February 25, 2014

Dear Maryland Breast and Cervical Cancer Program Provider:

Thank you for providing breast cancer screening for uninsured or underinsured women aged 40-64 enrolled in the Maryland Breast and Cervical Cancer Program (BCCP). The Maryland BCCP is a grantee of the National Breast and Cervical Cancer Early Detection Program, funded by the Centers for Disease Control and Prevention (CDC). The policies of the national program are based on evidence in scientific literature and recommendations from national organizations such as the American Cancer Society, the United States Preventive Task Force, the National Comprehensive Cancer Network and the American College of Radiology.

We are pleased to enclose the revised “Minimal Clinical Elements for Breast Cancer Detection and Diagnosis” developed by the Medical Advisory Committee for the BCCP to serve as guidelines for the screening and management of women receiving breast cancer screening through the BCCP and diagnostic services through the BCCP Expanded.

The changes include:

- Clarification of mammogram type for women with a history of breast cancer.
- Guidelines for reimbursement for immunohistochemistry (IHC) for benign breast biopsy and reimbursement rate.
- Revisions to follow-up options after any CBE result with a mammogram result = BI-RADS 4 and negative biopsy.
- Clarification of reimbursement for surgical consult or follow-up visits.
We appreciate your cooperation in using these new guidelines. If you have any questions regarding the new “Minimal Clinical Elements for Breast Cancer Detection and Diagnosis” for the Maryland Breast and Cervical Cancer Program, please contact Courtney Lewis, Director of the Center for Cancer Prevention and Control (CCPC) at (410) 767-0824 or Courtney.lewis@maryland.gov.

Sincerely,

[Signature]
Stanley Watkins, M.D.
Chairman, Medical Advisory Committee
Maryland Breast and Cervical Cancer Program

Enclosure

Cc  Courtney Lewis, M.P.H., Director, CCPC
    Dawn Henninger, R.N., M.S., Program Manager, BCCP
    Holly Harshbarger, R.N., B.S., Program Nurse Consultant, BCCP
    Local BCCP Coordinators
Goal:
The goal of the Minimal Clinical Elements for Breast Cancer Detection and Diagnosis is to provide clients of the Maryland Breast and Cervical Cancer Program (BCCP) with optimal, up-to-date screening for breast cancer and management of findings.

Objective:
- To provide clinical guidelines for breast cancer screening and diagnostic testing including interpretation and management of results of clinical breast examination, mammography, and diagnostic testing.
- To outline appropriate management and approved indications for procedure payment.

Detection and Management of Breast Abnormalities in the Breast and Cervical Cancer Program—Breast Cancer Minimal Clinical Elements

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Attachment A

Flow Charts of the Maryland Breast and Cervical Cancer Program: Management of Clinical Breast Examination and Mammogram Results

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Detection and Management of Breast Abnormalities in the Breast and Cervical Cancer Program

Breast Cancer Minimal Clinical Elements (MCE)

I. Maryland Breast and Cervical Cancer Program (BCCP)—Eligibility for Screening, Procedures for Screening or Initial Testing, and Eligibility for Expanded Diagnostic Testing

A. BCCP Eligibility and Procedures for Screening or Initial Testing
1. A woman is eligible for breast cancer screening with clinical breast examination (CBE) and mammogram in the BCCP regardless of symptoms, risk factors, or prior breast cancer/findings if she:
   a. Is 40 – 64 years old or 65+ without Medicare Part B;
   b. Meets income eligibility of household income <250% of the Federal Poverty Guideline;
   c. Has no health insurance, has health insurance that does not cover breast cancer screening, or has coverage but has not met deductible for the year; and
   d. Has not had bilateral mastectomies.
2. A woman should have a diagnostic mammogram if a woman has:
   a. A CBE with results that include:
      i. Nipple discharge that is:
         (a) Bloody;
         (b) Crystal clear (like water); or
         (c) Any other color or clarity (for example, yellow, white, milky, gray, green) if the discharge is unilateral, single duct, and spontaneous.
      ii. Discrete palpable mass—suspicious for cancer;
      iii. Nipple/areolar scaliness; or
      iv. Skin dimpling/retraction;
   b. A recommendation for a diagnostic mammogram from the Medical Case Manager.
3. A woman should have a screening mammogram as the annual exam if the woman has:
   a. A CBE with Normal findings or a CBE with Benign findings, including:
      i. Nipple discharge that does not meet the requirement for diagnostic mammogram (2., a., i., above);
      ii. Breast implant(s);
      iii. Fibrocystic changes,
      iv. Mastitis;
      v. “Lumpy” breasts;
      vi. Family history of breast cancer (premenopausal breast cancer in sister/mother); or
vii. Prior benign biopsy (within past year) when surgeon or radiologist recommends screening mammogram.

b. A history of negative screening mammogram(s) (American College of Radiology, Breast Imaging and Database Reporting System [BI-RADS] category 1, negative, or BI-RADS 2, benign finding).

4. A woman with a prior history of breast cancer (in situ or invasive, in patient who has not had bilateral mastectomies) should have a:
   a. Diagnostic mammogram for 5 years post diagnosis then;
   b. May resume screening mammogram after 5 years at the discretion of the medical case manager, radiologist and client.

5. CBE should be performed 90 days prior to the screening mammogram.
   a. Each breast should be examined including the retroareolar and peripheral areas and the upper lateral quadrant into the axilla.
   b. The preferred method of CBE is the strip technique using three levels of pressure in small circular motions with pad of three middle fingers without lubrication (MammaCare® method).

**B. Eligibility for Diagnostic Testing in the BCCP Expanded Services**

A woman is eligible for breast cancer diagnostic testing **in the BCCP Expanded Services** if she:

1. Is 40 – 64 years old, or 65+ without Medicare Part B;
2. Meets income eligibility of <250% of the Federal Poverty Guideline;
3. Has no health insurance, has health insurance that does not cover breast cancer diagnostic testing/visits, or has coverage but has not met deductible for the year;
4. Has not had bilateral mastectomies; and
5. Provides the BCCP with a recommendation from a clinician for diagnostic workup and test results of:
   a. CBE requiring further diagnosis (see I. A. 2. a.);
   b. Mammogram requiring further diagnosis;
   c. Ultrasound abnormal finding other than simple cyst(s); or
   d. Persistent, unexplained, localized pain in the breast with a negative mammogram.
II. Findings, Management of Results, Additional Procedures, and Program Coverage

A. Results and Reports

1. CBE findings:
   a. Should be reported as:
      i. Normal exam
      ii. Benign findings
      iii. Abnormal findings:
         1. Nipple discharge that is bloody, crystal clear (like water) or any other color or clarity (for example, yellow, white, milky, gray, green) if the discharge is unilateral, single duct, and spontaneous.
         2. Discrete palpable mass—suspicious for cancer
         3. Nipple/areolar scaliness
         4. Skin dimpling/retraction
   
   b. CBE should report whether there are breast implants; however, this finding would be categorized as a “Benign finding” if no other abnormalities were found.
   
   c. CBE should report whether the patient has had a lumpectomy or a mastectomy and which breast was affected; however, this finding would be categorized as a “Benign finding” if no other abnormalities were found.

2. Mammogram findings should be reported using American College of Radiology BI-RADS® (Breast Imaging-Reporting and Database System) Assessment Categories:
   
   a. Assessment is Incomplete
      0 Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison
   
   b. Assessment is Complete – Final Categories
      1 Negative
      2 Benign Finding(s)
      3 Probably Benign Finding – Initial Short-Interval Follow-Up Suggested
      4 Suspicious Abnormality – Biopsy Should Be Considered
      5 Highly Suggestive of Malignancy – Appropriate Action Should Be Taken
      6 Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken
         (Category reserved for lesions identified on imaging study with biopsy proof of malignancy prior to definitive therapy)

   Ref. The American College of Radiology BI-RADS® ATLAS and MQSA: Frequently Asked Questions (Updated: 7/1/09)

   c. Breast composition on mammogram should be described for all patients using the following patterns:
      i. The breast is almost entirely fat (<25% glandular)
      ii. There are scattered fibroglandular densities (approximately 25-50% glandular)
      iii. The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51-75% glandular)
iv. The breast tissue is extremely dense. This may lower the sensitivity of mammography (>75% glandular).

Ref. 2003 ACR® BI-RADS Atlas

3. **Ultrasound definitions:** The terms “simple cyst,” “complicated cyst,” and “complex cyst” are defined by the radiologist and stated in the report of an ultrasound examination.

4. The radiologist’s diagnostic workup/evaluation report should include the results of the diagnostic mammogram, ultrasound (when performed), CBE, and the correlation of each test with each other.

**B. Management of Findings of CBE, Initial Mammogram, and Testing**

1. **See Attachment A.** Flow Charts of the Maryland Breast and Cervical Cancer Program: Management of Clinical Breast Examination and Mammogram Results.

2. A woman with persistent, unexplained, localized pain in the breast should be evaluated by a breast specialist or surgeon.

3. If a radiologist recommends obtaining results or copies of prior mammograms following a BI-RADS category 0 result, local programs should assist in obtaining the results or copies.

4. Image-guided percutaneous needle biopsy is the diagnostic procedure of choice for image-detected abnormalities, with few exceptions.

5. When a non-palpable or questionably palpable mass that was found on imaging is excised, the specimen should be verified by using the appropriate imaging modality while the patient is still in the operating room.

6. At least one breast tissue specimen positive for cancer should be tested for tumor markers (e.g. estrogen/progesterone receptors, her2neu etc.) to guide clinical management.

**C. Additional Procedures and Program Coverage**

1. Providers should consult with the local BCCP for questions about coverage for payment of procedures.

2. Magnetic Resonance Imaging (MRI)
   a. The DHMH BCCP **will not reimburse** for MRI for breast cancer **screening**.

   b. If recommended by the managing physician, the BCCP **will reimburse** for a MRI of the breast for:
      i. Extent of disease in the ipsilateral breast in patients with a recent diagnosis of breast cancer;
ii. Screening of the contralateral breast in women with a current, newly diagnosed, unilateral breast cancer;
iii. Evaluation of patients undergoing current neoadjuvant chemotherapy for breast cancer;
iv. Positive margins after surgery for breast malignancy; or
v. Chest wall invasion suspected.

c. The BCCP will not reimburse for MRI of the breast for:
i. Surveillance of breast findings (for example, the program will not reimburse for MRI follow-up every 3-6 months for a surgical consult of “benign findings”);
ii. Problem solving for inconclusive clinical or mammographic findings; or
iii. Evaluation of silicone breast implant integrity.

3. The BCCP will reimburse for a surgical or breast specialist consultation for a woman who has a negative mammogram but who has persistent, unexplained, localized pain in the breast.

4. BCCP funds surgical consults or follow-up visits intended to confirm or rule out breast cancer when screening tests yield abnormal results. BCCP will:
a. Reimburse a maximum of two consults or visits to the same breast surgeon for the same breast problem (initial consultation plus a follow-up consultation).
b. Reimburse follow-up of post-operative/post-biopsy complications of infection, hematoma, etc., following a BCCP-funded biopsy.
c. Consider reimbursement on a case-by-case basis for follow-up surgical visits where the surgical pathology may be associated with recurrence or the presence of a more severe abnormality in the breast (e.g. certain types of atypia, phyllodes tumors) and the surgeon recommends short-term follow-up (every 3-6 months) for a maximum of 12 months.
d. Not reimburse for on-going surveillance for those cases in which the medical case manager or surgeon recommends frequent follow-up visits for surveillance based on a benign breast condition that is considered chronic and or based on a woman’s risk factors.

5. The BCCP will reimburse for immunohistochemical (IHC) stains as indicated below:
a. When cancer is diagnosed on the biopsy: the BCCP will reimburse for IHC stains ordered by the clinician or pathologist.
b. When cancer is suspected or needs to be ruled out: IHC should not be used reflexively to evaluate every breast biopsy. IHC is best used when ordered by the pathologist where IHC will clarify an ambiguous pathologic diagnosis. The most frequent use of this is where the pathologist wants to know whether an adenoma or papilloma harbors invasive disease, or whether the tumor is ductal or lobular. The BCCP will reimburse in these cases but may request more information to justify the use of IHC.
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Attachment A

Flow Charts
of the Maryland Breast and Cervical Cancer Program:

Management of Clinical Breast Examination and
Mammogram Results

I. Management when Clinical Breast Examination is
   Normal/Benign Findings

II. Management when Clinical Breast Examination is
    Abnormal
Management of Clinical Breast Exam and Mammogram Results:

**Clinical Breast Examination: Normal or Benign Findings**

Women who:
- are asymptomatic; and
- have implant(s), fibrocystic changes, mastitis, "lumpy" breasts, family history of breast cancer (premenopausal breast cancer in sister/mother), prior benign biopsy (within past year) when surgeon or radiologist recommends screening mammogram.

Women who have:
- a prior history of breast cancer should have a diagnostic mammogram for 5 years post diagnosis then at the discretion of the medical case manager, radiologist and client; or
- Medical Case Manager recommendation for Diagnostic Mammogram

- **Screening mammogram**
- **Diagnostic mammogram**

**Mammogram Results**

**BI-RADS 0:**
Needs additional imaging evaluation

Follow up per radiologist:
- Diagnostic work-up (spot compression, magnification, special views, ultrasound, aspiration...)

Follow-up based on revised BI-RADS category

See Bi-RADS 1, 2 or See Bi-RADS 3 or See Bi-RADS 4 or 5 above.

**BI-RADS 1:**
Negative Finding

Annual follow-up:
CBE with screening mammogram (if asymptomatic)

**BI-RADS 2:**
Benign Finding

Follow up per radiologist:
(usually 6 month repeat imaging)

Refer to surgeon or breast specialist

**BI-RADS 3:**
Probably benign--short interval follow-up suggested

Radiologist communicates findings to the patient, the referring physician

**BI-RADS 4:**
Suspicious Abnormality – Biopsy Should Be Considered

BI-RADS 5: Highly Suggestive of Malignancy – Appropriate Action Should Be Taken

**BI-RADS 5:**
AND Negative biopsy (that is, biopsy is not cancer, LCIS or atypical ductal hyperplasia)

CBE, pathology and imaging results are concordant:
- Refer to surgeon or breast specialist.

And
- Offer referral to surgeon or breast specialist.

Management and Treatment of Cancer
Surgeon stages and initially manages breast cancer;
- Stage 0 must be offered oncologist consult
- Stage 1-4 must see oncologist

Positive biopsy (invasive cancer or DCIS+)

BI-RADS 4 or 5 with:
Negative biopsy OR
biopsy that is LCIS or atypical ductal hyperplasia

Further follow-up per surgeon*

Positive biopsy (invasive cancer or DCIS)

Surgeon performs biopsy

Further follow-up per surgeon*

Cancer (invasive or DCIS) on prior image-guided biopsy; surgeon performs no additional biopsy

No cancer on image-guided biopsy; and Surgeon does NOT perform biopsy

BI-RADS 4 or 5 with biopsy that is LCIS or atypical ductal hyperplasia

BI-RADS 5 and Negative biopsy OR

Refer to surgeon or breast specialist.

CBE, pathology and imaging results are discordant:
- Refer to surgeon or breast specialist.

Further follow-up per surgeon*

DCIS: Ductal carcinoma in situ

LCIS: Lobular carcinoma in situ

*Please refer to The Minimal Clinical Elements for Breast Cancer Detection and Diagnosis, Section II, C, number 4 page 7 for further details and program coverage.
Management of Clinical Breast Exam and Mammogram Results:

Clinical Breast Examination: Abnormal (other than Normal or Benign Finding) **

Diagnostic mammogram (always); with Ultrasound, if recommended

CBE, Mammogram, and Ultrasound Results

BI-RADS 0: Needs additional imaging evaluation
- Follow up per radiologist:
  - Diagnostic work-up (spot compression, magnification, special views, ultrasound, aspiration…)
- Follow-up based on revised BI-RADS category
  - See BI-RADS 1, 2 or 3 or See BI-RADS 4 or 5 above

BI-RADS 1: Negative BI-RADS 2: Benign Finding
- Annual follow-up: CBE with screening mammogram (if asymptomatic)
- Refer to surgeon or breast specialist

BI-RADS 3: Probably benign—short interval follow-up suggested
- Follow up per radiologist (usually 6 month repeat imaging)
- Positive biopsy (invasive cancer or DCIS+)
- Surgically performs biopsy
- Management and Treatment of Cancer
  - Surgeon stages and initially manages breast cancer;
  - Stage 0 must be offered oncologist consult
  - Stage 1-4 must see oncologist

BI-RADS 1, 2, or 3, and
- Non-cystic palpable mass;
- Nipple discharge that is bloody, crystal clear, or any color if unilateral, single duct, and spontaneous;
- Nipple/areolar scaliness, or
- Skin dimpling/retraction

No aspiration of cyst
- Cancer (invasive or DCIS) on prior image-guided biopsy;
  - surgeon does not perform additional biopsy
- Surgeon performs biopsy
- Further follow-up per surgeon*

Aspirate cyst
- Positive biopsy (invasive cancer or DCIS+)

Clear fluid
- Negative biopsy OR
- Biopsy that is LCIS or atypical ductal hyperplasia

Bloody fluid
- Negative biopsy OR
- Biopsy that is LCIS or atypical ductal hyperplasia

BI-RADS 4 AND Negative biopsy (that is, biopsy is not cancer, LCIS or atypical ductal hyperplasia)

BI-RADS 5: and Negative biopsy
- Radiologist and primary care provider recommend next steps;
- Offer referral to surgeon or breast specialist.

CBE, pathology and imaging results are discordant:
- Refer to surgeon or breast specialist.

CBE, pathology and imaging results are concordant:
- Surgeon performs biopsy
- Further follow-up per surgeon*

** "Abnormal Clinical Breast Exam" includes:
- Nipple discharge that is bloody, crystal clear, or of any color if unilateral, single duct, and spontaneous;
- Discrete palpable mass—suspicious for cancer
- Nipple/areolar scaliness
- Skin dimpling/retraction

Management and Treatment of Cancer
- Surgeon stages and initially manages breast cancer;
- Stage 0 must be offered oncologist consult
- Stage 1-4 must see oncologist

DCIS: Ductal carcinoma in situ
LCIS: Lobular carcinoma in situ

** Please refer to The Minimal Clinical Elements for Breast Cancer Detection and Diagnosis, Section II, C, number 4 page 7 for further details and program coverage.

* Please refer to The Minimal Clinical Elements for Breast Cancer Detection and Diagnosis, Section II, C, number 4 page 7 for further details and program coverage.