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I. INTRODUCTION

This protocol has been developed for use in the Michigan Breast and Cervical Cancer Control Navigation Program (BCCCNP) and addresses the provision of services related ONLY to breast and cervical cancer screening and follow-up care.

BCCCNP coordinating agencies (or subcontractors), which have the ability and willingness to screen for and manage other health problems (e.g. STD testing) may, at their own discretion, do so at the time of the woman's visit to the BCCCNP.

However, BCCCNP funds cannot be used for the time and materials needed to assess and manage problems unrelated to breast or cervical cancer. The protocol for assessment and management of other health problems should be developed by the BCCCNP coordinating agency and added to this core protocol for individual agency use.

The Michigan Cancer Consortium’s (MCC) Breast Cancer Advisory Committee (BCAC) and the Cervical Cancer Advisory Committee (CCAC) promote the use of national breast and cervical cancer screening and follow-up recommendations as part of the BCCCNP Medical Protocol.

The breast clinical protocol is based upon screening guidelines developed by the American Cancer Society (ACS), the US Preventative Services Task Force (USPSTF), and the National Comprehensive Cancer Network (NCCN) Breast Cancer Screening and Diagnosis Guidelines (V.1. 2014). For follow-up of abnormal clinical breast exam (CBE) and/or mammogram results, the BCAC promotes the use of the NCCN Clinical Practice Guidelines Breast Cancer Screening and Diagnosis Guidelines (V.1. 2014).

The cervical clinical protocol is based upon screening guidelines developed by the ACS, the USPSTF, and the American Society for Colposcopy and Clinical Pathology (ASCCP) (2012). For follow-up of abnormal Pap test results, the CCAC promotes the use of the ASCCP 2012 Updated Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors. Guidelines are referenced in this document and may be found at http://www.asccp.org.
II. BCCCNP AGE CRITERIA FOR RECEIVING SCREENING AND/OR DIAGNOSTIC SERVICES

A. The BCCCNP provides breast and cervical cancer screening services and specific diagnostic services to women who meet the following age criteria:

- Age 40-64: eligible to receive both breast/cervical cancer screening and/or diagnostic follow-up of breast/cervical cancer screening abnormalities.

- Women age 40-64 who meet BCCCNP eligibility criteria, but receive breast or cervical cancer screening services from a non-BCCCNP provider, may be referred to the program to receive appropriate diagnostic follow-up care for the identified breast or cervical abnormality.

- Women who have insurance which paid for the breast and/or cervical cancer screening service, but does not pay for indicated follow-up diagnostic testing, may be referred to BCCCNP to pay for indicated follow-up testing.

- Age 21-45: referred to BCCCNP for diagnostic follow-up of a cervical cancer screening abnormality.

- Women 25 - 39 years of age identified with any of the following abnormal clinical breast exams may be eligible to enroll in BCCCNP for breast diagnostic procedures. This includes clinician identification of:
  - Palpable, Dominant Mass
  - Unilateral, spontaneous, nipple discharge that is clear or colorless, serous, sanguineous, or serosanguineous
  - Asymmetric thickening/nodularity

PRE APPROVAL BY MDHHS NURSE CONSULTANT MUST BE OBTAINED PRIOR TO ENROLLING THE WOMAN IN BCCCNP. SEE APPENDIX F FOR GUIDELINES AND PROCEDURE FOR ENROLLMENT.

NOTE:
* Women age 65 and over are eligible for the program if they meet the BCCCNP income criteria and are ineligible for Medicare, or have not purchased Medicare Part B
* Women who are pregnant (regardless of age) are not eligible for participation in the BCCCNP. Care in the program may commence or resume once client is no longer pregnant.
B. BCCCNP Services Provided to Eligible Clients

The BCCCNP provides screening and/or diagnostic services to confirm or rule-out breast or cervical cancer ONLY.

1. Screening Services Provided by the BCCCNP
   a. Definition: Screening is the attempt to detect unsuspected disease in average risk, asymptomatic women.
   b. Breast cancer screening: annual clinical breast exam (CBE) and Screening Mammogram
   c. Cervical cancer screening services: annual Pelvic Exam, Pap test (for eligible women only, see Table 3)

2. Diagnostic Services Provided by the BCCCNP
   BCCCNP women identified with abnormal breast and/or cervical cancer screening results are referred for appropriate diagnostic follow-up procedures to confirm or rule out a cancer diagnosis. BCCCNP UNIT COST REIMBURSEMENT RATE SCHEDULE.

3. Cancer Treatment
   The BCCCNP cannot pay for cancer treatment. In the event a breast or cervical cancer is diagnosed, all BCCCNP enrolled women are assisted in obtaining necessary breast or cervical cancer-related treatment in a timely manner. Refer to MTA Enrollment policy
III. BREAST AND CERVICAL CANCER SCREENING RECOMMENDATIONS

A. Annual Screening Test Recommendations

Table 1  Breast Cancer Screening Recommendations for AVERAGE Risk Women

<table>
<thead>
<tr>
<th>Agency</th>
<th>Age to Begin</th>
<th>Interval</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCCN (2016)</td>
<td>40</td>
<td>Annually</td>
<td>Yearly exams should continue for as long as a woman is in good health and life expectancy &gt; 10 years</td>
</tr>
<tr>
<td>ACS (2015) 2</td>
<td>40-54</td>
<td>Annually (S)*</td>
<td>Yearly exams should continue for as long as a woman is in good health and life expectancy &gt; 10 years</td>
</tr>
<tr>
<td></td>
<td>40-44</td>
<td>Annually (Q)*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 55</td>
<td>Biannual or Annual (Q)*</td>
<td></td>
</tr>
<tr>
<td>USPSTF (2016) 3</td>
<td>50-74</td>
<td>Biennial</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≤ 50</td>
<td>Personal decision when to start and how often</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 75</td>
<td>Insufficient evidence – No recommendation</td>
<td></td>
</tr>
</tbody>
</table>

Clinical Screening for Breast Cancer:

A. Clinical encounter (Includes ongoing risk assessment/risk reduction counseling and Clinical Breast Exam): Adequate clinical breast exams include the following: upright and supine position during inspection, and palpation of all components of the breast, axilla, and clavicular lymph node basins. Time spent on the palpable portion of the exam is associated with increased detection of palpable abnormalities.

1. NCCN:
   - Age: 25-39: Clinical Breast Exam every 1-3 years
   - Age: ≥ 40: Clinical Breast Exam annually

2. ACS:
   - Clinical Breast Exam not recommended (Q)

3. USPSTF:
   - Clinical Breast Exam – insufficient evidence Not recommended (Q)
B. Additional Information*
1. All recommending societies recognize the benefit of regular mammography screening for breast cancer.
2. All women should be familiar with the known benefits, limitations, and potential harms associated with breast cancer screening.
3. Breast Awareness: Women should be familiar with how their breasts normally look and feel and report any changes to a health care provider right away.

Cervical Cancer Screening:

- Pap test (may or may not be performed according to eligibility guidelines in Table 3)
- Speculum (Pelvic) exam - should be part of annual office visit

**NOTE:**
- BCCNP funds can only reimburse for SCREENING Pap tests according to the guidelines in Table 2.
- These guidelines DO NOT apply to women requiring Pap tests as follow-up for an abnormal Pap test result, women with a history of invasive cervical cancer or other “Special Considerations” (Table 3).

Table 2 – Recommendations for Cervical Cancer Screening

<table>
<thead>
<tr>
<th>Age to Begin</th>
<th>Screening Exam</th>
<th>Screening Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 30-65</td>
<td>HPV and cytology “co-testing” (preferred)</td>
<td>Every 5 years OR</td>
</tr>
<tr>
<td>Age 30-65</td>
<td>Conventional Pap Test (slide) or Liquid-Based Cytology (LBC) (acceptable)</td>
<td>Pap Test alone every 3 years</td>
</tr>
</tbody>
</table>

B. Upper Age Limit for Screening:

1. Women aged older than 65 years with evidence of adequate negative prior screening* and NO history of CIN2+ within the last 20 years should not be screened for cervical cancer with any modality

* Adequate negative prior screening is defined as 3 consecutive negative cytology results or 2 consecutive negative co-tests within the 10 years before ceasing screening, with the most recent test occurring within the past 5 years.

2. A Pap test or Pap/HPV co-test is encouraged if no adequate history can be obtained
3. Once screening is discontinued, it should not be started for any reason, even if a woman reports having a new sexual partner.

C. Provision of Screening and Diagnostic Services to Special Populations in the B CCCNP (FP/B CCCNP Joint Project)

The following populations are eligible to participate in the B CCCNP as long as they meet the program’s income requirements

1. Women ≤ age 39 seen in any Family Planning/Title X clinics who have an abnormal Pap test result requiring immediate follow-up, can be referred to B CCCNP for diagnostic services to confirm or rule-out a cervical cancer diagnosis. See Appendix F; eligibility criteria for women age 25-39 identified with an abnormal CBE through Family Planning/Title X clinics requiring diagnostic follow-up.

2. Women age 40-64 seen in a Family Planning/Title X Clinics for cervical services may be referred to B CCCNP for breast screening and diagnostic services (if needed and as caseload is available); otherwise, follow-up diagnostic testing may be provided through the FP/B CCCNP Joint Project.

D. Special Considerations: Breast Cancer Screening Transgender women (male to female)

1. Transgender women (male-to-female) who have taken or are taking hormones and meet all program eligibility requirements, are eligible to receive breast cancer screening and diagnostic services through the B CCCNP. Screening and diagnostic services (if needed) will be reimbursed by the program.

2. Although there are limited data regarding the risk for breast cancer among transgender women, evidence has shown that long term hormone use does increase the risk for breast cancer among women whose biological sex was female at birth.

3. While CDC does not make any recommendation about routine screening among this population, transgender women are thus eligible under federal law to receive appropriate cancer screening.

4. CDC recommends that grantees and providers counsel all eligible women, including transgender women, about the benefits and harms of screening and discuss individual risk factors to determine if screening is medically indicated.

E. Special Considerations: Cervical Cancer Screening for Transgender men (female to male)

1. Transgender men (female-to-male) who still have a cervix should receive cervical cancer screening per protocol for initiation, cessation, and frequency of screening.

2. Transgender men (female-to-male), whether or not they still have breasts, should have
a CBE. If breast tissue is present, screening mammogram should be considered.

F. Screening Immunocompromised Women

**NOTE:** Changes in the 2012 cervical screening guidelines are for the general population and do not address women who are immunocompromised

1. Immunocompromised women are defined as those who have been exposed to DES, are transplant recipients or have been infected with the human immunodeficiency virus (HIV).
2. Women who had in utero DES exposure or are transplant recipients—continue ANNUAL cervical cancer screening (Pap test only) regardless of the testing method.
3. Women diagnosed with HIV
   - Pap screening should be begin for females who have initiated sexual activity regardless of age or at age 21 for women who have not initiated sexual activity.
   - The Pap test should be obtained twice during the first year after diagnosis of HIV infection.
   - After determining that baseline cervical screening results show no atypical cells or neoplasia, the Pap test should be repeated annually.

4. **NOTE:**
   - There are no data to support the use of HPV- testing for HIV- seropositive women >30 years to increase or decrease the frequency of Pap tests from 1 year intervals for women with normal cervical cytology.
   - Published data is insufficient to support use of HPV DNA testing in triage of ASC-US among HIV- seropositive women resulting in a recommendation to perform colposcopy for HIV- seropositive women with ASC-US.
   - Routine screening of HIV- seropositive women with vaginal cytology after hysterectomy for benign disease is not recommended.
   - An upper age limit on Pap cervical screening has not been established for HIV-seropositive women.
   - For follow-up, immunosuppressed women with abnormal cytology results should be managed in the same way as immunocompetent women.

5. Per the ASCCP guidelines (follow-up of abnormal Pap test results) adolescents and pregnant women are also given special consideration. See guidelines for details at [http://www.asccp.org/](http://www.asccp.org/).
   - Endocervical curettage is unacceptable in pregnant women
   - Colposcopy may be deferred until the postpartum examination
   - During pregnancy, invasive cervical cancer is the only indication for treatment
   - Guidelines for women aged 21-24 years can be extrapolated to adolescents inadvertently screened.
Table 3 – Special Considerations for Performing Pap Tests

<table>
<thead>
<tr>
<th>Pap Test Special Consideration</th>
<th>Follow-up</th>
<th>Recommendation</th>
<th>BCCCNP Test Reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORMAL Pap test</td>
<td>Immediate (within 90 days)</td>
<td>To rule out cervical cancer: perform Pap test. Consider referral for colposcopy. (Approval by MDHHS Nurse Consultant required)</td>
<td>Pap Test</td>
</tr>
<tr>
<td>ABNORMAL pelvic examination (abnormal appearance of cervix indicating possible cervical cancer)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfactory Pap test but NO endocervical cells</td>
<td>No Follow-up</td>
<td>Pap is considered negative/normal; continue with routine screening (every 3 years for Pap test alone; 5 years for negative Pap test/HPV co-test; yearly for negative Pap test/Positive HPV co-test</td>
<td>Pap in 3 years Pap/HPV in 5 years or Pap/HPV in 3 years</td>
</tr>
<tr>
<td>Satisfactory Pap but obscured/ partially obscured by inflammation</td>
<td>Short-term Follow-up</td>
<td>Repeat the Pap Test in 6 months. If 2nd Pap test is interpreted as obscured, partially obscured or otherwise abnormal: refer for colposcopy</td>
<td>6 month follow-up Pap Colposcopy (if indicated)</td>
</tr>
<tr>
<td>Unsatisfactory Pap test result</td>
<td>Short-term Follow-up</td>
<td>Repeat Pap test in 2-4 months. If 2nd Pap unsatisfactory or abnormal, refer for colposcopy.</td>
<td>Repeat Pap test Colposcopy (if indicated)</td>
</tr>
<tr>
<td>Hysterectomy for invasive cervical cancer (CERVIX PRESENT OR NOT)</td>
<td>Annual Screening</td>
<td>Continue ANNUAL cervical cancer screening (indefinitely) regardless of type of Pap test</td>
<td>Annual Pap test</td>
</tr>
</tbody>
</table>
# Breast and Cervical Cancer Control Navigation Program

## Medical Protocol

**Effective December 1, 2016**

<table>
<thead>
<tr>
<th>Pap Test Special Consideration</th>
<th>Follow-up</th>
<th>Recommendation</th>
<th>BCCCNP Test Reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysterectomy for cancer OTHER than cervical (E.g. endometrial, ovarian)</td>
<td>No Pap test indicated.</td>
<td>Pelvic exam indicated Screening with vaginal cytology is NOT indicated; this does not preclude a pelvic exam.</td>
<td>Pelvic exam</td>
</tr>
<tr>
<td>Confirmed biopsy diagnosis of CIN 2 or greater, after follow-up surveillance completed</td>
<td>Regular Screening* x 20 years</td>
<td>Regular screening* is defined as a Pap test every 3 years or Pap/HPV co-test every 5 years (Table 3)</td>
<td>Pap test every 3 years or Pap/HPV co-test every 5 years</td>
</tr>
<tr>
<td>NOTE: In these women screening for cervical cancer past age 65 may be indicated.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunocompromised (e.g., transplant recipient) or DES-exposed woman</td>
<td>Annual Screening</td>
<td>ANNUAL Pap tests regardless of type of Pap test</td>
<td>Annual Pap test</td>
</tr>
<tr>
<td>Immunocompromised (HIV+) woman</td>
<td>Twice in first year after diagnosis (every 6 months) then annual screening</td>
<td>ANNUAL Pap tests (only) regardless of type of Pap test. No Pap with HPV co-testing.</td>
<td>Bi-annual x 1 year, then annual Pap test</td>
</tr>
<tr>
<td>Immunocompromised (HIV+) woman</td>
<td>ASC-US Pap</td>
<td>Do not perform reflex HPV test; refer for colposcopy regardless of HPV test result</td>
<td>Pap test and colposcopy</td>
</tr>
</tbody>
</table>
I. Recommendations for Breast Cancer Screening with Mammography

Women at Average Risk for Breast Cancer

<table>
<thead>
<tr>
<th>Agency</th>
<th>Age to Begin</th>
<th>Interval</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NCCN (2016)</strong></td>
<td>&lt;40</td>
<td>Annually</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 40</td>
<td>Annually (S)*</td>
<td></td>
</tr>
<tr>
<td><strong>ACS (2015)</strong></td>
<td>45-49</td>
<td>Annually (Q)*</td>
<td></td>
</tr>
<tr>
<td>(S) Strong</td>
<td>≥ 55</td>
<td>Biennial or Annual (Q)*</td>
<td>Yearly exams should continue for as long as a woman is in good health and life expectancy ≥ 10 years</td>
</tr>
<tr>
<td>recommendation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>USPSTF (2016)</strong></td>
<td>50-74</td>
<td>Biennial</td>
<td></td>
</tr>
<tr>
<td></td>
<td>40-49</td>
<td>Shared decision when to start</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 75</td>
<td>Insufficient evidence – No recommendation</td>
<td></td>
</tr>
</tbody>
</table>

II. Clinical Screening for Breast Cancer:

A. Clinical encounter (includes ongoing risk assessment/risk reduction counseling and Clinical Breast Exam – components of adequate CBE below [Addendum 1]):

1. NCCN:
   - Age: 25-39: Clinical Breast Exam every 1-3 years
   - Age: ≥ 40: Clinical Breast Exam annually

2. ACS:
BREAST AND CERVICAL CANCER CONTROL NAVIGATION PROGRAM

MEDICAL PROTOCOL

Effective December 1, 2016

- Clinical Breast Exam not recommended (Q)

3. USPSTF:
   - Clinical Breast Exam – insufficient evidence: Not recommended

B. Breast Awareness: Women should be familiar with how their breasts normally look and feel and report any changes to a health care provider right away.

III. Additional Information

- 1. All recommending societies recognize the benefit of regular mammography screening for breast cancer.
- 2. All women should be familiar with the known benefits, limitations, and potential harms associated with screening and of not screening for breast cancer.

*ACS: Interpretation of Strong and Qualified Recommendations: 2

Strong (S): Most individuals in this situation would want the recommended course of action, and only a small proportion would not.

Qualified (Q): The majority of individuals in this situation would want the suggested course of action, but many would not. Patient preferences and informed decision making are desirable for making decisions.
II. Recommendations for Breast Cancer Screening – **Increased Risk for Breast Cancer (NCCN)** \(^1,^4\)

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Screening Exam</th>
<th>Interval</th>
<th>Age to Begin</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known Genetic predisposition (i.e. BRCA1/2) or pedigree suggestive of predisposition including Hereditary Breast and Ovarian Cancer Syndrome and untested 1st degree relative of BRCA case.</td>
<td>CBE</td>
<td>6-12 months</td>
<td>Age 25</td>
<td>Referral to genetic counselor * See Additional Information IIB Consider Risk Reduction Strategies (See NCCN Breast Cancer Risk Reduction Guidelines)</td>
</tr>
<tr>
<td></td>
<td>Mammogram</td>
<td>Annual</td>
<td>&gt; age 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MRI</td>
<td>Annual</td>
<td>Age 25</td>
<td></td>
</tr>
<tr>
<td>High Breast Cancer Risk (&gt; 20% lifetime risk) (^1,^2) Per models largely based on family history</td>
<td>CBE</td>
<td>6-12 months</td>
<td>The age risk is identified</td>
<td>* See Additional Information IIB Consider referral to genetic counselor Consider Risk Reduction Strategies (See NCCN Breast Cancer Risk Reduction Guidelines)</td>
</tr>
<tr>
<td></td>
<td>Mammogram</td>
<td>Annual</td>
<td>Age &gt; 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MRI</td>
<td>Annual</td>
<td>Age &gt; 30</td>
<td></td>
</tr>
<tr>
<td>Prior thoracic radiation therapy between ages of 10-30</td>
<td>CBE</td>
<td>6-12 months</td>
<td>Begin 8-10 years after Radiation Therapy or age 40, whichever occurs first.</td>
<td>* See Additional Information IIB</td>
</tr>
<tr>
<td></td>
<td>Mammogram</td>
<td>Annual</td>
<td>As above, no earlier than age 25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MRI</td>
<td>Annual</td>
<td>As above, no earlier than age 25</td>
<td></td>
</tr>
<tr>
<td>Personal History of Breast Cancer (^2)</td>
<td>CBE</td>
<td>6-12 months</td>
<td>Post Diagnosis</td>
<td>* See Additional Information IIB See NCCN Breast Cancer Guidelines- Surveillance Section</td>
</tr>
<tr>
<td></td>
<td>Mammogram</td>
<td>Annual</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Risk Factor | Screening Exam | Interval | Age to Begin | Additional Information
--- | --- | --- | --- | ---
Moderate Breast Cancer Risk (15% - 20% lifetime risk)\(^1\) | CBE | 6-12 months | Age risk is identified | * See Additional Information IIB
Mammogram | Annual | | |
Personal history of atypical hyperplasia or Lobular Carcinoma In Situ (LCIS)\(^2\) | CBE | 6-12 months | Post diagnosis | * See Additional Information IIB
Mammogram | Annual | | |
MRI (consider) | Annual | | |
If also >20% lifetime risk with LCIS or atypical hyperplasia | | | |
Women >\(=\) 35 with 5-year risk of invasive breast cancer >\(=\) 1.7%\(^2\) (Per Gail model) | CBE | 6-12 months | >35 | * See Additional Information IIB
Mammogram | Annual | | |
Addendum 1: Mammography Screening Considerations (NCCN)

- Women should be counselled regarding potential benefits, risks, and limitations of breast screening.
- Adequate clinical breast exams include the following: upright and supine position during inspection, and palpation of all components of the breast, axilla, and clavicular lymph node basins. Time spent on the palpable portion of the exam is associated with increased detection of palpable abnormalities.
- Consider severe comorbid conditions limiting life expectancy (e.g. ≤ 10 years) and whether therapeutic interventions are planned.
- Upper age limit for screening is not yet established.
- Dense breasts limit the sensitivity of mammography. Dense breasts are associated with an increased risk for breast cancer, but there is insufficient evidence to support routine supplemental screening in women with dense breasts and no other risk factors. Important outcomes are not yet established for supplemental screening; some states have passed legislation mandating patient notification of breast density.*
- There are several studies supporting the use of supplemental screening for breast cancer as an adjunct to screening mammography for women with dense breast tissue. Different modalities may be considered based on risk and patient values/preference.  
- Digital mammography appears to benefit young women and women with dense breasts.  
- Multiple studies show a combined use of digital mammography and tomosynthesis appears to improve cancer detection and decreased call-back rates. Of note, most studies used double the dose of radiation. The radiation dose can be minimized by synthetic 2-D reconstruction.
- Current evidence does not support the routine use of breast scintigraphy (i.e.: sestamibi scan) as a screening procedure, but there is emerging evidence that breast scintigraphy may improve detection of early breast cancers among women with mammographically dense breasts.
- Current evidence does not support the routine use of thermography or ductal lavage as a screening procedure.
- In high-risk settings based on current evidence and considering the FDA warning 7, (Gadolinium-based contrast agents), NCCN continues to recommend annual MRI in these select populations.

*Michigan has a breast density notification law (2015)

II. Evaluation of Abnormal Clinical Breast Exam and/or Mammogram Results
Refer to National Comprehensive Cancer Network (NCCN) Guidelines for Breast Cancer Screening and Diagnosis (V 1.2016)
References

1. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis Version 1. 2016 NCCN.org


IV. **CLINICAL HISTORY BREAST AND CERVICAL EXAMINATION**

A. Clinical history should consist of the following:

1. Breast Screening History
   - Description of current breast symptoms (if any)
   - Past history of breast problems (abnormal CBES, abnormal Mammograms, breast biopsies, results of biopsies)
   - Personal history of breast cancer or other cancers
   - Last mammogram date and result

2. Cervical Screening History
   - Description of current gynecological symptoms (if any)
   - Past history of cervical cancer screening, including abnormal Pap test results
   - Hysterectomy history (if applicable), and reason for hysterectomy, to Determine if Pap test is required or appropriate.
   - Last Pap test date and result

3. Family history of breast/ovarian/colorectal cancer (both maternal and paternal, Including age at diagnosis).

4. Smoking history: past, current, packs per day, and duration. Women who wish to quit smoking may be referred to the QuitLine for help with tobacco cessation.

B. Physical exam as indicated

   1. Clinical Breast Examination
   2. Pelvic Exam
   3. Obtain Pap test (if indicated as per recommendations in Table 3)

C. Mammography Screening

   1. Order the appropriate mammogram based on clinical breast exam findings:
      a. **Screening mammogram** - performed on an asymptomatic woman to detect early, clinically unsuspected breast cancer.
      b. **Diagnostic Mammogram** - performed on a woman with clinical signs or symptoms that suggest breast cancer or past history of a breast cancer or abnormality that requires ongoing monitoring.
   2. Request copy of mammogram report. Review report to determine appropriate
BREAST AND CERVICAL CANCER CONTROL NAVIGATION PROGRAM

MEDICAL PROTOCOL

Effective December 1, 2016

Follow-up (if indicated as per radiologist's recommendations).

D. Mammography Screening Based on Breast Density
   1. Breast Density Definition: the ratio of fat to fibroglandular tissue in the breast.
   2. Breast density has a two-fold effect on mammographic screening:
      a. High breast density is known to result in decreased mammographic sensitivity for the detection of breast cancer.
      b. Women with dense breasts are at moderately increased risk for breast cancer compared to women of average breast density and this risk is felt to be greatest for the small subset of women (approximately 10%) with extremely dense breasts. The magnitude is in the range of a relative risk of 1.2-2.1 for heterogeneously dense and extremely dense breasts respectively.

3. The following four categories of breast composition are defined by the visually estimated content of fibroglandular-density tissue within the breasts. Please note that the categories are listed as a, b, c, and d so as not to be confused with the numbered Bi-RADS® assessment categories:
   a. Bi-RADS 1 – The breasts are almost entirely fatty,
   b. Bi-RADS 2 – There are scattered areas of fibroglandular density
   c. Bi-RADS 3 – The breasts are heterogeneously dense, which may obscure small masses
   d. Bi-RADS 4 – The breasts are extremely dense, which lowers the sensitivity of mammography

4. Heterogeneously dense and extremely dense breast tissue reduces the sensitivity of screening mammography to identify a suspicious from a non-suspicious lesion.

4. The BCCCN will pay for tomosynthesis (“3-D Mammogram”)

5. The NCCN, USPSTF, ACS, ACOG, ACR do not recommend routine supplemental screening for women with dense breasts without other risk factors since such screening has not been shown to result in a decrease in mortality.

6. If supplementary screening is desired, preliminary evidence suggests that MRI is more sensitive than ultrasound for cancer detection. In these cases, pre-approval for MRI is required by a MDHHS Nurse Consultant prior to the MRI being performed.

V. CLINICAL PERFORMANCE INDICATORS

Clinical performance indicators evaluate timely and appropriate delivery of breast
and cervical clinical services to program women.

A. Immediate Follow-up
   1. Defined as abnormal breast or cervical cancer screening results that have a high probability of being cancer. Results coded for immediate follow-up are evaluated according to the CDC clinical performance indicators for timeliness and completeness. (Table 4)
   2. Timeliness Standard
      a. Defined as the amount of time (measured in number of days) from an abnormal screening result to final diagnosis.

Table 4 – Abnormal Screening Results requiring Immediate Follow-up

<table>
<thead>
<tr>
<th>CBE Results</th>
<th>Mammogram</th>
<th>Pap test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormality - R/O Breast Cancer (includes the following results: • Dominant mass, • Nipple discharge-no palpable mass, • Asymmetric thickening/nodularity, • Skin changes (Peau d’orange, erythema, nipple excoriation, scaling, eczema, skin ulcers)</td>
<td>• ACR 0 – Assessment Incomplete-additional imaging required • ACR 4 - Suspicious Abnormality • ACR 5 - Highly Suggestive of Malignancy</td>
<td>• ASC-US with POSITIVE HPV • ASC-H • LSIL • HSIL • AGC • Squamous cell carcinoma • Adenocarcinoma</td>
</tr>
</tbody>
</table>

b. Timeliness Indicators are as follows:
   • 75% of abnormal BREAST cases requiring IMMEDIATE follow-up should have a final diagnosis within 60 days
   • 75% of abnormal CERVICAL cases requiring IMMEDIATE follow-up should have a final diagnosis within 90 days
   • 80% of all breast and cervical cancer diagnoses should begin treatment within 60 days of the final diagnosis

3. Completeness Standard
   a. Defined as documentation of appropriate diagnostic services (according to the BCCCNP medical protocol) for all abnormal screening test results requiring IMMEDIATE follow-up

b. Completeness Indicators are as follows:
   • 90% of abnormal breast or cervical cases requiring IMMEDIATE follow-up have at least ONE follow-up diagnostic procedure and a final
diagnosis documented
- 100% of cases with a breast or cervical cancer diagnosis must have a treatment disposition documented within 100 days of the diagnosis

4. Documenting in the Michigan Breast and Cervical Information System (MBCIS) Breast/Cervical Screening Results Requiring immediate follow-up to confirm or rule out a cancer diagnosis or short-term follow-up (i.e. results that have a low probability of being cancer.

VI. FOLLOW-UP OF BREAST CANCER SCREENING RESULTS

A. Screening Recommendations Based on CBE Results (Table 5)
B. Screening Recommendations Based on Mammogram Results (Table 6)
C. MRI Recommendation – BCCCNP reimbursement for MRIs will be evaluated on a case by case basis for women age 40-64 meeting the following criteria:

1. Lifetime risk of breast cancer of about 20% to 25% or greater, according to risk assessment tools that are based mainly on family history. Determination of risk is based on a risk assessment that is performed by the mammography facility or the client’s provider.

2. Has a BRCA1 or BRCA2 gene mutation or has a first-degree relative (parent, brother, sister, or child) with a BRCA1 or BRCA2 gene mutation, but has not had genetic testing themselves

3. Has had prior radiation therapy to the chest between the ages of 10 and 30 years

Reimbursement for MRIs that are requested for reasons other than stated above will be evaluated on a case by case basis. Justification for the MRI is needed for evaluation prior to review. Pre-approval for MRIs is required by MDHHS Nurse Consultant prior to MRI being performed.
Table 5 – Follow-up of Clinical Breast Exam Screening Results for Women ≥ Age 40

<table>
<thead>
<tr>
<th>CBE Result</th>
<th>Type of Follow-up</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. No Breast Abnormality (Normal glandular tissue felt upon palpation)</td>
<td>No Follow-up Required</td>
<td>Refer for Screening Mammogram</td>
</tr>
<tr>
<td>b. Benign Breast Condition (Symmetrical thickening or area of thickened tissue palpated in the same location in BOTH breasts; simple cyst(s) previously evaluated)</td>
<td>No Follow-up Required</td>
<td>Refer for Screening Mammogram</td>
</tr>
<tr>
<td>c. Probably Benign Breast Condition (Nodularity, irregularity or lumpiness that is not clinically suspicious)</td>
<td>Short-term Follow-up (&gt; 3 months)</td>
<td>Refer for Screening or Diagnostic Mammogram (based on client’s history)</td>
</tr>
<tr>
<td>d. Abnormal CBE Results that include any of the following: • Dominant Mass • Nipple Discharge – no palpable mass • Asymmetric Thickening/Nodularity • Skin or nipple changes (Peau d’orange, erythema, nipple excoriation, scaling, eczema, skin ulcers)</td>
<td>Immediate Follow-up (within 60 days) to confirm or rule/out cancer</td>
<td>Refer for Diagnostic Mammogram AND additional follow-up procedures as indicated. See NCCN Clinical Practice Guidelines in Oncology for Breast Cancer Screening and Diagnosis (V.1.2011)</td>
</tr>
</tbody>
</table>
Table 6 – Follow-up of Screening Mammogram Results for Women ≥ age 40

<table>
<thead>
<tr>
<th>Mammogram Result</th>
<th>Type of Follow-up</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR 1 – Negative</td>
<td>No Follow-up</td>
<td>Annual screening unless CBE is abnormal – See Appendix B</td>
</tr>
<tr>
<td>ACR 2 – Benign Breast Condition</td>
<td>No Follow-up</td>
<td>Annual screening unless CBE is abnormal – See Appendix B</td>
</tr>
<tr>
<td>ACR 3 – Probably Benign</td>
<td>Short-term Follow-up (6 months)</td>
<td>Refer for diagnostic mammogram and/or ultrasound based on radiologist recommendations.  See NCCN Clinical Practice Guidelines in Oncology for Breast Cancer Screening and Diagnosis V.1.2011</td>
</tr>
<tr>
<td>ACR 0 – Assessment is Incomplete</td>
<td>Immediate Follow-up for additional work-up/imaging (mammogram and/or ultrasound) (within 60 days)</td>
<td>Refer for diagnostic mammogram and/or ultrasound based on radiologist’s recommendation. Based on result, additional referral to a breast surgeon/ specialist for evaluation may or may not be indicated.  See Appendix B</td>
</tr>
<tr>
<td>ACR 4 – Suspicious Abnormality</td>
<td>Immediate Follow-up (within 60 days) to confirm or rule/out cancer</td>
<td>Refer for full diagnostic work-up – See Appendix B</td>
</tr>
<tr>
<td>ACR 5 – Highly Suggestive of Malignancy</td>
<td>Immediate Follow-up (within 60 days) to confirm or rule/out cancer</td>
<td>Refer for full diagnostic work-up – See Appendix B</td>
</tr>
</tbody>
</table>

*NOTE:* Based on the mammogram findings, client history and degree of breast density identified by the radiologist, a diagnostic mammogram and/or Ultrasound may be ordered with the screening mammogram to confirm the initial mammogram findings OR to identify new findings.
VII. FOLLOW-UP OF CERVICAL CANCER SCREENING RESULTS

A. Screening Recommendations (Figure 1)
   1. Pap test and HPV results
   2. Pap test Adequacy
   3. Client History

B. Follow-up of ABNORMAL CYTOLOGY RESULTS

1. Management of HSIL cytology for all women
   a. A diagnostic excisional procedure is recommended for adolescents and young
      women with HSIL when CIN of any grade is identified on ECC
   b. For diagnostic loop electrosurgical excision procedure (LEEP or Cervical
      Conization) (and for data entry authorizing payment), approval from a MDHHS
      Nurse-Consultation will need to be obtained.
   c. Ablation is unacceptable for HSIL cytology if:
      - No colposcopy was performed
      - CIN 2/3 is not identified colposcopically
      - ECC identifies CIN of any grade

2. Management and follow-up of AGC or Adenocarcinoma in Situ (AIS)
   a. In women less than 35 years of age with an AGC cytology result, an
      endometrial biopsy should be performed in the presence of, but not limited
      to, the following conditions:
      - Dysfunctional uterine bleeding
      - At risk for chronic anovulation
      - A change in menstrual flow
   b. In women 35 years of age or older
      Initial Evaluation:
      - Colposcopy with endocervical sampling is recommended for women with all
        subcategories of atypical glandular cells (AGC) (AGC “not otherwise specified
        [NOS],” AGC “favor neoplasia”) and adenocarcinoma in situ (AIS)
      - Endometrial biopsy should be considered for women age 35 or older as part
        of the initial evaluation. Contact MDHHS Nurse-Consultant who will
        authorize payment and enter data in the Michigan Breast and Cervical
        Information System (MBCIS) so service can be reimbursed.
      - Management of women with initial AGC or AIS using a program of repeat
        cervical cytological testing is unacceptable and will NOT be reimbursed by
        the program.
• Triage of AGC Pap results with HR-HPV is unacceptable

Subsequent Evaluation or Follow-up:
• If biopsy-confirmed CIN is identified during the initial workup of a woman with AGC (NOS), the woman should be referred to a qualified colposcopist for treatment.
• If invasive disease is not identified during the initial colposcopic workup, it is recommended that women with AGC “favor neoplasia” or endocervical AIS undergo a cold-knife conization or LEEP.

C. Indications for Referral to a Qualified Colposcopist:

1. Women age 24 and under requiring colposcopy
2. Women with a significant cervical lesion in which “see and treat” may be indicated.
3. Women desiring fertility who, after excisional treatment, have recurrent or persistent cervical dysplasia.
4. Women who have had two “unsatisfactory for evaluation” Pap tests 2-4 months apart
5. Women with AGC or AIS on cytology. Management follows the algorithm found at www.asccp.org.
6. Women with any gynecologic cancer should be referred to a Gynecologic Oncologist.
Pap test Screening Algorithm (Revised 7/2014)

Follow-up Based on Pap test Adequacy

Satisfactory
Pap test Result = Negative but NO Endo Cells or T-zone
(In MBCIS: Choose NO T zone/Endo cells (negative) in Results Section)

For Negative Pap test (alone):
- Screen in 3 years

Co-test
Negative Pap/ Negative HPV: Screen in 1 (ONE) year
(In MBCIS: Code as Pap Surveillance)

Satisfactory
Pap test Result = Negative but obscured/partially obscured by inflammation (HPV Negative or Positive)
(In MBCIS: Choose Inflammation in Results section)

Co-test
Negative Pap/ Positive HPV
Screen in 1 (ONE) year
(In MBCIS: Code as Pap Surveillance)

Pap test (alone) in 6 (SIX) MONTHS
(In MBCIS: Code as Follow-up Pap)
If 2nd Pap inflammation—refer for colp/bx.

Unsatisfactory
Pap test HPV NEGATIVE or POSITIVE

Repeat Pap test (alone) after 2-4 months
(In MBCIS: Repeat Pap test entered as Screening Pap AND Rpt (repeat) box is checked)
If 2nd Pap Unsatisfactory—refer for colp/bx

Follow-up Based on Pap test Adequacy

Follow-up Based on Client History

Biopsy history (not current biopsy result) of CIN 2 or CIN 3

Pap test (alone) in 3 years OR
Co-test Pap/HPV in 5 years

Immune-compromised woman (HIV, DES, transplant recipient)

Hysterectomy for INVASIVE Cervical Cancer

History of INVASIVE Cervical Cancer (no hysterectomy) treated with radiation and/or chemotherapy

Hysterectomy for CIN 2/CIN 3 OR other reproductive cancers

Hysterectomy for benign conditions

NO Pap test

Figure 1 – Use for MBCIS Documentation ONLY

NOT FOR CLINICAL USE

January 2017
D. Website resource for follow-up of abnormal cytology results listed below:

The website [www.asccp.org](http://www.asccp.org) contains algorithms on the follow-up of:

- Unsatisfactory Cytology
- Cytology NILM but EC/TX Absent/Insufficient
- Management of Women ≥ Age 30, who are Cytology Negative, but HPV Positive
- Management of Women with Atypical Squamous Cells of Undetermined Significance (ASC-US) on Cytology
- Management of Women with Low-grade Squamous Intraepithelial Lesion (LSIL)
- Management of Pregnant Women with Low-grade Squamous Intraepithelial Lesion (LSIL)
- Management of Women with Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC-H)
- Management of Women Ages 21-24 years with Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC-H) and High-grade Squamous Intraepithelial Lesion (HSIL)
- Management of Women with High-grade Squamous Intraepithelial Lesion (HSIL)
- Initial Work-up of Women with Atypical Glandular Cells (AGC)
- Subsequent Management of Women with Atypical Glandular Cells (AGC)
- Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia – Grade 1 (CIN1) Preceded by “Lesser Abnormalities”
- Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia
- Management of Women Ages 21-24 with No Lesion or Biopsy-confirmed Cervical Intraepithelial Lesion – Grade 1 (CIN1)
- Management of Women with Biopsy-confirmed Cervical Intraepithelial Neoplasia – Grade 2 and 3 (CIN2, 3)
- Management of Young Women with Biopsy-confirmed Cervical Intraepithelial Neoplasia – Grade 2 and 3 (CIN2, 3) in Special Circumstances
- Management of Women Diagnosed with Adenocarcinoma in-situ (AIS) during a Diagnostic Excisional Procedure
- Interim Guidance for Managing Reports using the Lower Anogenital Squamous Terminology (LAST) Histopathology Diagnoses
VIII. PATIENT EDUCATION

1. Review physical exam findings with client
   a. CBE
      • Discuss normal findings and variances
      • Discuss Breast Self- Awareness: Emphasize that any time a woman detects a breast change or a palpable mass she should seek evaluation from a health care provider.

   b. Pelvic Exam
      • Discuss components of the pelvic exam, including whether or not a Pap and/or HPV test is performed, and whether or not the woman is being tested for sexually transmitted infections.

   c. Discuss abnormal breast and/or cervical signs/symptoms that require provider notification and possible evaluation.

   NOTE: Given the recommended increase in screening interval, strong consideration should be given to providing women with copies of their Pap test/HPV test results.

2. Discuss the importance of breast and cervical cancer screening. The following information should be included in the discussion:
   a. Breast Cancer Screening:
      • Includes BOTH a clinical breast exam and mammogram
      • Type of mammogram performed (screening or diagnostic) is based on the woman’s breast density, risk factors and past medical history, including biopsy history.

   b. Cervical cancer screening:
      • Includes a Pap test
      • Frequency of Pap testing depends on BCCCNP Pap test history, NOT risk factors, and does NOT include Pap tests performed prior to BCCCNP enrollment.
      • Pelvic exams should be performed yearly, whether or not a Pap test is needed.

3. Discuss limitations of screening procedures in detecting cancer
   a. Normal results on a screening exam do not necessarily indicate absence of disease.
   b. No screening test is 100% accurate; therefore, some cases of the disease may be unavoidably missed.
   c. Normal results never rule out the later development of the disease, which
is why annual screening is so strongly recommended.
d. The detection of an abnormality does not mean the abnormality is cancerous.

4. Discuss BCCCNP limitations regarding reimbursement of services
   a. Inform the client that not all BCCCNP screening and diagnostic services are paid by the program.
   b. That providers may order additional screening and follow-up tests which are either not reimbursed by BCCCNP or not related to a breast or cervical problem. As a result, the client may be responsible for charges incurred.

See Appendices C, D, and E for services reimbursed and not-reimbursed by BCCCNP

Note:
Depending on client history and circumstances, reimbursement for certain breast and/or cervical screening/diagnostic services may be approved. These exceptions are listed in Appendix E.

IX. CLIENT NOTIFICATION OF TEST RESULTS

A. Each local coordinating agency should develop and implement an agency specific policy/protocol that describes how the client will be notified of test results and procedures for tracking clients who require follow-up.

1. This protocol should include the process for notifying and tracking clients with the following test results:

   a. Normal breast or cervical screening results – continue screening recommendations as per program guidelines

   b. Results requiring short-term follow-up:
      • Indications for short-term follow-up based on test result
      • Date of follow-up exam/test.

   c. Results requiring immediate follow-up - should include a discussion of the following:
      • The need for further testing to provide definitive diagnosis before treatment
      • Treatment options available, benefits and risks of each BCCCNP reimbursement/non-reimbursement of follow-up tests/procedures
BREAST AND CERVICAL CANCER CONTROL NAVIGATION PROGRAM

MEDICAL PROTOCOL

Effective December 1, 2016

- Scheduling/referring for appropriate follow-up

2. Inability to Contact Clients with Abnormal Test Results
   
   a. Each local coordinating agency should develop and implement an agency-
      specific protocol that describes the procedure to follow if a client is unable
      to be contacted regarding abnormal test results.

   b. The protocol should include:
      
      - Contacting the woman by telephone and/or sending a certified letter
      - Total number of times the agency will initiate the contact
      - Documentation of the attempted contact(s) in the medical record

X. REIMBURSEMENT OF BCCCNP SCREENING AND DIAGNOSTIC SERVICES

A. Due to limited program funding, and CDC policy restrictions on the type of screening and
   follow-up tests that may be reimbursed by the program, the BCCCNP may not be able to
   reimburse for all recommended follow-up testing according to the ASCCP or NCCN
   management guidelines.

B. As part of yearly contract renewals with BCCCNP providers, BCCCNP coordinators should
   discuss the program’s limitations regarding covered and non-covered program services
   provided to enrolled women.

C. Any questions regarding coverage for BCCCNP services should be directed towards one of
   the MDHHS clinical or reimbursement staff PRIOR to the service being performed to
   determine if the service will be reimbursed by the BCCCNP.

QUESTIONS REGARDING THIS PROTOCOL MAY BE DIRECTED TO:

E.J. Siegl, RN OCN, MA, CBCN, BCCCNP Nurse Consultant
517/335-8814 or siegle@michigan.gov

Ann Garvin, MS, CNM, BCCCNP Nurse Consultant
517/335-9087 or garvina@michigan.gov

Washington Square Building
Cancer Prevention and Control Section,
109 Michigan Ave, WSB - 5th Floor, Lansing, MI 48933
Appendix A

Follow-up of Abnormal CBE Results
Follow-up of Abnormal CBE Results

Palpable Mass in WOMEN \( \geq 40 \) Years of Age

**Diagnostic Work-up Required**

ELIGIBLE FOR BCCCP

Diagnostic Mammogram/ Ultrasound

**BCCCP Pay**

Dx Mamm results

Bi-RADS 0, 4, 5

Refer for Tissue Biopsy

(Exception: US result = simple cyst

**BCCCP Pay**

Dx Mamm results

Bi-RADS 1, 2, 3

US Findings

Solid Mass

Bi-RADS 3

Observation for low clinical suspicion

Refer Back to PCP

NO LONGER Eligible for BCCCP

US Findings

Non-Simple Cyst

Complex Cyst or Bi-RADS 4, 5

Refer for Image Guided/Tissue Biopsy

**BCCCP Pay**

US Findings

Simple Cyst

Bi-RADS 2

Complicated Cyst

Bi-RADS 3

OR

Refer for aspiration/additional Follow-up as needed

**BCCCP Pay**

Observation for low clinical suspicion

Refer Back to PCP

NO LONGER Eligible for BCCCP

No ULTRASONIC Abnormality

Bi-RADS 1

Refer for Surgical consult and possible Tissue Biopsy

**BCCCP Pay**

Reviewed

Dec 2016
BREAST AND CERVICAL CANCER CONTROL NAVIGATION PROGRAM

MEDICAL PROTOCOL

Effective December 1, 2016

BCCCNP Medical Protocol
Follow-up of Abnormal CBE Results
NIPPLE DISCHARGE: WOMEN >/= AGE 40

Nipple Discharge
No palpable mass

Non-Spontaneous: Multiduct

Refer for Diagnostic mammogram if not done recently. Mammogram result determines if further work-up required.

Persistent and reproducible on Exam
Spontaneous, unilateral, single duct and clear or colorless, serous, sanguineous or serosanguineous

Diagnostic Mammogram AND Ultrasound

Bi-RADS 1,2,3

Ductogram or MRI Possible Duct Excision
Pre-approval required by MDHHS Nurse Consultant

Bi-RADS 4-5

Refer for Surgical Consult and Tissue Biopsy

Based on NCCN Breast Cancer Screening and Diagnosis Clinical Practice Guidelines v.1.2014

Reviewed Dec 2016
BCCCNP Medical Protocol
ASYMMETRIC THICKENING/NODULARITY in Women >= 40 Years of Age

Based on NCCN Breast Cancer Screening and Diagnosis Clinical Practice Guidelines v.1.2014

Diagnostic Mammogram +/- Ultrasound

Bi-RADS 1, 2, 3

Simple Cyst

Surgical Consult

Clinically assessed as Benign

Refer Back to PCH
NO LONGER Eligible for BCCCNP

Bi-RADS ACR 4, 5

Tissue Biopsy

Clinically suspicious Refer for Surgical Consult

Reviewed
Dec 2016
BREAST AND CERVICAL CANCER CONTROL NAVIGATION PROGRAM

MEDICAL PROTOCOL

Effective December 1, 2016

BCCCNP Medical Protocol
Follow-up of Abnormal CBE Results
SKIN CHANGES in Women >/= 40 Years of Age

CLINICAL FINDING:
1. Clinically suspicious of inflammatory breast cancer: Peau’d orange or Erythema OR
2. Clinically suspicious of Paget’s Disease: Nipple Excoriation, scaling, or eczema, skin ulceration

Refer for:
1. Mammogram +/- Ultrasound
2. Breast Consult

If clinically of low suspicion short trial 7-10 days of antibiotics for mastitis may be indicated

BI-RADS
1, 2, or 3

Punch biopsy of skin or nipple biopsy (Pre-approval required*)

BI-RADS
4, 5

Tissue Biopsy or Punch biopsy (Pre-approval required for Punch Biopsy)

Biopsy Results: Benign

1. Reassess clinical/pathology correlation
2. Consider Breast MRI (Pre-approval required)
3. Consider Repeat Biopsy

Biopsy Results: Malignant

Enroll in BCCCNP MTA or assist with obtaining treatment if not MTA eligible
Appendix B

Follow-up of Normal and Abnormal Mammogram Results
BCCCNP Medical Protocol
Follow-up of Normal and Abnormal
DIAGNOSTIC Mammogram Results

Diagnostic Mammogram Follow-up

ACR 0 - Assessment
In complete - Work-Up
Required

Diagnostic work-up includes any or
all of the following:
1. Comparison to Prior Films
2. Diagnostic Mammogram
3. Ultrasound as indicated

ACR 1 - Negative
ACR 2 - Benign Finding

Routine Screening: Annual CBE/Mammogram/ Breast
Awareness
EXCEPTION: IF CBE Abnormal - additional work-up
required to include any or all of the following: Ultrasound,
Breast Consult and/or Tissue Biopsy

ACR 3 - Probably Benign

Diagnostic Mammogram at 6 months then every
6-12 months x 1-2 years
If return visit uncertain or client very anxious
consider consult and possible biopsy

ACR 4 - Suspicious Abnormality
ACR 5 - Highly Suggestive of
Malignancy

Breast consult
Referral for Tissue
Biopsy**

Benign

Dx Mammogram/US in 6-
12 mos for 1-2 years

Possible Excisional Biopsy per
surgeon/radiologist
recommendation

Atypical
Hyperplasia

Enroll in BCCCNP MTA
or assist with obtaining
treatment if not eligible

Malignant
APPENDIX C

Office Visits & Consults
Reimbursed by BCCCNP
Appendix C – **Office Visits & Consults Reimbursed by BCCCNP**

<table>
<thead>
<tr>
<th>Service</th>
<th>BCCCNP Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Office Visit (to include CBE, and/or Pelvic Exam, and/or Pap test (if eligible per BCCCNP guidelines) &gt; 365 days from previous FIRST annual screening office visit</td>
<td>Will reimburse <strong>ONE ANNUAL visit/year</strong> (&gt; 365 days)</td>
</tr>
</tbody>
</table>
| Office Visits/Breast Consults                                          | • Will reimburse up to two (2) surgical consults/office visits pre and post breast biopsy/consult/year  
• MDHHS Nurse Consultant review required for office visit/consult beyond the post biopsy visit; evaluated on an individual basis |
| Office Visits/Cervical Consults                                        | • Reimburse for consult on **DAY** of cervical diagnostic procedure  
• **NO** reimbursement for consult pre-colposcopy or post colposcopy unless cervical cancer is diagnosed |
APPENDIX D

Breast/Cervical Screening/Diagnostic Services Reimbursed by BCCCNP
Appendix D – Breast Screening/Diagnostic Services Reimbursed by BCCCNP

<table>
<thead>
<tr>
<th>Service</th>
<th>BCCCNP Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Mammogram</td>
<td>Will reimburse <strong>ONE/year</strong> (≥ 365 days)</td>
</tr>
<tr>
<td>&gt; 365 days from previous Screening Mammogram</td>
<td></td>
</tr>
<tr>
<td>Diagnostic Mammograms</td>
<td>Will reimburse up to <strong>TWO</strong> Diagnostic mammograms/year:</td>
</tr>
<tr>
<td></td>
<td><strong>ONE</strong> immediately performed as follow-up a Screening Mammogram result of</td>
</tr>
<tr>
<td></td>
<td>ACR 0: Assessment Is Incomplete</td>
</tr>
<tr>
<td></td>
<td>The <strong>second</strong> within a 12-month time period (&lt;365 days) as 6 month follow-up</td>
</tr>
<tr>
<td></td>
<td>post screening as per radiologist recommendation or post biopsy as per provider’s</td>
</tr>
<tr>
<td></td>
<td>recommendation.</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>Will reimburse up to <strong>TWO</strong> Ultrasound exams/year:</td>
</tr>
<tr>
<td></td>
<td>Ultrasounds may be performed:</td>
</tr>
<tr>
<td></td>
<td>• On the same day to confirm a stable finding found on screening mammogram.</td>
</tr>
<tr>
<td></td>
<td>• As immediate follow-up to a screening mammogram result of ACR 0: Assessment is</td>
</tr>
<tr>
<td></td>
<td>Incomplete to identify the type of NEW abnormality</td>
</tr>
<tr>
<td></td>
<td>• As a short term follow-up within a 12-month time period (&lt;365 days) or post biopsy</td>
</tr>
<tr>
<td></td>
<td>as per radiologist recommendation.</td>
</tr>
<tr>
<td></td>
<td>Prior approval by MDHHS Nurse Consultant required for additional ultrasound testing</td>
</tr>
<tr>
<td></td>
<td>beyond the two stated above</td>
</tr>
<tr>
<td>Breast Magnetic Resonance Imaging (MRI)</td>
<td>Screening or Diagnostic MRI is covered ONLY for women identified as being at increased</td>
</tr>
<tr>
<td></td>
<td>risk for breast cancer. Prior approval by MDHHS Nurse Consultant required prior to</td>
</tr>
<tr>
<td></td>
<td>MRI being performed.</td>
</tr>
<tr>
<td>Imaging Tests PRE-Biopsy</td>
<td>Ultrasound will be reimbursed separately from biopsy <strong>ONLY</strong> if used to determine</td>
</tr>
<tr>
<td>Ultrasound performed prior to Ultrasound</td>
<td>if used to determine if abnormality still present prior to performing biopsy</td>
</tr>
<tr>
<td>guided biopsy (performed on same day)</td>
<td>Ultrasound will <strong>NOT</strong> be reimbursed if performed as part of a provider’s routine</td>
</tr>
<tr>
<td>Imaging Tests POST-Biopsy</td>
<td>practice prior to performing biopsy</td>
</tr>
<tr>
<td>Post Breast Biopsy mammogram/ultrasound</td>
<td>Will reimburse post biopsy imaging</td>
</tr>
<tr>
<td>imaging for: clip placement and/or to</td>
<td></td>
</tr>
<tr>
<td>determine specimen adequacy</td>
<td></td>
</tr>
</tbody>
</table>
Appendix D – Cervical Screening/Diagnostic Services Reimbursed by BCCCNP – continued

<table>
<thead>
<tr>
<th>Service</th>
<th>BCCCNP Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Pap test</td>
<td>Reimbursement denied if prior to “Client Eligible for Pap Test” Date unless approved by MDHHS Nurse Consultant.</td>
</tr>
<tr>
<td>Frequency depends on type and result of Pap test or Pap/HPV co-test – See Table 1</td>
<td></td>
</tr>
<tr>
<td>High Risk (HR) - HPV as an adjunct to screening Pap test</td>
<td>Pap/HPV (co-test) will be reimbursed only <strong>ONCE</strong> every 5 years if both tests are negative</td>
</tr>
<tr>
<td>Follow-up Pap tests</td>
<td>Only Pap tests performed according to the medical protocol for follow-up of screening Pap test abnormalities will be reimbursed.</td>
</tr>
<tr>
<td>High Risk (HR) - HPV test may be performed alone (without Pap test) as 12 month follow-up of colposcopy</td>
<td>Will reimburse High Risk (HR) - HPV test no more than <strong>ONE/year</strong> (&gt;364 days)</td>
</tr>
</tbody>
</table>
| High Risk (HR) - HPV tests performed as immediate follow-up for ASC-US Pap in order to determine triage or as part of diagnostic work-up for AGC test result | **FOR BCCCNP CLIENTS AGE 40 AND OLDER:**  
  • Only **ONE** High Risk (HR) - HPV test within a 12 month time-period will be reimbursed  
  • High Risk (HR) - HPV performed as 12 month follow-up for colposcopy results of CIN1 will be reimbursed (no Pap performed at that time) |
| LEEP/Cold Knife Cone                                                   | Notify MDHHS Nurse Consultant for approval of diagnostic LEEP/Cold Knife Cone for Pap test results of HSIL followed by a colposcopy with biopsy result of “not cancer”, atypia, CIN 1 or unsatisfactory colposcopy |
| Endometrial Biopsy (EMB) (for women with AGC Pap result only)          | Notify MDHHS Nurse Consultant for approval of EMB as diagnostic work-up of AGC Pap test result. |
APPENDIX E

Breast/Cervical Screening/Diagnostic Services
NOT Reimbursed by BCCCNP
### Appendix E – Breast/Cervical Services NOT reimbursed by B CCCNP

<table>
<thead>
<tr>
<th>Breast Services</th>
<th>Rationale</th>
<th>B CCCNP Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Ultrasound (US)</td>
<td>Ultrasounds are performed with a mammogram, to confirm a previous finding or to identify new finding; not instead of a mammogram to further define a breast abnormality.</td>
<td>Reimbursed if performed WITH a Screening Mammogram NOT in place of a Screening Mammogram</td>
</tr>
<tr>
<td>Computer Aided Device (CAD)</td>
<td>Used in conjunction with mammogram- aids in interpretation of mammogram</td>
<td>NOT reimbursed</td>
</tr>
<tr>
<td>Ductogram</td>
<td>If performed for unilateral bloody, serous or serosanguineous discharge.</td>
<td>Contact MDHHS Nurse Consultant to determine if service can be reimbursed</td>
</tr>
<tr>
<td>Axillary Node Biopsy</td>
<td>If performed to confirm or rule/out breast cancer diagnosis in absence of abnormal mammogram</td>
<td>Contact MDHHS Nurse Consultant to determine if service can be reimbursed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cervical Services</th>
<th>Rationale</th>
<th>B CCCNP Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pap test to rule/out endometrial cancer</td>
<td>Only Cervical Cancer Screening Services are reimbursed by B CCCNP</td>
<td>NOT reimbursed</td>
</tr>
<tr>
<td>Endometrial Biopsy (EMB) for follow-up of Pap result of “endometrial cells in a woman &gt; age 40”</td>
<td>Only Cervical Cancer Services are reimbursed by B CCCNP</td>
<td>NOT reimbursed</td>
</tr>
<tr>
<td>Pap test post hysterectomy performed for BENIGN gynecological disease - NO CERVIX PRESENT</td>
<td>Screening with vaginal cytology is NOT indicated; Pelvic exam is indicated.</td>
<td>Pap test NOT reimbursed. Office visit (pelvic exam) reimbursed</td>
</tr>
<tr>
<td>Polypectomy</td>
<td>Not a covered service</td>
<td>NOT reimbursed</td>
</tr>
<tr>
<td>Low-risk HPV test</td>
<td>Low-risk HPV test has is not an appropriate test in cancer screening program</td>
<td>NOT reimbursed</td>
</tr>
</tbody>
</table>
APPENDIX F

Enrolling Women Ages 25-39 in BCCCNCP Identified with Breast Abnormality for Diagnostic Work-up

A. **Eligibility Requirements:**
   1. Women 25 - 39 years of age identified with any of the following abnormal clinical breast exam results from a Title X/Family Planning Provider
      - Palpable, Dominant Mass
      - **Unilateral**, spontaneous, nipple discharge that is clear or colorless, serous, sanguineous, or serosanguineous
      - Asymmetric thickening/nodularity
   2. Income between 139%-250% FPL
   3. Uninsured or underinsured with a high deductible that must be met and/or inadequate insurance coverage for diagnostic testing. (**NOTE:** This does not include Plan First Clients. Plan First clients ARE eligible to enroll in BCCCNP.)

B. Women 25-39 years of age **NOT** eligible to enroll in BCCCNP include:
   1. Self-referred women (not seen by Title X/Family Planning Provider) complaining of a breast lump
   2. Asymptomatic women with family history of breast cancer or other risk factors based on personal history that may increase their individual breast cancer risk
   3. Women who are BRCA1/2 positive
   4. Women who present with bilateral fibrocystic disease
   5. Women who present with bilateral nipple discharge
   6. Women on Medicaid or who have Healthy Michigan Plan

II Enrollment Procedure
A. Title X/Family Planning Provider
   1. Identifies a woman between ages 25-39 with abnormal CBE results.
   2. Contact BCCCNP Coordinator to determine client eligibility for BCCCNP.
   3. Send client information and progress notes of CBE findings to BCCCNP Coordinator.

B. BCCCNP Coordinator
   1. Verifies the woman’s income and insurance eligibility for BCCCNP
   2. Reviews client CBE progress note determining eligibility
   3. Contacts MDHHS Nurse Consultant, E.J. Siegl (517-335-8814) or Ann Garvin (517-335 9087) in her absence to verify client eligibility based on breast symptoms **PRIOR** to enrolling in BCCCNP
   4. If client eligible, enrolls in BCCCNP and arranges for breast diagnostic follow-up
III  Breast Diagnostic Services Provided by the BCCCNP
   A. BCCCNP Coordinator/Clinician/Case Manager refers the woman for appropriate
diagnostic follow-up procedures based on the identified breast abnormality to confirm
or rule out a breast cancer diagnosis

   B. See attached algorithms to determine diagnostic follow-up:
      1. Palpable Mass in Women 25-39 years of age
      2. Nipple Discharge in Women 25-39 years of age
      3. Asymmetric Thickening/Nodularity in Women 25-39 years of age

IV. Reimbursement of BCCCNP Diagnostic Services
    A. Due to limited program funding, and CDC policy restrictions on the type of diagnostic
procedures that may be reimbursed by the program, the BCCCNP may not be able to
reimburse for all follow-up testing that may be recommended by to the NCCN management
guidelines.

    B. Depending on the breast abnormality, some diagnostic procedures may be covered through
the BCCCNP, in addition to services identified on the BCCCNP Unit Cost Reimbursement
Rate Schedule. This may include: MRI, Ductograms, Ductal Excision, and ultrasound
of a mass in the axilla.

Pre-approval by MDHHS Nurse Consultant is required prior to these services being
delivered.

    C. BCCCNP cannot reimburse for chemoprevention therapy. In some circumstances, genetic
counseling and/or genetic testing can be provided. Contact Ann Garvin, MDHHS Nurse
Consultant, to discuss or refer.

V. Cancer Treatment
   A. The BCCCNP cannot pay for cancer treatment.

   B. Women diagnosed with breast cancer are assisted in enrolling in the BCCCNP Medicaid
Treatment Act (MTA) for cancer treatment.

   C. If the woman is not eligible for MTA, BCCCNP Coordinator will assist her in
obtaining needed treatment.
Follow-up of Abnormal CBE Results

_Palpable Mass in WOMEN 25 - 39 Years of Age_

**Diagnostic Work-up Required**
- **ELIGIBLE FOR BCCCP**
  - Diagnostic Mammogram/ Ultrasound
  - **BCCCP Pay**

**Dx Mamm results BI-RADS 1, 2, 3**
- **Refer for Tissue Biopsy BCCCP Pay**

**Dx Mamm results BI-RADS 4, 5**
- **Refer for Tissue Biopsy BCCCP Pay**

**US Findings**
- **Solid Mass**
  - **Bi-RADS 3**
    - Observation for low clinical suspicion
    - **Refer Back to PCP NO LONGER Eligible for BCCCP**

- **Non-Simple Cyst**
  - **Complex Cyst or Bi-RADS 4, 5**
    - Observation for low clinical suspicion
    - **Refer for Image Guided/ Tissue Biopsy BCCCP Pay**

- **Simple Cyst B-RADS 2**
  - **Complicated Cyst Bi-RADS 3**
    - **Refer for aspiration/additional Follow-up as needed BCCCP Pay**
    - **OR**
  - Observation for low clinical suspicion
    - **Refer Back to PCP NO LONGER Eligible for BCCCP**

**No ULTRASONIC Abnormality**
- **Bi-RADS 1**
  - **Refer for Surgical consult and possible Tissue Biopsy BCCCP Pay**
**BCCCNP Medical Protocol**

**NIPPLE DISCHARGE in Women 25 - 39 years of Age**

1. **Non-Spontaneous OR Multi-duct**
   - Observation
   - **NOT ELIGIBLE FOR BCCCNP**

2. **Nipple Discharge**
   - **No palpable mass**
   - Persistent and reproducible on Exam
   - Spontaneous, unilateral, single duct and clear or colorless, serous, sanguineous or serosanguineous

3. **Bi-RADS 1,2,3**
   - Diagnostic Mammogram +/− Ultrasound
   - **BCCCNP Pay**

4. **Bi-RADS 4-5**
   - Refer for Surgical Consult and Tissue Biopsy
   - **BCCCNP Pay**

5. **Ductogram or MRI. Possible Duct Excision**
   - Pre-approval required by Nurse Consultant
BCCCNP Medical Protocol
ASYMMETRIC THICKENING/NODULARITY in Women 25 - 39 Years of Age

Diagnostic Mammogram =/- Ultrasound

BCCCNP Pay

Bi-RADS 1, 2, 3

Simple Cyst

Refer Back to PCP
NO LONGER Eligible for BCCCNP

Bi-RADS ACR 4, 5

Tissue Biopsy

BCCCNP Pay

Surgical Consult

BCCCNP Pay

Clinically suspicious
Refer for Surgical Consult

BCCCNP Pay

Clinically Assessed as Benign