Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

November 8, 2021

Dear Participating Providers:

Thank you for providing cervical cancer screening for uninsured or underinsured women aged 21 – 64 enrolled in the Maryland Breast and Cervical Cancer Program (BCCP). The BCCP is a grantee of the National Breast and Cervical Cancer Early Detection Program, funded by the Centers for Disease Control and Prevention. The policies of the national program are based on evidence in scientific literature and recommendations from national organizations such as the American Society for Colposcopy and Cervical Pathology (ASCCP), United States Preventive Services Task Force, and the American Cancer Society.

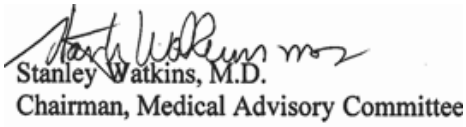
We are pleased to enclose the revised "Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis" developed by the Medical Advisory Committee (MAC) for the BCCP to serve as guidelines for the screening and management of women receiving cervical cancer screening through the BCCP. Notable updates to the Cervical Cancer Minimal Clinical Elements include:

1. Changed the flow of the various sections to make the document more user-friendly.
2. Added client residency, income, and health insurance eligibility criteria.
3. Replaced the word "women" with "individuals" to be more inclusive of all program clients.
4. Added new sub-groups of individuals in the screening recommendations, and updated screening recommendations for certain sub-groups.
5. Updated the definition of "adequate screening."
6. Added a section on prior approvals and reimbursement policies based on program guidelines.
7. Added a statement that "all eligible individuals" will undergo a risk assessment during the provider's office visit to determine if they are at high risk for cervical cancer.

8. Removed the prior ASCCP algorithm reprints and included a link to the no-cost ASCCP Risk-Based Management web application tool, based on ASCCP's recommendations.
9. Removed the prior "Cervical Specimen Collection and Cytology Findings" section and added an online link to the 2014 Bethesda System for Reporting Cervical Cytology.
10. Added a statement to say that the providers will need to provide the immediate and 5-year risk in their notes, as applicable. Local BCCP programs will review the immediate risk and 5 year risk percentage and approve the screening and diagnostic procedures, as appropriate based on the risk evaluation algorithm.
11. Updated the MAC members list.

We appreciate your cooperation in using the new guidelines effective December 1, 2021. If you have any questions regarding the new "Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis", please contact Ken Lin Tai, Director for the Center for Cancer Prevention and Control at kenlin.tai@maryland.gov **OR** Srishti Singh, Nurse Consultant for the Cancer Screening Programs Unit at srishti.singh@maryland.gov.

Sincerely,



Stanley Watkins, M.D.
Chairman, Medical Advisory Committee

Enclosure

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Maryland Department of Health Center for Cancer Prevention and Control
Maryland Breast and Cervical Cancer Program
Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis
Updated November 2021

Goal: The goal of the Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis is to provide evidence-based cervical cancer screening and diagnostic guidelines for Maryland Breast and Cervical Cancer Program providers.

Section I: Client Eligibility

Program eligibility for the Maryland Breast and Cervical Cancer Program's (BCCP) Cervical Cancer Screening and Diagnostic Services:

a) Individuals between the ages of 21 years and 64 years without Medicare Part B[1], and individuals 65 years and older without Medicare Part B[2] who have not had adequate screening[3]; **AND**
Either:
- Has an intact cervix (no hysterectomy or supracervical hysterectomy); **OR**
- Has had a hysterectomy with a history of cervical cancer, high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3), or for an indication and/or medical history that is unknown to the individual.

b) Individuals will also need to meet the residency, income, and health insurance requirements listed below:
- Are a Maryland resident; **AND**
- Have an annual household income ≤ 250% of the federal poverty level; **AND**
- Have no health insurance, **OR** have health insurance that does not completely pay for required services, **OR** have health insurance but will need assistance or navigation services to obtain screening or diagnostic care.

[1] Note about Medicare Part B participation: This includes individuals who are not eligible to receive Medicare Part B, and Medicare-eligible individuals who cannot pay the premium to enroll in Medicare Part B.
[2] See footnote 1.
[3] Adequate prior screening is defined as 3 consecutive negative cytology results, 2 consecutive negative co-tests, or 2 consecutive negative HPV tests within 10 years before stopping screening, with the most recent test occurring within 5 years.

Section II: Screening Recommendations

The recommendations below apply to program-enrolled individuals regardless of their sexual history or human papillomavirus (HPV) vaccination status.

Target Group	Screening Recommendation for BCCP Clients
Average risk individuals, below the age of 21 years	Do not screen.
Average risk individuals, ages 21 to 29 years	Screen with cytology alone every 3 years.
Average risk individuals, ages 30 to 65 years	Screen with cytology alone every 3 years; **or** co-testing with cytology and high-risk HPV (hrHPV) every 5 years; **or** hrHPV alone every 5 years.
Individuals older than 65 years, who have had adequate prior screening and are not high-risk[4] (e.g., no CIN 2+ within the prior 25 years)	Do not screen. ***Adequate prior screening*** *is defined as 3 consecutive negative cytology results, 2 consecutive negative co-tests, or 2 consecutive negative HPV tests within 10 years before stopping screening, with the most recent test occurring within 5 years.*
Individuals after hysterectomy with removal of the cervix and with no history of a high-grade precancerous lesion (e.g., CIN 2 or 3) within prior 25 years or cervical cancer diagnosis[5]	Do not screen.

[4] Individuals who are at high-risk include individuals with HIV infection, individuals with non-HIV immunocompromising medical conditions (e.g., solid organ transplant), or individuals with in utero exposure to diethylstilbestrol.

[5] See Section III (1) (g-h) for more details on documentation of the hysterectomy and history of cervical cancer/pre-cancer.

Individuals with HIV infection ***Note:*** *Further guidance can be obtained from the Centers for Disease Control and Prevention/National Institutes of Health/HIV Medicine Association of the Infectious Diseases Society of America's "Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV."*	**For individuals ages 21-29 years:** Baseline cytology at the time of initial diagnosis with HIV. Cytology every year; if results of 3 consecutive cytology results are normal, perform cytology every 3 years. **For individuals ages 30-65 years:** Baseline co-testing with cytology plus hrHPV testing, **or** baseline cytology alone, at the time of initial diagnosis with HIV. **For co-testing:** If baseline result of cytology is normal and HPV is negative, co-testing can be performed every 3 years. **For cytology-only testing:** Screen every year; if results of 3 consecutive cytology results are normal, perform cytology every 3 years.
Individuals with non-HIV immunocompromising medical conditions (e.g., solid organ transplant) ***Note:*** *Further guidance on individuals with non-HIV immunocompromising conditions can be obtained from Moscicki et al's "Guidelines for Cervical Cancer Screening in Immunosuppressed Individuals Without HIV Infection."*	**For individuals ages 21-29 years:** Cytology every year; if results of 3 consecutive cytology results are normal, perform cytology every 3 years. **For individuals ages 30-65 years:** Baseline co-testing with cytology plus hrHPV testing, **or** cytology alone. Co-testing is preferred. **For co-testing:** If baseline result of cytology is normal and HPV is negative, co-testing can be performed every 3 years. **For cytology-only testing:** Screen every year; if results of 3 consecutive cytology results are normal, perform cytology every 3 years.
Individuals with in utero exposure to diethylstilbestrol	Screen with annual cytology.

Section III: Reimbursement and Prior Approvals

1. Screening Services

a) A minimum of 20% of all BCCP-reimbursed screening Pap tests should be provided to program-eligible individuals who have NEVER been screened for cervical cancer.
b) All eligible individuals will undergo a risk assessment during the provider's office visit to determine if they are at high risk for cervical cancer. BCCP funds can be used for routine cancer screening among individuals who are considered high-risk for cervical cancer.
c) BCCP will not reimburse for cervical cancer screening in individuals under the age of 21 years.
d) Transgender men (female-to-male) who have not undergone a total hysterectomy (i.e., still have a cervix) and meet all eligibility requirements are eligible to receive cervical cancer screening and diagnostic services through BCCP.
e) Routine screening options are recommended for average-risk individuals. Individuals at high-risk may benefit from one screening option versus another.
f) Screening recommendations should be evaluated for individuals who have comorbidities or circumstances that would make the routine screening difficult or where the risks of screening outweigh the benefits (e.g., undergoing active treatment for a diagnosed cancer).
g) For individuals for whom the reason for the hysterectomy or final diagnosis of no neoplasia or invasive cancer cannot be documented, BCCP funds can be used to reimburse for cervical cancer screening. For these individuals, cervical cancer screening should continue until there is a 10-year history of negative screening results, including documentation that the Pap tests were technically satisfactory.
h) If it is unknown if the individual's cervix was removed at the time of a hysterectomy, a physical examination (e.g., speculum examination) can be done to determine if the cervix is present. BCCP funds can be used to reimburse for an initial examination to determine if the individual has a cervix.
i) BCCP funds cannot be used to reimburse for cervical cancer screening in individuals who have had total hysterectomies (i.e., those without a cervix), unless the hysterectomy was performed because of cervical neoplasia or invasive cervical cancer.
j) For individuals with a history of cervical neoplasia or in situ disease, BCCP funds can be used to reimburse for routine cervical cancer surveillance for 20 years post treatment.
k) For individuals with a history of invasive cervical cancer, BCCP funds can be used to reimburse cervical cancer surveillance indefinitely, as long as the individual is in good health.

2. HPV Testing

a) Testing for low-risk HPV types is not reimbursable by BCCP.
b) Testing for the hrHPV panel[6] is reimbursable as a screening test by BCCP if used alone every 5 years or when co-testing with cytology every 5 years.

[6] The high-risk (oncogenic) HPV panel includes types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68 without differentiation of the individual type.

c) Testing for the hrHPV panel is reimbursable if performed as guided by the American Society for Colposcopy and Cervical Pathology (ASCCP) algorithm in the management of abnormal cytology/histology. Providers should specify the high-risk HPV DNA panel only.
d) Testing for HPV genotyping[7] (e.g. HPV 16/18) is reimbursable by BCCP, if performed as guided by the ASCCP algorithm in the management of abnormal cytology/histology.
e) HPV DNA testing is not a reimbursable procedure if used as an adjunctive screening test to the Pap for individuals under 30 years of age.

3. Individuals with History of Cervical Cancer without Hysterectomy (e.g., radiation, implant, conization)

a) If the individual is being released from a gynecologic oncologist to routine screening (e.g., after 5 years of follow-up post diagnosis), obtain and review medical history of Pap test results to know what will be expected on the Pap tests in the BCCP (e.g., presence of endocervical cells or not).
b) If the individual has no medical records, refer first (before testing in the BCCP) to a gynecologic oncologist for consultation on appropriate Pap testing and test result interpretation.

4. Management of Abnormal Findings

a) Only screening, diagnostic, and surveillance procedures as recommended in the current 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors based on the Cytologic or Histologic findings will be reimbursed by BCCP (see Section IV: Management of Cervical Cytologic Abnormalities) to the extent that funding is available. If funding is not available for screening or diagnostic procedures, the local BCCP program may link the individual to other funding sources (e.g., Cigarette Restitution Fund Cancer Prevention, Education, Screening and Treatment Program or the Breast and Cervical Cancer Diagnosis and Treatment Program). As these guidelines cannot cover all clinical situations, clinical judgment is advised in those circumstances. However, as additional or alternative procedures are usually not reimbursed by BCCP, providers **should consult** with their local BCCP program about the justification and reimbursement of these procedures before proceeding further. The local BCCP program will contact the Maryland Department of Health's (MDH) Cancer Screening Programs Unit (CSPU) Nurse Consultant for further guidance and reimbursement pre-approval, if needed.
b) To arrive at a definitive diagnosis for an individual with an abnormal cervical cancer screening test, in unusual cases, BCCP funds may be used to reimburse diagnostic excisional procedures such as LEEP and cold-knife excisions, as well as associated pathology to the extent that funding is available. However, providers **should consult** with their local BCCP program about the justification and reimbursement of these procedures before proceeding further. The local BCCP program will contact the MDH CSPU Nurse Consultant for further guidance and reimbursement pre-approval, if needed.

[7] Genotyping detects the presence or absence of specific high-risk HPV types (e.g. 16 and 18) only.

c) Treatment procedures **are not** reimbursable by the BCCP program. Individuals requiring treatment for cervical cancer should be referred to the Maryland Breast and Cervical Cancer Diagnosis and Treatment Program.

Section IV: Management of Cervical Cytologic Abnormalities

Please refer to the 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors for the management of cervical cytologic abnormalities. Providers can use the free online version of the guidelines, which are available at https://www.asccp.org/mobile-app.

Below are the steps to access the ASCCP's free online application link:

1. Type in or click on the link provided here: https://www.asccp.org/mobile-app
2. Then click on the "Web Application" icon.
3. A new web page will open; enter your email address, click on the checkbox to accept ASCCP's terms, and click "Next".
4. Go to your email inbox to confirm your email address, and click on the "Get Started" blue icon inserted in the body of the email to access the Web Application for free.
5. Enter the patient's information/findings into the Web Application, as appropriate.

Note: Providers can also download the ASCCP Mobile App on their smart devices; however, the Mobile App is not a free service.

Providers will need to provide the immediate and 5 years' risk in their notes, as applicable, which would be shared with the local BCCP program. Local BCCP programs will review the immediate risk and 5 years' risk percentage and approve the screening and diagnostic procedures, as appropriate based on the risk evaluation algorithm.

Section V: Reporting of Results

For reporting of cervical specimen collection and cytology findings, please refer to the 2014 Bethesda System for Reporting Cervical Cytology, available at https://www.karger.com/Article/Pdf/381842

Section VI: References

American Society for Colposcopy and Cervical Pathology. (2020). 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. *Journal of Lower Genital Tract Disease*, 24(2), 102–131. https://journals.lww.com/jlgtd/FullText/2020/04000/2019_ASCCP_Risk_Based_Management_Consensus.3.aspx

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Section VII: Cervical Cancer Medical Advisory Committee

The following members participated in the update of the Minimal Clinical Elements:

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