RMF BREAST CARE MANAGEMENT ALGORITHM

IMPROVING BREAST PATIENT SAFETY

Improving Breast Patient Safety

Failure to diagnose breast cancer affects CRICO-insured providers across a spectrum of specialties. To reduce the likelihood of such events, a task force of breast care specialists, coordinated by Risk Management Foundation (RMF) of the Harvard Medical Institutions, identified the key factors contributing to allegations of mismanaged breast care and subsequently developed the RMF Breast Care Management Algorithm.

The RMF Algorithm is a risk management tool designed for providers involved in the care of women's breast health at various decision points across three domains of care:

- women without known breast cancer risks,
- individuals seeking an assessment of their risk for developing breast cancer, and
- patients who present with specific breast complaint.

The RMF algorithm is designed to help providers of primary breast care appropriately use available diagnostic tools. The provider is expected to gather information such as family history, atypia on previous biopsy, thoracic radiation before age 30, and reproductive risk factors to determine if changes to normal screening, or a referral to high-risk counseling, is indicated.

Even after a referral, providers of primary breast care have an ongoing responsibility for tracking and coordinating their patients' routine breast care. In addition to being a tenet of good care, comprehensive provider follow-up is a significant safeguard against allegations of failure to diagnose breast cancer.

The RMF Breast Care Management Algorithm is a suggested guideline and should not be construed as a standard of care.

The RMF Breast Care Management Algorithm is a suggested guideline for the evaluation of a woman's breast health and the care of a patient with a breast complaint. It is intended for use by clinicians providing primary breast care. It should not be construed as a standard of care.

Questions about the RMF Algorithm should be directed to Robert Hanscom at Risk Management Foundation, 617.679.1519.

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The entire RMF Breast Care Management Algorithm, along with related information and links, is available to CRICO-insured providers on line at www.rmf.harvard.edu/bca.

The RMF Breast Care Management Algorithm

Risk Assessment and Potential Interventions

Risk Factors Checklist

Aytpia or Cancer on Previous Biopsy

- ❑ Atypical ductal hyperplasia (ADH)
- ❑ Atypical lobular hyperplasia (ALH)
- ❑ Lobular carcinoma in situ (LCIS)
- ❑ Previous history ductal carcinoma in situ (DCIS)
- ❑ Previous history of invasive breast cancer

Thoracic Radiation Before Age 30[a]

- ❑ e.g., Hodgkin's
- ❑ Infant thymus radiation
- ❑ Frequent fluoroscopy for TB
- ❑ Multiple X-rays for scoliosis

Family History

Three Generations Maternal and Paternal

- ❑ Known or suspected gene mutation
- ❑ Early age onset <40
- ❑ Bilateral breast cancer
- ❑ Breast and/or ovarian cancer
- ❑ Male breast cancer
- ❑ Ethnicity[b], e.g. Jewish ancestry with family history
- ❑ Cluster of rare tumors in a biological family

Reproductive Risk Factors[c]

- ❑ >5 years of combined estrogen/progesterone hormone replacement therapy
- ❑ Age at menarche <12
- ❑ Nulliparity
- ❑ Age at first born >30
- ❑ Age at menopause >55

Notes

a. Risk from theraputic radiation is much greater than risk from diagnostic radiation.

b. The prevalence of BRCA1 or BRCA2 mutation is about two percent in the Ashkenazi Jewish population.

c. Reproductive risk factors alone are generally insufficient to put a patient in the "high risk" category.

The RMF Breast Care Management Algorithm

Risk Assessment and Potential Interventions

Definitions of Risk	Screening Recommendations[d]		Other Options
	Clinical Breast Exam	Mammogram	
Usual Two or more reproductive risk factors (see checklist) with no family history Weak family history (i.e., two or fewer distant relatives with breast cancer, or 1st degree relative with post-menopausal breast cancer)	Annual after age 20	Annual after age 40	
Moderate – Histology Atypical ductal hyperplasia (ADH) Atypical lobular hyperplasia (ALH) Lobular carcinoma in situ (LCIS) Previous history of ductal carcinoma in situ (DCIS) Previous history of invasive breast cancer	At least once per year	Annual after diagnosis	Referral to high-risk counseling Chemoprevention Prophylactic mastectomy and/or oophorectomy
Moderate – Radiation[a] Thoracic radiation < age 30	Annual after age 20	Annual after age 40 or 10 years after radiation	
Moderate – Strong Family History Any 1st or 2nd degree relative with breast cancer < age 50 Two or more relatives with early onset breast cancer in the same lineage	At least once per year	Annual after age 40 or 5–10 years earlier than youngest affected relative, but not before age 25.	
High – Features associated with 10% or greater prior probability of carrying a BRCA1/BRCA2 mutation Personal history of breast cancer diagnosed ≤ age 40, or ovarian cancer Family history of breast cancer ≤ age 40 in 1st degree relative Family history of breast cancer ≤ age 40 in paternal 2nd degree relative Family history of breast cancer in two 1st degree relatives, at least one diagnosed ≤ age 50 Family history of ovarian cancer and breast cancer in one 1st or 2nd degree relative or in close relatives in the same lineage One or more male relatives with breast cancer	At least once per year	Annual after age 40 or 5–10 years earlier than youngest affected relative, but not before age 25.	Referral to high-risk counseling Chemoprevention Prophylactic mastectomy and/or oophorectomy
Known carrier of a BRCA1 or BRCA2 mutation, or close relative with known mutation Note: Women of Ashkenazi Jewish ancestry may be included despite fewer affected relatives or later age onset.	After age 25, at least once per year. Consider twice yearly.	Annual after age 25 or individualized based on earliest age onset in family. Preliminary data suggest that alternating MRI and mammography every six months may be helpful. Note: More Intensive screening for mutation carriers	

The **Gail Model** calculates actuarial estimates of future breast cancer risk based on race, age, reproductive risk factors, maternal family history, and previous biopsy status. The computerized version of the Gail Model is available at: http://bcra.nci.nih.gov/brc/. The Gail Model score represents the cumulative risk of developing cancer over the next five years. For values >2, consider high-risk counseling. However, the Gail Model may underestimate the risk for those with a strong family history of breast cancer. In these cases the Claus Model may provide more useful information.

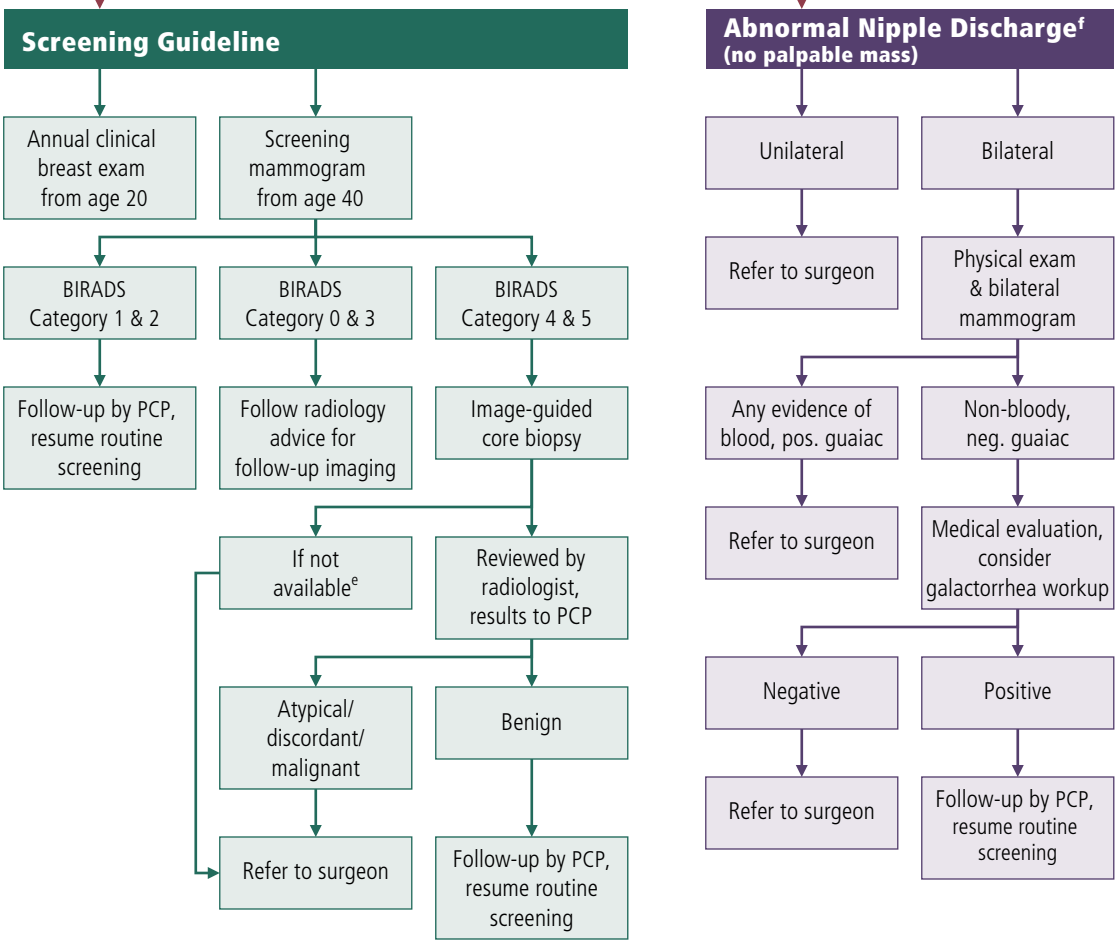
The **Claus Model** is an empiric risk model that predicts a woman's chance of developing breast cancer based on her family history. This model considers the number for affected relatives in both the maternal and paternal lineages (up to two), their relationship to the patient (whether they are first or second-degree relatives) and the age of onset of breast cancer in each relative. It does not factor in ethnic background, whether the cancer was bilateral, or a family history of ovarian cancer. All eight Claus Model tables are available at: www.rmf.harvard.edu/bca.

Notes

a. Risk from theraputic radiation is much greater than risk from diagnostic radiation.

d. Based on the NCCN guidelines (see reference list).

The RMF Breast Care Management Algorithm



Mammographic Screening

- Women 40–49 years old should be screened at least biennially. The American Cancer Society recommends these asymptomatic women have an annual screening mammogram.
- Women 50–69 years old should be screened annually.
- Women more than 70 years old should be screened bi-annually (as directed by their overall quality of life).
- In a screening mode, digital mammography is of equivalent sensitivity to screening mammogram.
- Data do not support the use of MRI and/or whole breast ultrasound as screening tools for women at usual risk.

American College of Radiology Breast Imaging Reporting and Data System (BIRADS)

0 Assessment is incomplete; additional imaging needed

1 Negative

2 Benign finding

3 Probably benign finding – short interval follow-up suggested. Probable risk of breast cancer 2%

4 Suspicious abnormality – biopsy should be considered Probable risk of breast cancer 25–30%

5 Highly suspicious of malignancy – do biopsy Probable risk of breast cancer is greater than 80%

e. Patients should be informed about their options for image-guided core biopsy.

f. Spontaneous nipple discharge other than lactating state.

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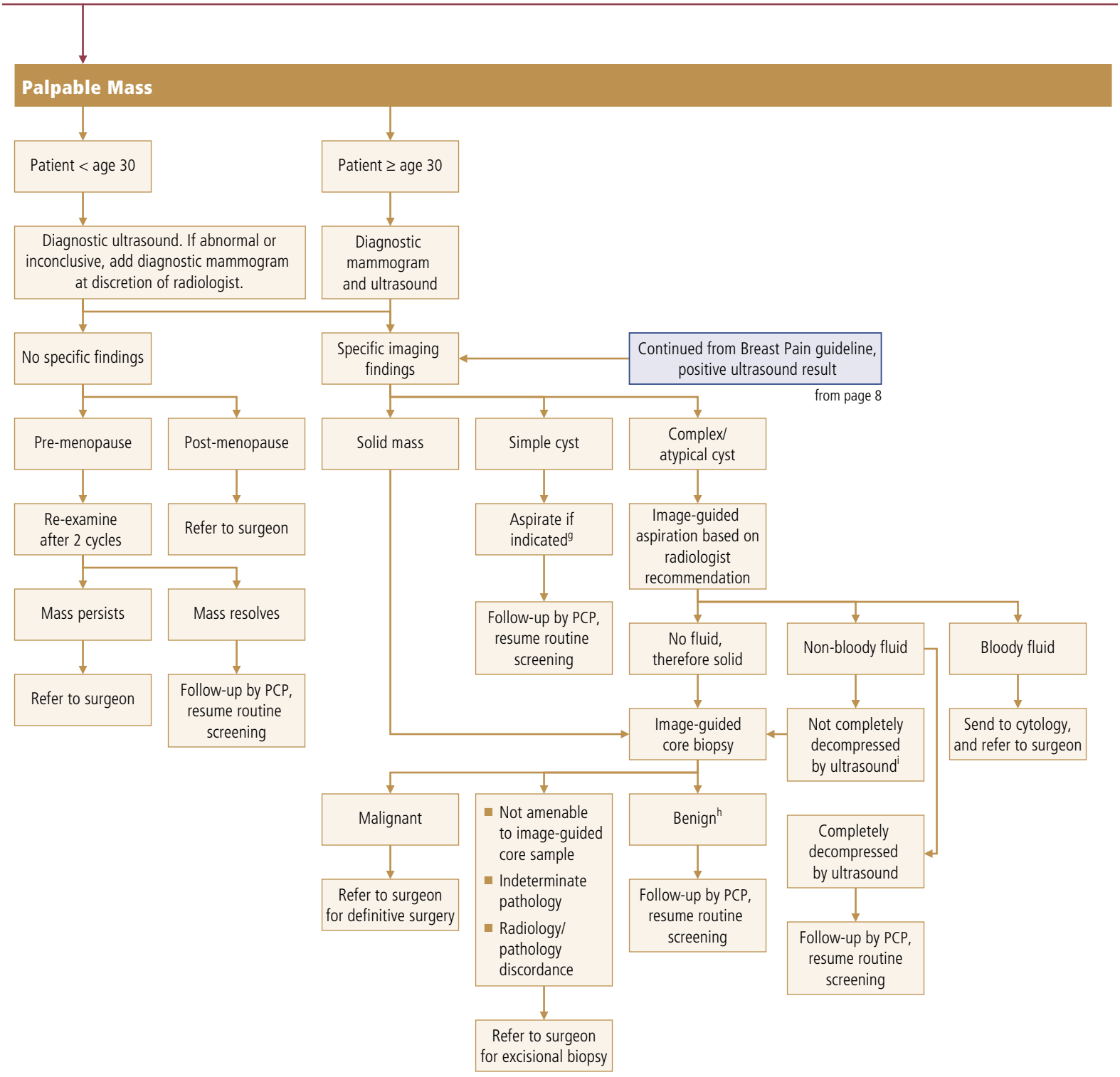

g. Uncomfortable for patient or patient requests.

h. Consider referral to surgeon for excision of mass > 2cm.

i. Image-guided core biopsy or ultrasound after two cycles at discretion of radiologist.

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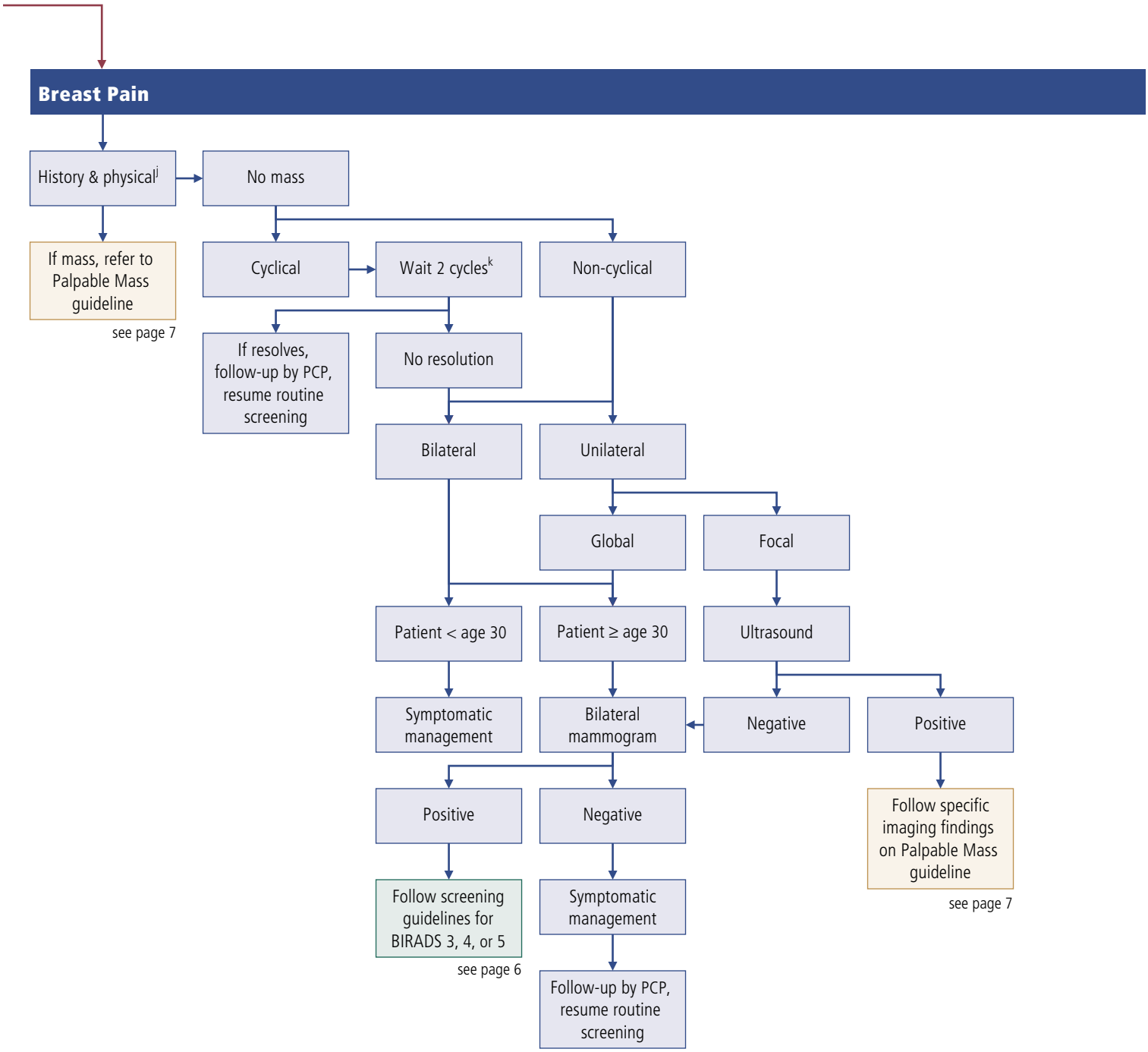

j. Differential diagnosis: chest wall pain, costochondritis, cervical radiculopathy, MI, lung disease, hiatal hernia, cholelithiasis, thoracic dissection, aortic aneurysm, post partum mastitis.

k. Cycles if premenopausal; months if postmenopausal.

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