INTRODUCTION

This protocol has been developed for use in the Michigan Breast and Cervical Cancer Control Program (BCCCP) and addresses the provision of services related to breast and cervical cancer screening and follow-up care, only. BCCCP coordinating agencies (or subcontractors), which have the ability and willingness to screen for and manage other health problems (STD testing, blood glucose testing, hemocult, etc.), may, at their own discretion, do so at the time of the woman's visit to the BCCCP. However, BCCCP 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 BCCCP 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 BCCCP 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. 2011). For follow-up of abnormal clinical breast exam (CBE) and/or mammogram results, the BCAC also recognizes and promotes the use of the NCCN Clinical Practice Guidelines Breast Cancer Screening and Diagnosis Guidelines (V.1. 2011).

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 also recognizes and promotes the use of the ASCCP 2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening Tests and 2006 Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia or Adenocarcinoma in Situ. Guidelines are referenced in this document and may be found at http://www.asccp.org
II  BCCCP PROGRAM ELIGIBILITY

A. BCCCP Age Criteria for Program Eligibility

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

1. Age 40-64: eligible to receive both breast/cervical cancer screening and/or diagnostic follow-up of breast/cervical cancer screening abnormalities
2. Age 21-45: referred to BCCCP from the Title X Program for diagnostic follow-up of a cervical cancer screening abnormality

NOTE:
- Women age 65 and over are eligible for the program if they meet the BCCCP 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 BCCCP. Care may commence or resume once client is post-partum

B. BCCCP Services Provided to Eligible Clients

The BCCCP is a cancer screening program for breast and cervical cancer ONLY. Screening is the attempt to detect unsuspected disease in average risk, asymptomatic women.

1. Screening Services Provided by the BCCCP include:
   a. Breast cancer screening services: annual Clinical Breast Exam (CBE) and Screening Mammogram
   b. Cervical cancer screening services: annual Pelvic Exam and Pap test (for eligible women, see Table 1)
2. BCCCP women identified with abnormal breast and/or cervical screening results are referred for appropriate diagnostic follow-up procedures to confirm or rule out a cancer diagnosis.
3. Women age 40-64 who meet BCCCP eligibility criteria, but receive breast or cervical cancer screening services from a non-BCCCP provider, may be referred to the program to receive appropriate diagnostic follow-up for the identified breast or cervical abnormality.
4. Women age 21 – 45 who meet BCCCP eligibility criteria, but receive cervical cancer screening services from a non-Title X agency, MUST become patients of Title X BEFORE they are referred to BCCCP for colposcopy services.
5. In the event a breast or cervical cancer is diagnosed, all BCCCP enrolled women are assisted in obtaining necessary breast or cervical cancer-related treatment in a timely manner.
III  BCCCP BREAST AND CERVICAL CANCER SCREENING RECOMMENDATIONS

A.  Annual Screening Test Recommendations
1.  Breast Cancer Screening:
   • Annual CBE
   • Annual Mammogram,
   • Breast Self-Awareness*

*Women should be familiar with their breasts and promptly report changes to their healthcare provider. Women should be informed about the benefits and limitations of Breast Self –Exam (BSE). Periodic, consistent BSE may facilitate breast self-awareness. Pre-menopausal women may find BSE most informative when performed at the end of menses.

2.  Cervical Cancer Screening:
   • Pap test (may or may not be performed according to eligibility guidelines in Table 1)
   • Speculum (Pelvic) exam - should be part of annual office visit

NOTE:
   • BCCCP funds can only reimburse for SCREENING Pap tests according to the guidelines in Table 1.
   • These guidelines DO NOT apply to women requiring Pap tests as follow-up for an abnormal Pap test result, or with a history of cervical cancer or colposcopy results ≥ CIN 2 (Cervical Intraepithelial Neoplasia). (Table 5)

Table 1: 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 “cotesting” (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. Clinical History/Examination

1. Clinical history should consist of the following:
   a. 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

   b. 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

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

   d. Smoking history: past, current, packs per day, and duration.

2. Physical exam
   a. Clinical Breast Examination
      • Sitting - inspection, palpation of auxiliary and supraclavicular nodes
      • Supine - inspection, palpation

   b. External Genitalia examination
      • Inspection and Palpation
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c. Internal examination
   • Inspection of cervix and vagina

d. Bimanual examination
   • Palpation of vaginal wall, cervix
   • Palpation of uterus and adnexae

e. Recto-vaginal exam

D. Obtain Pap test (if indicated as per recommendations in Table 1)

E. 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. Forward results of CBE to mammography facility (if able).

   3. Request copy of mammogram report. Review report to determine appropriate follow-up (if indicated as per radiologist’s recommended).

F. 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 qualified health care provider (breast surgeon/specialist).
      b. Pelvic Exam
         • Discuss components of the pelvic exam, including whether 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.
      d. 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
   - Frequency of breast cancer screening is based on the woman’s risk factors and past medical history, including biopsy history.

b. Breast cancer screening tests include both a clinical breast exam and mammogram.

c. Cervical cancer screening:
   - Includes a Pap test
   - Frequency of Pap testing depends on BCCCP Pap test history, NOT risk factors, and does NOT include Pap tests performed prior to BCCCP 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.
   e. Women with dense breasts (as identified on a mammogram) are at higher risk for developing breast cancer and should be vigilant about receiving annual screenings.

4. Discuss BCCCP limitations regarding reimbursement of services
   a. Inform the client that not all BCCCP screening and diagnostic services are paid by the program.
   b. Providers may order additional screening and follow-up tests either not reimbursed by BCCCP or not related to a breast or cervical problem.

See Section VI for services reimbursed and not-reimbursed by BCCCP

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 Tables 6 and 7.

G. Client Follow-up
   1. Client Notification of Test Results
      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. This protocol should include the process for notifying and tracking clients with the following test results:

a. Normal breast or cervical screening results – continue annual screening 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
   • BCCCP reimbursement/non-reimbursement of follow-up tests/procedures
   • Scheduling/referring for appropriate follow-up

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

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

IV CLINICAL PERFORMANCE INDICATORS
Clinical performance indicators evaluate timely and appropriate delivery of breast and cervical clinical services to program women

A. Timeliness Standard

1. Defined as the amount of time (measured in number of days) from an abnormal screening result to final diagnosis. Abnormal screening results include abnormal CBEs or Mammograms (as described in D 2) for breast screenings or abnormal Pap tests (as described in D 3) for cervical screenings.

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

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

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

C. Breast/Cervical Screening Results Requiring IMMEDIATE Follow-up
   1. IMMEDIATE Follow-up
      a. Results requiring immediate follow-up should have diagnostic work-up completed within 60 days for breast abnormalities and 90 days for cervical abnormalities
      b. Clinical Performance Indicators of timeliness and completeness ARE EVALUATED.
      c. A final diagnosis to confirm or rule/out cancer IS required.
      d. If cancer is diagnosed, a treatment disposition IS required.

   2. Breast Screening Results Requiring IMMEDIATE Follow-up include:
      a. CBE – “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)

      b. Mammogram results include:
         - ACR 0 – Assessment Incomplete-additional imaging required,
         - ACR 4 - Suspicious Abnormality,
         - ACR 5 - Highly Suggestive of Malignancy

   3. Cervical Screening Results Requiring IMMEDIATE Follow-up include
a. Atypical Squamous Cells – Undetermined Significance (ASC-US) with POSITIVE High Risk (HR) Human Papilloma Virus (HPV) ONLY,
b. Atypical Squamous Cells – cannot exclude high grade (ASC-H),
c. Low-Grade Squamous Intraepithelial Lesion (LSIL),
d. High Grade Squamous Intraepithelial Lesion (HSIL),
e. Atypical Glandular Cells (AGC),
f. Squamous cell carcinoma,
g. Adenocarcinoma

D. Breast/Cervical Screening Results Requiring SHORT-TERM Follow-up
   1. Short-Term Follow-up
      a. Results requiring short-term follow-up occur at > 3 months to monitor an abnormality identified as low risk for developing breast or cervical cancer.
      b. Clinical Performance Indicators of timeliness and completeness are NOT evaluated.
      c. A final diagnosis to confirm or rule/out cancer is NOT required.

   2. Breast Screening Results Requiring SHORT-TERM Follow-up include:
      a. CBE: “Probably Benign” Finding (nodularity, irregularity or lumpiness that is not clinically suspicious)
      b. Mammogram: ACR 3: Probably Benign

   3. Cervical Screening Results Requiring SHORT-TERM Follow-up include:
      a. Pap test result of ASC-US with negative HR HPV; Repeat Pap test in 1 year
      b. Pap test result of ASC-US, HPV test NOT done: repeat Pap test in 6 months, and refer for colposcopy if Pap test ≥ASC-US.
V BREAST CANCER SCREENING

Table 2: Follow-up of Clinical Breast Exam Screening Results

<table>
<thead>
<tr>
<th>CBE Result</th>
<th>Type of Follow-up</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| a. No Breast Abnormality  
(Normal glandular tissue felt upon palpation) | No Follow-up Required | Refer for Screening Mammogram |
| b. Benign Breast Condition  
(Symmetrical thickening or area of thickened tissue palpated in the same location in BOTH breasts; simple cyst(s) previously evaluated) | No Follow-up Required | Refer for Screening Mammogram |
| NOTE: Based on the type of mammogram ordered and client’s history, a diagnostic mammogram may be ordered. This mammogram is considered a screening as part of the annual exam for the client. |
| c. Probably Benign Breast Condition  
(Nodularity, irregularity or lumpiness that is not clinically suspicious) | Short-term Follow-up (> 3 months) | Refer for Screening or Diagnostic Mammogram (based on client’s history) |
| NOTE: Based on the type of mammogram ordered and client’s history, a diagnostic mammogram may be ordered. This mammogram is considered a screening as part of the annual exam for the client. |
| 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) | Immediate Follow-up (within 60 days) to confirm or rule/out cancer | 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) |
# BREAST AND CERVICAL CANCER CONTROL PROGRAM

## MEDICAL PROTOCOL

**Revised July 2012**

**Effective Date October 1, 2012**

<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 Table 4</td>
</tr>
<tr>
<td>ACR 2 – Benign Breast Condition</td>
<td>No Follow-up</td>
<td>Annual screening unless CBE is abnormal. - See Table 4</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>Short term Follow-up (for comparison films – obtain films within 30 days) 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.</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 NCCN Clinical Practice Guidelines in Oncology for Breast Cancer Screening and Diagnosis V.1.2011.</td>
</tr>
<tr>
<td>ACR 5 – Highly Suggestive of Malignancy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Follow-up of Non-Concordant CBE/Mammogram Results

<table>
<thead>
<tr>
<th>Result</th>
<th>Recommendation</th>
<th>BCCCP Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBE ABNORMAL Mammogram Result NORMAL (ACR 1, 2, or 3) OR ABNORMAL mammogram, NORMAL CBE</td>
<td>Refer for diagnostic work-up according to NCCN Clinical Practice Guidelines in Oncology for Breast Cancer Screening and Diagnosis V.1.2010 for abnormal CBE or mammogram result. NOTE: Breast cysts confirmed by ultrasound do not always require referral to breast surgeon. Follow-up determined by size of cyst, patient history, and recommendation by the radiologist.</td>
<td>BCCCP will pay for diagnostic follow-up based on the CBE abnormality and/or mammogram result (E.g. ultrasound, surgical consultation, biopsy) as recommended by the radiologist/breast specialist/surgeon. NOTE: Breast consult NOT required PRIOR to stereotactic biopsy by radiologist.</td>
</tr>
</tbody>
</table>

**VI CERVICAL CANCER SCREENING**

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11
# Table 5: Special Considerations for Performing Pap Tests

<table>
<thead>
<tr>
<th>Pap Test Special Consideration</th>
<th>Follow-up</th>
<th>Recommendation</th>
<th>BCCC P 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 MDCH Nurse Consultant required)</td>
<td>Pap Test</td>
</tr>
<tr>
<td>ABNORMAL pelvic examination (abnormal appearance of cervix)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfactory Pap test but NO endocervical cells</td>
<td>No Follow-up</td>
<td>Repeat Pap test in 12 months</td>
<td>Screening Pap test</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 abnormal: refer for colposcopy</td>
<td>Repeat Pap Colposcopy (if indicated)</td>
</tr>
<tr>
<td>Unsatisfactory Pap test result.</td>
<td>Short-term Follow-up</td>
<td>Repeat Pap test in 6-12 weeks. If 2nd Pap unsatisfactory, refer for colposcopy. <strong>NOTE:</strong> If 2nd Pap test is negative and satisfactory but lacks transformation zone cells – Pap test is considered NORMAL. Refer to protocol for “Satisfactory Pap test but NO endocervical cells” (above)</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>
<tr>
<td>Hysterectomy for cancer OTHER than cervical (E.g. endometrial, ovarian)</td>
<td>No Pap test indicated.</td>
<td>Pelvic exam indicated.</td>
<td>Pelvic exam.</td>
</tr>
<tr>
<td>Confirmed biopsy diagnosis of CIN 2 or greater</td>
<td>Regular Screening</td>
<td>Regular screening is defined as a Pap test every 3 years or Pap/HPV co-test every 5 years (Table 1)</td>
<td>Pap test every 3 years or Pap/HPV co-test every 5 years</td>
</tr>
<tr>
<td>Immunocompromised (e.g., transplant recipient) or DES-</td>
<td>Annual Screening</td>
<td>ANNUAL Pap tests regardless of type of Pap test</td>
<td>Annual Pap test</td>
</tr>
</tbody>
</table>
### Pap Test Special Consideration

<table>
<thead>
<tr>
<th>Pap Test Special Consideration</th>
<th>Follow-up</th>
<th>Recommendation</th>
<th>BCCCP Test Reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>exposed woman</td>
<td></td>
<td></td>
<td></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 cotesting.</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>
A. Follow-up of ABNORMAL CYTOLOGY RESULTS
The website www.asccp.org contains algorithms on the:

1. Follow-up of ASC-US cytology results for all women
   a. BCCCP funds CAN REIMBURSE for HR-HPV testing for BCCCP clients (age 40-64) ONLY as follow-up for screening Pap test results of ASC-US
   b. BCCCP funds CAN REIMBURSE for HR-HPV testing at the same time as colposcopy (etc.) for Pap test results of AGC in order to determine follow-up care

2. 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 MDCH Nurse-Consultant 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

3. 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 MDCH 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 (see B) 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.
- If NO neoplasia is identified during the initial workup of a woman with AGC (NOS), it is recommended that HR-HPV testing be performed. **Follow-up will depend on HPV results.** Management follows the algorithm located at [www.asccp.org](http://www.asccp.org)

B. Indications for Referral to a Qualified Colposcopist:

1. Women age 20 and under requiring treatment for CIN2/3
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](http://www.asccp.org)
6. Women with any gynecologic cancer should be referred to a Gynecologic Oncologist.

C. Management of Women and Adolescents with Histologically-confirmed Cervical Intraepithelial Neoplasm:

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

1. Women with histological results of CIN1, preceded by ASC-US, ASC-H or LSIL cytology
2. Women with histological results of CIN1, preceded by HSIL or AGC-NOS cytology
3. Adolescents, with a histological result of CIN1
4. Women with a histological result of CIN2/3
5. Women with AIS (Adenocarcinoma in situ) diagnosed from diagnostic excisional procedure.

D. Provision of Screening and Diagnostic Services to Special Populations in the BCCCP.

**The following populations are eligible to participate in the BCCCP 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 BCCCP for diagnostic services to confirm or rule-out a cervical cancer diagnosis **only.** (See ASCCP website for Management of adolescent women with HSIL results, ASC-US or LSIL cytology)
2. Women age 40-64 seen in a Family Planning/Title X Clinics for cervical services may be referred to BCCCP for breast screening and diagnostic services (if needed and as caseload is available).

VI REIMBURSEMENT OF BCCCP 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 BCCCP 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 BCCCP providers, BCCCP coordinators should discuss the program’s limitations regarding covered and non-covered program services provided to enrolled women.

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

Table 6: Office Visits/Consults Reimbursed by BCCCP

<table>
<thead>
<tr>
<th>Service</th>
<th>BCCCP Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Office Visit (to include CBE, and/or Pelvic Exam, and/or Pap test ( if eligible per BCCCP guidelines) ≥ 365 days from previous FIRST annual screening office visit</td>
<td>Will reimburse <strong>ONE initial visit/year (&gt; 365 days)</strong></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  
|                                                  | • MDCH 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 |
Table 7 Breast Screening/Diagnostic Services Reimbursed by BCCCP

<table>
<thead>
<tr>
<th>Service</th>
<th>BCCCP Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Mammogram ≥ 365 days from previous SCREENING Mammogram</td>
<td>Will reimburse ONE/year (&gt; 365 days)</td>
</tr>
<tr>
<td>Diagnostic Mammograms</td>
<td>Will reimburse up to TWO Diagnostic mammograms/year:</td>
</tr>
<tr>
<td></td>
<td><strong>ONE</strong> immediately performed as follow-up a Screening Mammogram result of 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 post screening as per radiologist recommendation or post biopsy as per provider’s recommendation.</td>
</tr>
<tr>
<td>Ultrasounds</td>
<td>Will reimburse up to TWO Ultrasound exams/year:</td>
</tr>
<tr>
<td></td>
<td><strong>ONE</strong> immediately performed to follow-up a Screening Mammogram result of 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 post screening as per radiologist recommendation or post biopsy as per provider’s recommendation.</td>
</tr>
<tr>
<td></td>
<td><strong>Prior authorization required for additional ultrasound testing beyond the two stated above</strong></td>
</tr>
<tr>
<td>Imaging Tests Pre Biopsy</td>
<td>Ultrasound will be reimbursed separately from biopsy <strong>ONLY</strong></td>
</tr>
<tr>
<td>Ultrasound performed prior to Ultrasound guided biopsy (performed on same day)</td>
<td>if used to determine if abnormality still present prior to performing biopsy</td>
</tr>
<tr>
<td></td>
<td>Ultrasound will <strong>NOT</strong> be reimbursed if performed as part of a provider’s routine practice prior to performing biopsy</td>
</tr>
<tr>
<td>Imaging Tests Post Biopsy</td>
<td>Will reimburse post biopsy imaging</td>
</tr>
</tbody>
</table>

Table 8: Cervical Screening/Diagnostic Services Reimbursed by BCCCP
### Service | BCCCP Reimbursement
--- | ---
**Screening Pap test**<br>Frequency depends on type and result of Pap test or Pap/HPV cotest – See Table 1 | Reimbursement denied if prior to “Client Eligible for Pap Test” Date unless approved by MDCH Nurse Consultant.

**HR-HPV as an adjunct to screening Pap test** | Pap and HPV (cotest) will be reimbursed only ONCE every 5 years if both tests negative

**Follow-up Pap tests** | Only Pap tests performed according to the medical protocol for follow-up of screening Pap test abnormalities will be reimbursed.

**HR-HPV test may be performed alone (without Pap test) as 12 month follow-up of colposcopy** | Will reimburse HR HPV test no more than ONE/year (>364 days)

**High Risk 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 BCCCP CLIENTS AGE 40 AND OLDER:**
- Only ONE High Risk (HR) HPV test within a 12 month time-period will be reimbursed
- 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 MDCH Nurse Consultant for reimbursement approval of diagnostic LEEP/Cold Knife Cone for Pap test results of HSIL followed by a colposcopy with biopsy result of \( \leq \) CIN 1

**EMB (for women with AGC Pap result only)** | Notify MDCH Nurse Consultant for reimbursement approval of EMB as diagnostic work-up of AGC Pap test result.

---

Table 9: Breast/Cervical Services NOT reimbursed by BCCCP

<table>
<thead>
<tr>
<th>Breast Services</th>
<th>Rationale</th>
<th>BCCCP Reimbursement</th>
</tr>
</thead>
</table>

---
### Breast Magnetic Resonance Imaging (MRI)

<table>
<thead>
<tr>
<th>Screening or Diagnostic MRI is not a covered service</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT reimbursed</td>
</tr>
</tbody>
</table>

### Screening Ultrasound (US)

<table>
<thead>
<tr>
<th>Ultrasounds are performed with a mammogram, not instead of a mammogram to further define a breast abnormality.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimbursed if performed WITH a Screening Mammogram NOT in place of a Screening Mammogram</td>
</tr>
</tbody>
</table>

### Computer Aided Device (CAD)

<table>
<thead>
<tr>
<th>Used in conjunction with mammogram- aids in interpretation of mammogram</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT reimbursed</td>
</tr>
</tbody>
</table>

### Ductogram

<table>
<thead>
<tr>
<th>Not a covered service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact MDCH Nurse Consultant to determine alternative option for service</td>
</tr>
</tbody>
</table>

### Axillary Node Biopsy (confirm breast cancer diagnosis in absence of abnormal mammogram)

<table>
<thead>
<tr>
<th>Not a covered service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact MDCH Nurse Consultant to determine alternative option for service</td>
</tr>
</tbody>
</table>

### Cervical Services

<table>
<thead>
<tr>
<th>Pap test to rule/out endometrial cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only Cervical Cancer Screening Services are reimbursed by BCCCP</td>
</tr>
<tr>
<td>NOT reimbursed</td>
</tr>
</tbody>
</table>

### Endometrial Biopsy (EMB) for follow-up of Pap result of “endometrial cells in a woman > age 40”

<table>
<thead>
<tr>
<th>Only Cervical Cancer Services are reimbursed by BCCCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT reimbursed</td>
</tr>
</tbody>
</table>

### Pap test post hysterectomy performed for BENIGN gynecological disease - NO CERVIX PRESENT

<table>
<thead>
<tr>
<th>Screening with vaginal cytology is NOT indicated; Pelvic exam is indicated.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pap test NOT reimbursed. Office visit (pelvic exam) reimbursed</td>
</tr>
</tbody>
</table>

### HR HPV tests performed on Pap test results of: ASC-H, LSIL, HSIL

<table>
<thead>
<tr>
<th>HR-HPV testing is ONLY indicated to determine clinical follow-up for ASC-US Pap results and as part of diagnostic follow-up of AGC Pap results.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HP-HPV test reimbursed once only ≥12 months</td>
</tr>
</tbody>
</table>

### Low-risk HPV test

<table>
<thead>
<tr>
<th>Low-risk HPV test has is not an appropriate test in cancer screening program</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT reimbursed</td>
</tr>
</tbody>
</table>
QUESTIONS REGARDING THIS PROTOCOL MAY BE DIRECTED TO:

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

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

Washington Square Building
Cancer Prevention and Control Section,
109 Michigan Ave, 5th Floor, Lansing, MI 48913