

This document shows the changes that were made to the SSDI manual and the Grade manual for the SEER\*RSA version 1.7 release on (August 9th).

List of Changes to SSDI Manual, Version 1.7

Manual Section	Page	Original Text	Updated Text
Timing for Collection of SSDIs	17		<p><b>NEW</b></p> <p><b>Timing for collection of SSDIs</b>                      The SSDIs are to be collected during the initial diagnosis, work up and first course of treatment. Some SSDIs have specific instructions as to when the SSDIs are collected (e.g., CEA is to be collected prior to polypectomy, or PSA is to be collected prior to needle core biopsy).</p> <ul style="list-style-type: none"> <li>Note: Active surveillance is first course of treatment.</li> </ul>
Rounding Rules	20		<p><b>NEW</b></p> <p><b>Rounding Rules</b></p> <p>SSDIs follow the standard definitions for rounding. These general rules can be followed for most SSDIs where lab values or percentages are recorded. All SSDIs that have lab values, percentages or measurements are set up to record in the 10ths (one digit after the decimal point). If a lab value, percentage or measurement is recorded in 100ths (two digits after the decimal point), then the last digit must be rounded.</p> <p>The general rounding rules are:</p> <ul style="list-style-type: none"> <li>If digit is 0-4, round down</li> <li>If digit is 5-9, round up</li> <li>Note: Currently (2018+), the only SSDIs that have exceptions to the general rounding rules are:</li> </ul>

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			<ul style="list-style-type: none"> <li>○ HER2 ISH Single Probe Copy Number</li> <li>○ HER2 ISH Dual Probe Copy Number</li> <li>○ HER2 ISH Dual Probe Ratio</li> </ul> <p><i>Examples</i></p> <ul style="list-style-type: none"> <li>• Breslow’s measurement 4.32 mm                             <ul style="list-style-type: none"> <li>○ Since the last digit is 2, round down and record 4.3</li> </ul> </li> <li>• CEA lab value 18.35                             <ul style="list-style-type: none"> <li>○ Since the last digit is 5, round up and record 18.4</li> </ul> </li> <li>• HER2 ISH Dual Probe Copy Number 6.78                             <ul style="list-style-type: none"> <li>○ Per Note 8: If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round. Record 6.7</li> <li>○ This also applies to HER2 ISH Single Probe Copy Number and HER2 ISH Dual Probe Ratio</li> </ul> </li> <li>• <i>Note:</i> ER (and PR) percent positive do not have decimal points in the data items, so anything with a decimal point will have to be rounded. Example: 78.6</li> </ul>

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			<ul style="list-style-type: none"> <li>○ Since the last digit is 6, round up and record 079 (79%)</li> <li>○ Note: For ER and PR percent positive, if a value is documented as 99.5% to 99.9%, round up to 100% (code 100)</li> </ul>
Recording Lab Values when “less than” or “greater than” are used	21	<p><b>Recording Lab Values when “less than” or “greater than” are used</b></p> <p>Record the lab value as <b>one less</b> than stated when a value is reported as “less than X.”</p> <p>Example 1: PSA stated as less than 5. Record 4.9                      Example 2: hCG lab value resulting findings of &lt;1. Record 0.9                      Example 3: ER Percent Positive stated as less than 60%. Record 059 (59%)</p> <p>Record the value as one more than stated when value is reported as “more than X.”</p> <p>Example 1: CEA stated as greater than 7. Record 7.1                      Example 2: PR Percent Positive greater than 75%. Record 076 (76%)</p>	<p><b>Recording Lab Values when “less than” or “greater than” are used</b></p> <p>Record the lab value as <b>one less</b> than stated when a value is reported as “less than X,” and as <b>one more</b> than stated when a value is reported as “more than X.” <b>One less</b> or <b>one more</b> may refer to a whole number (1), or a decimal (0.1), depending on the code structure of the field.</p> <p><b>SSDIs with decimals in their code structures</b>                      Example 1: PSA stated as &lt; (less than) 5. Record 4.9                      Example 2: hCG lab value resulting findings of &lt; (less than) 1. Record 0.9                      Example 3: Ki-67 reported as &gt; (greater than) 20%. Record 20.1</p> <p><b>SSDIs without decimals in their code structure:</b>                      Example 1: ER Percent Positive stated as &lt; (less than) 60%. Record 059 (59%)                      Example 2: PR Percent Positive stated as &gt; (greater than) 75%. Record 076 (76%)                      Example 3: ER Percent Positive &lt; (less than) 50%. Record 049 (49%)</p>
Source Documents	22	<ul style="list-style-type: none"> <li>• If a pathology report is suggested, that document includes                             <ul style="list-style-type: none"> <li>○ Addenda or revisions to the report</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• If a pathology report is suggested, that document includes                             <ul style="list-style-type: none"> <li>○ Addenda or revisions to the report</li> <li>○ Gross or microscopic description</li> </ul> </li> </ul>

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		<ul style="list-style-type: none"> <li>○ Synoptic reports</li> <li>○ CAP protocol, or cancer checklist information provided by the pathologist</li> </ul>	<ul style="list-style-type: none"> <li>○ Synoptic reports</li> <li>○ CAP protocol, or cancer checklist information provided by the pathologist</li> </ul>
Timing for Recording Laboratory Tests	22	<p><b>Timing for Recording Laboratory Tests.</b> Unless instructions for a specific laboratory test state otherwise, record only tests results obtained</p> <ul style="list-style-type: none"> <li>• before any cancer-directed treatment is given (neoadjuvant therapy or surgical), AND</li> <li>• no earlier than approximately three months before diagnosis AND</li> </ul>	<p><b>Timing for Recording Laboratory Tests.</b> Unless instructions for a specific laboratory test state otherwise, record only tests results obtained</p> <ul style="list-style-type: none"> <li>• before any cancer-directed treatment is given (neoadjuvant therapy or surgical), AND</li> <li>• no earlier than approximately three months before diagnosis AND</li> <li>• if multiple lab tests are available , record the highest value</li> </ul>
Schema ID Table	35	00230: Bile Ducts Perihilar	00230: Bile Ducts <b>Intrahepatic</b>
Schema ID Table	36	<p>Merkel Cell SSDIs</p> <p>3831: Extranodal Extension Path (non-Head and Neck)</p>	<p>Merkel Cell SSDIs</p> <p><b>3833:</b> Extranodal Extension Path (non-Head and Neck)</p>

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00200: Colon	3819: CEA PreTx Interpretation	<b>Note 3:</b> Code 9 if there is no statement that the CEA is positive/elevated, negative/normal, and the lab value with its normal range (from which you can determine interpretation), is not documented	<b>Note 3:</b> Code 3 when a CEA value was documented in the record, but there is no statement that the CEA is positive/elevated, negative/normal, and the normal range (from which you can determine interpretation), is not documented.
00200: Colon	3823: Circumferential Resection Margin	Coding Guidelines  Code XX.2 when the margins cannot be assessed	Coding Guidelines  <ul style="list-style-type: none"> <li>Code XX.2 when the margins cannot be assessed <ul style="list-style-type: none"> <li><b>Note: ONLY</b> when the pathology reports/CAP checklist states that the margin cannot be assessed/evaluated</li> </ul> </li> </ul>
00200: Colon	3823: Circumferential Resection Margin	Coding Guidelines  <ul style="list-style-type: none"> <li>Code XX.9 when <ul style="list-style-type: none"> <li>Not documented in the medical record</li> <li>CRM is not evaluated (assessed)</li> <li>Unknown if CRM is evaluated (assessed)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Code XX.9 when <ul style="list-style-type: none"> <li>Not documented in the medical record</li> <li>CRM is not evaluated (assessed)</li> <li>Checked “Not applicable: Radial or Mesenteric Margin” on CAP Checklist</li> <li>Unknown if CRM is evaluated (assessed)</li> </ul> </li> </ul>
00200: Colon	3823: Circumferential Resection Margin	<b>Note 3:</b> The CRM may also be referred to as the circumferential radial margin or mesenteric margin.	<b>Note 3:</b> The CRM may be referred to as <ul style="list-style-type: none"> <li>Circumferential radial margin</li> <li>Circumferential resection margin</li> <li>Mesenteric (mesocolon) margin</li> <li>Radial margin</li> <li>Soft tissue margin</li> </ul>

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00200: Colon	3823: Circumferential Resection Margin	<p><b>Note 6:</b> If the margin is involved (positive), code 0.0. If the margin is described as less than 1 mm with no more specific measurement, code 0.0; margins of 0-1 mm are recorded by the pathologist as involved.</p> <p><b>Note 7:</b> If the value is recorded in Centimeters, multiply by 10 to get the value in Millimeters (mm).</p> <ul style="list-style-type: none"> <li><b>Example:</b> CRM recorded as 0.2 cm. Multiply 0.2 x 10 and record 2.0</li> </ul> <p><b>Note 8:</b> Use code <b>XX.9</b> (CRM not mentioned) if the pathology report describes only <b>distal and proximal margins, or margins, NOS</b>.</p> <ul style="list-style-type: none"> <li><b>Only specific statements about the CRM are collected in this data item</b></li> </ul> <p><b>Note 9:</b> An exact measurement takes precedence over codes beginning with XX.</p>	<p><b>Note 6:</b> If the value is recorded in Centimeters, multiply by 10 to get the value in Millimeters (mm).</p> <ul style="list-style-type: none"> <li><b>Example:</b> CRM recorded as 0.2 cm. Multiply 0.2 x 10 and record 2.0</li> </ul> <p><b>Note 7:</b> If the margin is involved (positive), code 0.0. If the margin is described as less than 1 mm with no more specific measurement, Code 0.0; margins of 0-1 mm are recorded by the pathologist as involved.</p> <p><b>Note 8:</b> Code <b>XX.2</b> (Margins cannot be assessed) <b>ONLY</b> when the pathology reports/CAP checklist states that the margin cannot be assessed/evaluated.</p> <p><b>Note 9:</b> An exact measurement takes precedence over codes beginning with <b>0.0</b> and those with XX.</p> <ul style="list-style-type: none"> <li>Exact measurement takes priority even if the pathologists states the margin is positive.</li> <li><b>Example:</b> CRM stated as 0.3 mm in Final Diagnosis and Synoptic states: Circumferential (Radial) Margin Interpreted as involved by invasive carcinoma (tumor less than 1mm from margin). <ul style="list-style-type: none"> <li>Code the 0.3 mm instead of 0.0 (margin involved with tumor)</li> </ul> </li> </ul> <p><b>Note 10:</b> Code <b>XX.9</b> when</p>

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			<ul style="list-style-type: none"> <li>• Tumor is in situ only (/2)</li> <li>• Checked “Not applicable: Radial or Mesenteric Margin” on CAP Checklist</li> <li>• Pathology report describes only distal and proximal margins, or margins, NOS                             <ul style="list-style-type: none"> <li>○ Only specific statements about the CRM are collected in this data item</li> </ul> </li> <li>• CRM not mentioned in the record</li> </ul>
00200: Colon	3890: Microsatellite Instability	<p><b>Note 3:</b> Testing for MSI may be done by immunology or genetic testing. Only genetic testing results will specify whether the MSI is low or high.</p> <ul style="list-style-type: none"> <li>• Some laboratories only test for MSI via an immunologic test for Mismatch Repair (MMR) Protein. Results from immunology will only provide you with positive or negative results and will not specify whether the MSI is low or high</li> <li>• Results of Mismatch Repair (MMR) may be recorded in this data item - see codes 0 and 2</li> <li>• MMR proficient (pMMR or MMR-P) should be coded as a 0</li> </ul> <p><b>Note 4:</b> If both tests are done and one or both are positive, code 2.</p>	<p><b>Note 3:</b> Testing for MSI may be done by immunology or genetic testing. Only genetic testing results will specify whether the MSI is low or high.</p> <ul style="list-style-type: none"> <li>• MSI is looking at instability in informative markers</li> <li>• MSI results are recorded as                             <ul style="list-style-type: none"> <li>○ MSS (Code 0)</li> <li>○ Stable (Code 0)</li> <li>○ Negative (Code 0)</li> <li>○ Low probability of MSI-H (Code 0)</li> <li>○ MSS/MSI-L (Code 0)</li> <li>○ MSI-L (Code 1)</li> <li>○ Unstable, high (Code 2)</li> <li>○ Unstable, NOS (no designation of high or low) (Code 2)</li> <li>○ MSI-H (Code 2)</li> </ul> </li> </ul>



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			<ul style="list-style-type: none"> <li>○ MSI-I (intermediate) (Code 9)</li> </ul> <p><b>Note 4:</b> Testing for Mismatch Repair (MMR) is usually done by immunohistochemistry (IHC)</p> <ul style="list-style-type: none"> <li>• Most common markers are MLH1, MSH2, MSH6, PMS2</li> <li>• MMR results are recorded as                             <ul style="list-style-type: none"> <li>○ No loss of nuclear expression (code 0)</li> <li>○ Mismatch repair (MMR) intact (code 0)</li> <li>○ MMR proficient (pMMR or MMR-P) (code 0)</li> <li>○ MMR normal (code 0)</li> <li>○ Loss of nuclear expression (code 2)</li> <li>○ MMR deficient (pMMR or MMR-P) (code 2)</li> <li>○ MMR abnormal (code 2)</li> </ul> </li> </ul> <p><b>Note 5:</b> If both tests are done and one or both are positive, code 2.</p>
00220, 00230: Liver, Bile Ducts Intrahepat	3835: Fibrosis Score	<p><b>Note 5:</b> Code the absence (code 0) or presence (code 1) of fibrosis as documented in the pathology report.</p> <p><b>Note 6:</b> If no score is mentioned, descriptive terms may be used to assign</p>	<p><b>Note 5:</b> To use codes 0 and 1, you must have a histological (microscopic) confirmation of fibrosis/cirrhosis. Code the absence (code 0) or presence (code 1) of fibrosis as documented in the pathology report.</p>

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		<p>codes 0 and 1 - see specific terms in the table below.</p> <p><b>Note 7:</b> If a fibrosis score is stated but the scoring system is not recorded, consult with the physician. If no further information is available, code 9.</p>	<p><b>Note 6:</b> Use code 7 if there is a clinical diagnosis (no microscopic confirmation) of severe fibrosis or cirrhosis.</p> <p><b>Note 7:</b> If no score is mentioned, descriptive terms may be used to assign codes 0 and 1 – see specific terms in the table below.</p> <p><b>Note 8:</b> If a fibrosis score is stated but the scoring system is not recorded, consult with the physician. If no further information is available, code 9.</p>
00360: Lung	3929: Separate Tumor Nodules	<b>Note 3:</b> For this item, only code separate tumor nodules of the same histologic type as the primary tumor, also referred to as intrapulmonary metastases.	<p><b>Note 3:</b> For this item, only code separate tumor nodules of the same histologic type as the primary tumor, also referred to as intrapulmonary metastases.</p> <ul style="list-style-type: none"> <li>In the case of multiple tumor nodules determined to be the same primary, if not all nodules are biopsied, assume they are the same histology</li> </ul>
00470: Melanoma Skin	3817: Breslow's Depth	<b>Note 4:</b> Do not add measurements together from different procedures (even in the rare circumstance that the pathologist adds the measurements from two specimens).	<p><b>Note 4:</b> If there are multiple procedures and the pathologist adds the measurement together to get a final Breslow's depth, the registrar can use this.</p> <ul style="list-style-type: none"> <li>Do not add the measurements together, only the pathologist can do this</li> </ul>

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00470: Melanoma Skin	3933: Ulceration		<p><b>Note 4:</b> Code 9 if there is microscopic examination and there is no mention of ulceration.</p> <ul style="list-style-type: none"> <li>This instruction <b>does</b> apply to in situ tumors</li> </ul>
00470: Melanoma Skin	3932: LDH Pretreatment Lab Value	<p>Coding Guidelines</p> <ul style="list-style-type: none"> <li>Code the highest exact LDH lab value prior to treatment in the range 0.1 to 99,999.9</li> </ul>	<p>Coding guidelines</p> <ul style="list-style-type: none"> <li>Code the highest exact LDH lab value prior to systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site in the range 0.1 to 99,999.9</li> </ul>
00470: Melanoma Skin	3932:LDH Pretreatment Lab Value	<p><b>Note 2:</b> Record the lab value of the highest serum LDH test results documented in the medical record <b>prior to treatment</b> or within 6 weeks of diagnosis. Give priority to the first test performed. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.</p> <p><b>Note 3:</b> The same laboratory test should be used to record information in LDH Pretreatment Level [NAACCR Data Item #3869] and LDH Upper Limits of Normal [NAACCR Data Item # 3870]</p>	<p><b>Note 2:</b> LDH is only considered in melanoma staging in the setting of DISTANT metastasis. LDH level might only be ordered after re-excision/wide excision and/or nodal evaluation indicates a higher risk of distant metastasis. Imaging may then be performed and if distant metastasis are identified, LDH is ordered.</p> <p><b>Note 3:</b> Record the lab value of the highest serum LDH test results documented in the medical record either before or after surgical resection of the primary tumor with or without regional lymph node dissection. The LDH must be taken prior to systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site. The lab value may be recorded in a lab</p>

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			<p>report, history and physical, or clinical statement in the pathology report.</p> <p><b>Note 4:</b> The same laboratory test should be used to record information in <a href="#">LDH Pretreatment Level</a> [NAACCR Data Item #3869] and <a href="#">LDH Upper Limits of Normal</a> [NAACCR Data Item # 3870].</p>
00470: Melanoma Skin	3870: LDH Upper Limits of Normal	<p><b>Note 3:</b> The same laboratory test should be used to record information in LDH Pretreatment Lab Value [NAACCR Data Item # 3869] and LDH Pretreatment Lab Value [NAACCR Data Item #3932].</p>	<p><b>Note 3:</b> The same laboratory test should be used to record information in <a href="#">LDH Pretreatment Lab Value</a> [NAACCR Data Item #3932] and <a href="#">LDH Pretreatment Level</a> [NAACCR Data Item #3869].</p>
00480: Breast	3827: Estrogen Receptor Summary	<p><b>Note 2:</b> The result of the ER test performed on the primary breast tissue is to be recorded in this data item. Results from nodal or metastatic tissue may be used ONLY when there is no evidence of primary tumor.</p> <p><b>Note 3:</b> In cases where ER is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.</p> <ul style="list-style-type: none"> <li><b>Exception:</b> If ER is positive on an in situ specimen and ER is negative on all tested invasive specimens, code ER as negative (code 0).</li> </ul>	<p><b>Note 2:</b> The result of the ER test performed on the primary breast tissue is to be recorded in this data item.</p> <p><b>Note 3:</b> Results from nodal or metastatic tissue may be used ONLY when there is no evidence of primary tumor.</p> <p><b>Note 4:</b> In cases where there are invasive and in situ components and ER is done on both, ignore the in situ results.</p> <ul style="list-style-type: none"> <li>If ER is positive on an in situ component and ER is negative on all tested invasive components, code ER as negative (code 0)</li> <li>If in situ and invasive components present and ER only done on the in</li> </ul>

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		<p><b>Note 4:</b> If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy. If neoadjuvant therapy is given and there are no ER results from pre-treatment specimens, report the findings from post-treatment specimens.</p>	<p>situ component, code unknown (code 9)</p> <p><b>Note 5:</b> In cases where there is a single tumor with multiple biopsies and/or surgical resection with different ER results.</p> <ul style="list-style-type: none"> <li>Use the highest (positive versus negative)</li> </ul> <p><b>Note 6:</b> In cases where there are multiple tumors with different ER results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.</p> <ul style="list-style-type: none"> <li>Do not use specimen size to determine the largest tumor size</li> </ul> <p><b>Note 7:</b> If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy. If neoadjuvant therapy is given and there are no ER results from pre-treatment specimens, report the findings from post-treatment specimens.</p>
00480: Breast	3826: Estrogen Receptor Percent Positive or Range	<p><b>Note 2:</b> Code this data item using the same report used to record ER Summary.</p>	<p><b>Note 2:</b> Code this data item using the same report used to record <a href="#">Estrogen Receptor Summary</a> [NAACCR Data Item #3827].</p>
00480: Breast	3828: Estrogen Receptor Total Allred Score	<p><b>Note 2:</b> Code this data item using the same report used to record ER Summary.</p> <p><b>Note 3: Bullet 2</b></p>	<p><b>Note 2:</b> Code this data item using the same report used to record <a href="#">Estrogen Receptor Summary</a> [NAACCR Data Item #3827].</p>

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		<ul style="list-style-type: none"> <li>See the “Allred Score for Estrogen and Progesterone Receptor Evaluation” table in the SSDI manual for assistance in determining the Allred Score</li> </ul>	<p><b>Note 3, Bullet 2:</b></p> <ul style="list-style-type: none"> <li>See the <a href="#">Allred Score for Estrogen and Progesterone Receptor Evaluation</a> section in the SSDI manual for assistance in determining the Allred Score</li> </ul>
00480: Breast	3915: Progesterone Receptor Summary	<p><b>Note 2:</b> The result of the PR test performed on the primary breast tissue is to be recorded in this data item. Results from nodal or metastatic tissue may be used ONLY when there is no evidence of primary tumor.</p> <p><b>Note 3:</b> In cases where PR is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.</p> <ul style="list-style-type: none"> <li><b>Exception:</b> If PR is positive on an in situ specimen and PR is negative on all tested invasive specimens, code PR as negative (code 0).</li> </ul> <p><b>Note 4:</b> If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy. If neoadjuvant therapy is given and there are no ER results from pre-treatment specimens, report the findings from post-treatment specimens.</p>	<p><b>Note 2:</b> The result of the PR test performed on the primary breast tissue is to be recorded in this data item.</p> <p><b>Note 3:</b> Results from nodal or metastatic tissue may be used ONLY when there is no evidence of primary tumor.</p> <p><b>Note 4:</b> In cases where there are invasive and in situ components and PR is done on both, ignore the in situ results.</p> <ul style="list-style-type: none"> <li>If PR is positive on an in situ component and PR is negative on all tested invasive components, code PR as negative (code 0)</li> <li>If in situ and invasive components present and PR only done on the in situ component, code unknown (code 9)</li> </ul> <p><b>Note 5:</b> In cases where there is a single tumor with multiple biopsies and/or surgical resection with different PR results.</p>

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			<ul style="list-style-type: none"> <li>Use the highest (positive versus negative)</li> </ul> <p><b>Note 6:</b> In cases where there are multiple tumors with different PR results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.</p> <ul style="list-style-type: none"> <li>Do not use specimen size to determine the largest tumor size</li> </ul> <p><b>Note 7:</b> If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy. If neoadjuvant therapy is given and there are no PR results from pre-treatment specimens, report the findings from post-treatment specimens.</p>
00480: Breast	3914: Progesterone Receptor Percent Positive or Range	<b>Note 2:</b> Code this data item using the same report used to record PR Summary.	<b>Note 2:</b> Code this data item using the same report used to record <a href="#">Progesterone Receptor Summary</a> [NAACCR Data Item #3915].
00480: Breast	3916: Progesterone Receptor Total Allred Score	<p><b>Note 2:</b> Code this data item using the same report used to record PR Summary.</p> <p><b>Note 3: Bullet 2</b></p> <ul style="list-style-type: none"> <li>See the “Allred Score for Estrogen and Progesterone Receptor Evaluation” table in the SSDI manual for assistance in determining the Allred Score</li> </ul>	<p><b>Note 2:</b> Code this data item using the same report used to record <a href="#">Progesterone Receptor Summary</a> [NAACCR Data Item #3915].</p> <p><b>Note 3: Bullet 2:</b></p> <ul style="list-style-type: none"> <li>See the <a href="#">Allred Score for Estrogen and Progesterone Receptor Evaluation</a> section in the SSDI</li> </ul>

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			<p>manual for assistance in determining the Allred Score</p>
00480: Breast	3850: HER2 IHC Summary	<p><b>Note 4:</b> In cases where HER2 IHC is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.</p> <p><b>Note 5:</b> If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy.</p> <ul style="list-style-type: none"> <li>• If neoadjuvant therapy is given and there are no HER2 IHC results from pre-treatment specimens, report the findings from post-treatment specimens.</li> </ul> <p><b>Note 6:</b> If HER2 IHC is positive on an in situ specimen and HER2 IHC is negative on all tested invasive specimens, code HER2 IHC as negative (code 0).</p>	<p><b>Note 4:</b> In cases where there are invasive and in situ components and HER2 IHC is done on both, ignore the in situ results.</p> <ul style="list-style-type: none"> <li>• If HER2 IHC is positive on an in situ component and HER2 IHC is negative on all tested invasive components, code HER2 IHC as negative (code 0)</li> <li>• If in situ and invasive components present and HER2 IHC only done on the in situ component, code unknown (code 9)</li> </ul> <p><b>Note 5:</b> In cases where there is a single tumor with multiple biopsies and/or surgical resection with different HER2 IHC results.</p> <ul style="list-style-type: none"> <li>• Use the highest (positive versus negative)</li> </ul> <p><b>Note 6:</b> In cases where there are multiple tumors with different HER2 IHC results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.</p> <ul style="list-style-type: none"> <li>• Do not use specimen size to determine the largest tumor size</li> </ul>



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Schema ID/Name	Data Item # and Description	Original Text	Updated Text
			<p><b>Note 7:</b> If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy.</p> <ul style="list-style-type: none"> <li>If neoadjuvant therapy is given and there are no HER2 IHC results from pre-treatment specimens, report the findings from post-treatment specimens</li> </ul> <p><b>Note 8:</b> A 2+ (equivocal) finding by IHC should result in additional testing with ISH to determine gene copy number.</p>
00480: Breast	3854: HER2 ISH Summary	<p><b>Note 5:</b> In cases where HER2 ISH is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.</p> <p><b>Note 6:</b> If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy.</p> <ul style="list-style-type: none"> <li>If neoadjuvant therapy is given and there are no HER2 ISH results from pre-treatment specimens, report the findings from post-treatment specimens.</li> </ul> <p><b>Note 7:</b> If HER2 ISH is positive on an in situ specimen and HER2 ISH is negative on all tested invasive specimens, code HER2 as negative (code 0).</p>	<p><b>Note 5:</b> In cases where there are invasive and in situ components and HER2 ISH is done on both, ignore the in situ results.</p> <ul style="list-style-type: none"> <li>If HER2 ISH is positive on an in situ component and HER2 ISH is negative on all tested invasive components, code HER2 ISH as negative (code 0)</li> <li>If in situ and invasive components present and HER2 ISH only done on the in situ component, code unknown (code 9)</li> </ul> <p><b>Note 6:</b> In cases where there is a single tumor with multiple biopsies and/or surgical resection with different HER2 ISH results.</p>

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Schema ID/Name	Data Item # and Description	Original Text	Updated Text
			<ul style="list-style-type: none"> <li>Use the highest (positive versus negative)</li> </ul> <p><b>Note 7:</b> In cases where there are multiple tumors with different HER2 ISH results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.</p> <ul style="list-style-type: none"> <li>Do not use specimen size to determine the largest tumor size</li> </ul>
00480: Breast	3855: HER2 Overall Summary	<p><b>Note 4:</b> In cases where HER2 is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.</p> <ul style="list-style-type: none"> <li><b>Exception:</b> If HER2 is positive on an in situ specimen and HER2 is negative on all tested invasive specimens, code HER2 as negative (code 0).</li> </ul> <p><b>Note 5:</b> If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy.</p> <ul style="list-style-type: none"> <li>If neoadjuvant therapy is given and there are no HER2 results from pre-treatment specimens, report the findings from post-treatment specimens.</li> </ul>	<p><b>Note 4:</b> In cases where there are invasive and in situ components and HER2 is done on both, ignore the in situ results.</p> <ul style="list-style-type: none"> <li>If HER2 is positive on an in situ component and HER2 is negative on all tested invasive components, code HER2 as negative (code 0)</li> <li>If in situ and invasive components present and HER2 only done on the in situ component, code unknown (code 9)</li> </ul> <p><b>Note 5:</b> In cases where there is a single tumor with multiple biopsies and/or surgical resection with different HER2 results.</p> <ul style="list-style-type: none"> <li>Use the highest (positive versus negative)</li> </ul>

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Schema ID/Name	Data Item # and Description	Original Text	Updated Text
			<p><b>Note 6:</b> In cases where there are multiple tumors with different HER2 results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.</p> <ul style="list-style-type: none"> <li>Do not use specimen size to determine the largest tumor size</li> </ul> <p><b>Note 7:</b> If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy.</p> <ul style="list-style-type: none"> <li>If neoadjuvant therapy is given and there are no HER2 results from pre-treatment specimens, report the findings from post-treatment specimens</li> </ul>
00480: Breast	3853: HER2 ISH Single Probe Copy Number	<b>Note 5:</b> Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. The same test should be used to code all the HER2 ISH data items.	<b>Note 5:</b> Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. Code this data item using the same report used to record <a href="#">HER2 ISH Summary</a> [NAACCR Data Item #3854].
00480: Breast	3851: HER2 ISH Dual Probe Copy No.	<b>Note 5:</b> Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. The same test should be used to code all the HER2 ISH data items.	<b>Note 5:</b> Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. Code this data item using the same report used to record <a href="#">HER2 ISH Summary</a> [NAACCR Data Item #3854].
00480: Breast	3852: HER2 ISH Dual Probe Ratio	<b>Note 5:</b> Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. The same test should be used to code all the HER2 ISH data items.	<b>Note 5:</b> Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. Code this data item using the same report used to record <a href="#">HER2 ISH Summary</a> [NAACCR Data Item #3854].

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Schema ID/Name	Data Item # and Description	Original Text	Updated Text
00480: Breast	3894: Multigene Signature Method	<b>Note 2:</b> 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 the likelihood of future metastasis.	<p><b>Note 2:</b> 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 the likelihood of future metastasis.</p> <ul style="list-style-type: none"> <li>• Only record tests done on tumor tissue that help determine if the cancer is likely to recur. Don't include other tests, such as those that evaluate hereditary mutations that influence a patient's risk of developing cancer (e.g. myRisk, BRCA)</li> </ul>
00480: Breast	3895: Multigene Signature Result	<b>Note 2:</b> 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 the likelihood of future metastasis.	<p><b>Note 2:</b> 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 the likelihood of future metastasis.</p> <ul style="list-style-type: none"> <li>• Only record tests done on tumor tissue that help determine if the cancer is likely to recur. Don't include other tests, such as those that evaluate hereditary mutations that influence a patient's risk of developing cancer (e.g. myRisk, BRCA)</li> </ul>

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Schema ID/Name	Data Item # and Description	Original Text	Updated Text
00480: Breast	3867: Ki-67	<b>Note 3:</b> Ki-67 results are reported as the percentage cell nuclei that stain positive. As of early 2017 there are no established standards for interpretation of results or for cutoffs for positive and negative.	<b>Note 3:</b> Results from nodal or metastatic tissue may be used, ONLY when there is no evidence of primary tumor.  <b>Note 4:</b> Ki-67 results are reported as the percentage cell nuclei that stain positive. As of early 2017 there are no established standards for interpretation of results or for cutoffs for positive and negative.
00500, 00510, 00520, 00530, 00541, 00542, 00551, 00552, 00553, 00560 GYN Cancers	3836: FIGO Stage	<b>Note 3:</b> The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).	<b>Note 3:</b> If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.  <b>Note 4:</b> The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).  <b>Change made for the following schemas:</b> Vulva, Vagina, Cervix, Corpus Adenocarcinoma, Corpus Carcinoma and Carcinosarcoma, Corpus Sarcoma, Ovary, Fallopian Tube, Primary Peritoneal Carcinoma, Placenta
00600: Kidney	3864: Invasion Beyond Capsule	Coding Guidelines  Code 0: There is no invasion beyond capsule  Code 2: Renal sinus, which is the elongated oval indentation in the renal parenchyma	Coding Guidelines <ul style="list-style-type: none"> <li>• Code 0: There is no invasion beyond capsule <ul style="list-style-type: none"> <li>○ If tumor is “confined to kidney” and staging is based on size, then there has been no invasion through the</li> </ul> </li> </ul>

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Schema ID/Name	Data Item # and Description	Original Text	Updated Text
		occupied by the renal pelvis, renal calyces, blood vessels, nerves, and perisinus fat	<p>capsule (no invasion into perinephric fat)</p> <ul style="list-style-type: none"> <li>Code 2: Renal sinus, which is the elongated oval indentation in the renal parenchyma occupied by the renal pelvis, renal calyces, blood vessels, nerves, and perisinus fat                             <ul style="list-style-type: none"> <li>Synonyms include: renal hilum, renal sinus fat, medial invasion</li> </ul> </li> </ul>
00600: Kidney	3864: Invasion Beyond Capsule	<p><b>Note 2:</b> Information about invasion beyond the capsule is collected in primary tumor as an element in anatomic staging. It is also collected in this field as it may have an independent effect on prognosis.</p> <p><b>Note 3:</b> Perinephric/sinus fat invasion should be confirmed microscopically and is invasion into fat by tumor cells, with or without desmoplastic reaction, and vascular invasion into perinephric/sinus soft tissue.</p>	<p><b>Note 2:</b> Information about invasion beyond the capsule is collected in primary tumor as an element in anatomic staging. It is also collected in this field as it may have an independent effect on prognosis.</p> <ul style="list-style-type: none"> <li>If tumor is “confined to kidney” and staging is based on size, then there has been no invasion through the capsule (no invasion into perinephric fat)</li> </ul> <p><b>Note 3:</b> Perinephric/sinus fat invasion should be confirmed microscopically and is invasion into fat by tumor cells, with or without desmoplastic reaction, and vascular invasion into perinephric/sinus soft tissue.</p> <ul style="list-style-type: none"> <li>Synonyms include: renal hilum, renal sinus fat, medial invasion</li> </ul>
00600: Kidney	3861: Ipsilateral Adrenal Gland Involvement	<p>Coding Guidelines</p> <ul style="list-style-type: none"> <li>Code 0: There is no involvement of the ipsilateral adrenal gland</li> </ul>	<p>Coding Guidelines</p> <ul style="list-style-type: none"> <li>Code 0: There is no involvement of the ipsilateral adrenal gland</li> </ul>

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Schema ID/Name	Data Item # and Description	Original Text	Updated Text
			<ul style="list-style-type: none"> <li>○ If tumor is “confined to kidney” and staging is based on size, then there is no involvement of the adrenal gland</li> </ul>
00600: Kidney	3861: Ipsilateral Adrenal Gland Involvement	<b>Note 2:</b> Information about contiguous ipsilateral adrenal gland involvement is collected in primary tumor, and discontinuous ipsilateral adrenal gland involvement is collected in distant metastasis, as elements in anatomic staging. This information is also collected in this field as it may have an independent effect on prognosis.	<b>Note 2:</b> Information about contiguous ipsilateral adrenal gland involvement is collected in primary tumor, and discontinuous ipsilateral adrenal gland involvement is collected in distant metastasis, as elements in anatomic staging. This information is also collected in this field as it may have an independent effect on prognosis. <ul style="list-style-type: none"> <li>○ If tumor is “confined to kidney” and staging is based on size, then there is no involvement of the adrenal gland</li> </ul>
00600: Kidney	3866: Major Vein Involvement	Coding Guidelines  Code 0: There is no involvement of the major veins	Coding Guidelines  Code 0: There is no involvement of the major veins <ul style="list-style-type: none"> <li>• If tumor is “confined to kidney” and staging is based on size, then there is no involvement of major veins</li> </ul>
00600: Kidney	3866: Major Vein Involvement	<b>Note 2:</b> Information about major vein involvement beyond the kidney is collected in primary tumor as an element in anatomic staging. It is also collected in this field as it may have an independent effect on prognosis.	<b>Note 2:</b> Information about major vein involvement beyond the kidney is collected in primary tumor as an element in anatomic staging. It is also collected in this field as it may have an independent effect on prognosis.

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Schema ID/Name	Data Item # and Description	Original Text	Updated Text
			<ul style="list-style-type: none"> <li>If tumor is “confined to kidney” and staging is based on size, then there is no involvement of major veins</li> </ul>
00600: Kidney	3925: Sarcomatoid Features	<b>Note 3:</b> Record the presence or absence of sarcomatoid features as documented anywhere in the pathology report.	<p><b>Note 3:</b> Sarcomatoid features is mostly seen with renal cell carcinoma (all variants); however, if it’s seen with other histologies, it can be coded.</p> <p><b>Note 4:</b> Record the presence or absence of sarcomatoid features as documented anywhere in the pathology report.</p>
00795: Lymphoma-CLL/SLL	3885: Lymphocytosis	<b>Note 5:</b> If there is no mention of lymphocytosis, or relevant lab results, code 9.	<p><b>Note 5:</b> A physician’s statement of RAI Stage 0-4 means that lymphocytosis is present. If that is the only statement available, code 6.</p> <p><b>Note 6:</b> If there is no mention of lymphocytosis, or relevant lab results, code 9.</p>
00795: Lymphoma-CLL/SLL	3933: Thrombocytopenia	<p><b>Note 2: Bullet 2</b></p> <ul style="list-style-type: none"> <li>For cases that document platelet count in SI (Systeme Internationale) units as any of 10x9/L, 10^9/L, or 10E9/L, the cut point of 100,000 cells/μL is equivalent to (100 cells x 10*9/L), (11 cells x 10^9/L, or (100 cells x 10E9/L</li> </ul>	<p><b>Note 2 Bullet 2</b></p> <ul style="list-style-type: none"> <li>For cases that document platelet count in SI (Systeme Internationale) units as any of 10*9/L, 10^9/L, or 10E9/L, the cut point of 100,000 cells/μL is equivalent to (100 cells x 10*9/L), (100 cells x 10^9/L, or (100 cells x 10E9/L)</li> </ul>
00790, 00795: Lymphoma, Lymphoma-CLL/SLL	3896: NCCN International Prognostic Index (IPI)	<b>Note:</b> Physician statement of NCCN IPI must be used to code this data item. Do not calculate points or assign risk. Only record points or risk if a physician has documented	<b>Note 1:</b> Physician statement of NCCN IPI must be used to code this data item. Do not calculate points or assign risk. Only record points or risk if a physician has documented



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Schema ID/Name	Data Item # and Description	Original Text	Updated Text
		<p>them. Use points over risk if both are available.</p>	<p>them. Use points over risk if both are available.</p> <p><b>Note 2:</b> NCCN is applicable for non-Hodgkin lymphomas only.</p> <ul style="list-style-type: none"> <li>• If you have a score for Hodgkin lymphomas (IPS), do not record that information here. Code X9.</li> </ul> <p><b>Note 3:</b> A low, intermediate or high risk associated with RAI Stage is not recorded in this data item.</p>

List of Changes to Grade Manual, Version 1.7

Data Item #	Data Item Description	Original Text	Updated Text
NA	Grade Tables (In Schema Order), pg. 8 Column: Schema ID Name (EOD Schema Name)	00071 Buccal Mucosa 00072 Gum 00073 Floor of Mouth 00074 Lip 00075 Mouth Other 00076 Palate Hard 00077 Tongue Anterior	00071 Lip 00072 Tongue Anterior 00073 Gum 00074 Floor of Mouth 00075 Palate Hard 00076 Buccal Mucosal 00077 Mouth Other
NA	Grade Tables (In Alphabetical order of Schema ID), pg. 8 Column: SS Chapter	00071 Buccal Mucosa 00072 Gum 00073 Floor of Mouth 00074 Lip 00075 Mouth Other 00076 Palate Hard 00077 Tongue Anterior	00071 Lip 00072 Tongue Anterior 00073 Gum 00074 Floor of Mouth 00075 Palate Hard 00076 Buccal Mucosal 00077 Mouth Other
NA	Grade tables (in Alphabetical order of Schema ID name), pg. 13-17 Column: Schema ID Name (EOD Schema Name)	00071 Buccal Mucosa 00073 Floor of Mouth 00072 Gum 00074 Lip 00075 Mouth Other 00076 Palate Hard 00077 Tongue Anterior	00076 Buccal Mucosal 00074 Floor of Mouth 00073 Gum 00071 Lip 00077 Mouth Other 00075 Palate Hard 00072 Tongue Anterior
NA	Grade tables (in Alphabetical order of Schema ID name), pg. 13 Column: SS Chapter	00071 Buccal Mucosa 00073 Floor of Mouth 00072 Gum 00074 Lip 00075 Mouth Other 00076 Palate Hard 00077 Tongue Anterior	00076 Buccal Mucosal 00074 Floor of Mouth 00073 Gum 00071 Lip 00077 Mouth Other 00075 Palate Hard 00072 Tongue Anterior
NA	Grade Clinical, Grade Pathological, Grade Post-Therapy	Ovary/Fallopian Tube/Primary Peritoneal  Note 3, Bullet 1: Immature teratomas and serous carcinomas, codes L and H	Ovary/Fallopian Tube/Primary Peritoneal  Note 3, Bullet 1: Immature teratomas and serous carcinomas, codes L and H, otherwise code 9