BCSC Glossary of Terms, Version 2.1

This document details key terms and definitions used by the Breast Cancer Surveillance Consortium (BCSC).

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BCSC DEFINITIONS FOR BREAST IMAGING EXAMS

Screening mammography

Mammograms, including digital breast tomosynthesis, are performed for either screening or diagnostic purposes. To determine whether a mammogram was for screening, different criteria may be applied depending on the population of interest. The following conditions may be used to define a screening mammogram. **Conditions 1-8** comprise the standard strict definition of a screening mammogram in women without a history of breast cancer (BCSC variable *scrmam_c*) often used in BCSC papers.

At a minimum, the exam <u>must</u> meet the following conditions:

- Condition #1: The examination is a mammogram with an indication of "screening" The indication is usually provided by the radiologist or technologist.
- Condition #2: First mammogram of the day Because multiple exams may occur on the same day, we typically only include only the first exam in the sequence.

One or more of the following conditions <u>may</u> also be applied, to eliminate possible nonscreening exams:

- Condition #3: Unilateral views were not taken Unilateral exams may indicate that the woman had a previous unilateral mastectomy or that the exam was done for diagnostic purposes.
- Condition #4: No mammogram in prior 9 months A mammogram within the prior nine months may indicate a diagnostic exam since screening exams are not typically done at intervals less than 9 months.

The following four conditions <u>may</u> also be used to select screening mammograms among a population of women without a history of breast cancer.

- Condition #5: No history of breast cancer History of breast cancer is based on the database or self-report.
- Condition #6: No history of mastectomy Prior mastectomy is based on the database or self-report and may indicate a prior breast cancer diagnosis.
- Condition #7: No breast augmentation Breast augmentation is based on self-report and exams usually include diagnostic views.
- Condition #8: Exam assessment is not BI-RADS[®] 6
 BI-RADS 6 (known biopsy-proven malignancy) indicates prior breast cancer. ¹

The definition of a screening mammogram may vary depending on the analysis. For example, an analysis may require no self-reported breast symptoms. The analyst can exclude women with symptoms by using the BCSC computed variable *symp_c* (ordered by level of concern: lump, nipple discharge, other symptom not including pain, pain, other symptom not specified, and none). Studies focused on screening/surveillance in women with a personal history of breast

cancer may apply other conditions, defined on page X below. When an analysis includes both screening and diagnostic mammograms, the researchers may prefer to use only the radiologist's indication for exam to classify the mammogram as screening or diagnostic.

Appendix 1 provides BCSC variable names and SAS code pertaining to the definition of a screening mammograms.

Screening MRI

The BCSC collects up to three indications for magnetic resonance imaging (MRI) exams. The computed variable for indication applies a hierarchy (see **Appendix 2**) that keeps a screening indication only if no other indication is given.

The following conditions define a screening MRI (variable *scrmri_c*):

- Condition #1: The examination is an MRI with an indication of "screening"
- Condition #2: First MRI of the day
- Condition #3: Bilateral views taken
- Condition #4: No MRI in prior 9 months
- Condition #5: No history of breast cancer
- Condition #6: No history of mastectomy
- Condition #7: Exam assessment is not BI-RADS 6

Screening/surveillance mammography/MRI with history of breast cancer

Women with a personal history of breast cancer (**PHBC**) are recommended to have breast imaging exams for screening, also referred to as **surveillance exams**. These can be identified by the variable *scrmambc_c* for surveillance mammography and the variable *scrmribc_c* for surveillance MRI. The BCSC definition of a surveillance exam differs in a few respects from the screening definition in women without PHBC, as summarized in this table:

	Screening mammograghy/MRI without PHBC	Screening mammography/MRI with PHBC (surveillance)
Date of exam	No breast cancer history	≥6 months after breast cancer diagnosis, to allow the initial work-up and treatment period to end
Indication for exam	Screening	Screening; this is conservative as some screening exams are coded as diagnostic in the first few years after diagnosis
No prior imaging (of same exam type) time window	9 months	60 days, to allow for shorter screening intervals
BI-RADS assessment	Exclude BI-RADS 6	Exclude BI-RADS 6
Other	Not a unilateral exam No prior mastectomy (self-report at that exam or prior report in pathology, regardless of laterality)	No prior <u>bilateral</u> mastectomy (self- report at that exam or prior report in pathology or cancer registry)

Appendix 1 provides BCSC variable names and SAS code pertaining to definitions of a screening mammogram and screening MRI in women with and without a history of breast cancer.

Diagnostic mammography

The computed variable *dxmam_c* indicates whether a diagnostic mammogram, including digital breast tomosynthesis, was performed. A diagnostic mammogram is defined as a mammogram with an indication of additional evaluation of recent mammogram, short-interval follow-up, or evaluation of a breast problem or concern (variable *indicate* = 2, 3, or 4). Sometimes multiple diagnostic mammograms may be performed to fully work-up a finding or concern; therefore, only the first diagnostic mammogram performed within 90 days is included in analyses to avoid double counting of exams performed for the same work-up.

Note that performance characteristics differ among the different indications for diagnostic mammogram. ²⁻⁵ We do not recommend combining performance results across the different diagnostic indications.

Overall assessment

The BCSC currently uses the classification systems described in the BI-RADS Atlas Fifth Edition (2013) from the American College of Radiology for both mammography and MRI.¹

Assessment categories in the BI-RADS manual:

- 0 indicates that additional imaging evaluation is needed (i.e., incomplete assessment)
- 1-5 indicate the level of suspicion for malignancy
 - 1: negative
 - 2: benign finding
 - 3: probably benign finding
 - 4: suspicious abnormality
 - 5: highly suggestive of malignancy
- 6 indicates a known biopsy-proven malignancy

Each exam contains fields for the left assessment, right assessment, and overall assessment, though not all facilities submit breast-level assessments. The overall assessment (*assmtot_c*) reflects the most serious assessment between the left and right breast. The "highest" assessment between the left and right breast follows a hierarchy ordered from high to low association with cancer risk: 5 > 4 > 0 > 3 > 2 > 1. A BI-RADS 6 assessment should not appear in analyses of screening exams (and thus, should be excluded).

The BCSC computes the overall assessment from the left and right assessments. If left and right assessments are missing, we use the existing overall assessment.

Initial assessment (before any work-up)

The overall assessment may include results from additional work-up, which should not be included in most measures of screening performance. Instead, the initial assessment (*assminit_c*), which is made before any additional imaging is performed, should be used. Additional imaging includes diagnostic views or ultrasound done on the same day or used to help make the assessment (BCSC SCC detail: II.18 *diagview* = 1-5, II.20 *useaddv* = 1, II.21 *ultrasnd* = 1-5, II.22 *useultra* = 1, or a second diagnostic imaging exam.)

If additional imaging was done, the initial assessment is set to BI-RADS 0 (needs additional imaging evaluation). Otherwise, the overall assessment is considered to be the first recorded assessment in the imaging series.

We do not code initial assessment for diagnostic mammograms because performance is based on the final assessment.

End-of-day assessment (after same-day work-up)

The end-of-day assessment is the BI-RADS assessment at the end of the day and includes any same-day imaging work-up (*assminit_eod_c*). The end-of-day assessment should be used for most performance measures of surveillance mammography, because diagnostic views are often done as part of a surveillance exam and the SCC cannot distinguish these from exams performed to work-up of a new finding. The initial assessment and end-of-day assessment are the same for MRI because same-day additional work-up is not typically done.

Final assessment (after all work-up)

The final assessment (*assmfnl_c*) is made after all work-up is completed. Exams with a BI-RADS 0 initial assessment or missing assessment with another exam on the same day are resolved for final assessment. For all other exams, the final assessment is taken to be the overall assessment (*assmtot_c*). The BCSC methods for resolving BI-RADS 0 has been refined over time.

This follow-up algorithm for final assessment was implemented in 2016 (0315b data):

Follow-up algorithm for final assessment (applies to mammography and MRI)
Resolve if initial assessment is BI-RADS 0 or missing assessment with another exam on the same day
Look at all breast imaging exams occurring up to the earliest of 90 days, first biopsy, or breast cancer diagnosis (see note 1 below)
Use first non-zero BI-RADS from Radiology file or non-missing normal/abnormal result from the
Imaging Follow-up file. (BCSC detail: if Imaging Follow-up file used, BI-RADS assessment will be missing but result can be coded)
Use BI-RADS based on recommendation from last follow-up exam:
BI-RADS 4, if biopsy recommendation
BI-RADS 3, if short-interval follow-up
BI-RADS 2, if normal interval follow-up
If biopsy done, code as BI-BADS 4

Use BI-RADS based on recommendation from original exam: BI-RADS 4, if biopsy recommendation BI-RADS 3, if short-interval follow-up BI-RADS 2, if normal interval follow-up If none of the above: Final assessment = missing

Please note:

- 1. Some cancer registries define the diagnosis date as the date of first evidence of breast cancer. If an abnormality is noted on a screening mammogram and the radiologist gives an assessment of 0, the mammogram date may be used as the diagnosis date even if additional imaging is performed on a later day. Therefore, we may be truncating the follow-up period for final assessment too soon.
- 2. If the exam used for the final assessment is from the Imaging Follow-up file, the BI-RADS assessment is missing but the mammogram result may still be classified as positive or negative based on the imaging result (*imgrslt*) or recommendation (*imgrec*).
- 3. The definition of final assessment may be modified depending on the analysis. Also, analyses performed in 2015 and before may have used a modified definition based on earlier decisions. Please see the <u>prior version of the BCSC Glossary of Terms</u>.

Positive and negative result

We use the BI-RADS assessment to define an exam result as positive or negative.

For the **initial result** (*resinit_c*) and **end-of-day result** (*resinit_eod_c*), BI-RADS assessments 1 and 2 are considered negative and 0, 3, 4, and 5 are positive. BCSC began to consider assessments of 3 as positive starting in 2014 to be consistent with changes in the BI-RADS 5th edition. In earlier BCSC studies, BI-RADS 3 was considered positive only if immediate additional imaging (instead of short interval follow-up) was recommended. Please see the prior version of the BCSC Glossary of Terms. According to BI-RADS guidelines, the **initial result** is used with screening exams for these performance measures: sensitivity, specificity, false-positive recall rate, false-negative recall rate, recall rate, cancer detection rate, and PPV1 (see PERFORMANCE MEASURES). The **end-of-day result** is used for all screening MRI and screening surveillance mammography.

For the **final result** (*resfnl_c*), BI-RADS assessments 1, 2, and 3 are negative; 4 and 5 are positive. Typically, unresolved BI-RADS 0s are excluded; however, one should consider a sensitivity analysis that treats zeros as (a) all positive and (b) all negative, to ensure that exclusion does not bias the results. (Some women with an unresolved BI-RADS 0 exam may have had a biopsy that was not captured by BCSC. Excluding these exams may underestimate the percentage with a biopsy or biopsy recommendation.) According to the BI-RADS guidelines, the **final result** is used with screening exams for these performance measures: false-positive biopsy recommendation rate, PPV2, and PPV3 (see PERFORMANCE MEASURES) and for all performance measures with diagnostic mammograms. Note that PPV1 is not defined for diagnostic mammograms; in that case, it is the same as PPV2.

BCSC DEFINITIONS FOR BREAST CANCER DIAGNOSES

Breast cancer cases

We usually define breast cancer as invasive carcinoma or ductal carcinoma *in situ* (DCIS). Some analyses restrict to invasive breast cancer. Lobular carcinoma *in situ* (LCIS), lymphoma, and sarcoma (including cystosarcoma phyllodes) are excluded from the BCSC definition of breast cancer.

For a woman's first breast cancer diagnosis, we identify the earliest diagnosis of invasive breast cancer or DCIS using the cancer registry and pathology files and for one site, the biopsy follow-up file. If a woman has diagnoses of both invasive cancer and DCIS separated by more than 60 days, we take the earliest result as her first breast cancer. If the invasive cancer and DCIS diagnoses are within 60 days of each other, we use the invasive result, but retain the earlier date as the diagnosis date. For cancer characteristics (e.g., size, stage, nodal status) we use the most severe result from cancer registry records with the same cancer type (invasive or DCIS) within 60 days of diagnosis. We fill in missing values using the most several result from pathology, or, for one site, biopsy follow-up.

Follow-up period for breast cancer diagnosis after a breast imaging exam, for performance

For calculating performance measures, s<u>creening mammograms</u> are followed for one year (365 days) unless the next screening mammogram occurs within 270-365 days, in which case the followup period is truncated at that next screening mammogram (*Acad Radiol*, 2000). Non-screening exams done <270 days after the initial mammogram do not truncate the follow-up period. This definition differs from the American College of Radiology (ACR) BI-RADS definition, which uses a strict 365-day follow-up period. Cancer diagnosed within the follow-up period is indicated by the variable *cancscrfu1yr_c* with truncation and the variable *cancfu1yr_c* without truncation.

<u>Screening MRI exams</u> are followed for one year for cancer diagnosis. Truncation at the next screening exam if less than one year does not apply. Cancer diagnosed within the follow-up period is indicated by the variable *cancfu1yr_c*.

For <u>diagnostic mammograms</u>, the follow-up period for cancer diagnosis is from 30 days before to one year after the exam. Cancer diagnosed within the follow-up period before the exam is indicated by *cancdxfu1yr_c*. We include a short period before the diagnostic exam because diagnosis dates assigned by cancer registries often reflect the first evidence of cancer, which can occur on a clinical exam before the diagnostic exam. If multiple cancer diagnoses exist during follow-up then one is chosen using this hierarchy:

- 1) If one or more cancers are diagnosed within 0-60 days after the exam, then the cancer closest to the exam is chosen.
- 2) Otherwise, if one or more cancers are diagnosed within 1-30 days before the exam, then the cancer closest to the exam is chosen.
- 3) Otherwise, if one or more cancers are diagnosed within 61-365 days after the exam, then the cancer closest to the exam is chosen.

Mode of detection for breast cancer cases

The BCSC computed variable for mode of detection (*mode_of_detection*) is recommended for studies among breast cancer cases. Mode of detection is computed for a woman's first breast cancer diagnosis.

The figure illustrates the decision flow and definitions for *mode_of_detection*, coded as:

- 1: Screen detected
- 2: Interval detected (after false negative screening exam)
- 3: Clinically detected with no recent breast imaging exam
- 4: Interval detected (after diagnostic exam without screening exam in prior 12 months but with mammogram in prior 27 months)
- 5: Clinically detected, unknown if interval cancer

Missing: Mode unknown

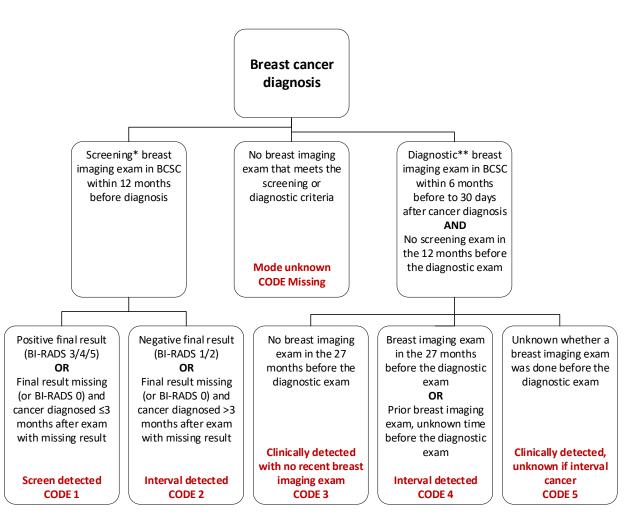


Figure. Decision Tree for Classifying Mode of Detection (mode_of_detection)

Breast imaging exam: mammogram, breast ultrasound, or breast MRI

- * Screening: indication is routine screen (*indication* code 1). Pre-0419 data also requires: >9 months since last screening exam (of any type) OR missing time since last mammogram.
- ** Diagnostic: indication is diagnostic (indication codes 2, 3, 4, or 7).

Mode of detection for breast cancer cases (continued)

<u>Notes</u>

• If there is a screening exam (indication=screening) of any type (mammogram, MRI or ultrasound) within 12 months prior to diagnosis, the BIRADS final assessment is used to determine if the cancer was screen-detected (SD) or interval detected (ID), as follows:

BIRADS assessment category

- 0: additional imaging evaluation needed (incomplete assessment) -> SD if ≤3 months to diagnosis; ID if >3 months to diagnosis
- 1: negative -> ID
- 2: benign finding -> ID
- 3: probably benign finding -> SD
- 4: suspicious abnormality -> SD
- 5: highly suggestive of malignancy -> SD
- 6: known biopsy-proven malignancy -> SD if either (a) initial BI-RADS assessment 0 or (b) initial BI-RADS not 0 and mammogram in prior 3 months has final BI-RADS 3/4/5 or 0/missing and ≤3 months to diagnosis; ID if initial BI-RADS not 0 and mammogram in prior 3 months has final BI-RADS 1/2 or 0/missing and >3 months to diagnosis
- **CODE 1** uses final assessment, not final result. Do not change code which treats final assessment 3 as "positive."
- **CODE 4:** As of the 0717 data release, the definition of *mode_of_detection* decreases the allowable time for a previous mammogram from 42 to 27 months for interval detection.
- The **definition of a screening exam** changed in the 0419 data release. Before 0419, a screening exam required >9 months since the previous screening exam (of any type) OR time since the previous mammogram was missing. This requirement was dropped in 0419.
- About 4000 cases with missing BCSC mode-of-detection were supplemented with mode-of-detection computed from Medicare data from 2006-2010.
- **CISNET** uses an alternative version of the mode-of-detection variable (*mod_CISNET*).
 - For CISNET, screen-detected cancers are further divided by screening interval, keeping information about symptoms.
 - CISNET mode of detection allows prior mammogram up to 42 (rather than 27) months for interval detection.
 - The 0419 change in the definition of a screening exam (to remove requirement of >9 months since the previous screening exam (of any type) OR time since the previous mammogram is missing) does NOT apply to *mod_CISNET*.

PERFORMANCE MEASURES

Definitions for performance measures often used in BCSC papers are provided in this section.

Exam Tuno	Imaging Result	Cancer diagnosis within follow-up period	
Exam Type		Yes	No
SCREENING	Positive (BI-RADS 0, 3, 4, 5)	ТР	FP
	Negative (BI-RADS 1, 2)	FN	TN
DIAGNOSTIC	Positive (BI-RADS 4, 5)	ТР	FP
	Negative (BI-RADS 1, 2, 3)	FN	TN

Positive and negative imaging results

Table adapted from 5th Edition BI-RADS Manual, Follow Up and Outcome Monitoring Section, Fig. 1, page 20.

- **TP** = true positive: a positive exam with DCIS or invasive breast cancer diagnosed within the follow-up period.
- **FP** = false positive: a positive exam with no breast cancer diagnosed within the follow-up period.
- **TN** = true negative: a negative exam with no breast cancer diagnosed within the follow-up period.
- **FN** = false negative: a negative exam with DCIS or invasive breast cancer diagnosed within the follow-up period.

Sensitivity = TP / (TP + FN)

Sensitivity is the proportion of cancers diagnosed during follow-up that had a positive mammography result.

Specificity = TN / (FP + TN)

Specificity is the proportion of non-cancers during follow-up that had a negative mammography result.

Abnormal interpretation rate = All positive exams / All exams. See note 1 below.

Positive Predictive Value (PPV) has three definitions:

PPV₁ (abnormal finding at screening) = TP / (TP + FP1), where FP1 = No known tissue diagnosis within 1 year after positive screening exam (initial assessment of 0, 3, 4, 5).

PPV₁ is the proportion of exams with a positive initial assessment that had a cancer diagnosis during follow-up. PPV₁ should be computed using the <u>initial assessment</u>. If no other PPV definitions are used, PPV₁ may be referred to as PPV.

The 5th edition of BI-RADS does not include PPV_1 , but we have chosen to include it as a performance measure since PPV_1 was included in earlier BI-RADS editions.

PPV₂ (biopsy recommended) = TP / (TP + FP2), where FP2 = No known tissue diagnosis within 1 year after recommendation for tissue diagnosis (final assessment of 4, 5).

 PPV_2 is the proportion of exams with a recommendation for biopsy or surgical consult (i.e., positive final result) that had a cancer diagnosis during follow-up.

PPV₃ (biopsy performed) = TP / (TP + FP3), where FP3 = Concordant benign tissue diagnosis (or discordant benign tissue diagnosis and no known tissue diagnosis of cancer) within 1 year after recommendation for tissue diagnosis. See note 3 below.

PPV₃ is the proportion of exams with recommendation for biopsy or surgical consult (i.e., positive final result) <u>and</u> biopsy performed within 1 year of the exam that had a cancer diagnosis during follow-up.

Negative Predictive Value (NPV) = TN / (TN + FN)

NPV is the proportion of exams with a negative assessment that did not have a cancer diagnosis during follow-up.

False Positive Rate (FPR) = FP / (FP + TN)

FPR is the proportion of non-cancers during follow-up that had a positive mammography assessment. FPR equivalent to 1- Specificity.

Cancer Detection Rate (CDR) = 1000 * TP / (TP + FP + FN + TN)

CDR is the proportion of exams with both a positive assessment and a cancer diagnosis during follow-up. It is usually computed per 1000 mammograms:

<u>Notes</u>

- 1. BI-RADS 3 is positive at screening, but negative at diagnostic exam. BI-RADS 3 was not intended to be applied to screening exams.
- 2. The BCSC does not necessarily capture every biopsy that occurs. Therefore, the denominators for PPV₂ and PPV₃ may differ. For PPV₃, the denominator is the number of biopsies for which there is a record in the pathology file and the numerator is the subset of those biopsies that result in a cancer diagnosis.

Note about follow-up time

The length of follow-up can affect screening mammogram classifications. For example:

Date	Event	Assessment	Classification (BCSC)
Jan 1, 2000	Screening mammogram	Negative	True negative
Nov 1, 2000	Screening mammogram	Positive	True positive
Nov 1, 2000	Cancer diagnosed		

Using the ACR definition, the first mammogram would be classified as false negative because breast cancer was diagnosed within 365 days after a negative exam. According to the BCSC definition, however, the follow-up period ended October 31, 2000 because of the November 1, 2000 screening exam—so the first mammogram would be classified as true negative. This results in increased sensitivity compared to the ACR definition.

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APPENDICES

Appendix 1

(Taken from SCC computed variables program CV0418_v1_2018_10_01.sas)

SAS code for screening mammogram without personal history of breast cancer:

```
* INDICATION IS ROUTINE SCREENING;
if indicate = 1 then scrcrit c1 = 1 ; else scrcrit c1 = 0 ;
* INITIAL EXAM OF THE DAY;
if examseq = 1 then scrcrit c2 = 1 ; else scrcrit c2 = 0 ;
* SCREENING MAMMOGRAMS WITHIN AGE LIMITS (18+);
if 18 <= age c <= 887 then scrcrit c3 = 1 ; else scrcrit c3 = 0 ;
* BILATERAL OR WOMAN-SPECIFIC ROUTINE VIEWS PERFORMED;
if routview in(4,5) or (routview in(8,9,.) and mammlat in(4,5))
then scrcrit c4 = 1; else scrcrit c4 = 0;
* NO SELF-REPORT OF BREAST CANCER;
if bchist in(1,2,3,4,5)
    or '00' < ageatdx <= '06'
     or '10' <= ageatdx <= '99'
    or (dxdati ^= 2 and . < dxdate < examdate )
     or ( dxdati = 2 and year( dxdate ) <= year( examdate ) )</pre>
then scrcrit c5 = 0;
else if (bchist = 0 or ageatdx = '00') and dxdate = . then scrcrit c5 = 1;
else scrcrit c5 = 9 ;
* NO PREVIOUS BREAST CANCER IN CANCER FILE;
if ( newdxdti ^{= 2} and . < newdxdt < examdate )
    or (newdxdti = 2 and year( newdxdt ) <= year( examdate ) )</pre>
then scrcrit c6 = 0;
else if newdxdt = .
         or ( newdxdti ^= 2 and newdxdt >= examdate )
         or ( newdxdti = 2 and year( newdxdt ) > year( examdate ) )
then scrcrit c6 = 1;
else scrcrit c6 = 9 ;
```

(Note: newdxdti indicates imputed date part: 1=day imputed, 2=month and day imputed)

```
* NO IMAGING IN PRIOR 9 MONTHS IN DATABASE;
if ( prvraddt_c = . or ( examdate - prvraddt_c ) >= 270 )
then scrcrit_c7 = 1 ; else scrcrit_c7 = 0 ;
* NO IMAGING IN PRIOR 9 MONTHS FROM LASTDATE, PREVDATE, COMPDATE;
if (lastdate_c = . or lastdate_c = examdate or (examdate - lastdate_c)>=270)
    and (prevdate_c = . or prevdate_c=examdate or (examdate - prevdate_c)>=270)
    and (compdate_c = . or compdate_c=examdate or (examdate - compdate_c)>=270)
    then scrcrit_c8 = 1 ; else scrcrit_c8 = 0 ;
* NO BREAST IMPLANTS;
if brstaugm in(0,8,9,.) then scrcrit c9 = 1 ; else scrcrit c9 = 0 ;
```

```
* ASSESSMENT SHOULD NOT BE '6' (KNOWN BIOPSY-PROVEN MALIGNANCY) IN EITHER THE LEFT,
RIGHT, OR OVERALL ASSESSMENT;
if not ( assessl = 6 or assessr = 6 or assmtot c = 6 )
then scrcrit c10 = 1 ; else scrcrit c10 = 0 ;
* NO REPORT OF MASTECTOMY - SCRCRIT C11;
* PART 2A 1: CREATE MASTECTOMY VARIABLES-SCRCRIT C11 AND MASTDATE (EARLIEST MASTECTOMY DATE)
* THESE ARE MERGED BACK INTO CV FILE FOR LATER USE & SCRCRIT C11 IS USED IN RISK
* MODULE
* THIS SECTION IS NEW IN 0717 CV3 - FOR DETAILS, SEE NOTES IN CHANGE LOG
* CREATES DATA SET OUT.MAST ALL THAT CONTAINS EARLIEST MASTECTOMY INFO FROM 4 SOURCES:
    CV FILE - USES MASTECT TO CREATE SCRCRIT C11, TAKES EXAM DATE AS MAST DATE
     LCIS FILE - USES SURGERY C AND SURGDATE C TO GET MAST INFO
     INTERMEDIATE CANC FILE - USES SURGERY C AND SURGDATE C TO GET MAST INFO
     PATHOLOGY FILE - USES PROCTYPE AND PROCDATE TO GET MAST INFO;
/* 1. Mast data from CV1 file */
data out.mast cv (keep=patientsite c studyid c mastdate cv scrcrit c11 );
      set out.cv1 (keep= examdate mastect studyid c patientsite c biopdate );
  length scrcrit c11 3;
     scrcrit_c11 = 1 ;
            * this if statement is from original scrcrit cll definition in out.cv2 file;
        if mastect in(1,2,3,4,5) /*and ^( mastectomy date < examdate and mastectomy date ^=
.) */
        /* remember that scrcrit = 1 means no mastectomy, 0 = there was a mastectomy */
    then do;
            scrcrit cll = 0;
            mastdate cv = examdate;
  * we'll only keep the records where scrcrit cl1 = 0 (there WAS a mastectomy).;
            output;
     end;
run;
/* 2. Mast data from LCIS file */
      * new data source for 0717CV3; not previously used for scrcrit cl1 or BCSC risk file;
data out.mast lcis (keep=patientsite c studyid c mastdate scrcrit c11);
      set oldlong.lcis&LCIS monyr. (keep=patientsite c studyid c diagdate c surgery c
surgdate c);
  length scrcrit c11 3;
  if surgdate c ^=. then mastdate=surgdate c;
  else mastdate=diagdate c;
      if surgery c in (3,4,5,6,7,8) then do;
            scrcrit c11=0;
            output out.mast_lcis;
     end;
run:
/* 3. Mast data from registry file */
      * this data source was in the original BCSC data file but was modified in 0717 CV3
     to use the newly added surgery c variable.;
data out.mast reg (keep=patientsite c studyid c mastdate scrcrit c11);
      set oldlong.intermed_cancer_&canc_monyr. (keep=patientsite_c studyid_c surgdate_c
surgery_c diagdate_c);
  length scrcrit c11 3;
```

```
if surgdate c ^=. then mastdate=surgdate c;
```

```
else mastdate=diagdate c;
      if surgery c in (3,4,5,6,7,8) then do;
             scrcrit c11=0;
             output out.mast reg;
      end;
run;
/* 4. Mast data from pathology file */
       * code was used in the BCSC risk file but not in scrcrit c11 previous to 0717 CV3;
data out.mast path (keep=patientsite c studyid c mastdate scrcrit c11);
       set oldlong.patholog&path monyr. (keep=patientsite c studyid c procdate typeproc
infodate);
      length scrcrit c11 3;
    if 30 <= typeproc <= 90 then do;
        scrcrit c11 = 0;
      if procdate ^=. then mastdate=procdate;
      else mastdate=infodate;
      output;
    end;
run:
/* now combine all of these records to get a comprehensive dataset of mastectomies. */
data out.mast all ;
      set out.mast cv
             out.mast lcis
             out.mast reg
             out.mast path;
       format mastdate mastdate cv mmddyy10.;
run:
/* 2/14/18 Decision to preferentially take the mastectomy date from a nonCV source and to
only use this date to infer mastectomy in cases where a woman self-reported a mastectomy on a
previous exam and not on the current exam
• If self-reported mastectomy is 1=yes, assume woman had a mastectomy prior to the exam:
      set scrcrit_c11=0=yes and mast_flag=1 no need to look at any dates)
0
• If self-reported mastectomy is 0=no, check for evidence of mastectomy in pathology and
cancer prior to the exam
      set scrcrit_cll=0=yes if .< Mast_date_data<=exam_date and 1=no otherwise</pre>
0
• If self-reported mastectomy is in (.,8,9) = missing, check for evidence of mastectomy in
pathology and cancer prior to the exam OR for self-reported mastectomy at prior exam
      set scrcrit_c11=0=yes if .< min(Mast_date_data, Mast_date_self) <=exam_date and</pre>
0
1=no otherwise
*/
* create two datasets - earliest mastdate cv and earliest mastdate, then merge them together
and then merge to the CV to see how this would work out.;
data first cvdt first othdt;
      set out.mast all;
       if mastdate_cv ne . then output first cvdt;
      if mastdate ne . then output first othdt;
run:
proc sort data=first_cvdt; by patientsite_c studyid_c mastdate_cv; run;
proc sort data=first othdt; by patientsite c studyid c mastdate; run;
data first cvdt (keep = patientsite c studyid c mastdate cv);
       set first cvdt;
      by patientsite c studyid c;
      if first.studyid c;
run;
data first othdt (keep = patientsite_c studyid_c mastdate);
       set first othdt;
      by patientsite c studyid c;
      if first.studyid c;
run;
```

```
data out.mastdt_first;
    merge first_othdt first_cvdt;
    by patientsite_c studyid_c;
run;
/* so, this is our comprehensive dataset of women who have had a mastectomy.
We'll merge this back into out.cvl to assign scrcrit_cll to all records. */
data out.cvla;
    merge out.mastdt_first (in =b) out.cvl (in=a);
    scrcrit_cll = 1;
    by patientsite_c studyid_c;
    if a;
        if mastect in (1,2,3,4,5) then scrcrit_cll = 0;
        else if mastect = 0 and . < mastdate < examdate then scrcrit_cll = 0;
        else if mastect in (.,8,9) and . < min(mastdate, mastdate_cv) then scrcrit_cll = 0;
        drop mastdate mastdate_cv;
```

run;

(Note: mastectomy_date is the earliest diagnosis date in the cancer file where mastectomy is reported)

```
* ANY MAMMOGRAM PERFORMED;
if (mamm_c=1) then scrcrit_cl2=1; else scrcrit_cl2=0;
*** CV: SCREENING MAMMOGRAM WITHOUT PERSONAL HISTORY OF BREAST CANCER ***;
if scrcrit_cl = 1 and scrcrit_c2 = 1 and scrcrit_c3 = 1 and
    scrcrit_c4 = 1 and scrcrit_c5 in(1,9) and scrcrit_c6 in(1,9) and
    scrcrit_c7 = 1 and scrcrit_c8 = 1 and scrcrit_c9 = 1 and
    scrcrit_c10 = 1 and scrcrit_c11 = 1 and scrcrit_c12 = 1
then scrmam c = 1 ; else scrmam c = 0 ;
```

SAS code for screening mammogram without personal history of breast cancer, not including 'no breast augmentation' criteria:

SAS code for screening MRI without personal history of breast cancer:

```
*** CV: SCREENING MRI WITHOUT PERSONAL HISTORY OF BREAST CANCER ***;
if mri in(4,5) and /* bilateral MRI */
    indicate_c = 1 and /* indication is screening */
    advseq = 1 and /* first MRI of the day */
    scrcrit_c3 = 1 and /* age 18 or older */
    scrcrit_c5 in(1,9) and /* no self-report of personal history of breast cancer */
    scrcrit_c6 in(1,9) and /* no previous breast cancer in cancer file */
    (prvmridt_c =. or (infodate-prvmridt_c)>=270) and /* no MRI in prior 9 months */
    scrcrit_c10 =1 and /* no BI-RADS assessment 6 */
    scrcrit_c11 = 1 /* no report of prior mastectomy */
```

```
then scrmri_c = 1; else scrmri_c = 0;
```

(Note: indicate_c is the computed indication for exam - see Appendix 2)

SAS code for screening mammogram with personal history of breast cancer:

(Note: prcancdt2 is the most recent prior cancer date and mast_bilat_date is the earliest diagnosis date in the cancer file where bilateral mastectomy is reported)

SAS code for screening MRI with personal history of breast cancer:

```
then scrmribc_c = 1; else scrmribc_c = 0;
```

(Note: indicate_c is the computed indication for exam - see Appendix 2, prcancdt2 is the most recent prior cancer date, and mast_bilat_date is the earliest diagnosis date in the cancer file where bilateral mastectomy is reported)

Appendix 2

Indication for MRI without history of breast cancer: hierarchy used in computed variable

MRI exams can have up to three indications. The computed variable for indication applies a hierarchy that keeps a screening indication only if no other indication is given. The first indication that appears in the list below is used in the computed variable:

Indication for exam, raw data	Raw	Indication for exam, computed variable (CV)	CV
(indic1, indic2, indic3)	code	(indicate_c)	code
Evaluation for extent of disease of	10	Evaluation for extent of disease or Axillary	6
recent breast cancer diagnosis		adenopathy (malignant), unknown primary	
Response to chemotherapy	21	Other procedures	5
Axillary adenopathy (malignant),	31	Evaluation for extent of disease or Axillary	6
unknown primary		adenopathy (malignant), unknown primary	
Additional evaluation of recent	41	Additional evaluation of recent breast imaging	2
imaging		exam	
Breast problem	30	Evaluation of breast problem (symptomatic)	4
Recurrence vs. scar	42	Evaluation of breast problem (symptomatic)	4
Short interval follow-up	32	Short interval follow-up	3
Diagnostic, not otherwise specified	70	Diagnostic, not otherwise specified	7
Implant evaluation*	40	Other procedures	5
Screening	10	Routine screening (asymptomatic)	1
Other	50	Other procedures	5
Unknown	99	Unknown	9
Structural missing	88	Structural missing	8

* MRI exams done on women with implants can be for screening if the exam includes contrast administration. This cannot be determined in BCSC data so implant evaluation is excluded from screening because some non-contrast exams are performed to evaluate for implant rupture and are not for cancer screening or surveillance. Do not exclude if there is only self-report of breast implants.

SAS code for computed indication for exam (CV0315_v2_2016_05_03.sas):

```
if advcrec = 0 then indicate c = indicate;
else if advcrec = 1 then do ;
       indic1 = 20 or indic2 = 20 or indic3 = 20 then indicate c = 6;
   if
   else if indic1 = 21 or indic2 = 21 or indic3 = 21 then indicate c = 5;
   else if indic1 = 41 or indic2 = 41 or indic3 = 41 then indicate c = 6;
   else if indic1 = 31 or indic2 = 31 or indic3 = 31 then indicate c = 2;
   else if indic1 = 30 or indic2 = 30 or indic3 = 30 then indicate c = 4;
   else if indic1 = 42 or indic2 = 42 or indic3 = 42 then indicate c = 4;
   else if indic1 = 32 or indic2 = 32 or indic3 = 32 then indicate c = 3;
   else if indic1 = 70 or indic2 = 70 or indic3 = 70 then indicate c = 7;
   else if indic1 = 40 or indic2 = 40 or indic3 = 40 then indicate c = 5;
   else if indic1 = 10 or indic2 = 10 or indic3 = 10 then indicate c = 1;
   else if indic1 = 50 or indic2 = 50 or indic3 = 50 then indicate c = 5;
   else if indic1 = 99 or indic2 = 99 or indic3 = 99 then indicate c = 9;
   else if indic1 = 88 or indic2 = 88 or indic3 = 88 then indicate c = 8;
```