

CODING INSTRUCTIONS FOR BREAST CANCER CHART AUDIT



I. GENERAL INSTRUCTIONS

About this study:

Study period. Chart audits will be conducted among women diagnosed with breast cancer. The *Breast Cancer Audit* will capture the clinical experience of each woman, with a focus on breast-related encounters or visits that occurred during a 36-month time period prior to the dx of cancer. Please audit all outpatient charts containing information regarding care during the relevant time period per pt.

Study period start point. The study period starting point for each woman will be 36 months prior to the date of cancer dx. If, however, the first visit during the study period is a f/u breast procedure (e.g., a diagnostic mammogram or biopsy), then the abstraction should start at the breast-related visit that prompted the f/u breast procedure. To find this visit, please search the pt's chart up to 36 additional months backwards in time (up to a total of 72 months prior to the date of dx) to find the initial breast-related visit.

Study period end point. The ending point for each audit will be the date of the histology report that generated the dx. The histology report may be found up to 6 months after the dx date. The occurrence of all ambulatory visits and hospitalizations will be identified, but we will focus the audit on breast-related examinations, findings, and procedures.(mod 7/12/00)

Using the Pt Data Cover Sheet:

Each site programmer will provide the dx date and a summary of all known encounters and breast-related procedures that occurred in the inpatient and outpatient settings during the 36-month period before breast cancer dx. This *Pt Data Cover Sheet* should include a list of all ambulatory visits, hospitalizations, mammograms, ultrasounds and biopsy procedures. The chart abstractor will audit the outpatient charts for each listed event, as well as breast-related hospitalizations not documented in the chart. Appropriate audit forms need to be completed for breast-related visits.

The forms include a *Case Descriptor Summary, Breast-Related Clinical Encounter Summary, Pathology Summary, Mammography & Ultrasound Summary, Hospitalization Summary, Other Contact Summary, Missed Appointment Summary, and Additional Information Summary*. You should be able to go through the chart's sections and find the appropriate information. At some institutions there may be more than one ambulatory care chart for the study period. Please audit all outpatient charts containing information regarding care during the relevant time period. If you find events that are not listed, please include them in the audit and add them to the *Pt Data Cover Sheet* generated by your site programmer. Please also confirm the listed events. We expect dates may be inconsistent at times. Please document the actual dates of the events as recorded in the chart.

Study period:

The 36-month period prior to dx of breast cancer. This is the core period of interest that will be constant for all women.

Abstraction before or after the study period:

For cases where the first visit in the study period is a breast-related f/u visit, the visit that prompted the f/u visit will be abstracted as well. This prompting visit could be up to 72 months before dx. The prompting visit could be a CBE, or bilateral mammogram (screening or diagnostic). When a unilateral exam precedes the first clinical encounter, continue looking back in time until a bilateral exam is found. After auditing the prompting visit, document any pre-existing conditions using question #C-12 of the *Case Descriptor Summary*.

For cases where the histology report that confirmed the dx of breast cancer follows the dx date, all procedures that generate a pathology report (either histology or cytology) will be abstracted up to the date of the confirmatory histology report or up to six months after the dx date, whichever comes first. Procedures occurring in this window of time will be audited using the *Pathology Summary* form. There is no need to complete other summary forms for procedures or visits occurring after the dx date. (mod. 7/12/00)

<u>Abbreviations used in the audit forms:</u>	
Dx	Diagnosis (refers to the initial breast cancer dx)
Pt(s)	Patient(s)
#	Number
CBE	Clinical breast examination
Unk	Unknown
I.M.	Internal Medicine
F.P.	Family Practice, Family Medicine
M.D.	Medical doctor, physician
f/u	Follow-up
L	Left
R	Right
PRN	As needed

Common codes:

In general, code 88=Other and 99=Undetermined (unk, not stated, missing). For yes/no questions, 1=Yes and 2=No.

Dates:

When 8 spaces are given (__ __ / __ __ / __ __ __ __) use the mm/dd/yyyy format. For example, July 15, 1999 is coded as 07/15/1999. **Code an unk day or month as “99”.** **Code an unk year as “9999”.** An unk day in July, 1999 would be coded as 07/99/1999; an unk day and month in 1998 would be coded as 99/99/1998; an unk day, month, and year would be coded as 99/99/9999.

Conflicting information:

When dates disagree between the automated source (as recorded on the *Pt Data Cover Sheet*) and chart, we will record each. Investigators will use the best chart source as the “gold standard”. The best chart source, i.e., a clinic note, a mammography report stamp, is one that Investigators agree documents the event.

Checking:

Check for completeness and consistency (of codes) when finished reviewing a chart.

Items in the header of all forms:

The following items should be recorded on the header of each page of the audit. If pages get separated it is important that we are able to link them back together.

Study ID

A 6-digit study ID# will be provided on the pt data cover sheet (supplied by the programmer at your site). Please record the study ID# at the upper R-hand corner of each page. Pre-printed Study ID labels will be sent to sites upon completion of the training period.

Abstractor ID

Record your 3-digit abstractor ID (first digit = site, second & third digits = abstractor ID).

Photocopying & completing the forms:

Photocopy blank abstraction forms onto paper of the designated color. Color-coding and recognition is important to the abstraction process.

L justify all #s smaller than the # of spaces provided. For dates, use leading zeros (e.g., January 1, 1999 would be recorded as 01/01/99).

“X” boxes that contain codes without obscuring the # code. Please do not use check marks.

Overview of the forms:

Data Collection Forms:	Form Description	Color
Case Descriptor Summary	One form per subject. To be completed for all study participants. Contains health history and descriptive information.	WHITE
Breast-Related Clinical Encounter Summary	Potentially multiple forms per subject. To be completed for any visit during the study period that included a CBE, diagnostic breast procedure, or a visit where breast-related issues were noted.	WHITE
Mammography & Ultrasound Summary	Potentially multiple forms per subject. To be completed for any mammogram and/or ultrasound that took place during the study period.	YELLOW
Pathology Summary	Potentially multiple forms per subject. To be completed for any procedures during the study period that involved removal of tissue from the breast (biopsy). A clinical examination where aspiration of fluid was obtained and sent for cytology should also be recorded on this form. In addition to breast tissue and cells, lung thoracentesis should be recorded on this form. (mod. 7/12/00)	BLUE
Hospitalization Summary	Potentially multiple forms per subject. To be completed for any breast related hospitalization that took place during the study period.	GREEN
Other Contact Summary	One form per subject. Log all <u>non-visit</u> (e.g., telephone or mail) contacts between pts and providers that are not otherwise recorded on summary pages.	WHITE
Missed Appointment Summary	Potentially multiple forms per subject. To be completed for no-shows and cancelled appointments.	PINK
Additional Information Summary	Optional. Complete only as needed, one per subject. Note: this form does not need to be data entered. It should be set aside for shipment to GHC.	WHITE

Photocopying

The following items should be photocopied for eventual shipment to GHC:

- All pathology reports. Obscure pt and physician identifiers. **Please do not obscure the pathology accession #.**
- Copies of chart notes with provider's exact words if patient refusal or non-compliance (Question B-14c).
- Additional Information summary.

II. CHART AUDIT INSTRUCTIONS

The chart audit will collect those pieces of information not available in automated form. In some cases, the data are available but we are collecting them from charts to validate the automated information. The audit includes several forms as noted in *General Instructions* (Section I). To keep track of the audit process for each case, there should be a *Pt Data Cover Sheet*, as noted in Section I. This cover sheet includes the dx date, dates of visits, and other information that will be helpful in conducting the chart audit. Please record the date the chart audit was completed on the *Pt Data Cover Sheet*.

❖CASE DESCRIPTOR SUMMARY ❖[WHITE]

To be completed for all study participants. This information only needs to be collected once.

C-1. **Is there evidence in the chart that the patient was diagnosed with invasive breast cancer or suspicion of invasive breast cancer on the same date (or within 2 weeks of the date) as it appears on the *Patient Data Cover Sheet*, i.e. “Diagnosis Date”, or “SEER” Cancer Registry Diagnosis Date?**

Evidence of invasive breast cancer or suspicion of invasive breast cancer can be a histology report confirming invasive disease, cytology report highly suspect for cancer or malignant cells, mammogram/ultrasound with assessment of suspicious abnormality or highly suggestive of malignancy, or CBE with conclusion of positive or probably cancer.

C-2. **Was the first relevant visit in the study period a breast-related f/u visit?** (mod. 7/12/00)

Indicate if yes/no.

If yes, please go back up to 36 additional months until you find the visit that prompted the f/u visit.

If the earliest relevant (i.e., breast-related) visit in the study period is a f/u visit, look back in the chart until you find a visit that was the original visit that generated the f/u visit. You may need to look back in time as far as 36 months, or a total of 72 months from the dx date. When you find the initial visit, start abstracting information at that visit and abstract all relevant visits from that point forward. (mod. 7/12/00)

F/u visit = any breast-related visit that was described in the chart notes as a f/u visit to an earlier visit; this includes any diagnostic procedure (such as a biopsy), or any diagnostic (non-screening) imaging (mammogram, ultrasound, etc.).

C-3. **Are any visits abstracted prior to the study period?**

Indicate if yes/no.

C-4. **Menopausal status at dx date**

Indicate menopausal status at dx date. If status is not noted in chart at dx date and pt is noted post-menopausal before dx date, indicate “03=Post-menopausal”. Similarly, if pt is pre-menopausal after the dx date, it is safe to indicate “01=Pre-menopausal”. If you are uncertain or there is conflicting information, please select “99=Undetermined”.

Code	Category	Explanation/Examples
01	Pre-menopausal	Regular periods.
02	Peri-menopausal	Irregular menses.
03	Post-menopausal	No menses for 12 months or more.
99	Undetermined	Not noted in chart or unable to discern status at dx date.

C-5. **Record parity/gravidity as of the dx date or closest visit prior to dx date.** (mm/dd/yyyy)

Indicate # and date noted. If parity and gravidity are recorded on two separate dates, record the date closest to the dx date.

Parity = # of live births.

Gravidity = # of total pregnancies (including still births, spontaneous abortions, induced abortions, and live births).

If unk parity or gravidity, code as “99”.

99/99/9999=unk date

C-6. **Pregnancy during observation period?**

a-c. Indicate if yes/no. If yes, please include # of pregnancies, date (mm/dd/yyyy; 99/99/9999 =unk date), and outcome of most recent pregnancy.

C-7. **Is there a known family history of breast cancer?** (mm/dd/yyyy)

Indicate if yes/no. If it is noted that there is no family history, please record the date of the chart note and skip to question 9. Please note that patient's response to a general health survey is an acceptable source for this information. 99/99/9999 =unk date. If yes, complete question 8.

C-8. # of relatives for each type and date of earliest chart note in study period. (mm/dd/yyyy)

Enter # and earliest date that chart notes document the history of breast cancer in a blood relative. If a paternal family history is noted please include. For an aunt or grandmother where lineage (maternal, paternal) is unspecified, please code as "unspecified". For women who were adopted, include only biologic family history. Please code grandfather, uncle, cousin, niece, or nephew as "Other".

C-9. Pt history and date of breast cancer or potentially pre-cancerous lesion.

Indicate all that apply. Potentially pre-cancerous lesions may include lobular carcinoma in situ and atypical hyperplasia (see glossary for definitions). If the history is positive for invasive carcinoma, please consult with principal investigator or project coordinator before continuing with audit. If records are unavailable or there is no mention of prior history of breast cancer, select "undetermined". If information on history of breast cancer or pre-cancerous lesions cannot be found in the notes abstracted during the study period or in the current health summary of the medical chart, STOP, and indicate "undetermined". If you incidentally come across relevant information recorded outside the study period, please include that information. (mod. 7/12/00)

C-10. Using notes recorded during study period, is there a history of breast biopsy prior to study period?

Indicate if yes/no or undetermined. Do not count aspiration of cyst as a breast biopsy. A breast biopsy involves the removal of tissue for histologic dx. If information on prior biopsies cannot be found in the notes abstracted during the study period or in the current health summary of the medical chart, STOP, and indicate "undetermined". If you incidentally come across relevant information recorded outside the study period, please include that information.

C-11. If yes, # of biopsies. (mm/dd/yyyy)

Enter the # of biopsies performed before the study period and note the chart date that documents the # of biopsies. Indicate the earliest date that chart notes were reviewed. 99/99/9999 =unk date

C-12. Evidence of pre-existing breast conditions

Indicate whether there is evidence of a pre-existing condition prior to the study period. Pre-existing conditions include symptoms (for example, longstanding breast pain), mammographic abnormalities, and clinical findings. If evidence of pre-existing conditions, specify year of abnormal finding. If more than one instance of pre-existing conditions, please specify the year of the most recent abnormal finding. If information on pre-existing breast conditions cannot be found in the notes abstracted during the study period or in the current health summary of the medical chart, STOP, and indicate "undetermined". If you incidentally come across relevant information recorded outside the study period, please include that information. If records are unavailable or there is no mention of pre-existing breast conditions, select "99=undetermined". 9999=undetermined year. (mod. 7/12/00)

C-13. Evidence that pt was non-compliant or refused breast care prior to observation period?

Indicate if yes/no. If undetermined, select "00=No evidence".

C-14. Notation of last mammogram prior to the study period?

Enter how long ago last mammogram was done.

C-15. # of Paps and dates in the study period. (mm/dd/yyyy)

PLEASE COMPLETE ONLY IF THIS INFORMATION IS NOT AVAILABLE THROUGH AUTOMATED DATA AT YOUR SITE.

Check with your project coordinator if you are uncertain whether or not to complete this question. Note that automated data on Pap slides need not be validated through chart audit. Record the number of Paps that took place during the 36 month study period prior to the cancer registry dx date. (mod. 7/12/00)
99/99/9999 =unk date

❖BREAST-RELATED CLINICAL ENCOUNTER SUMMARY ❖[WHITE]

To be completed for any visit during the study period that included a CBE, diagnostic breast procedure (see definitions on Diagnostic Summary), or a visit where breast-related issues were noted. Please note that Dermatology visits may be relevant to breast encounters and should be reviewed (e.g., a visit for skin changes on breasts). If multiple visits in one day, indicate visit # in space provided.

B-1. Date of visit (mm/dd/yyyy)

99/99/9999 =unk date

B-2. Type of visit

Indicate if ambulatory care or hospitalization. If hospitalization, please also complete *Hospitalization Summary* [GREEN]. All outpatient visits, including emergency room visits should be coded as ambulatory care.

B-6. Provider gender

Select a code from the list.

B-7. Reason for visit

Select a code from the list. If more than one reason is listed, include all that apply. The intent of this question is to capture the reason why the pt came through the door for today's visit. If it is the first visit to assess a known abnormality, indicate "3=Breast-related finding by provider". Only select "4=Pt report of breast symptom or concern" if it is the reason for the visit. If pt reports a symptom incidentally, it will be captured in question 8. If you cannot determine reason for visit at all, indicate "99=Undetermined" and leave all other fields blank.

B-8a. Were pt reported breast symptoms noted?

Select a code from the list. If yes, continue with question #B-8b. If no, skip to question #B-9.

B-8b. Pt reported breast symptoms

Indicate all that apply. These are symptoms reported by the pt. They will usually appear as a chief complaint (cc) or there may be a note indicating symptoms, i.e., "Pt. c/o pain in L upper outer quadrant of L breast." Visual change includes skin changes, dimpling, retraction, skin lesion, etc. If there is no comment about breast symptoms, select "99=Undetermined, nothing noted".

B-8c. Duration of breast symptoms

99=Undetermined. If multiple breast symptoms of varying duration are reported in B-8b, record the longest duration of symptoms here. (mod. 7/12/00)

B-9. Was a CBE performed?

Indicate if yes/no. If yes, continue with question #B-10. If no, skip to question #B-11.

B-10. Location, findings, and size from CBE

Laterality (L/R/B/U)

Indicate the laterality for the given finding: Left (L), Right (R), Both (B), Unknown (U). For example, for a finding in the L breast, code "L".

[Data entry note: if you wish to assign codes to L/R/B/U, the recommended coding convention is 1=Left, 2=Right, 3=Both, 9=Unknown.] (mod. 7/12/00)

Location:

If location is indicated using location on the clock (i.e., “mass found in R breast at 2 o’clock”), please convert to the appropriate location code using the diagram below. If axillary node or axilla is noted, select "07=Axillary tail".

If more than one location is noted for a single finding, use “LOC2” to indicate the second location. For example, if a single mass is noted in the upper two quadrants of the breast, code LOC1 as “05” for Upper outer and code LOC2 as “03” Upper Inner. Note that for multiple locations for a single finding, the ordering of LOC1 and LOC2 is arbitrary.

Also note that in the case of the same type of finding in two locations, please use separate rows to record. For example, calcifications in the Upper Inner and Lower Outer would be coded on two separate rows each with only one location indicated per row. Similarly, two separate masses in Lower Outer and Upper Outer would be coded separately on two different rows, each with a single location.

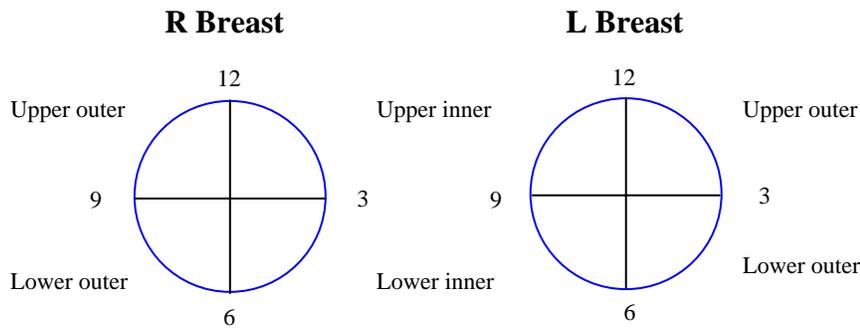
If a finding is not specified by quadrant, but by half, code as both quadrants using LOC1 and LOC2. For example, mass in medial half would be coded as upper outer and lower outer; mass in lateral half would be coded as upper inner and lower inner in the location fields.

If only one location is noted, leave “LOC2” blank. If no location is noted for a given finding, indicate “99=undetermined”.

If location is indicated using location on the clock (i.e., “mass found in R breast at 2 o’clock”), please convert to the appropriate location code using the diagram below.

CONVERSION TABLE:

Location Code	Clock Location (R Breast)	Clock Location (L Breast)
Upper Inner	12:00 through 2:59	9:00 through 11:59
Lower Inner	3:00 through 5:59	6:00 through 8:59
Upper Outer	9:00 through 11:59	12:00 through 2:59
Lower Outer	6:00 through 8:59	3:00 through 5:59



Findings:

Breast exam finding refers to what the provider notes is present on CBE. If there are no findings noted, indicate "09=Undetermined". If it is a negative or normal exam, indicate "00=Normal negative findings". There may be a finding without a location noted. In this case, note the finding and indicate the location as "99=Undetermined". If there is more than one finding, indicate all that apply.

Code	Category	Explanation/Examples
00	Normal, negative findings	<i>Absence of any findings:</i> Normal exam, within normal limits, no findings, no mass, no discharge, fibrocystic changes.
01	Mass	Mass or lump.
02	Cyst	
03	Density	Area of increased density, a density exists. <i>Not a comment on general breast density or a measure of the density of the breast tissue overall.</i>
04	Asymmetry	Asymmetric finding, asymmetric size, asymmetric mass.
05	Skin changes	Skin changes, skin thickening, induration, rash, ulceration, skin lesion. (mod. 7/12/00)
06	Dimpling	Skin dimpling, dimple.
07	Nodularity	Lumpiness, palpable irregularity of breast tissue. <i>Not a discrete nodule (mass), not a comment on lymph nodes.</i>
08	Palpable nodes	Nodes palpable, (axillary) nodes palpable or positive.
09	Nipple changes	Visual change.
10	Discharge	Puss, discharge, fluid, discharge from nipple or lesion.
11	Tenderness to palpation	Tenderness to touch, tenderness to palpation.
88	Other	Any findings not listed above.
99	Undetermined	Not specified, no findings noted.

Size:

Response categories are given in centimeters.

00=0-.99 cm

01=1.0-1.99 cm

02=2.0-2.99 cm

03=3.0-3.99 cm

04= \geq 4.0 cm

99=Undetermined, nothing noted, not applicable, not specified

If multiple dimensions are given for a particular finding, record the **largest dimension**. For example, a 1.0 cm by 2.0 cm mass would be coded as 2 cm or "02=2.0-2.99 cm."

If mass/tumor size is only given in descriptive terms (without any reference to an actual measurement size), please convert to centimeters using the following SEER standards:

ITEM	Cm	ITEM	Cm	ITEM	cm
<u>Fruits</u>		<u>Nuts</u>		<u>Money</u>	
Apple	7.0	Almond	3.0	Dime	1.0
Apricot	4.0	Chestnut	4.0	Dollar (silver)	4.0
Cherry	2.0	Chestnut (horse)	4.0	Half dollar	3.0
Date	4.0	Hazelnut	2.0	Nickel	2.0
Fig (dried)	4.0	Hickory	3.0	Quarter	2.0
Grape	2.0	Peanut	1.0	Penny	1.0
Grapefruit	10.0	Pecan	3.0		
Kumquat	5.0	Walnut	3.0	<u>Other</u>	
Lemon	8.0			Golf ball	4.0
Olive	2.0	<u>Miscellaneous Food</u>		Ping-pong ball	3.0
Orange	9.0	Doughnut	9.0	Tennis ball	6.0
Peach	6.0	Egg (unspecified)	5.0	Baseball	7.0
Pear	9.0	Bantam egg	1.0	Eraser on pencil	<1.0
Plum	3.0	Goose egg	7.0	Fist	9.0
Tangerine	6.0	Hen egg	3.0	Marble	1.0
		Pigeon egg	3.0	Match (head)	<1.0
<u>Vegetables</u>		Robin egg	2.0	Microscopic	<1.0
Bean (unspecified)	1.0	Millet	<1.0		
Bean (lima)	2.0				
Pea (unspecified)	<1.0				
Pea (split)	<1.0				
Lentil	<1.0				

To convert mass/tumor size from inches or millimeters to centimeters:

- 10 millimeters (mm) = 1 centimeter (cm)
- 1 millimeter (mm) = 0.10 centimeter (cm)
- 1 inch (in) = 2.5 centimeters (cm)
- 0.394 inch (in) = 1 centimeter (cm)

B-11. Conclusion of CBE

Indicate one conclusion per breast. Conclusion of CBE should be a separate statement in addition to the CBE findings. The conclusion is meant to indicate the physician's level of suspicion. If no separate statement is made about conclusions, code "99=No conclusion noted". **Code the highest (most serious) conclusion per breast.**

Code	Category	Examples
00	No conclusion noted	THIS CODE HAS BEEN DROPPED. PLEASE USE "99" (mod. 7/12/00)
01	Negative	Normal exam, no findings, no dominant mass, fibrocystic changes
02	Benign	Benign cyst or other benign finding, probably benign
03	Indeterminate finding	Suspicious abnormality, probably malignant, suspicious mass, dominant mass, cannot rule out cancer.
04	Positive or probably cancer	Suggestive of cancer, probably cancer.
88	Other	Specify
99	Undetermined, no conclusion noted (mod. 7/12/00)	

B-12. Recommendations

One or more of the recommendations may be noted. Indicate all that apply. Recommendations must be explicitly stated during the visit date (if no recommendations are noted at the visit date, but one week later you find that the pt had a biopsy, you should record "99=Undetermined"). If a recommendation is hypothetical (e.g., "consider mammogram", or "possible surgical referral") **do not include** as a recommendation unless it contains a qualifier explaining under what conditions this recommendation should be pursued (e.g., "if pain persists, consider mammogram"). If the hypothetical recommendation contains such a qualifier, code as "88=Other" and record the exact language. (mod. 7/12/00)

“01=Surgical referral” includes breast clinic referral.

“02=Re-exam by provider” if number of months to re-exam is less than 1 month, please code number of months as “00”.

Use “99=Undetermined” if no recommendations noted.

Code	Category	Explanation/Examples
03	Immediate mammogram	Mammogram recommended 0-5 months or evidence that the clinician had a sense of urgency in getting it done in the near future.
04	Short-interval f/u mammogram	Mammogram recommended 6-11 months.
05	Routine mammogram	Mammogram recommended 12-24 months.
07	Breast biopsy	Include any type of breast biopsy: open biopsy, incisional biopsy, excisional biopsy, needle biopsy, core biopsy, tru-cut biopsy. Also include lumpectomy.
08	Aspiration	Aspiration of fluid via fine needle.

B-13. Procedure performed

Indicate all that apply. Indicate any procedures that took place on that day in addition to the CBE. For specimens sent to pathology (either histology or cytology report is generated), please complete the *Pathology Summary*. (mod. 7/12/00)

Code	Category	Explanation/Examples
00	No procedure noted	No note or evidence of procedures. No procedures performed.
01	Needle used to extract fluid or tissue; specimen sent to pathology.	Fine needle aspiration, FNA, fine needle aspiration cytology, or fine needle biopsy. A fine needle is used to remove fluid or tissue from a breast mass or cyst. For aspiration of fluid, FNA, FNAC: There may be a comment in the chart regarding the color of the fluid but you need not record that information. There should also be a comment about whether the fluid was sent for cytology analysis. Cytology is the examination of cells. There may be reference to a smear or slide being made at the time of the procedure. Either the fluid or the slide (smear) could be sent for cytology. If fluid is sent for cytology, there should be a corresponding pathology report commenting on the cells. <i>Complete Pathology Summary.</i>
02	Needle used to extract fluid or tissue; specimen <u>not</u> sent to pathology.	If the chart states that the fluid was discarded, indicate “specimen not sent for cytology”. <i>Do not complete Pathology Summary.</i>
03	Biopsy	Include open biopsy (incisional or excisional), lumpectomy, core needle biopsy (Tru-cut biopsy) and biopsy, unspecified type. Code fine needle biopsy as “01=Needle used to extract fluid or tissue”. <i>Complete Pathology Summary.</i>
88	Other	Specify. If pathology report is generated, complete <i>Pathology Summary</i> .

B-14a. Explicit pt refusal or non-compliance

Select a code from the list when there is documented evidence that the pt has chosen to do something other than the recommended plan. If evidence of pt refusal or non-compliance, complete question #B-14b. If nothing noted, skip to question #B-15.

B-14b. If pt refusal or non-compliance, what were the reasons?

Select a code from the list.

B-14c. Photocopy chart notes containing provider’s exact words about pt refusal or non-compliance.

Please photocopy chart notes or reports containing provider’s exact words regarding patient refusal or non-compliance. Photocopies should be stored at your site for eventual shipment to GHC.

B-15. Evidence of f/u contact with pt that did not involve in-person contact?

Note: Any contact regarding a breast concern that does not involve an appointment, i.e., via telephone or mail.

Indicate if yes/no. If yes, please also complete *Other Contact Summary* [WHITE].

❖**MAMMOGRAPHY & ULTRASOUND SUMMARY** ❖[YELLOW]

To be completed for any mammogram and/or ultrasound that took place during the study period. If mammogram and ultrasound are performed on the same date, one form should be completed. If mammogram and ultrasound are performed on different dates and there are separate reports for each procedure, one form should be completed per date. If mammogram and ultrasound are performed on different dates, but there is a single report covering both procedures, one form should be completed and the two dates recorded. This form should be completed even if the radiology report is missing but the chart indicates that the patient had a mammogram or ultrasound.

M-1. Date of mammogram (mm/dd/yyyy)

If two separate mammographic exams are recorded on a single mammography report with a single set of findings, please specify date of first exam. If date of mammogram is missing, use date of dictation or radiologist assessment.

Note: if procedure was performed but date was missing, enter 99/99/9999 . If procedure was not performed, leave blank. 99/99/9999 =unk date

M-2. Date of ultrasound (mm/dd/yyyy)

Note: if procedure was performed but date was missing, enter 99/99/9999 . If procedure was not performed, leave blank. 99/99/9999 =unk date

M-3. Facility

Enter the 4-digit facility (physical location) # that represents the name of the facility in which the pt received the mammogram/ultrasound. If your code is not 4 digits, L justify your entry.

M-4. Reason for procedure

Indicate all that apply. This information may be found in chart notes, on the mammogram order form, or on the mammogram report. (mod. 7/12/00)

Code	Category	Explanation
01	Screening	Pt was without symptoms when mammogram was ordered. Routine exam. Screening exam.
02	Evaluation of a clinical finding	A clinical finding has been detected by CBE. Example: mass found on CBE.
03	Evaluation of a reported symptom without clinical finding	Example: If pt. reports pain or mass and CBE is negative or not performed.
04	Work-up of abnormal mammogram	A diagnostic exam that is prompted by an abnormal finding on previous mammogram.
05	Short-interval f/u of mammogram	Note: definition of "short interval" may vary by site. Select only if this terminology is utilized.
06	One-year f/u of mammogram	
07	Evaluation of breast after biopsy	
88	Other	Specify
99	Undetermined	Unspecified. Not noted.

M-5. Imaging used

Indicate all that apply. If "88", please specify.

M-6. Evidence that comparison films were available?

Indicate if yes/no/undetermined. Indicate yes if there is evidence that prior radiologic films (mammogram, ultrasound, etc.) were used as a comparison at the time of the interpretation for this particular mammogram or ultrasound. Indicate undetermined if there is no mention of whether or not comparison films were used.

M-7. Mammogram views

Indicate all mammogram view that apply for each breast. If ultrasound only, select "00=Not applicable, ultrasound only." If not specified, indicate "99=Undetermined"

Code	Category	Examples
00	Not applicable, ultrasound only	Select if ultrasound only.
01	Screening or routine views	Screening or routine <u>views</u> (must mention screening or routine views, not merely "screening mammogram"). 2 films per breast. Names of screening views: Medial Lateral Oblique (MLO) Cranial Caudal (CC)
02	Diagnostic views	Diagnostic or additional <u>views</u> (must mention diagnostic views, not merely "diagnostic mammogram"). 4 or more films per breast. Names of dx views: Magnification (Mag) Spot or focal compression 90° lateral Lateromedial (LM) Tangential Cleavage Eckland Cleopatra Rolled cc view Supplemental angled view
88	Other	Specify
99	Undetermined	No mention of # of films, name of views, or distinction between screening and diagnostic.

M-8. Location, findings, and size

Indicate all that apply. For each finding, indicate type of finding, location and size, by filling in the blanks for the respective breast. If the particular breast is not specified, complete the appropriate information in the "Unk" section.

Laterality (L/R/B/U)

Indicate the laterality for the given finding: Left (L), Right (R), Both (B), Unknown (U). For example, for a finding in the L breast, code "L".

Location:

If location is indicated using location on the clock (i.e., "mass found in R breast at 2 o'clock"), please convert to the appropriate location code using the diagram below. If axillary node or axilla is noted, select "7=Axillary tail".

If more than one location is noted for a single finding, use "LOC2" to indicate the second location. For example, if a single mass is noted in the upper two quadrants of the breast, code LOC1 as "5" for Upper outer and code LOC2 as "3" Upper Inner. Note that for multiple locations for a single finding, the ordering of LOC1 and LOC2 is arbitrary. Select "08=Overlap" only if that term is used by the radiologist and the overlapping regions are not specified. (mod. 7/12/00)

Also note that in the case of the same type of finding in two locations, please use separate rows to record. For example, calcifications in the Upper Inner and Lower Outer would be coded on two separate rows each with only one location indicated per row. Similarly, two separate masses in Lower Outer and Upper Outer would be coded separately on two different rows, each with a single location.

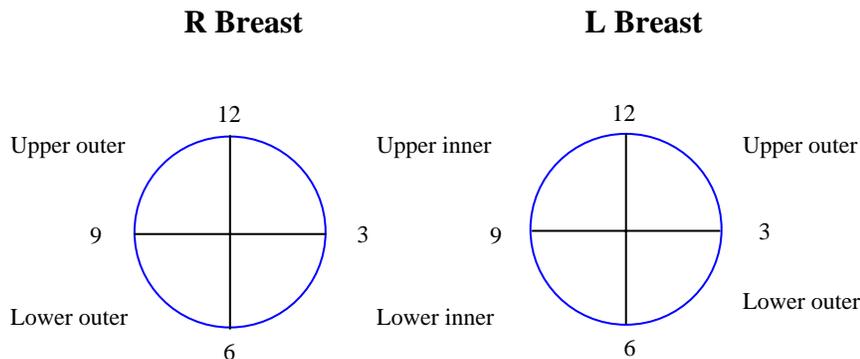
If a finding is not specified by quadrant, but by half, code as both quadrants using LOC1 and LOC2. For example, mass in medial half would be coded as upper inner and lower inner; mass in lateral half would be coded as upper outer and lower outer in the location fields.

If only one location is noted, leave "LOC2" blank. If no location is noted for a given finding, indicate "99=undetermined". Note: code "00=No location noted" has been deleted. (mod. 7/12/00)

If location is indicated using location on the clock (i.e., "mass found in R breast at 2 o'clock"), please convert to the appropriate location code using the diagram below.

CONVERSION TABLE:

Location Code	Clock Location (R Breast)	Clock Location (L Breast)
Upper Inner	12:00 through 2:59	9:00 through 11:59
Lower Inner	3:00 through 5:59	6:00 through 8:59
Upper Outer	9:00 through 11:59	12:00 through 2:59
Lower Outer	6:00 through 8:59	3:00 through 5:59



Findings:

Findings refer to what the radiologist notes is present on mammogram or ultrasound. There may be a finding without a location noted. In this case, note the finding and indicate the location as "99=Undetermined". If there is more than one finding, indicate all that apply.

Code	Category	Explanation/Examples
00	No findings, normal (mod. 7/12/00)	Normal, negative findings (normal exam, within normal limits)
01	Mass	Lump, mass, lesion.
02	Cyst	Cyst. Cyst-like mass. Fluid filled sac. (mod. 7/12/00)
03	Density	Area of increased density, a density exists. <i>Not a comment on general breast density or a measure of the density of the breast tissue overall.</i>
04	Asymmetry	
05	Skin thickening	
06	Calcifications	Calcification, microcalcification.
07	Spiculations	If "spiculated mass", code as "07=spiculations" and "01=mass".
08	Architectural distortion	
09	Nipple retraction	
10	Indeterminate exam	
11	Lymph node	Lymph node, enlargement of lymph node, axillary node visible.
88	Other, specify: _____	
99	Undetermined, nothing noted	Not specified, no findings noted

Size:

Response categories are given in centimeters.

- 00=0-.99 cm
- 01=1.0-1.99 cm
- 02=2.0-2.99 cm
- 03=3.0-3.99 cm
- 04= ≥ 4.0 cm
- 99=Undetermined

If multiple dimensions are given for a particular finding, record the largest dimension. For example, a 1.0 cm by 2.0 cm mass would be coded as "02=2.0-2.99 cm."

If there are conflicting sizes from mammogram and ultrasound for the same finding in the same radiology report, use the size from ultrasound as the gold standard.

If mass/tumor size is only given in descriptive terms (without any reference to an actual measurement size), please convert to centimeters using the following SEER standards:

ITEM	Cm	ITEM	cm	ITEM	Cm
<u>Fruits</u>		<u>Nuts</u>		<u>Money</u>	
Apple	7.0	Almond	3.0	Dime	1.0
Apricot	4.0	Chestnut	4.0	Dollar (silver)	4.0
Cherry	2.0	Chestnut (horse)	4.0	Half dollar	3.0
Date	4.0	Hazelnut	2.0	Nickel	2.0
Fig (dried)	4.0	Hickory	3.0	Quarter	2.0
Grape	2.0	Peanut	1.0	Penny	1.0
Grapefruit	10.0	Pecan	3.0		
Kumquat	5.0	Walnut	3.0	<u>Other</u>	
Lemon	8.0			Golf ball	4.0
Olive	2.0	<u>Miscellaneous Food</u>		Ping-pong ball	3.0
Orange	9.0	Doughnut	9.0	Tennis ball	6.0
Peach	6.0	Egg (unspecified)	5.0	Baseball	7.0
Pear	9.0	Bantam egg	1.0	Eraser on pencil	<1.0
Plum	3.0	Goose egg	7.0	Fist	9.0
Tangerine	6.0	Hen egg	3.0	Marble	1.0
		Pigeon egg	3.0	Match (head)	<1.0
<u>Vegetables</u>		Robin egg	2.0	Microscopic	<1.0
Bean (unspecified)	1.0	Millet	<1.0		
Bean (lima)	2.0				
Pea (unspecified)	<1.0				
Pea (split)	<1.0				
Lentil	<1.0				

To convert mass/tumor size from inches or millimeters to centimeters:
 10 millimeters (mm) = 1 centimeter (cm)
 1 millimeter (mm) = 0.10 centimeter (cm)
 1 inch (in) = 2.5 centimeters (cm)
 0.394 inch (in) = 1 centimeter (cm)

M-9. Imaging Assessment

Indicate highest assessment per breast. Select only one assessment per breast. For example, if benign cyst and suspicious mass are noted in the L breast, code “04=Suspicious abnormality” only for the L breast. (Coding based on BIRADS-Breast Imaging Reporting and Data System.)

Code	Category	Explanation/Examples	Pre-BI-RADS™ Equivalents
00	Needs additional imaging evaluation	Finding for which additional imaging is needed. This is almost always used in a screening situation and should rarely be used after a full imaging work up. A recommendation for additional imaging evaluation includes the use of additional mammographic views, ultrasound, etc. Incomplete examination.	The radiologist refuses to render an opinion or comment on findings without additional imaging. No findings or conclusions appear on the report. There is a simple recommendation for additional imaging.
01	Negative	Normal. There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances or suspicious calcifications are present. Assessment is complete.	Finding and/or Conclusion: Normal breast tissue, no significant abnormalities, negative, normal examination.
02	Benign finding	This is also a negative mammogram, but the interpreter may wish to describe a finding. The interpreter might wish to describe intramammary lymph nodes, implants, calcified fibroadenomas, multiple secretory calcifications, fat containing lesions such as oil cysts, lipomas, galactoceles, and mixed density hamartomas, etc. while still concluding that there is no mammographic evidence of malignancy.	Benign qualifier in front of any finding, and no conclusion. OR Conclusion: Benign
03	Probably benign finding	Short interval f/u suggested. A finding placed in this category should have a very high probability of being benign. It is not expected to change over the f/u interval, but the radiologist would prefer to establish its stability.	“Probably benign” qualifier in front of any finding Or Conclusion: Probably benign, unlikely to be cancer, unlikely to be malignant, doubt malignancy.
04	Suspicious abnormality	Biopsy should be considered. These are lesions that do not have the characteristic morphologies of breast cancer but have a definite probability of being malignant. The radiologist has sufficient concern to urge a biopsy.	Qualifier of “suspicious” before any finding. Conclusion: Cancer cannot be ruled out, suspicious abnormality, suspicious for cancer, suspicious malignancy, worrisome for metastatic disease.
05	Highly suggestive of malignancy	High probability of malignancy. Typically biopsy recommended.	Cancer, cancer likely, likely represents cancer, probably malignant, probably cancer.
99	No assessment noted, missing	Indicate if there is no overall assessment or conclusion of findings.	

M-10. Recommendations

Indicate all that apply.

Code	Category	Explanation/Examples
01	Non-surgical clinical evaluation	
02	Surgical referral	Surgical evaluation
03	Biopsy	Include all types of biopsy including nipple, fine needle, core, Tru-Cut, incisional, excisional and open biopsy.
08	Aspiration	Aspiration of cyst, FNA.
09	Short-interval f/u mammogram	6-11 month recommendation
10	Normal interval f/u	12-24 month recommendation, routine mammogram
11	Ultrasound	Immediate ultrasound, 0-6 month recommendation.
12	Additional mammographic views	Immediate mammogram, diagnostic views or exam.
13	Short-interval f/u ultrasound	6-11 month recommendation.
88	Other	Specify
99	Undetermined, nothing noted	

M-11a. Explicit pt refusal or non-compliance

Select a code from the list when there is documented evidence that the pt has chosen to do something other than the recommended plan. If evidence of pt refusal or non-compliance, complete question #M-11b. If nothing noted, skip to question #M-12.

M-11b. If pt refusal or con-compliance, what were the reasons?

Select a code from the list.

M-11c. Photocopy chart notes containing provider's exact words about pt refusal or non-compliance.

Please photocopy chart notes or reports containing provider's exact words regarding patient refusal or non-compliance. Photocopies should be stored at your site for eventual shipment to GHC.

M-12. Evidence of f/u contact with pt that did not involve in-person contact?

Note: Any contact regarding a breast concern that does not involve an appointment, i.e., via telephone or mail. Indicate if yes/no. If yes, please also complete *Other Contact Summary*.

❖**PATHOLOGY SUMMARY** ❖[BLUE]

To be completed for histology or cytology. To be completed for any procedures during the study period that involved removal of tissue from the breast (biopsy). A clinical examination where aspiration of fluid was obtained and sent for cytology should also be recorded on this form. In addition to breast tissue and cells, lung thoracentesis should be recorded on this form. A *Breast-Related Clinical Encounter Summary* should be completed as well. Please photocopy each pathology report.

P-1. **Date of procedure** (mm/dd/yyyy)

Use pathology report as source for date of procedure. Please note, it could be missing in some cases. If date of procedure is missing, but date of tissue dx is available, use date of tissue dx.
99/99/9999 =unk date

P-2. **Department in which tissue was collected**

Indicate department.

P-3. **Procedure that generated pathology report**

Indicate all that apply, making sure to distinguish which procedures were performed on each breast.

Code	Category	Explanation/Examples
01	Fine needle biopsy or aspiration	Fine needle biopsy or Fine needle aspiration cytology (FNAC or FNA): You may find either term or just “needle biopsy”. Type of needle biopsy where a # of cells are removed without surgery. Fine needle aspiration is not a biopsy but a removal of cells. In any case, evidence that a 16 gauge or smaller needle was used to obtain tissue or cells is evidence of a fine needle biopsy or fine needle aspiration. The needle size gets smaller as the # gets bigger. Most fine needle biopsies will be done with a 21-gauge needle. Any biopsy done with a # ≥ 16 would be classified as a fine needle biopsy. The sample taken is spread on a glass slide, fixed with alcohol or some other preservative, and examined under a microscope for malignant cells.
02	Core biopsy	Type of needle biopsy where a small core of tissue is removed without surgery. Includes Tru-cut biopsy. A large biopsy needle (a # <16) is used to obtain tissue that can be fixed in formalin and sectioned for examination under a microscope. Because the sample is larger than that obtained by a fine needle, it retains the breast architecture and makes histologic dx somewhat more accurate.
03	Open biopsy	Surgical biopsy. Includes “excisional” and “incisional” biopsies. Involves removal of part (“incisional”) or all (“excisional”) of lump.
04	Stereotactic biopsy	Stereotactic needle biopsy uses a <i>stereotactic mammogram</i> apparatus to localize the abnormality. The apparatus uses two different views to triangulate the breast abnormality. A computer then calculates the depth of the lesion and the apparatus is directed to position the biopsy needle at that depth.
05	Mastectomy	
88	Other	Specify

P-4. Method of imaging for localization

Indicate all that apply.

03	Use of a wire marker	This is one method of identifying where the tumor is located within the breast. This is especially important when the abnormality is seen on a mammogram but cannot be felt (i.e., is non-palpable). Use of a wire marker (needle, hook) and placement of a dye track are two of the most common methods. Both require some type of imaging to first locate the abnormality. Once the marker is in place, the surgeon then follows it from the skin surface down to the tip of the marker to remove the tissue there at the tip.
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P-5. Pathology specimen

Indicate all that apply.

Code	Category	Explanation/Examples
01	Histology	Histology diagnosis is based on examination of tissue, not cells. Results from any type of biopsy procedure.
02	Cytology	Cytology diagnosis is based on examination of cells. Typically results from aspiration of fluid (FNA, FNAC).

P-6. Results-histology, biopsy of breast tissue

Indicate all that apply for each breast. The results may not be available on the date of the procedure. Include all results associated with this diagnostic procedure even if the results were recorded on a later date. If pathology report is missing, code as "99=Undetermined".

Code	Category	Explanation/Examples
00	Inconclusive, insufficient	Insufficient cells, insufficient sample, inadequate cell preparation, could not interpret, unsatisfactory.
01	Normal breast tissue	Normal. Within normal limits (WNL). Fibrocystic changes. (mod. 7/12/00)
02	Atypical hyperplasia	Cells that are not only abnormal but increased in #.
03	Fibroadenoma	Benign fibrous breast tumor.
04	Cancer <i>in situ</i>	Carcinoma in situ, DCIS, LCIS
05	Invasive ductal carcinoma	Infiltrating ductal carcinoma.
06	Invasive lobular carcinoma	Infiltrating lobular carcinoma.
07	Mucinous carcinoma	
08	Invasive cancer, other or unspecified type	Invasive disease of other or unspecified type. Medullary carcinoma, papillary carcinoma, tubular carcinoma.
09	Ductal hyperplasia	
10	Cystosarcoma phylloides	
88	Other	Specify other.
99	Undetermined	

P-7a. Source of cytology cells

Select a code from the list. Note: lung thoracentesis should be recorded here when applicable. If pathology report is missing, code as "99=Undetermined".

Code	Category	Explanation/Examples
01	Breast Aspirate	From Breast FNA or FNAC. Aspirated fluid from breast.
02	Thoracic fluid	From lung.
88	Other	Specify
99	Undetermined	

P-7b. Results of cytology

Indicate all that apply for each breast. Indicate results of cytology.

Code	Category	Explanation/Examples
00	Insufficient sample	
01	Normal cells	WNL, Normal, Benign.
02	Atypical cells	Atypia. Atypical hyperplasia.
03	Abnormal cells	
04	Malignant cells	Malignant, cancerous.

P-8. Photocopy pathology report masking any pt identifiers.

Mask pt and physician identifiers. Do not obscure accession #. Attach Study ID label.

Pathology report copies should be kept separate from the completed chart abstraction forms. Site Coordinators will be asked to ship copies to GHC periodically.

❖**HOSPITALIZATION SUMMARY** ❖[GREEN]

To be completed for any breast related hospitalization that took place during the study period. (Information may be obtained from hospital discharge summary in outpatient chart.)

H-1. **Hospitalization date** (mm/dd/yyyy)

99/99/9999 =unk date

H-2. **Reason for admission**

Select one code from the list.

H-3. **Breast-related procedures**

Indicate all that apply. Please also complete appropriate *Summary* form.

❖OTHER CONTACT SUMMARY ❖[WHITE]

Please use this grid to log non-visit (e.g., telephone or mail) contacts between pts and providers. These contacts may or may not be prompted by prior visits. (mod. 7/12/00) For those contacts that are prompted by a visit, i.e., ambulatory care breast exam, please indicate date of visit in space provided. For those that are not associated with a particular visit, leave that space blank. If a given subject has more than seven contacts, please continue to a second *Other Contact Summary* form and label the forms with unique “series #” at top of form.

T-1. **Contact Date(s)** (mm/dd/yyyy)

Record the dates of contact.

99/99/9999 =unk date

T-2. **Visit Date(s) (if contact arose from a visit)** (mm/dd/yyyy)

Record the dates of contact. If contact did not arise from a particular visit, leave blank.

99/99/9999 =unk date

T-3. **Mode**

Select a code from the list.

T-4. **Initiator**

Select a code from the list.

This is the person who initiated the contact.

T-5. **Reason (for contact)**

Select a code from the list. If “4” is selected, please complete *Missed Appointment Summary* [PINK].

Indicate all that apply.

T-6. **Recommendation**

Indicate all that apply.

T-7. **Pt refusal and f/u**

Select a code from the list.

❖MISSED APPOINTMENT SUMMARY ❖[PINK]

To be completed for no-shows as well as cancelled appointments for breast-related clinical encounters or procedures. If it is unclear whether or not a missed-appointment was breast-related, please complete this form (e.g., if the missed appointment was in family medicine, but there is no mention of the reason for the visit, please abstract this missed appointment). (mod. 7/12/00)

A-1. **Appointment date** (mm/dd/yyyy)

Record the date of missed appointment.

99/99/9999 =unk date

A-2. **Facility**

Please indicate 4-digit facility code. (Abstractors will be provided with a list of valid facility codes for their site.)

A-3. **Department**

~~Please indicate 4 digit department code.~~ Select a code from the list. For breast cancer screening program, select "Breast Clinic/Breast Center". General health screening center includes Health Appraisal Program or HAP.

A-4. **F/u contact codes on missed appointments** (mm/dd/yyyy)

Select the appropriate code and record date(s) of attempt.

99/99/9999 =unk date

A-5. **New appointment scheduled?** (mm/dd/yyyy)

Select a code from the list. If yes, please record date.

99/99/9999 =unk date

❖ADDITIONAL INFORMATION SUMMARY ❖[WHITE]

To be completed for information that would not be captured on the abstraction forms. Items such as chart completeness/sufficiency, unusual circumstances or explicit provider notes for non-compliance.

Data entry note: Please data enter question I-1 only.

This form should be photocopied and stored for eventual shipment to GHC. Text from question I-2 will be coded at GHC.