC) markers</td>
</tr>
<tr>
<td>001</td>
<td>Regional lymph nodes negative on routine H&amp;E, TILs positive on immunohistochemistry (IHC) markers</td>
</tr>
<tr>
<td>002</td>
<td>Regional lymph nodes negative on routine H&amp;E, TILs negative on immunohistochemistry (IHC) markers</td>
</tr>
<tr>
<td>003</td>
<td>Regional lymph nodes negative on routine H&amp;E, TILs negative, no immunohistochemistry (IHC) markers</td>
</tr>
<tr>
<td>004</td>
<td>Regional lymph nodes positive for TILs</td>
</tr>
<tr>
<td>005</td>
<td>Regional lymph nodes positive for TILs</td>
</tr>
<tr>
<td>006</td>
<td>Regional lymph nodes positive for TILs</td>
</tr>
<tr>
<td>007</td>
<td>Not applicable - TILs not ordered</td>
</tr>
<tr>
<td>008</td>
<td>Not applicable - TILs not performed</td>
</tr>
<tr>
<td>009</td>
<td>Not applicable - TILs not interpreted</td>
</tr>
</tbody>
</table>

**Note:** Information not collected for this case.
- If this item is required by your standard set, use code 000 will result in an audit error.
CS Site-Specific Factor 5
Molecular (IHC) Studies of Regional Lymph Nodes
- HER2: 0 = No expression, negative
- 999 = HER2 unknown
- 0 to 1+ = HER2 negative
- 2+ = HER2 positive
- 3+ = HER2 positive

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td>Regional lymph nodes negative or non-reactive (and 0 or 1+) or HER2 molecular (IHC) studies done and 999 result IHC- IHC studies done</td>
</tr>
<tr>
<td>001</td>
<td>Regional lymph nodes negative or non-reactive (and 0 or 1+) or HER2 molecular (IHC) studies done and 2+ result IHC- IHC studies done</td>
</tr>
<tr>
<td>002</td>
<td>Regional lymph nodes negative or non-reactive (and 0 or 1+) or HER2 molecular (IHC) studies done and 3+ result IHC- IHC studies done</td>
</tr>
<tr>
<td>003</td>
<td>Not applicable - CS Lymph nodes not tested 999</td>
</tr>
<tr>
<td>004</td>
<td>Not applicable - information not collected in this case (If this information is required by your institutional ethics, use of code 999 may result in an audit error.)</td>
</tr>
</tbody>
</table>

CS Site-Specific Factor 8
HER2: Immunohistochemistry (IHC) Lab Value
- HER2: 0 = No expression, negative
- 2+ = HER2 positive
- 3+ = HER2 positive

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td>HER2: 0 = No expression, negative</td>
</tr>
<tr>
<td>001</td>
<td>HER2: 2+ = HER2 positive</td>
</tr>
<tr>
<td>002</td>
<td>HER2: 3+ = HER2 positive</td>
</tr>
<tr>
<td>003</td>
<td>HER2: Unknown or no information</td>
</tr>
</tbody>
</table>

CS Site-Specific Factor 9
HER2: Immunohistochemistry (IHC) Test Interpretation
- HER2: 0 = No expression, negative
- 2+ = HER2 positive
- 3+ = HER2 positive

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td>HER2: 0 = No expression, negative</td>
</tr>
<tr>
<td>001</td>
<td>HER2: 2+ = HER2 positive</td>
</tr>
<tr>
<td>002</td>
<td>HER2: 3+ = HER2 positive</td>
</tr>
<tr>
<td>003</td>
<td>HER2: Unknown or no information</td>
</tr>
</tbody>
</table>
## CS Site-Specific Factor 10

**HER2: Fluorescence In Situ Hybridization (FISH) Lab Value**

Note 1: Record the results of the Fluorescence In Situ Hybridization (FISH) test for Human Epidermal Growth Factor Receptor 2 (HER2) in this table. The results are reported as the signal to noise ratio (S/N) of the HER2 gene. The results are calculated using the fluorescent intensity of the HER2 gene and the internal control gene. The results are reported as a ratio of the signal intensity of the HER2 gene to the internal control gene.

Note 2: The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.

Note 3: The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.

Note 4: The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.

Note 5: The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.

Note 6: The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>180</td>
<td>Value of 1.00 - 1.50</td>
</tr>
<tr>
<td>181</td>
<td>Value of 1.00 - 1.50</td>
</tr>
<tr>
<td>200</td>
<td>Value of 2.00 - 3.00</td>
</tr>
<tr>
<td>201</td>
<td>Value of 2.00 - 3.00</td>
</tr>
<tr>
<td>300</td>
<td>Value of 5.00 - 6.99</td>
</tr>
<tr>
<td>301</td>
<td>Value of 5.00 - 6.99</td>
</tr>
<tr>
<td>500</td>
<td>Value of 6.50 - 9.99</td>
</tr>
<tr>
<td>501</td>
<td>Value of 6.50 - 9.99</td>
</tr>
<tr>
<td>900</td>
<td>Value of 10.00 or greater</td>
</tr>
<tr>
<td>901</td>
<td>Value of 10.00 or greater</td>
</tr>
</tbody>
</table>

## CS Site-Specific Factor 11

**HER2: Fluorescence In Situ Hybridization (FISH) Test Interpretation**

Note 1: Record the interpretation of only the Fluorescence In Situ Hybridization (FISH) test for Human Epidermal Growth Factor Receptor 2 (HER2) in this table.

Note 2: The HER2 FISH test may be used to help determine the HER2 status of a tumor. The results are reported as the signal to noise ratio (S/N) of the HER2 gene. The results are calculated using the fluorescent intensity of the HER2 gene and the internal control gene. The results are reported as a ratio of the signal intensity of the HER2 gene to the internal control gene.

Note 3: The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Tumor, non-amplified</td>
</tr>
<tr>
<td>101</td>
<td>Tumor, non-amplified</td>
</tr>
<tr>
<td>200</td>
<td>Tumor, moderate amplification</td>
</tr>
<tr>
<td>201</td>
<td>Tumor, moderate amplification</td>
</tr>
<tr>
<td>300</td>
<td>Tumor, high amplification</td>
</tr>
<tr>
<td>301</td>
<td>Tumor, high amplification</td>
</tr>
<tr>
<td>400</td>
<td>Tumor, triple-negative</td>
</tr>
<tr>
<td>401</td>
<td>Tumor, triple-negative</td>
</tr>
<tr>
<td>500</td>
<td>Tumor, negative</td>
</tr>
<tr>
<td>501</td>
<td>Tumor, negative</td>
</tr>
</tbody>
</table>

## CS Site-Specific Factor 12

**HER2: Chromogenic In Situ Hybridization (CISH) Lab Value**

Note 1: Record the results of the Chromogenic In Situ Hybridization (CISH) test for Human Epidermal Growth Factor Receptor 2 (HER2) in this table. The results are reported as the signal to noise ratio (S/N) of the HER2 gene. The results are calculated using the fluorescent intensity of the HER2 gene and the internal control gene. The results are reported as a ratio of the signal intensity of the HER2 gene to the internal control gene.

Note 2: The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Value of 0.00 - 0.99</td>
</tr>
<tr>
<td>101</td>
<td>Value of 0.00 - 0.99</td>
</tr>
<tr>
<td>200</td>
<td>Value of 1.00 - 1.99</td>
</tr>
<tr>
<td>201</td>
<td>Value of 1.00 - 1.99</td>
</tr>
<tr>
<td>300</td>
<td>Value of 2.00 - 2.99</td>
</tr>
<tr>
<td>301</td>
<td>Value of 2.00 - 2.99</td>
</tr>
<tr>
<td>400</td>
<td>Value of 3.00 - 3.99</td>
</tr>
<tr>
<td>401</td>
<td>Value of 3.00 - 3.99</td>
</tr>
<tr>
<td>500</td>
<td>Value of 4.00 - 4.99</td>
</tr>
<tr>
<td>501</td>
<td>Value of 4.00 - 4.99</td>
</tr>
<tr>
<td>600</td>
<td>Value of 5.00 - 6.99</td>
</tr>
<tr>
<td>601</td>
<td>Value of 5.00 - 6.99</td>
</tr>
<tr>
<td>700</td>
<td>Value of 7.00 - 9.99</td>
</tr>
<tr>
<td>701</td>
<td>Value of 7.00 - 9.99</td>
</tr>
<tr>
<td>800</td>
<td>Value of 10.00 or greater</td>
</tr>
<tr>
<td>801</td>
<td>Value of 10.00 or greater</td>
</tr>
</tbody>
</table>

## Note

- The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.
- The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.
- The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.
- The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.
- The HER2 gene is located on chromosome 17. The chromosome number is provided only if the code is greater than 0.

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### CS Site-Specific Factor 13
**HER2: Chromogenic In Situ Hybridization (CISH) Test Interpretation**

- Note 1: Recall the interpretation of only the Chromogenic In Situ Hybridization (CISH) test for Human Epidermal Growth Factor Receptor 2 (HER2) in this test.
- Note 2: The same interpretation test should be used to record information in CS Site-Specific Factors 12 and 13.
- Note 3: If the test is not mentioned in the medical record, code to 999 unless there are circumstances under which the test isn't performed, for example, on histologic specimen.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>810</td>
<td>Positive/reduced amplified</td>
</tr>
<tr>
<td>820</td>
<td>Negative/normal, within normal limits, not amplified</td>
</tr>
<tr>
<td>830</td>
<td>Not applicable, information not collected for this case</td>
</tr>
<tr>
<td>850</td>
<td>Test ordered, results not in chart</td>
</tr>
<tr>
<td>999</td>
<td>Unknown or no information</td>
</tr>
</tbody>
</table>

### CS Site-Specific Factor 14
**HER2: Result of Other or Unknown Test**

- Note 1: FISH and/or in situ hybridization (ISH) tests performed for human epidermal growth factor receptor 2 (HER2) are not Chromogenic In Situ Hybridization (CISH) tests.
- Note 2: If it is unknown which type of test was performed, record the results here.
- Note 3: If an unknown HER2 test is mentioned in the medical record, codes to 999 unless there are circumstances under which the test isn't performed, for example, on histologic specimen.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>810</td>
<td>Positive/reduced amplified</td>
</tr>
<tr>
<td>820</td>
<td>Negative/normal, within normal limits, not amplified</td>
</tr>
<tr>
<td>830</td>
<td>Not applicable, information not collected for this case</td>
</tr>
<tr>
<td>850</td>
<td>Test ordered, results not in chart</td>
</tr>
<tr>
<td>999</td>
<td>Unknown or no information</td>
</tr>
</tbody>
</table>

### New Data Items

<table>
<thead>
<tr>
<th>Schema Number</th>
<th>Schema Name</th>
<th>NEW FDOS Required</th>
<th>CaC Additional Required/NCI/SEER</th>
</tr>
</thead>
<tbody>
<tr>
<td>106</td>
<td>Breast</td>
<td>15, 16, 20, 22, 23</td>
<td>6, 7</td>
</tr>
</tbody>
</table>
CS Site-Specific Factor 15
HER2: Summary Result of Testing

- Note 1: The summary of the results of the immunohistochemistry (IHC), Fluorescent in Situ Hybridization (FISH), Chromogenic in Situ Hybridization (CISH), or attenuation Human Epidermal Growth Factor Receptor 2 (HER2) test is recorded here. This result is based on CS Site-Specific Factors 11, 15, and 16. If HER2 test (FISH or CISH) are performed, record the result of the gene amplification test in this fact box. However, if the gene amplification test is given first and the result is borderline or equivocal and an IHC test is done to clarify those equivocal results, code the result of the IHC test here.

- Note 2: If the results of one test are available and it is known that a second test is performed but the results are not available, use code 987.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td>Positive/weakly amplified</td>
</tr>
<tr>
<td>002</td>
<td>Negative/normal, within normal limits, not amplified</td>
</tr>
<tr>
<td>003</td>
<td>Undetermined, uncertain/normal, undetermined/positive or negative</td>
</tr>
<tr>
<td>986</td>
<td>Not applicable; Information not collected for this case</td>
</tr>
<tr>
<td>987</td>
<td>Test ordered, results not in chart</td>
</tr>
<tr>
<td>988</td>
<td>Test not done (test not obtained and not performed)</td>
</tr>
<tr>
<td>989</td>
<td>Unknown or no information</td>
</tr>
<tr>
<td></td>
<td>Not documented in patient record</td>
</tr>
</tbody>
</table>

CS Site-Specific Factor 16
Combinations of ER, PR, and HER2 Results

- Note 1: There is a clinical evidence that high estrogen receptor (ER) and progesterone receptor (PR) levels in breast cancer that is negative for estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) amplification or overexpression.

- Note 2: The data used in CS Site-Specific Factors 11, 15, and 16 are not mutually exclusive.

- Note 3: IHC results are coded in the second digit for negative and 1 for positive.

- Note 4: HER2 results are coded in the third digit. If the hormone is 1 for hormone positive.

- Note 5: IHC results are not available in one or more of the three types of tests and in one of the three types of tests results are not performed. Code 983.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>000</td>
<td>ER Negative, PR Negative, HER2 Negative (Type Negative)</td>
</tr>
<tr>
<td>001</td>
<td>ER Negative, PR Negative, HER2 Positive</td>
</tr>
<tr>
<td>002</td>
<td>ER Negative, PR Positive, HER2 Positive</td>
</tr>
<tr>
<td>003</td>
<td>ER Negative, PR Positive, HER2 Negative</td>
</tr>
<tr>
<td>004</td>
<td>ER Positive, PR Negative, HER2 Positive</td>
</tr>
<tr>
<td>005</td>
<td>ER Positive, PR Positive, HER2 Positive</td>
</tr>
<tr>
<td>006</td>
<td>ER Positive, PR Positive, HER2 Negative</td>
</tr>
<tr>
<td>983</td>
<td>Not applicable; Information not collected for this case</td>
</tr>
</tbody>
</table>

CS Site-Specific Factor 21
Response to Neoadjuvant Therapy

- Note 1: This is a specific statement by a physician about the response to neoadjuvant therapy. Do not try to integrate or alter a response based on other documentation in the medical record such as a description of wound closure or the pathology report. Use code 995 if a response if neoadjuvant therapy was given.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>010</td>
<td>Complete response (CR)</td>
</tr>
<tr>
<td>020</td>
<td>Partial response (PR)</td>
</tr>
<tr>
<td>030</td>
<td>No response (NR)</td>
</tr>
<tr>
<td>987</td>
<td>Not applicable; Neoadjuvant therapy not given</td>
</tr>
<tr>
<td>988</td>
<td>Not applicable; Information not collected for this case</td>
</tr>
<tr>
<td>989</td>
<td>NS (Data not available, see code 995)</td>
</tr>
</tbody>
</table>

CR: Complete Remission
PR: Partial Remission
CS Site-Specific Factor 22
Multigene Signature Method

- Note 1: Multigene signatures or classifiers are assays of a panel of genes from a tumor specimen intended to provide a quantitative assessment of the likelihood of response to chemotherapy and to evaluate prognosis or distant recurrence. O纫rature Dr and BaslineTM plus assay.
- Note 2: Code the type of test performed. This code set should be used to record information in CS Site-Specific Factors 22 and 23.
- Note 3: This information may not be available at diagnosis and may require follow-up with the physician.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>PCR</td>
</tr>
<tr>
<td>002</td>
<td>BaselineTM</td>
</tr>
<tr>
<td>005</td>
<td>HRM</td>
</tr>
<tr>
<td>020</td>
<td>Test not performed, type of test unknown</td>
</tr>
<tr>
<td>030</td>
<td>Not applicable, information not collected for this case</td>
</tr>
<tr>
<td>040</td>
<td>Different data conversion (e.g., use code 040)</td>
</tr>
<tr>
<td>050</td>
<td>Test ordered, results not in chart</td>
</tr>
<tr>
<td>060</td>
<td>Test not done (not ordered and not performed)</td>
</tr>
<tr>
<td>070</td>
<td>Unknown or no information</td>
</tr>
<tr>
<td>080</td>
<td>Not documented in patient record</td>
</tr>
</tbody>
</table>

CS Site-Specific Factor 23
Multigene Signature Results

- Note 1: The results for the Genetics of Breast Cancer are expressed as a percentage. Recurrence Score ranges from 0 to 100, with a score of 100 representing the highest risk of recurrence at 5 years.
- Note 2: The results for the Oncotype DX are expressed as low risk for distant recurrence and high risk for distant recurrence.
- Note 3: Code the score or results of the multigene signature assays calculated in CS Site-Specific Factor 22. Code the percentage score for Oncotype DX. Information not collected for this case may require follow-up with the physician.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>011</td>
<td>Score of 0 - 100</td>
</tr>
<tr>
<td>020</td>
<td>Low risk of recurrence (good prognosis)</td>
</tr>
<tr>
<td>030</td>
<td>Intermediate risk of recurrence (good prognosis)</td>
</tr>
<tr>
<td>040</td>
<td>High risk of recurrence (poor prognosis)</td>
</tr>
<tr>
<td>050</td>
<td>Not applicable, information not collected for this case</td>
</tr>
<tr>
<td>060</td>
<td>Test ordered, results not in chart</td>
</tr>
<tr>
<td>070</td>
<td>Test not done (not ordered and not performed)</td>
</tr>
<tr>
<td>080</td>
<td>Unknown or no information</td>
</tr>
<tr>
<td>090</td>
<td>Not documented in patient record</td>
</tr>
</tbody>
</table>

Treatment
Breast Treatment

- Surgical Treatment
- Chemotherapy
- Hormone therapy
- Radiotherapy
- Biologic therapy


Genetic Difference in Breast Tissue Among Races

Breast Cancer Treatment by Stage

### Stage IA
- T1 N0 M0
- T1 N1 mi M0
- Lumpectomy or mastectomy
- Radiation therapy following surgery if margins are <1 mm
- Radiation therapy following chemotherapy if indicated
- Hormone therapy following radiation therapy if indicated

### Stage IB
- T0 N1 mi M0
- Lumpectomy or mastectomy
- Radiation therapy following surgery if margins are <1 mm
- Radiation therapy following chemotherapy if indicated
- Hormone therapy following radiation therapy if indicated

### Stage IIA
- T0 N1 M0
- T1 N1 M0
- T2 N0 M0

### Stage IIB
- T2 N1 M0
- T3 N0 M0

### Clinical Stage IIIA*
- T0 N2 M0
- T1 N2 M0
- T2 N2 M0
- T3 N2 M0
- T4 N0 M0
- T4 N1 M0
- T4 N2 M0

### Clinical Stage IIIB
- Any T4 N0 M0
- Any T4 N1 M0
- Any T4 N2 M0

### Clinical Stage IIIC
- Any T N3 M0

### Pre-Operative (Neoadjuvant) Chemotherapy
- Anthracycline-based chemotherapy +/- taxane

- If response:
  - Surgical options:
    - Total mastectomy with axillary dissection
    - Lumpectomy with axillary dissection
  - Radiation therapy following surgery
  - Delayed breast reconstruction
  - Additional chemotherapy if not completed preoperatively

- If no response:
  - Additional chemotherapy and/or preoperative radiation therapy
  - Post-operative chemotherapy should be considered

- Post Surgical Chemotherapy should be considered

### Collaborative Decisions
- Weigh and balance risk of disease recurrence
- Review benefits of adjuvant therapy
- Understand therapy toxicities
- Consider comorbidities
- Treatment should be individualized for age groups >70

### Pathologic Stage IIIA
- T0 N2 M0
- T1 N2 M0
- T2 N2 M0
- T3 N2 M0

### Pathologic Stage IIB
- T4 N0 M0
- T4 N1 M0
- T4 N2 M0

### Pathologic Stage IIIC
- Any T N3 M0

### Post Operative Chemotherapy
- May have the option of post-operative or pre-operative chemotherapy
- Pre-operative chemotherapy should be considered for women with T4 N0 M0 tumors (Stage IIIA) with minimal lymph node involvement who meet the criteria for R0 except for tumor size >5 cm.

- Post-operative chemotherapy should be considered for women with T3 N1 M0 tumors (Stage IIB) with large tumor size with minimal lymph node involvement who meet the criteria for R0 except for tumor size >5 cm.

- Patients in this group may follow the same path as Stage I and II patients with surgery followed by chemotherapy and radiation.

- Post Surgical Chemotherapy should be considered

- Weigh and balance risk of disease recurrence
- Review benefits of adjuvant therapy
- Understand therapy toxicities
- Consider comorbidities
- Treatment should be individualized for age groups >70

### Pathologic Stage IIIA
- T0 N2 M0
- T1 N2 M0
- T2 N2 M0
- T3 N2 M0
- T4 N0 M0
- T4 N1 M0
- T4 N2 M0

### Pathologic Stage IIB
- T4 N0 M0
- T4 N1 M0
- T4 N2 M0

### Pathologic Stage IIIC
- Any T N3 M0
Breast Cancer: Commonly Used Chemotherapy & Targeted Therapy Drugs

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Abbreviations</th>
<th>NEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carboplatin</td>
<td>CEPATIN</td>
<td>CEP, CARP</td>
<td>250g</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>Cytoxan</td>
<td>CHP, CYC, CYC-20, CTX, CTX, ATOPOCY</td>
<td>1000mg</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>ADRIAMYCIN</td>
<td>ADR, DOX</td>
<td>50mg</td>
</tr>
<tr>
<td>Fluorouracil</td>
<td>ALIMOSIN</td>
<td>5-FU</td>
<td>50mg</td>
</tr>
<tr>
<td>Herceptin</td>
<td>HERCEPTIN</td>
<td>HER</td>
<td>50mg</td>
</tr>
<tr>
<td>Mitomycin</td>
<td>MITOMycin</td>
<td>MITOM, MMYC</td>
<td>50mg</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>TAXOTERE</td>
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<td>50mg</td>
</tr>
<tr>
<td>docetaxel</td>
<td>TAXEL</td>
<td>TAX</td>
<td>50mg</td>
</tr>
<tr>
<td>vinorelbine</td>
<td>NIBLESIN</td>
<td>NVB</td>
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</tr>
<tr>
<td>vinblastine</td>
<td>VELBE</td>
<td>VLB</td>
<td>50mg</td>
</tr>
</tbody>
</table>

Breast Cancer (HER2-): Common Regimens of Different Chemotherapy Drugs

<table>
<thead>
<tr>
<th>Region</th>
<th>Herceptin Dose</th>
<th>Gemcitabine Dose</th>
<th>Doxorubicin Dose</th>
<th>Cyclophosphamide Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAC</td>
<td>75mg</td>
<td>1000mg</td>
<td>50mg</td>
<td>1000mg</td>
</tr>
<tr>
<td>AT</td>
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<td>1000mg</td>
</tr>
<tr>
<td>ACT</td>
<td>75mg</td>
<td>1000mg</td>
<td>50mg</td>
<td>1000mg</td>
</tr>
<tr>
<td>TAC</td>
<td>75mg</td>
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<td>75mg</td>
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<tr>
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<td>1000mg</td>
<td>50mg</td>
<td>1000mg</td>
</tr>
</tbody>
</table>

Breast Cancer (HER2+): Common Regimens of Different Chemotherapy Drugs

<table>
<thead>
<tr>
<th>Region</th>
<th>Herceptin Dose</th>
<th>Gemcitabine Dose</th>
<th>Doxorubicin Dose</th>
<th>Cyclophosphamide Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAC</td>
<td>75mg</td>
<td>1000mg</td>
<td>50mg</td>
<td>1000mg</td>
</tr>
<tr>
<td>AT</td>
<td>75mg</td>
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<td>ACT</td>
<td>75mg</td>
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</tr>
<tr>
<td>TAC</td>
<td>75mg</td>
<td>1000mg</td>
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</tr>
<tr>
<td>TAC</td>
<td>75mg</td>
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</tr>
<tr>
<td>TAC</td>
<td>75mg</td>
<td>1000mg</td>
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</tr>
<tr>
<td>TAC</td>
<td>75mg</td>
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<tr>
<td>TAC</td>
<td>75mg</td>
<td>1000mg</td>
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</tr>
<tr>
<td>TAC</td>
<td>75mg</td>
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</tr>
<tr>
<td>TAC</td>
<td>75mg</td>
<td>1000mg</td>
<td>50mg</td>
<td>1000mg</td>
</tr>
</tbody>
</table>
Table lists the various combinations of ER/PR, HER2 and menopausal status.

This table is for ductal, lobular, mixed or metasplastic histologies only.

- This table shows these same factors, except for tubular or colloid carcinoma histologies.
- The tumor size and node status are also factors and endocrine therapy may not be recommended for node negative cancers in which the tumor size is less than 3cm.

### Breast Cancer Commonly Used Endocrine (Hormone) Therapy Drugs

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Type</th>
<th>NSC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastrozole</td>
<td>Arimidex®</td>
<td>Aromatase Inhibitors (AI)</td>
<td>719344</td>
</tr>
<tr>
<td>Letrozole</td>
<td>Femara®</td>
<td>Aromatase Inhibitors (AI)</td>
<td>719345</td>
</tr>
<tr>
<td>Exemestane</td>
<td>Aromasin®</td>
<td>Aromatase Inhibitors (AI)</td>
<td>713563</td>
</tr>
<tr>
<td>Tamoxifen</td>
<td>Nolvadex®</td>
<td>Selective Estrogen Receptor Modulators (SERM)</td>
<td>110973</td>
</tr>
<tr>
<td>Raloxifene</td>
<td>Evista®</td>
<td>Selective Estrogen Receptor Modulators (SERM)</td>
<td>7065725</td>
</tr>
<tr>
<td>Toremifene</td>
<td>Fareston®</td>
<td>Estrogen Receptor Downregulator (ERD)</td>
<td>5999998</td>
</tr>
<tr>
<td>Fulvestrant</td>
<td>Faslodex®</td>
<td>Estrogen Receptor Downregulator (ERD)</td>
<td>719276</td>
</tr>
</tbody>
</table>
## Common Biological Response Modifier Therapy Drugs

<table>
<thead>
<tr>
<th>Type/BRM</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Comments</th>
<th>NSC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cytokines</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Cytokines</td>
<td>PEG-IL-2</td>
<td>Interleukin-2 or Aldesleukin</td>
<td>Code as BRM</td>
<td>62537</td>
</tr>
<tr>
<td>- PEG-IL-2</td>
<td>Interferon alfacon-1</td>
<td>Interferon Alpha</td>
<td>IFN</td>
<td>89999-9</td>
</tr>
<tr>
<td><strong>Colony-stimulating factors (hematopoietic growth factors)</strong></td>
<td>G-CSF</td>
<td>Filgastrim</td>
<td>AA</td>
<td>Do not code</td>
</tr>
<tr>
<td>- GM-CSF</td>
<td>Sargramostim</td>
<td>Code as BRM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- GM-CSF</td>
<td>Sargramostim</td>
<td>Code as BRM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Epotin</td>
<td>Filgastrim</td>
<td>Proleukin</td>
<td>IL-2</td>
<td></td>
</tr>
<tr>
<td>- Epotin</td>
<td>Filgastrim</td>
<td>Proleukin</td>
<td>IL-2</td>
<td></td>
</tr>
<tr>
<td>- Oprelvekin</td>
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<td>Rituximab</td>
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<td>Code as chemo</td>
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<td>- Rituximab</td>
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<tr>
<td>- Trastuzumab</td>
<td>Herceptin</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Non-specific immunomodulating agents</strong></td>
<td>Levamisole</td>
<td>Levamisole</td>
<td>LEV</td>
<td>Code as BRM</td>
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### Treatment for Triple-Negative Breast CA

- ER (-) PR (-) Her2neu (+)
- 15% of Breast cases
- Response to Treatment
- Surgery
- Radiation Therapy
- Chemotherapy
- Hormonal Therapy
- Adjuvant systemic therapy Aramataze
Stage 0 Breast Treatment

- Surgery: Lumpectomy, partial mastectomy or modified radical mastectomy
- Sentinel lymph node bx or
- Axillary lymph node dissection
- Breast reconstruction
- Radiation therapy after conserving surgery
- No radiation increased recurrence
- Adjuvant systemic therapy ER/PR positive (tamoxifen or an aromatase inhibitor) tumor larger than 0.5 cm (1/4 inches)
  - Arimidex (chemical name: anastrozole)
  - Aromasin (chemical name: exemestane)
  - Femara (chemical name: letrozole)
- Adjuvant chemotherapy if tumor is >1cm with high grade, er/pr negative, HER2 positive or high score gene panels
- For HER2 positive cancers, adjuvant trastuzumab (Herceptin) is usually recommended as well


Stage I Breast Treatment

- Surgery: Lumpectomy, partial mastectomy or modified radical mastectomy
- Sentinel lymph node bx or
- Axillary lymph node dissection
- Breast reconstruction
- Radiation therapy (if necessary) after conserving surgery
- No radiation increased recurrence
- Adjuvant systemic therapy ER/PR positive (tamoxifen or an aromatase inhibitor) tumor larger than 0.5 cm (1/4 inches)
  - Arimidex (chemical name: anastrozole)
  - Aromasin (chemical name: exemestane)
  - Femara (chemical name: letrozole)
- Adjuvant chemotherapy if tumor is >1cm with high grade, er/pr negative, HER2 positive or high score gene panels
- Herceptin should be used for HER2 (+)
- For HER2 + adjuvant trastuzumab (Herceptin)

Stage II Breast Treatment

- Age
- Treatment
  - Lumpectomy, partial mastectomy or modified radical mastectomy
  - Sentinel lymph node bx and/or Axillary lymph node dissection
  - Breast reconstruction
  - Radiation therapy (if necessary) after mastectomy
  - ER/PR + and premenopausal (tamoifinen x 5 years or an aromatase inhibitor) tumor larger than 0.5 cm (1/4 inches)
  - HER2 + or high score gene panels Adjunct chemotherapy
  - If tumor is >1cm with high grade, er/pr negative,
  - HER2 + Trastuzumab (Herceptin)

Stage III
Breast Treatment

- Lumpectomy, partial mastectomy or modified radical mastectomy
- Sentinel lymph node bx and/or
- Axillary lymph node dissection
- Breast reconstruction
- Radiation therapy after mastectomy (if necessary)
- Adjuvant systemic therapy ER/PR + (tamoxifen or an aromatase inhibitor) tumor larger than 0.5 cm (1/4 inches)
  - There are three aromatase inhibitors:
    - Arimidex (chemical name: anastrozole)
    - Aromasin (chemical name: exemestane)
    - Femara (chemical name: letrozole)
- Chemotherapy combinations that don’t contain doxorubicin. One such regimen is called TCH. Chemotherapy drugs docetaxel (Taxotere) and carboplatin given every 3 weeks along with weekly trastuzumab (Herceptin) for 6 cycles. This is followed by trastuzumab every 3 weeks for a year.

Stage IV
Breast Treatment

- Lumpectomy, partial mastectomy or (MRM) modified radical mastectomy
- Sentinel lymph node bx and/or
- Axillary lymph node dissection
- Radiation therapy treat small number of metastases bone/liver
- Chemotherapy(TCH) Docetaxel (Taxotere), Carboplatin x every 3 wks, If HER2 + weekly trastuzumab (Herceptin) or lapatinib (Tykerb) combination of treatments.
- Regional chemotherapy is given for brain metastasis.ChemoRX delivering directly into certain area of brain.
- If Bone mets beam radiation and/or bisphosphonates such as pamidronate (areda) or zoledronic acid (Zometa)

Stage IV
Breast Treatment

- HER2-positive cancers that no longer respond to trastuzumab may respond to lapatinib (Tykerb), another drug that attacks the HER2 protein. This drug is usually given along with the chemotherapy drug capecitabine (Xeloda). Both of these drugs are taken as pills.

Breast Case

- 65 yo who on annual physical the physician noticed a non-tender mass in the upper outer quadrant (UOQ) of the right breast
- Family hx of breast ca in maternal aunt at age 60
- PE reveals a firm, mobile, 3.5 cm mass in the UOQ with no changes in the skin or palpable adenopathy
- XM: 3.5 cm density UOQ Right Breast, Left Breast negative
- Ultrasound breast: 3.5 cm hypoechoic area UOQ
- R breast, R axillary nodes and L breast negative

Breast Case

- Procedure:
  - U/S guided core needle bx UOQ right breast
- Pathology Report:
  - Infiltrating duct cell carcinoma, Bloom-Scarff-Richardson (BSR) grade 3, ER/PR positive, HER2 negative by IHC/FISH
- Clinical stage:
  - Uses information from the physical exam, imaging, and diagnostic workup and biopsy
  - Select the appropriate treatment and provide an estimate of prognosis
Breast Case Clinical Stage

- Clinical Stage
  - T2 for 3.5cm primary tumor
  - N0 nodes were clinically (-) on physical exam and imaging
  - M0 there was nothing to suggest distant metastases; if there was, appropriate tests would be performed before developing a treatment plan
  - Clinical stage T2 N0 M0 Stage Group IIA

- Prognostic Factors
  - Paget’s disease: no
  - BSR: Grade 3
  - Estrogen & Progesterone receptor: positive
  - HER2 status: negative
  - Node assessment: PE and radiographic
  - There are NO prognostic factors required for staging
  - There are prognostic factors significance for treatment

Breast Case Treatment

- Surgery
  - Lumpectomy UOQ right breast
  - Sentinel lymph node (SLN) biopsy

- Operative findings
  - Sentinel nodes were reported as negative on frozen section, additional stains performed were negative

- Pathology
  - Infiltrating duct carcinoma, poorly diff, BSR Grade III, 3.8cm with dermal invasion. All margins were negative. Sentinel nodes negative by H&E, Sentinel Node 2 – cytokeratin IHC revealed cluster of isolated tumor cells (ITCs), <0.1mm in size
Breast Case Pathologic Staging

- Pathologic staging
  - Uses all of the information from the clinical staging along with the surgical pathology
  - Reason for a pathologic staging for treatment, prognosis and survival
- Pathologic Stage answer TNM Stage Group IIA
  - pT2
  - pN0(i+)
  - cM0
  - pT2 Skin invasion, CS 200
  - pN0(i+) sentinel nodes had ITCs found on IHC only, H&E stains negative. ITCs usually have no histologic evidence of malignant activity, CS 050
  - cM0 - use clinical M there was no pathologic confirmation of distant metastases
- pN0(i+) is defined as Positive ITCs found on H&E or IHC, no ITCs >0.2mm

4th FCDS Webinar

WEBCAST SCHEDULE (All Webcasts will be 2 hours duration occurring from 9am-11am Eastern):

- 10/20/11 Myeloid Neoplasms (CML/AML/MDS) – Steve Peace
  - MPH Rules/CSv02.03/Site
  - Specific Factors and Treatment

Any Questions?