Breast and Cervical Cancer Control Navigation Program

Medical Protocol

I. Introduction

Guidelines in the Breast and Cervical Cancer Control Navigation Program (BC3NP) Medical Protocol are to be used to assist clinicians in providing breast and cervical cancer screening and diagnostic services, if needed, to program enrolled women.

BC3NP funds cannot be used for the time and materials needed to assess and manage problems unrelated to breast or cervical cancer. Approval for reimbursement of breast and/or cervical services not described in this protocol need to be obtained from the Michigan Department of Health and Human Services (MDHHS) Program Director or Nurse Specialists prior to the client receiving the service.

Guidelines for providing breast cancer screening services were developed based on recommendations from the following organizations: American Cancer Society, www.cancer.org; the US Preventative Services Task Force (USPSTF), www.uspreventiveservicestaskforce.org; and the National Comprehensive Cancer Network (NCCN) Breast Cancer Screening and Diagnosis Guidelines, www.nccn.org. Diagnostic services required for women as follow-up of an abnormal breast finding or imaging result are according to the NCCN Breast Cancer Screening and Diagnosis Guidelines.

Guidelines for providing cervical cancer screening services were developed based on recommendations from the following organizations: American Cancer Society, www.cancer.org; the US Preventative Services Task Force (USPSTF), www.uspreventiveservicestaskforce.org. Diagnostic services required for women for follow-up of an abnormal Pap/HPV test are according to the 2019 ASCCP Cervical Risk-Based Management Guidelines, www.asccp.org.

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II. BC3NP Clinical Services Provided to Eligible Clients

The BC3NP provides breast and cervical cancer screening and/or diagnostic services to program eligible women to confirm or rule-out a breast or cervical cancer diagnosis.

A. Screening Services Provided by the BC3NP
   1. Definition: Screening is the attempt to detect unsuspected disease in asymptomatic women.
   2. Breast cancer screening recommendations:
      a. Women ages 40-64 at Average Risk for Breast Cancer:
         - Annual screening mammogram (Refer to Table 1)
      b. Women ages 25-64 at High-Risk for Breast Cancer:
         - Screening recommendations based on a woman's risk factors (Refer to Table 2)
   3. Cervical cancer screening recommendations:
      a. Women ages 21-29: (Refer to Table 3)
         - Pap test alone every 3 years
      b. Women ages 30-64: ANY of the following is acceptable (Refer to Table 3)
         - Pap test alone every 3 years **or**
         - HPV -HR (primary HPV testing **only**) every 5 years **or**
         - Pap/HPV co-test every 5 years
      c. Women ages 21-64 at High Risk for Cervical Cancer:
         - Screening recommendations based on a woman's risk factors
         - Refer to Tables 4 and 5

B. Diagnostic Services Provided by the BC3NP
   1. BC3NP women identified with incomplete or abnormal breast and/or cervical cancer screening results are referred for appropriate diagnostic follow-up procedures to confirm or rule out a cancer diagnosis. (See Appendix A and B)
   2. Refer to the BC3NP Unit Cost Reimbursement Rate Schedule for a list of diagnostics procedures approved for reimbursement.
      - BC3NP Unit Cost Reimbursement Rate Schedule

C. Cancer Treatment
   1. The BC3NP cannot pay for cancer treatment.
   2. In the event a breast or cervical cancer is diagnosed, all BC3NP enrolled women are assisted in obtaining necessary breast or cervical cancer-related treatment in a timely manner.

3. Women meeting the BC3NP eligibility criteria may also be eligible to enroll in a special Medicaid program for cancer treatment.
   - Refer to BC3NP MTA Enrollment policy for eligibility criteria.

III. BC3NP Age and Insurance Eligibility to Receive Breast and Cervical Screening And/or Diagnostic Services

A. Uninsured/underinsured women < 250% Federal Poverty Level and between the ages of 21-39 are eligible to receive the following program approved services:
   1. Cervical cancer screenings: Pap test and/or HPV test (based on age).
   2. Cervical cancer diagnostic tests for evaluation of an abnormal Pap test and/or HPV test.
   3. Breast cancer diagnostic tests for evaluation of an abnormal breast clinical finding, symptom, mammogram, and/or ultrasound.

B. Uninsured/underinsured women < 250% Federal Poverty Level and between the ages of 40-64 are eligible to receive the following program approved services:
   1. Breast and cervical cancer screening tests.
   2. Cervical cancer diagnostic tests for evaluation of a cervical screening abnormality.
   3. Breast cancer diagnostic tests for evaluation of an abnormal breast clinical finding, symptom, mammogram, and/or ultrasound.

IV. Clinical History: Breast and Cervical Examination

A. Clinical history should consist of the following:
   1. Breast Cancer Screening History
      a. Description of current breast symptoms (if any).
      b. History of breast problems (abnormal CBEs, abnormal mammograms, breast biopsies, results of biopsies).
      c. Last mammogram date and result before enrolling in BC3NP.
      d. Family history of breast/ovarian/colorectal cancer (both maternal and paternal, including age at diagnosis).
      e. Personal risk factors that increase her risk for breast cancer (See Table 2).
   2. Cervical Cancer Screening History
      a. Description of current gynecological symptoms (if any).
      b. History of cervical cancer screening, including abnormal Pap test results.

c. Last Pap/HPV test date and result.

d. Hysterectomy history (if applicable), and reason for hysterectomy.

e. Personal risk factors that increase her risk for cervical cancer (See Table 3).

3. Smoking History

a. Assess past, current, number of packs per day, and duration.

b. Assess readiness to quit smoking.

c. Provide resources to help with tobacco cessation.

See smoking cessation guidelines, www.nccn.org.

4. TeleHealth Visits

- Telehealth services include telemedicine and telephone-only visits with BC3NP clients and their healthcare providers.
- These visits occur in place of in-person office visits.
- TeleHealth visits are reimbursable through BC3NP at the current FY office visit reimbursement rates if allowable by CDC. (Appendix C)

B. Physical Exam as indicated (all are included as part of the Clinical Encounter)

1. Clinical Breast Examination
2. Pelvic Exam

C. Mammography Screening

1. Order the appropriate mammogram based on clinical breast exam findings and/or client history:

a. **Screening Bilateral Mammogram** - performed on an **asymptomatic** woman to detect early, clinically unsuspected breast cancer.

b. **Diagnostic Bilateral Mammogram** - performed on a woman with **clinical signs or symptoms** that suggest breast cancer or history of a breast cancer or abnormality that requires ongoing monitoring or an incomplete finding following a screening mammogram.

2. Request copy of mammogram report. Review report to determine appropriate follow-up per radiologist's recommendations.

3. Mammography Screening Based on Breast Density

a. Breast Density Definition: the ratio of fat to fibroglandular tissue in the breast.

b. Breast density has a two-fold effect on mammographic screening:

- High breast density is known to result in decreased mammographic sensitivity for the detection of breast cancer.
- Women with dense breasts are at mildly increased risk for breast cancer compared to women of average breast density.
- Patients with heterogeneously or extremely dense breasts are notified of this result by the radiologist. The possible need for supplemental imaging can be discussed with their provider.

c. The NCCN, USPSTF, ACS, ACOG, ACR do not recommend routine supplemental screening for women with dense breasts without other risk factors.

d. If supplementary screening is desired, MRI has been shown to be more sensitive than ultrasound for cancer detection.

- Pre-approval for MRI is required by a MDHHS Nurse Specialist prior to the MRI being performed.
- Ultrasound may be performed based on radiologist discretion.

V. Patient Education

A. Clinical Encounter: Review physical exam findings with client.

1. Clinical Breast Exam
   a. Discuss findings and need for follow-up if abnormal.
   b. 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 even following a recent normal mammogram.**
2. Pelvic Exam
   a. Discuss components of the pelvic exam, including whether a Pap and/or HPV test is performed, and whether the woman is being tested for sexually transmitted infections.
   b. Discuss abnormal cervical signs/symptoms that require provider notification and possible evaluation.

   Note: Given the recommended increase in cervical cancer screening interval, **strong** consideration should be given to providing women with copies of their Pap test/HPV test results.
3. Discuss the importance of obtaining regular breast and cervical cancer screenings at the appropriate intervals as recommended.

B. Discuss benefits and limitations of screening procedures in detecting cancer.

1. Benefits
   a. Cancers caught in the early stages are easier to treat.
   b. Routine screening decreases cancer mortality.
2. Limitations
   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 regular screening is so strongly recommended.
   d. The detection of an abnormality does not mean the abnormality is cancerous.

C. Discuss BC3NP limitations regarding reimbursement of services Inform the client that:
   1. Not all screening modalities and diagnostic services are paid by the program.
   2. Providers may order additional screening and follow-up tests which are either not reimbursed by BC3NP or not related to diagnosing a breast or cervical cancer.
   3. Clients may be responsible for charges incurred for services not paid by the program.

VI. Special Considerations: Transgender Clients

A. 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 BC3NP.
   2. Screening and diagnostic services (if needed) will be reimbursed by the program.

B. Special Considerations: Breast and 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 they still have breasts or not, should have a CBE. If breast tissue is present, breast cancer screening like cis-gendered women is recommended.

VII. 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.

B. This protocol should include the process for notifying and tracking clients with the following test results:
   1. Normal breast or cervical screening results:
      a. Continue screening recommendations as per program guidelines or provider recommendation.
   2. Results requiring short-term follow-up (6 months or less):
      a. The need for short-term follow-up based on test result.
      b. Date of follow-up exam/test.

3. Results requiring immediate follow-up (< 2 months):
    a. Discuss the need for further testing to provide a definitive diagnosis to confirm or rule out a cancer or pre-cancerous condition.
    b. Assist the client with scheduling/referring for appropriate follow-up.
4. Inability to Contact Clients with Abnormal Test Results.
    a. Each local coordinating agency should develop 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 and in the Michigan Breast and Cervical Information System (MBCIS) data base.

VIII. Breast and Cervical Cancer Screening Test Recommendations

A. Table 1: Breast Cancer Screening Recommendations for Average Risk Women

Agency Recommendation

NCCN (2021)

Exam	Interval	Age to Begin
Clinical Breast Exam (as part of the *Clinical Encounter)	1-3 years	25-39
Screening Mammogram (Consider tomosynthesis) Clinical Breast Exam (as part of the *Clinical Encounter)	Annual	≥40

Additional Information:

- Clinical encounter (Includes ongoing risk assessment/risk reduction counseling and Clinical Breast Exam).
- Breast awareness (women should be familiar with their breasts and promptly report changes to their health care provider).
- A clinical breast exam alone is **not** considered breast cancer screening.

ACS (2015)

S (Strong Recommendation)
Q (Qualified Recommendation)

Screening Mammogram

Interval	Age to Begin	Additional Information
Annually (Q)	40-44	Women should have the opportunity to begin annual screening.
Annually (S)	45-54	NA
Biennial or Annual (Q)	≥ 55	Yearly exams should continue for as long as a woman is in good health and life expectancy > 10 years.

CBE

Interval	Age to Begin	Additional Information
Not recommended	NA	NA

USPSTF (2016)

Screening Mammogram

Interval	Age to Begin	Additional Information
Biennial	50-74	B rating: The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.
Personal decision when to start and how often	40-49	C rating: The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.
Personal decision when to start and how often	≥ 75	Insufficient evidence – No recommendation

CBE

Interval	Age to Begin	Additional Information
Not recommended	NA	Insufficient evidence – No recommendation

B. Table 2: Breast Cancer Screening Recommendations for Women at Increased Risk for Breast Cancer (NCCN 2021)

Breast Risk Factor

Personal History of Breast Cancer

Exam	Interval	Age to Begin
CBE	Annual	Post Diagnosis
Mammogram	Annual	Post Diagnosis

Prior Thoracic Radiation Therapy Between Ages of 10-30 (Current Age > 25 years)

Exam	Interval	Age to Begin
Clinical Encounter (to include CBE)	6-12 months	Begin 8 years after Radiation Therapy
Screening Mammogram Consider tomosynthesis	Annual	Begin 8 years after Radiation Therapy but not prior to age 30 years
MRI	Annual	Begin 8 years after Radiation Therapy but not prior to age 25 years *Consider contrast-enhanced mammography or whole breast ultrasound for those who qualify for but cannot undergo MRI

Women Who Have a Lifetime Risk ≥ 20% As Defined by Models That Are Largely Dependent on Family History (e.g. Claus, Brcapro, Boadicea, Tyler-Cuzick)

*Consider referral to genetic counselling if not already done and breast specialist as appropriate.

Exam	Interval	Age to Begin
Clinical Encounter (to include CBE)	6-12 months	Begin when identified as being at increased risk, but not prior to 21 years
Screening Mammogram-Consider tomosynthesis	Annual	Begin 10 years prior to the youngest family member age at diagnosis, but not prior to age 30 years or age 40 years (whichever comes first)
MRI	Annual	Begin 10 years prior to youngest family member age at diagnosis, but not prior to age 25 years or age 40 years (whichever comes first) *Consider contrast-enhanced mammography or whole breast ultrasound for those who qualify for but cannot undergo MRI

Women ≥ 35 Years With 5-Year Gail Model Risk of Invasive Breast Cancer ≥ 1.7%

Exam	Interval	Age to Begin
Clinical Encounter (to include CBE)	6-12 months	Begin when identified as being at increased risk by Gail Model
Screening Mammogram Consider tomosynthesis	Annual	NA

Women With a History of Lobular Neoplasia (LCIS/ALH) Or ADH and Have a Lifetime Risk > 20%

Exam	Interval	Age to Begin
Clinical Encounter (to include CBE)	6-12 months	Begin post diagnosis LCIS or ADH/ALH
Screening Mammogram Consider tomosynthesis	Annual	Begin post diagnosis LCIS or ADH/ALH but not prior to age 30 years
MRI (consider)	Annual	Begin post diagnosis LCIS or ADH/ALH but not prior to age 25 years *Consider contrast-enhanced mammography or whole breast ultrasound for those who qualify for but cannot undergo MRI

Pedigree Suggestive Of/Or Known Genetic Predisposition (i.e. BRCA1/2, P53, PTN) Or Other Gene Mutation

Exam	Interval	Age to Begin
CBE	6-12 months	Age 25 years
Mammogram Consider tomosynthesis	Annual	≥ Age 30 years
MRI	Annual	≥ Age 25 years, or per NCCN guidelines for high-risk mutations

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.

C. Table 3: Cervical Cancer Screening Recommendations for Women at Average Risk for Cervical Cancer (ASCCP 2012, 2014)

Age to Begin	Exam/Interval	Additional Information
Age 21-29	Pap test alone : Every 3 years	• HPV testing is unacceptable for screening women ages 21-29 years.
Age 30-64	Pap test alone: Every 3 years **or** HPV-HR test alone: Every 5 years **or** Pap test and HPV-HR co-test: Every 5 years	Upper Age Limit for Screening Women aged older than 65 years: • If evidence of adequate negative prior screening* and **no** history of CIN2+ within the last 20 years, women should not be screened for cervical cancer with any modality. • Once screening is discontinued, it should not be started for any reason, even if a woman reports having a new sexual partner.
Age > 65	Pap/HPV test: Dependent on history	• Discontinue screening if adequate negative prior screening history*. • History of abnormal Pap/HPV tests – continue screening until negative results obtained.
After hysterectomy	Pap/HPV test: Dependent on history	• Continue screening for 25 years if client has a cervix or history of CIN 2 or cervical cancer.

*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.

D. Table 4: Cervical Cancer Screening Recommendations for Women (21 and older) at Increased Risk for Cervical Cancer (ASCCP 2012)

Risk Factor	Exam	Interval	Additional Comments
• Prior history of CIN or cervical cancer • Prior DES exposure • Immunosuppression from other causes • HIV/AIDS infection • Organ transplantation	Pap test (alone)	Pap test (alone) annually for 3 years.	If normal, Pap/HPV Co-test every 3 years for at least 25 years after treatment of histologic HSIL, CIN2, CIN3 is recommended.

IX. Clinician Guidelines for Follow-up of Abnormal Breast/Cervical Cancer Screening Results

A. Breast follow-up of normal and abnormal CBE Results (Clients > age 25) (Appendix D). See NCCN Clinical Practice Guidelines in Oncology for Breast Cancer Screening and Diagnosis (V.1.2021) (www.nccn.org).

B. Breast follow-up of normal and abnormal Mammogram/Ultrasound Results (Clients > age 25) (Appendix D) See NCCN Clinical Practice Guidelines in Oncology for Breast Cancer Screening and Diagnosis (V.1.2021) (www.nccn.org).

C. Cervical follow-up care provided for BC3NP clients are according to the 2019 ASCCP Cervical Risk-Based Management Guidelines (https://www.asccp.org/mobile-app).