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BREAST CANCER

GYN 1.1

Includes Paget's Disease.

For Breast Implants and Reconstructive Surgery; See "Breast Implants and Reconstructive Surgery" Guideline.

INFORMATION REQUIRED

If Applicable:

- Biopsy Evaluation (Coredels) Report or Oncologist letter to the medical oncologist with the following information:
 - Date of diagnosis
 - Cancer type
 - Stage
 - Number of positive lymph nodes (Tumor)
 - Treatment: include all chemotherapy, radiation, and endocrine therapy (if applicable)
 - Chemotherapy and hormone therapy: include date initiated, completed, and response
 - Current status
 - Recommended follow-up or follow-up completed in next 3 years.
- Copy of mammogram report within the past 1 year.
- Copy of liver function tests (LFTs) within the past 1 year.

If Applicable:

- Discharge summary of all related hospitalizations and surgeries. Includes day and out-patient surgery.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
<p>1. Breast cancer Stage IIA or IIB.</p> <p>2. Positive lymph nodes.</p> <p>3. No history of recurrences.</p>		

<p>Meets clearance criteria 1-4, AND</p> <ul style="list-style-type: none"> • Breast cancer <u>Stage IIA or IIB.</u> • <u>Positive lymph nodes.</u> • No history of recurrences. 	<p>years, and annually thereafter.</p> <p>Annual mammogram.</p>	<p>MED ADVISOR</p> <p>Risk varies - assess based on detailed history. If cleared, Mammogram Accomodation.</p>
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BREAST CANCER

Meets clearance criteria 1-4, AND

- Breast cancer Stage III.
- No history of recurrence for *at least* the past 5 years.

MED ADVISOR

Risk varies - assess based on detailed history.

If cleared: Mammogram Accommodation.

Does not meet clearance criteria due to one or more of the following:

- Breast cancer Stage 0, I, II A and IIB: Status post primary and adjuvant treatments *less than* 2 years. Surgical treatments include lumpectomy and mastectomy (subtotal, modified, and radical). Adjuvant treatments include radiation and chemotherapy. For the purposes of this guideline adjuvant treatment does not include hormone therapy, e.g., Tamoxifen.
- If on hormonal therapy, e.g., Tamoxifen, *not* stable for *at least* the past 6 months, or associated with *significant* complications
- Breast cancer Stage III with history of recurrence *within* the past 5 years.

MED ADVISOR

DEFER

Deferral letter requires review by screening manager.

Note: Deferral period begins at the end of treatment.

Does not meet clearance criteria due to one or more of the following:

- Age < 35 years at diagnosis.
- Post surgical or treatment complications.

MED ADVISOR

Risk varies - assess based on detailed history.

Does not meet clearance criteria due to one or more of the following:

- Breast cancer Stage IV.

MED ADVISOR

DEFER/MNQ

Deferral/MNQ letter requires review by screening manager.

DIAGNOSTIC CODES

174 Breast Cancer
174 Paget's Disease

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- Key prognostic indicators, i.e., number of positive lymph nodes, size of excised tumor-free margins, and intraductal component of primary tumor.
- Applicants cleared to a mammography country should bring, to their country of assignment, their most recent mammogram films for comparison.

COMMENTS:

Staging of Breast Cancer: Based on the TNM (tumor, nodes, metastases) system:

- Stage 0: Carcinoma in situ (intraductal carcinoma, lobular), no positive nodes, no distant metastases.
- Stage I: Tumor <2.0 cm in greatest dimension, no positive nodes, no distant metastases.
- Stage IIA: No evidence of primary tumor, movable positive ipsilateral nodes (not fixed to another structure), no distant metastases
- Stage IIB: Tumor 2-5 cm in greatest dimension, no or metastases to movable ipsilateral nodes, no distant metastases; or tumor >5 cm, no positive nodes, no distant metastases.

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- Stage III A: Tumor any size, metastases to movable or fixed ipsilateral nodes.
- Stage III B: Tumor any size; with direct extension to skin or chest wall, metastasis to ipsilateral internal mammary lymph node(s).
- Stage IV: Tumor, positive nodes, distant metastases. [Phillips & Balducci 1996]

Key Indicators of Severity:

- Node positive at diagnosis
- <35 years of age at diagnosis
- Excision of primary tumor not with wide tumor-free margins
- Extensive intraductal component of primary tumor
- Higher number of positive nodes at surgery [Phillips & Balducci 1996]
 - No positive nodes: 19% 5-year recurrence; 72% 5-year survival
 - 3 positive nodes: 43% 5-year recurrence; 59% 5-year survival
 - 10+ positive nodes: 75% 5-year recurrence; 22% 5-year survival

Progression, Relapse, and Recurrence: Women who have had breast cancer are, on average 3 times more likely than others to develop a second primary cancer in the opposite breast, with an absolute risk of about 0.75% per year. Women who have had breast conserving surgery (BCS) also have a risk of recurrence in the same breast. In one study, by 5 years this occurred in about 17% of women; and by 20 years, 71%. In general, survival is somewhat poorer for younger women (<50). [SCCPGCTBC 1998]

Relatively few women die from localized breast cancer, following appropriate surgery and, in some cases radiotherapy, chemotherapy, or both. About three-quarters of women with regional spread of the primary tumor, including those with spread to regional lymph nodes survive at least 5 years after diagnosis. Survival is much better for those without involved lymph nodes, however (about 80-90+% survival vs about 60-75% survival). The corresponding figures for survival without recurrence are about 70-85% vs about 50-70%). [EBCTCG 1998a; 1998b]

Survival of Breast Cancer Patients by Stage at Diagnosis
1985-1990 Cases, All Treatments

Stage	# Starting	5-year	10-year
0	9381	99%	95%
I	37,152	97%	88%
II	34,349	83%	66%
III	8512	54%	36%
IV	5428	16%	7%

[American College of Surgeons 1998]

Managment: Treatment of early breast cancer includes some form of surgery (breast-conserving surgery [BCS; lumpectomy] or various types of mastectomy) and may include radiotherapy (the main benefit of which is to reduce the chances of a local recurrence), chemotherapy, hormonal therapy (both of which improve survival), or a combination of adjuvant therapies. Chemotherapy is usually given for no more than about 6 months to a year. The optimal length of treatment with hormonal therapy (tamoxifen) has not been determined, but the benefit of continuing for at least 5 years has been proven conclusively. [EBCTCG 1998a]

Follow-Up:

Patient Education: Women should be informed about symptoms of recurrence, because the majority of recurrences are detected between scheduled visits. Significant symptoms include enduring bone pain or tenderness and persistent pulmonary, neurologic, or gastrointestinal symptomatology

Eliciting of Symptoms: Includes both general medical symptoms as well as those suggesting the presence of metastatic disease or long-term toxicity from therapy. These include:

- general performance status
- bone pain or tenderness
- skin rash
- results of breast self-examination

BREAST CANCER

- changes in the breast
- chest pain and dyspnea
- abdominal pain
- gynecologic symptoms (especially for women on tamoxifen)
- weight loss

Physical Examination: The next examination should be for general health and for physical findings suggesting contralateral breast cancer, recurrence in the same breast, locoregional, or systemic recurrence of disease, including lymphedema in the arm. Patients should also be encouraged to perform monthly breast self-examinations.

- Every 2-6 months for the first 2 years after primary therapy

• Every 6-12 months for the next 2 years

• Annually thereafter

Mammography: For women treated with BCS, the first mammogram should occur 6 months after completing radiation, then annually, in the absence of other indications for the test. All women with a prior diagnosis of breast cancer should have annual mammograms.

Pelvic Examination: All women should have pelvic examinations at regular intervals (not specified in manual reviewed). Longer intervals may be appropriate for women who have had a total abdominal hysterectomy and oophorectomy.

Patient Taking Tamoxifen: Attention should be paid to the increased risk of endometrial cancer and patients should be asked specifically about vaginal discharge or bleeding. Current data do not support annual endometrial biopsies for all women taking tamoxifen.

Measures Not Recommended for Routine Use During Follow-Up:

- Complete blood count
- Automated chemistry studies
- Chest x-ray
- Bone scans: low predictive value (10% in one study), with most results being false positives (7 in 8); selection of metastases by bone scan does not alter survival
- Liver ultrasound scans
- CT scans
- Breast cancer tumor marker CA 15-3
- Breast cancer tumor marker CEA (ASCO 1994; SCDPGCTBC 1995)

Resources: There are 2 good courses for www.nccn.org, www.NCI-NCES.org, www.nationalcancerfunding.gov. The NCCN also has conducted a special study of breast cancer treatment and survival and has reported 10-year data.

For Fibrocystic Breast Changes and Atypical Hyperplasia; See "Fibrocystic Breast Changes" Guideline.

For Solid (Discrete) Breast Masses; See "Solid (Discrete) Breast Mass" Guideline.

INFORMATION REQUIRED *If history within the past 5 years.*

Applicants With History of, or Resolved, Cyst(s):

- Report of Medical Examination.
- If biopsy (needle aspiration or excision) performed, copy of pathology report.

Applicants With Current Cyst(s):

- Specialist Evaluation (Gynecologist or General Surgeon) within the past 6 months to include:
 - Size, location, and number of cysts.
 - Treatment
 - Recommendations for follow-up over the next 3 years.
- If ultrasound performed, copy of most recent ultrasound report.
- If mammogram performed, copy of most recent mammogram report.
- If biopsy (needle aspiration or excision) performed, copy of pathology report.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
<ol style="list-style-type: none"> 1. Single cyst noted on evaluation; current or by history. 2. No history of recurrent cysts. 3. No history of breast cancer. 		
Meets clearance criteria 1-3, AND <ul style="list-style-type: none"> • Cyst <u>resolved</u>: spontaneously, via aspiration, or via excision. 	RN	CLEAR
Meets clearance criteria 1-3, AND <ul style="list-style-type: none"> • Current cyst. • <u>Ultrasound documentation of stability</u> of cyst for <i>at least</i> the past 2 years. 	RN	CLEAR PCMO FOLLOW-UP Ultrasound and periodic breast exam as recommended by radiologist or provider.
Meets clearance criteria 1-3, AND <ul style="list-style-type: none"> • Current cyst. • <u>No ultrasound documentation</u> of stability of cyst for <i>at least</i> the past 2 years. 	RN	DEFER Defer until resolved, or until ultrasound documentation of stability for at least the past 2 years. Deferral letter requires review by screening manager.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Two or more cysts noted on evaluation; current or by history. • Recurrent cysts. 	MED ADVISOR	Risk varies - assess based on detailed history.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • History of breast cancer. 	MED ADVISOR	See "Breast Cancer" Guideline.

BREAST CYSTS

DIAGNOSTIC CODES

610.0 Breast Cysts

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- None

COMMENTS:

Background: Breast cysts are palpable fluid-filled sacs within the breast tissue. They are common and usually benign, but should be investigated to rule out possible cancer. Bloody fluid aspirated on a clean puncture is highly suspicious of cancer. A mammogram, sonogram, and biopsy are indicated to rule out malignancy. Women with a history of recurrent cysts need access to adequate sonograms to diagnose recurrent cysts.

Sonographic Criteria for a Simple Cyst: Well circumscribed margins, a bright posterior wall, round or oval contours, absence of internal echoes, and increased through transmission. If all these criteria are met the accuracy for the diagnosis of a cyst is 100%. Also, if these criteria are met, aspiration, biopsy, or close follow-up are not necessary as long as the cyst does not interfere with physical examination. [Feig, Stephen. *Breast Masses*. "Radiology Clinics of North America," Vol. 30, No. 1, 1992.]

Cysts and Cancer: The relationship of gross cysts to cancer is controversial. Haagensen reported a fourfold increase in the incidence of subsequent cancer in his follow-up of 2017 sequential patients. Harrington and Lesnik demonstrated an incidence of subsequent cancer that was 3.5 times greater than normal, over a period of 13 year, in women with gross cysts. The average interval from aspiration of a breast cyst to the development of cancer was 7.9 years. Other authors have disputed this relationship. [Issacs, John H. *Benign Tumors of the Breast*. "Obstetrics and Gynecology Clinics of North America", Vol.21, No.3, 1994.]

Literature review available.

BREAST IMPLANTS AND RECONSTRUCTIVE SURGERY

GYN 1.3

Includes Saline, Silicone, and Polyurethane Foam-Covered Implants.

If History of Breast Cancer; See "Breast Cancer" Guideline.

INFORMATION REQUIRED *Any history.*

Applicants Under Age 50:

- Specialist Evaluation (General Surgeon) within the past 1 year to include the following:
 - If reconstructive surgery: date of last surgery.
 - If implant: type, size, and location of implant.
 - Post surgical complications.
 - Recommendations for follow-up over the next 3 years to include need for mammography and specific views.
- Copy of *baseline* mammogram report.

Applicants Age 50 and Over; Applicants With a History of Breast Cancer:

- Specialist Evaluation (General Surgeon) within the past 1 year to include the following:
 - If reconstructive surgery: date of last surgery.
 - If implant: type, size, and location of implant.
 - Post surgical complications.
 - Recommendations for follow-up over the next 3 years to include need for mammography and specific views.
- Copy of mammogram report *within* the past 1 year.

If Applicable:

- Discharge summary of *all* related hospitalizations.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Status post implant surgery and reconstructive surgery <i>greater than</i> 6 months. 2. No post surgical complications, e.g., rupture, fibrosis, contracture.		
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • Age under 50. • No history of breast cancer. 	RN	CLEAR If annual mammogram recommended by provider. Mammogram Accommodation.
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • Age 50 and over. • No history of breast cancer. 	RN	CLEAR WITH RESTRICTION Mammogram Accommodation PCMO FOLLOW-UP Annual mammogram.
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • History of breast cancer. • Meets clearance criteria for breast cancer (See "Breast Cancer" guideline). 	RN	CLEAR WITH RESTRICTION Mammogram Accommodation PCMO FOLLOW-UP Annual mammogram.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Status post implant surgery and reconstructive surgery <i>less than</i> 6 months. 	RN	DEFER

BREAST IMPLANTS AND RECONSTRUCTIVE SURGERY

DIAGNOSTIC CODES

85.53 Unilateral Breast Implant

85.54 Bilateral Breast Implant

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- Applicants cleared to a mammography country should bring, to their country of assignment, their most recent mammogram films for comparison.

COMMENTS:

Background: "There is currently little evidence to support the notion that breast implants increase the risk of subsequent breast cancer. Although the diminished ability to mammographically visualize lesions in women with implants has been well documented, there is no conclusive evidence that the prognosis of the disease is affected. The relationship of breast implants to subsequent cancer risk should become clearer as results emerge from several ongoing follow-up studies, including one being conducted currently by the National Cancer Institute. [*Journal of the National Cancer Institute*, Vol. 89, No. 18, 1997]

Implant Rupture: Implant rupture has been shown to correlate significantly with the age of the implant. Camera, et al., showed after 1-9 years, 35.7% of implants aged 1-9 years were ruptured; after 10-17 years, 95.7% of implants had either ruptured or showed evidence of leaking silicone. Peter's et al., showed 25.6% of implants aged 2-10 years and 53.6% of implants aged 11-26 years had ruptured and 64.3% were ruptured or leaking. Robinson, et al., showed 58.1% of implants aged 1-10 years and 80.7% of implants aged 11-25 years had ruptured or were leaking. Robinson concluded that women with implants would have them removed as a prophylactic measure, preferably within 8 years of implantation, to reduce the risk for rupture or severe bleed. "The wide range of estimates of rupture and overall failure can be attributed to several factors, including differences in the patient samples and duration of follow-up after breast implantation. A study of implant rupture rates stratified by age and type of implant. For all these reasons, rupture rates previously reported to the FDA are of questionable value." Studies are currently in progress and are expected to shed further light on this issue. [*Journal of the National Cancer Institute*, Vol. 89, No. 18, 1997]

Follow-Up: Current recommendations are that implant patients have mammograms according to the same schedule as recommended for women without implants. At least four views (two compression and two displacement techniques) should be done. [*Journal of the National Cancer Institute*, Vol. 89, No. 18, 1997]

Literature review available.

FIBROCYSTIC BREAST CHANGES

GYN 1.4

Includes Atypical Hyperplasia.

For Palpable Breast Cysts; See "Breast Cyst" Guideline.

For Solid (Discrete) Breast Mass or Fibroadenoma; See "Solid Breast (Discrete) Mass" Guideline.

INFORMATION REQUIRED *Any history.*

Applicants Age 40 or Under:

- Report of Medical Examination to include the following:
 - Recommendations for follow-up over the next 3 years.
- If mammogram performed, copy of most recent mammogram report.
- If biopsy (needle or excision) performed, copy of pathology report.

Applicants Over Age 40:

- Specialist Evaluation (Gynecologist or General Surgeon) within the past 6 months to include:
 - Recommendations for follow-up over the next 3 years.
- Copy of most recent mammogram report.
- If biopsy (needle or excision) performed, copy of pathology report.

CLEARANCE CRITERIA

REVIEWER

GUIDANCE

1. No defined breast masses noted on evaluation.
2. No defined breast cysts noted on evaluation.
3. If biopsy performed, no atypical hyperplasia.
4. No history of breast cancer.

Meets clearance criteria 1-4, AND

- Provider or radiologist recommends annual breast exams, routine follow-up, or no recommendations specified.

RN

CLEAR

Does not meet clearance criteria due to one or more of the following:

- Atypical hyperplasia noted on biopsy.

RN

**CLEAR WITH
RESTRICTION**
Mammogram
Accommodation

PCMO FOLLOW-UP

Mammogram and periodic (as recommended by radiologist or provider) breast exam by a general surgeon or an experienced provider.

Does not meet clearance criteria due to one or more of the following:

- Provider or radiologist recommends follow-up other than annual breast exams or routine follow-up.

MED ADVISOR

Risk varies – assess based on detailed history.

If annual mammogram recommended;
Mammogram Accommodation.

Does not meet clearance criteria due to one or more of the following:

- Defined breast mass noted on evaluation.

RN

See "Solid (Discrete) Breast Mass" Guideline. Breast masses require surgical evaluation and specific diagnosis.

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FIBROCYSTIC BREAST CHANGES

Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Defined breast cysts noted on evaluation. 	RN	See "Breast Cyst" Guideline. Breast cysts require surgical evaluation and specific diagnosis.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • History of breast cancer. 	RN	See "Breast Cancer" Guideline.

DIAGNOSTIC CODES

610.1 Fibrocystic Breast Changes

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- Need for specialist evaluation in applicants under age 40.
- Need for mammogram in applicants under age 40.
- Applicants cleared to a mammography country should bring, to their country of assignment, their most recent mammogram films for comparison.

COMMENTS:

Fibrocystic Breast Changes: Usually a benign condition appearing in approximately 50% of pre-menopausal women. Fibrocystic disease is a gross amount of nodular fluid filled growths in the breasts. The individual growths are too small to be aspirated with a needle. The condition usually resolves with menopause. Any cysts or fibrocystic growths appearing after menopause are considered highly suspicious and must be investigated promptly. Women with proven benign fibrocystic changes are at no added risk of cancer. A women with severe fibrocystic disease (breasts that are very nodular or feel like gravel on exam) are at additional risk for cancer. These women may need physical exams every 6 months and yearly mammograms.

Atypical Hyperplasia: Atypical hyperplasia is a pathologic diagnosis and is considered a precancerous condition. Any applicant with atypical hyperplasia on biopsy should have a physical exams every 6-12 months by a physician experienced in breast exams and a yearly mammogram. These women are at increased risk (3-5%) for developing cancer.

Literature review and abstract available.