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August 1, 2012

Dear Maryland Breast and Cervical Cancer Program Provider:

Thank you for providing cervical cancer screening for uninsured or underinsured women aged 40 – 64 enrolled in the Maryland Breast and Cervical Cancer Program (BCCP). The Maryland BCCP is a grantee of the National Breast and Cervical Cancer Early Detection Program, funded by the Centers for Disease Control and Prevention. 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) 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 for the BCCP to serve as guidelines for the screening and management of women receiving cervical cancer screening through BCCP.

In March 2012, The U. S. Preventative Services Task Force, The American Cancer Society, American Society for Colposcopy and Cervical Pathology and American Society for Clinical Pathology published updated "Screening Guidelines for the Prevention and Early Detection of Cervical Cancer.[1]" The Medical Advisory Committee revised the Minimal Clinical Elements based on the new 2012 Screening Guidelines for the Prevention and Early Detection of Cervical Cancer.

Some of the major changes include:

- Screening average risk women with cytology alone every 3 years, **or** co-testing with cytology and HPV every 5 years.
- Defining average versus high risk women.
- Defining adequate screening for women 65+.
- Clarifying screening for women with a history of hysterectomy due to CIN 2/3 or cervical cancer.

[1] Saslow, D, Solomon, D, Lawson, H., et al, Am J Clin Pathol 2012;137:516-542

The BCCP will continue to follow the ASCCP algorithms based on the "2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening Tests,[2]" and the "2006 Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia or Adenocarcinoma in situ.[3]"

Enclosed are the revised "Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis" and *Selected* ASCCP Flow Charts relevant to the Maryland Breast and Cervical Cancer Program: Cytology and Histology, ©2006, 2007.

We appreciate your cooperation in using the new guidelines. If you have any questions regarding the new "Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis" for the Maryland BCCP, please contact Diane Dwyer, M.D., Medical Director of the Center for Cancer Prevention and Control (CCPC) at (410) 767-5088 or diane.dwyer@maryland.gov.

Sincerely,

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

Maryland Breast and Cervical Cancer Program

Enclosure

Cc: Courtney Lewis, M.P.H., Director, CCPC
Diane Dwyer, M.D., Medical Director, CCPC
Dawn Henninger, R.N., M.S., Program Manager, BCCP
Holly Harshbarger, R.N., B.S., Program Nurse Consultant, BCCP
Local BCCP Coordinators

[2] Wright, TC, Cox, JT, Massad, LS, et al, Am J Ob Gyn. October 2007;346-55
[3] Wright, TC, Cox, JT, Massad, LS, et al Am J Ob Gyn. October 2007;340-45

Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis
Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
July 2012

Goal:

The goal of the Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis is to provide clients of the Maryland Breast and Cervical Cancer Program (BCCP) with optimal, up-to-date screening for cervical cancer and management of findings.

Objectives:

- To assist local BCCPs in evaluating cervical cytology screening interval, results and recommended management.
- To incorporate into the Minimal Clinical Elements the 2012 USPSTF Recommendations for Screening for Cervical Cancer.
- To assure the Minimal Clinical Elements remain in line with the 2001 Bethesda System Terminology for Reporting Results of Cervical Cytology.
- To inform clinicians of these guidelines.
- To incorporate into the Minimal Clinical Elements the 2006 American Society for Colposcopy and Cervical Pathology (ASCCP) Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia and Cervical Cytological Abnormalities.

Attachment A: Detection of Cervical Cytologic Abnormalities in the BCCP

- **Attachment A1:** Screening Interval
- **Attachment A2:** Program Guidelines
- **Attachment A3**: Cervical Specimen Collection and Cytology Findings Reported (2001 Bethesda System)

Attachment B: Management of Cervical Cytologic Abnormalities in the BCCP

- *Selected* ASCCP Flow Charts relevant to the Maryland Breast and Cervical Cancer Program: Cytology and Histology, ©2006, 2007 (The entire set of ASCCP Flow Charts is available at http://www.asccp.org/consensus.shtml

References:

1. Solomon D, Davey D, Kurman, R, et al. for the Forum Group Members and the Bethesda 2001 Workshop. The 2001 Bethesda System: Terminology for Reporting Results of Cervical Cytology. JAMA. 2002;287: 2114-9.
2. Robert A. Smith, Vilma Cokkinides and Otis W. Brawley. Cancer screening the United States, 2009: A review of current American Cancer Society guidelines and issues in cancer screening. CA Cancer J Clin 2009;59;27-41.
3. Thomas C. Wright Jr, MD, L. Stewart Massad, MD, Charles J. Dunton, MD, Mark Spitzer, MD, Edward J. Wilkinson, MD, Diane Solomon, MD for the 2006 American Society for Colposcopy and Cervical Pathology–sponsored Consensus Conference. 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ. Am J Ob Gyn. October 2007;340-5.
4. Thomas C. Wright Jr, MD, L. Stewart Massad, MD, Charles J. Dunton, MD, Mark Spitzer, MD, Edward J. Wilkinson, MD, Diane Solomon, MD for the 2006 American Society for Colposcopy and Cervical Pathology–sponsored Consensus Conference. 2006 consensus

guidelines for the management of women with abnormal cervical cancer screening tests. Am J Ob Gyn. October 2007;346-55.
5. Saslow, D, Solomon, D, Lawson, HW, et al. "American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology Screening Guidelines for the Prevention and Early Detection of Cervical Cancer" *Am J Clin Pathol* 2012;137:516-542.

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Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
Attachment A—Detection of Cervical Cytologic Abnormalities in the BCCP

Attachment A1
Screening Interval

Population	Recommendation
Women ages 40-64	Screen with cytology alone every 3 years **or** Co-testing with cytology and HPV every 5 years
Women older than 65 who have had adequate prior screening and are not high risk	Do not screen if adequate prior screening. (See Attachment A2 Program Guidelines #5)
Women after hysterectomy with removal of the cervix and with no history of a high-grade precancerous lesion (CIN 2 or 3) or cervical cancer	Do not screen women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer**.**
Women after hysterectomy with removal of the cervix and with history of a high-grade pre cancerous lesion (CIN 2 or 3) or cervical cancer	Women who have had a hysterectomy for CIN disease should undergo cervical cancer screening with cytology alone every three years or co-testing with cytology and HPV every 5 years for 20 years even if it goes past the age of 65. Women who have had cervical cancer should continue annual screening indefinitely as long as they are in reasonable health.

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Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
Attachment A2
Program Guidelines

1. Program eligibility for the Maryland Breast and Cervical Cancer Program
    a. Women 40 – 64 years old or 65+ without Medicare Part B;
    b. Meets income eligibility of ≤ 250% of the Federal Poverty Guideline;
    c. Has no health insurance, has no health insurance that covers cervical cancer screening, or has coverage but has not met the deductible for the year; and
    d. Either:
        i. Has an intact cervix (no hysterectomy or supracervical hysterectomy); or
        ii. Has had a hysterectomy for cervical cancer, for CIN 2/3, or for an indication unknown to the woman.

2. Vaginal Pap tests may be performed ***only*** on women who required a hysterectomy due to cervical cancer or CIN 2/3.
    a. For other indications (symptoms or vaginal lesion), refer the woman to another program for Pap testing or evaluation.
    b. Women who have had a hysterectomy for CIN 2/3 disease should undergo cervical cancer screening every 3 years with cytology alone or co-testing with cytology and HPV every 5 years for 20 years even if screening extends beyond the age of 65.
    c. Women who have had a hysterectomy due to cervical cancer should continue annual screening indefinitely as long as they are in reasonable health.
    d. If the reason for the hysterectomy cannot be documented, she should continue routine screening with Pap testing every 3 years or co-testing every 5 years.

3. The screening interval for average risk women—
    a. Cytology alone every 3 years **OR**
    b. Co-testing with cytology and HPV every 5 years.

4. Women who are considered high-risk may need more intensive (i.e. annual) screening. This pertains to women who:
    a. Were exposed in utero to diethylstilbestrol (DES);
    b. Are immunocompromised; or
    c. Are HIV-infected.

5. Women age 65+ who have had adequate prior cervical cancer screening and are not otherwise at high risk for cervical cancer should not be tested. (Adequate prior screening is defined as 3 consecutive negative cytology results or 2

consecutive negative HPV results within 10 years before cessation of screening, with the most recent test occurring within 5 years.)

6. HPV DNA Testing
    a. HPV DNA testing is reimbursable as a screening test in the BCCP if used in co-testing with cytology every 5 years.
    b. Only HPV DNA testing for high-risk genotypes is reimbursable.
    c. Reimbursement for HPV genotyping is not allowed.
    d. HPV DNA testing is reimbursable if performed as guided by ASCCP Flow Sheets in the management of abnormal cytology/histology, for example:
        i. As a follow-up test to an ASC-US result (See attachment B, ASCCP Flow, Page 7 of 16); or
        ii. For surveillance at 12 months following LSIL without evidence of CIN on colposcopy-directed biopsy (See attachment B, ASCCP Flow, page 9 of 16).

7. If the Pap test is read as "unsatisfactory for evaluation,"
    a. If the woman had prior Negative Pap test results, repeat Pap test in 4 months.
    b. If the woman had (one or more) prior Abnormal Pap test results, repeat the Pap test in 4 months.

8. If the Pap test on a premenopausal woman is read as "Normal. Satisfactory for evaluation; no endocervical cells present,"
    a. If the woman had prior Negative Pap tests for the prior 2-3 tests, then return for repeat Pap test in 12 months.
    b. If the woman did not have a history of several prior Negative Pap tests, then return for repeat Pap in 4 months.

9. If a patient has a history of cervical cancer *without* hysterectomy (e.g., radiation, implant, conization)
    a. If the woman is being released from 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., endocervical cells or not).
    b. If the woman 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.

10. Follow ASCCP Flow Sheets (Attachment B) based on Cytologic and Histologic findings.

11. Only procedures recommended in the ASCCP Flow Sheets based on the Cytologic or Histologic findings will be paid. Additional or alternative procedures are usually not paid for by the BCCP. Consultation with the local BCCP public

health program is advised before proceeding with further procedures.

Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
Attachment A3
Cervical Specimen Collection and Cytology Findings Reported (2001 Bethesda System)

1. Specimen Collection
    a. Collection of conventional Pap smear
        i. A sample of the ectocervix is collected with a spatula rotating 360 degrees at least once around the cervix.
        ii. A sample of the endocervix is collected preferably with a cytobrush rotating at least 90 degrees.
        iii. If no cervix present, a sample of the vaginal cuff only is collected (see BCCP Program Guidelines #1 d and #2 a, b, & c above).
    b. Collection of liquid-based cervical cytology
        i. A gynecologic sample is collected using a broom-type or cytobrush/spatula cervical sampling device and then rinsed into the collection medium following directions of the manufacturer.

2. Specimen Adequacy
    a. Satisfactory for evaluation (note presence or absence of endocervical/transformation zone component).
    b. Unsatisfactory for evaluation because of… (specify reason).
        i. Specimen rejected/not processed (specify reason).
        ii. Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of (specify reason).

3. Results
    a. Negative for Intraepithelial Lesion or Malignancy (reporting non-neoplastic findings is optional)
        i. Organisms (e.g., Trichomonas; fungal org. consistent with Candida; bacterial vaginosis; Actinomyces species; cellular changes consistent with Herpes simplex virus).
        ii. Other non-neoplastic findings (e.g., Reactive changes/Glandular status post hysterectomy/Atrophy).
    b. Epithelial Cell Abnormalities
        i. Squamous Cell
            - ASC-US (atypical squamous cells of undetermined significance).
            - ASC-H (atypical squamous cells-cannot exclude high grade squamous intraepithelial lesion [HSIL]).
            - LSIL (low grade squamous intraepithelial lesion—includes Human Papilloma Virus [HPV]/ mild dysplasia/CIN 1).

- HSIL (high grade squamous intraepithelial lesion—includes mod. and severe dysplasia, CIS; CIN-2 & CIN-3).
- Squamous cell carcinoma

ii. Glandular Cell

- Atypical glandular cells (AGC) specify endocervical, endometrial, or not otherwise specified (NOS).
- Atypical glandular cells, favor neoplastic (specify endocervical, or NOS).
- Endocervical adenocarcinoma in situ (AIS).
- Adenocarcinoma (all types).

c. Other

i. Endometrial cells (in women > 40 years of age).
ii. Other Malignant Neoplasms (specify).

Educational Notes and Suggestions—Women who are pregnant or who still desire pregnancy should have additional consultation beyond these guidelines.

Attachment B—Management of Cervical Cytologic Abnormalities in the BCCP

Selected ASCCP Flow Charts

Relevant to the Maryland Breast and Cervical Cancer Program: Cytology and Histology

Footnotes in the charts may refer to text or special situations further clarified in these references:

- Thomas C. Wright Jr, MD, L. Stewart Massad, MD, Charles J. Dunton, MD, Mark Spitzer, MD, Edward J. Wilkinson, MD, Diane Solomon, MD for the 2006 American Society for Colposcopy and Cervical Pathology-sponsored Consensus Conference. 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ. Am J Ob Gyn. October 2007;340-5

- Thomas C. Wright Jr, MD, L. Stewart Massad, MD, Charles J. Dunton, MD, Mark Spitzer, MD, Edward J. Wilkinson, MD, Diane Solomon, MD for the 2006 American Society for Colposcopy and Cervical Pathology-sponsored Consensus Conference. 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. Am J Ob Gyn. October 2007;346-55

The entire set of ASCCP Flow Charts including the charts not included here are available at http://www.asccp.org/consensus.shtml

Charts **not** included here are:

- Management of Adolescent Women with Either ASC-US or LSIL
- Management of Pregnant Women with LSIL
- Management of Adolescent Women (20 years and younger) with HSIL
- Management of Adolescent Women (20 years and younger) with CIN-1
- Management of Adolescent and Younger Women with a Histological Diagnosis of CIN 2,3

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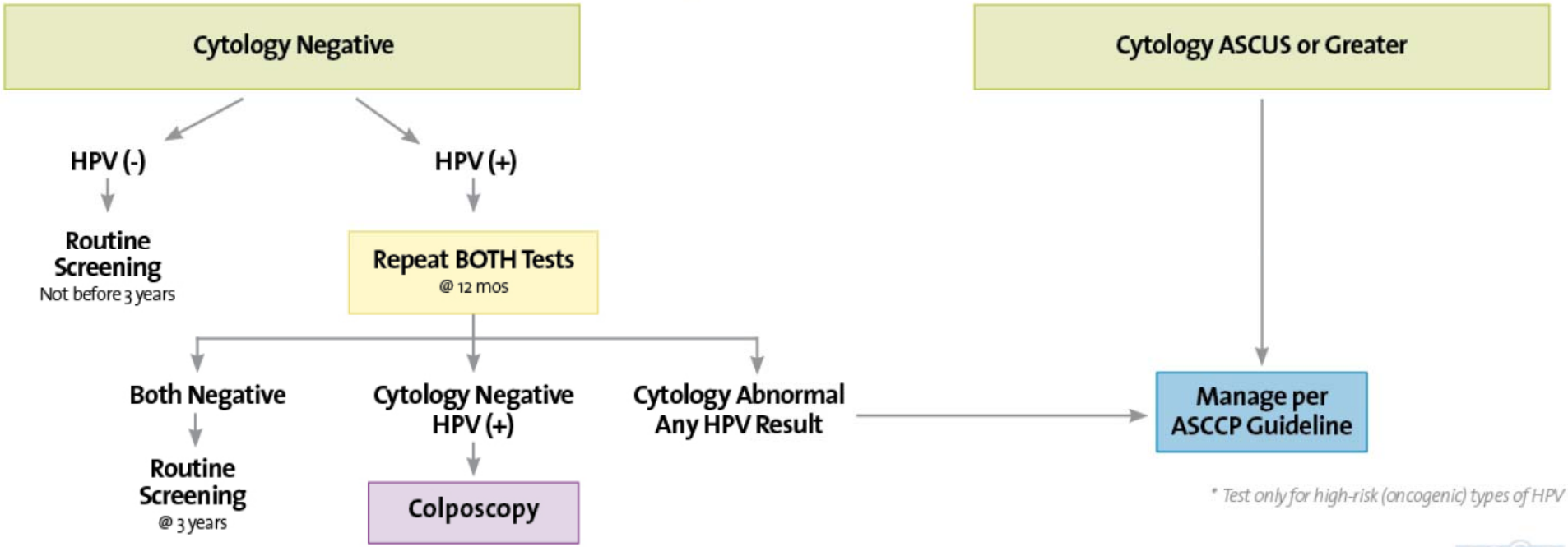
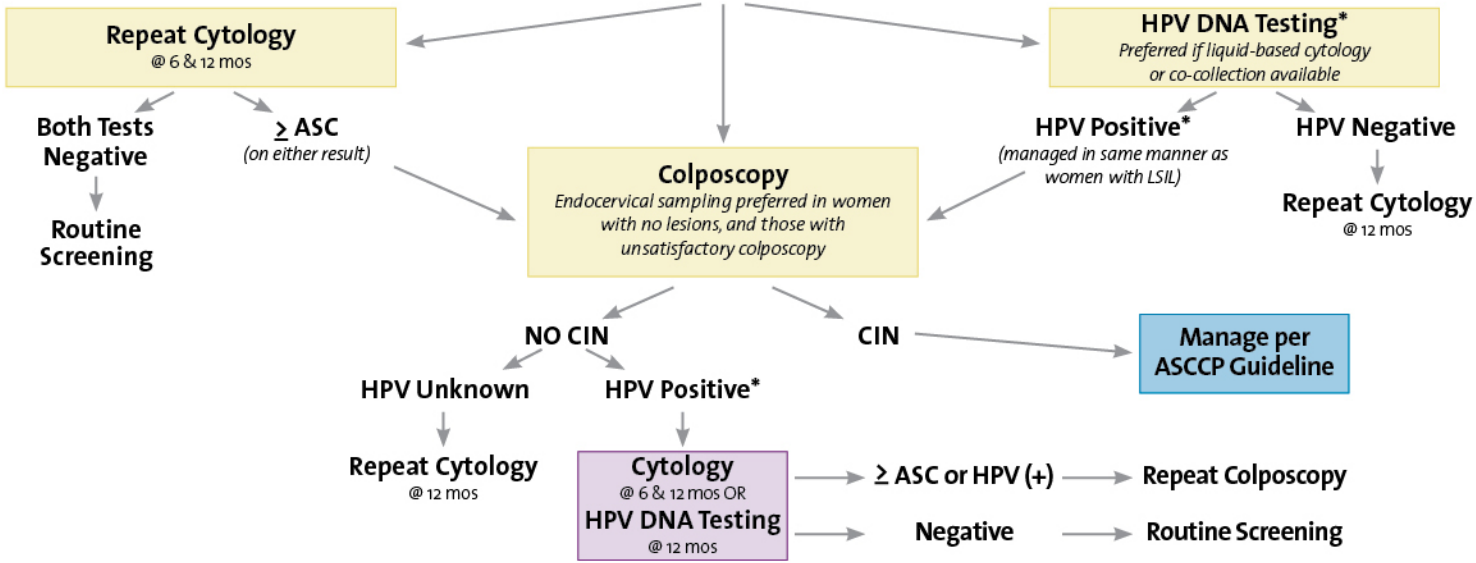
Use of HPV DNA Testing * as an Adjunct to Cytology for Cervical Cancer Screening in Women 30 Years and Older



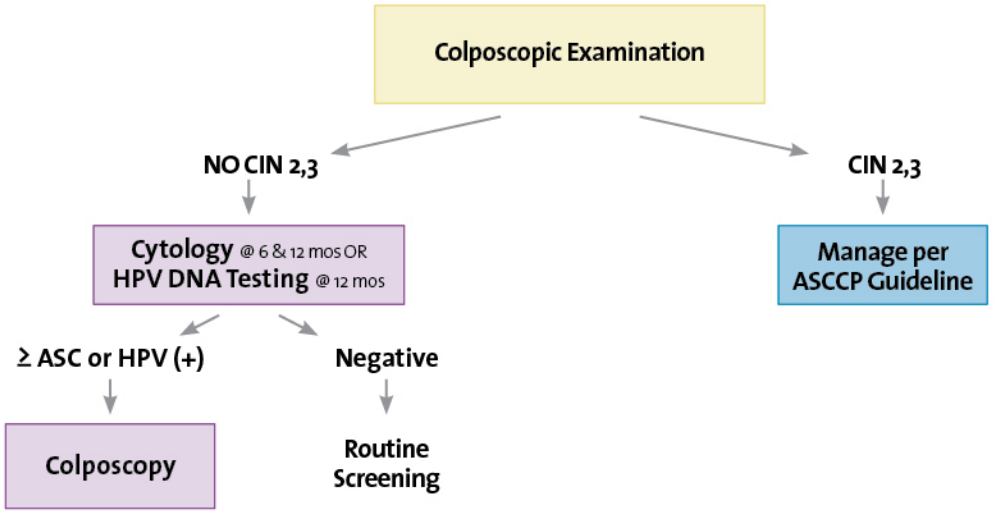
* Test only for high-risk (oncogenic) types of HPV

Management of Women with Atypical Squamous Cells of Undetermined Significance (ASC-US)

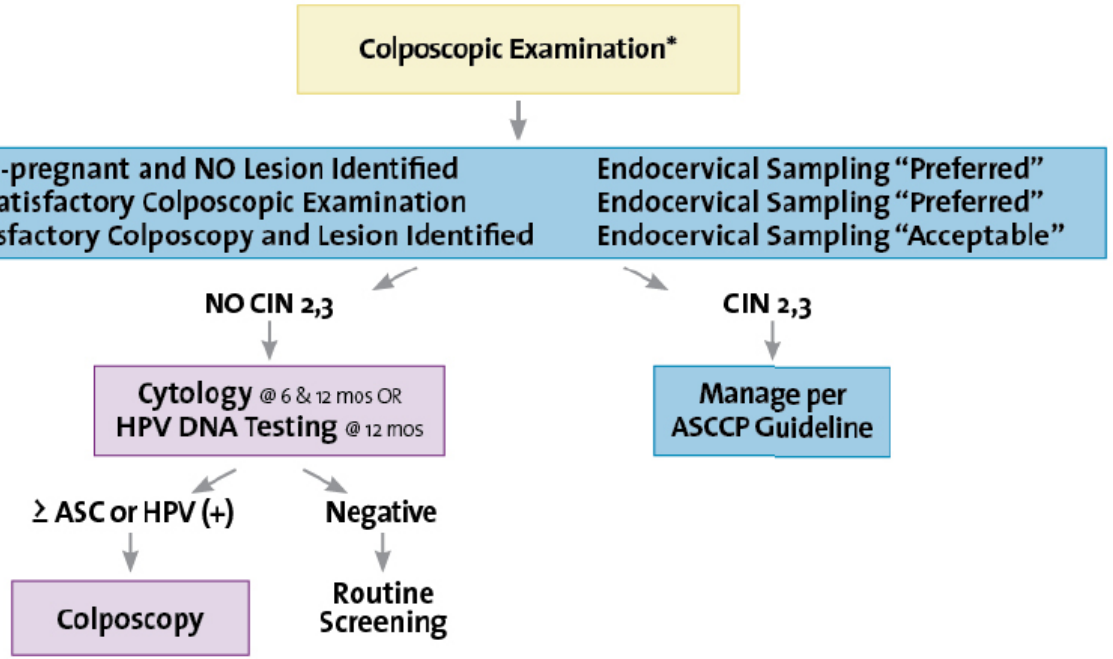


*Test only for high-risk (oncogenic) types of HPV

Management of Women with Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC - H)



Management of Women with Low-grade Squamous Intraepithelial Lesion (LSIL) *

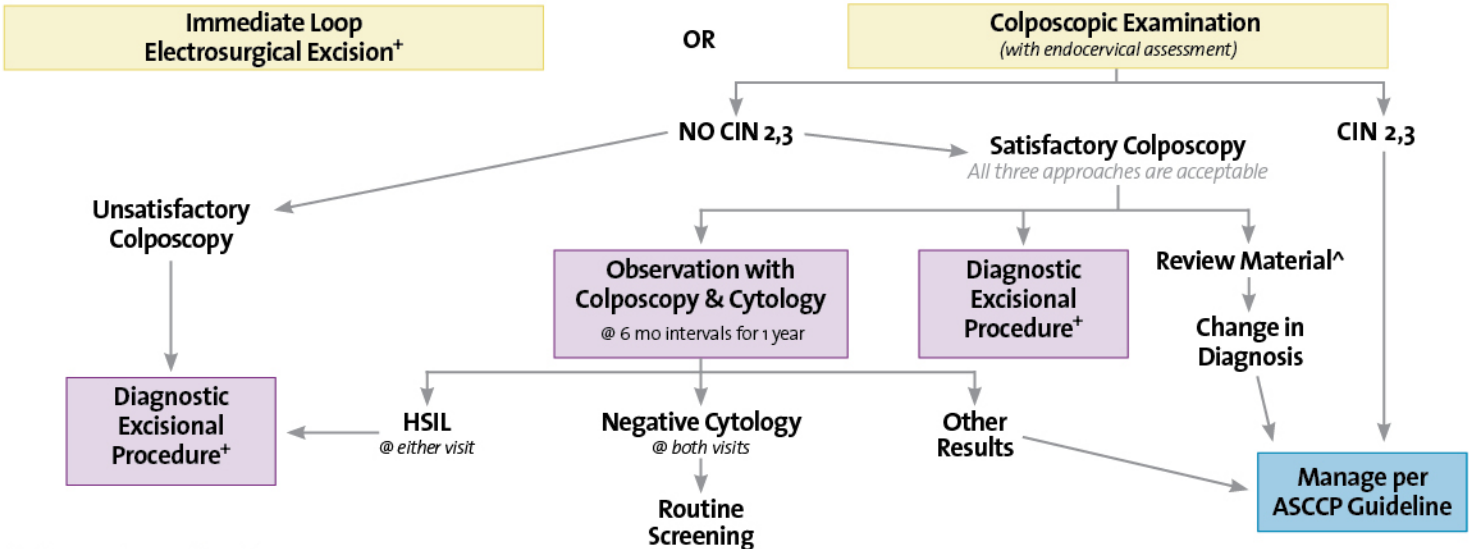


*Management options may vary if the woman is pregnant, postmenopausal or an adolescent - (see text, below)

Note: The management of LSIL in Postmenopausal women is essentially the same as the management of ASC-US:

Text: Wright TC, Cox, JT, Massad LS, et al, Am J Ob Gyn. October 2007;349-50.
"Postmenopausal women: Acceptable options for the management of postmenopausal women with LSIL include "reflex" HPV DNA testing, repeat cytological testing at 6 and 12 months, and colposcopy.
If the HPV DNA test is negative or CIN is not identified at colposcopy, repeat cytology in 12 months is recommended.
If either the HPV DNA test is positive or the repeat cytology is ASC-US or greater, colposcopy is recommended.
If 2 consecutive repeat cytologic tests are negative for intraepithelial lesion or malignancy, return to routine cytologic screening is recommended."

Management of Women with High-grade Squamous Intraepithelial Lesion (HSIL) *

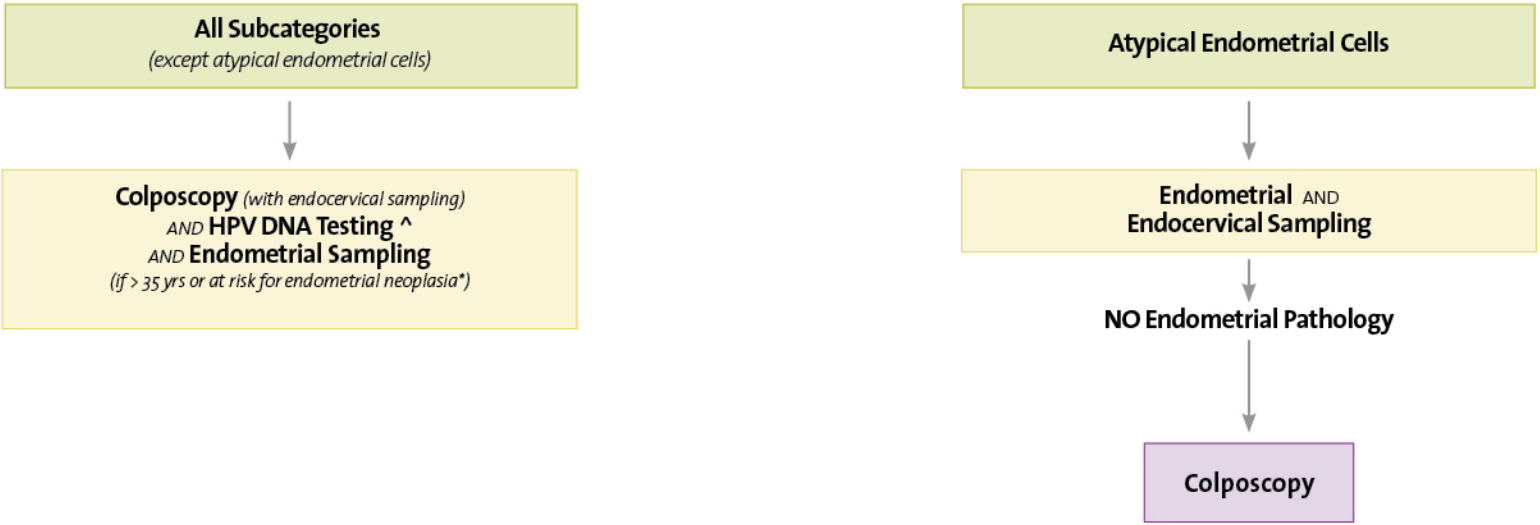


+ Not if patient is pregnant or an adolescent

^ Includes referral cytology, colposcopic findings, and all biopsies

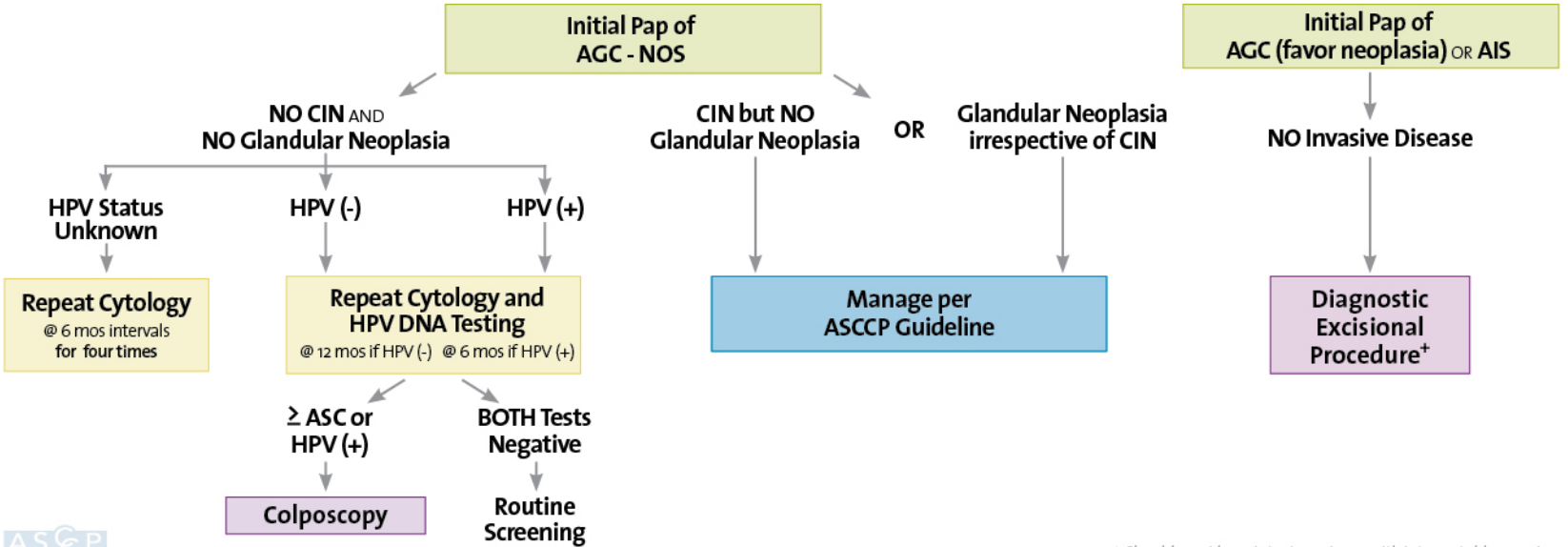
* Management options may vary if the woman is pregnant, postmenopausal, or an adolescent

Initial Workup of Women with Atypical Glandular Cells (AGC)



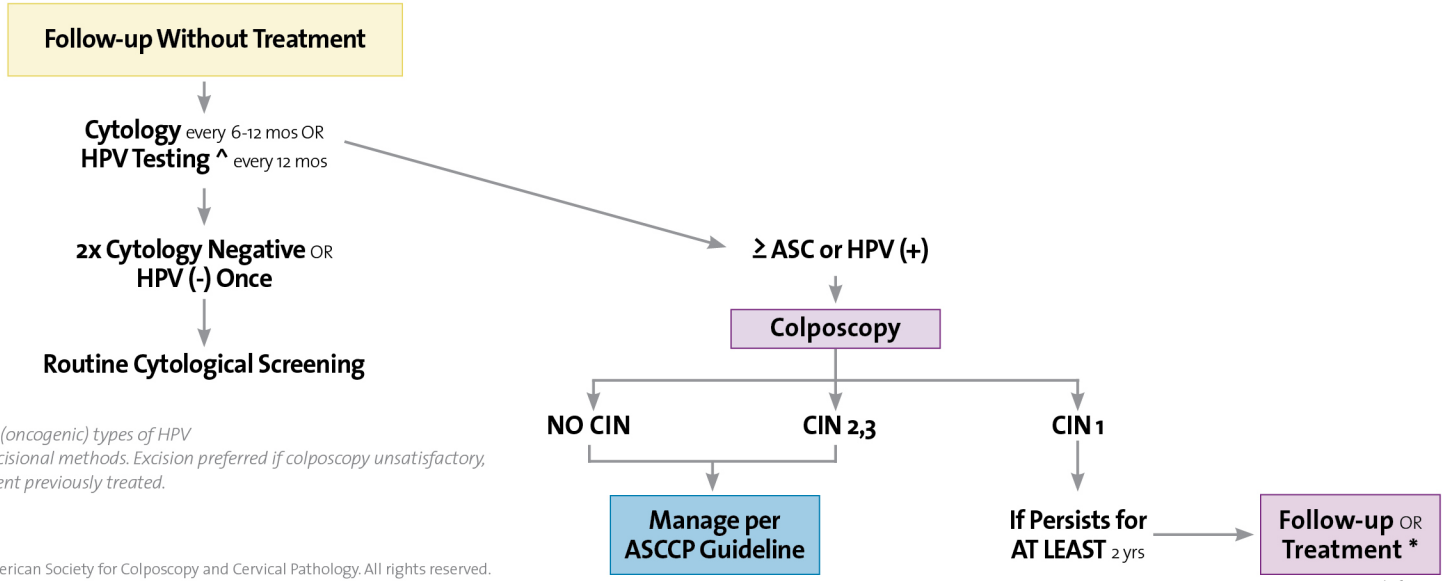
^ If not already obtained. Test only for high-risk (oncogenic) types.
* Includes unexplained vaginal bleeding or conditions suggesting chronic anovulation.

Subsequent Management of Women with Atypical Glandular Cells (AGC)



+ Should provide an intact specimen with interpretable margins. Concomitant endocervical sampling is preferred.

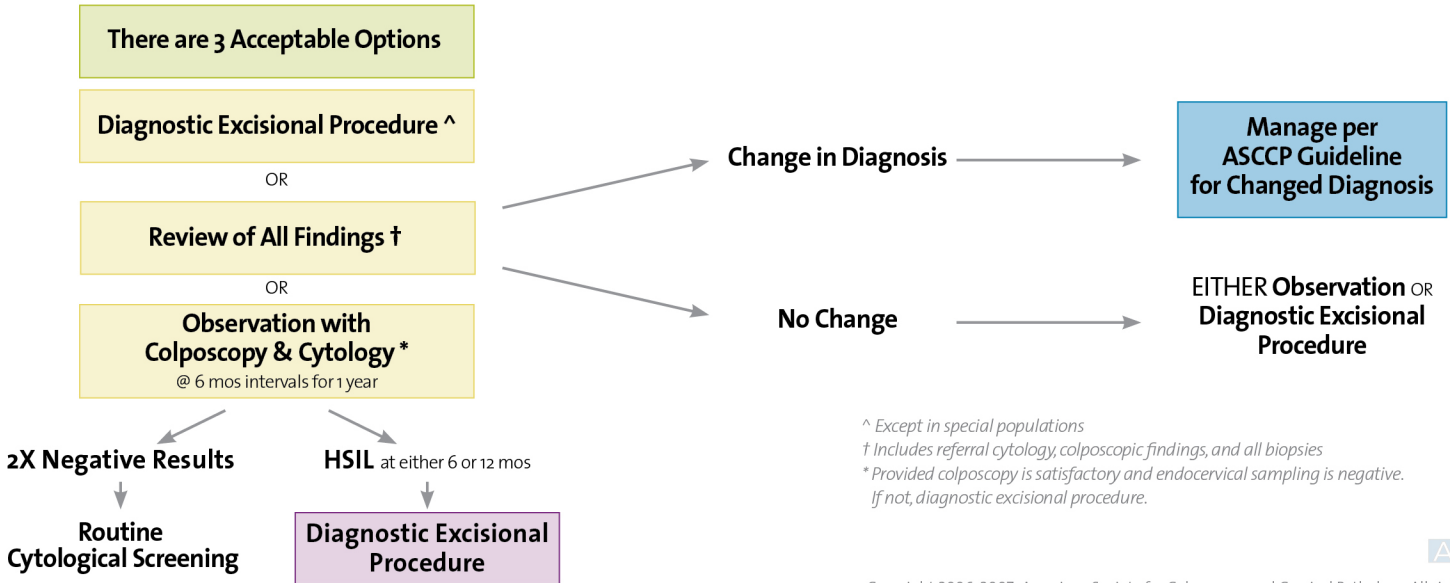
Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia Grade 1 (CIN 1) Preceded by ASC-US, ASC-H or LSIL Cytology



^ *Test only for high-risk (oncogenic) types of HPV*

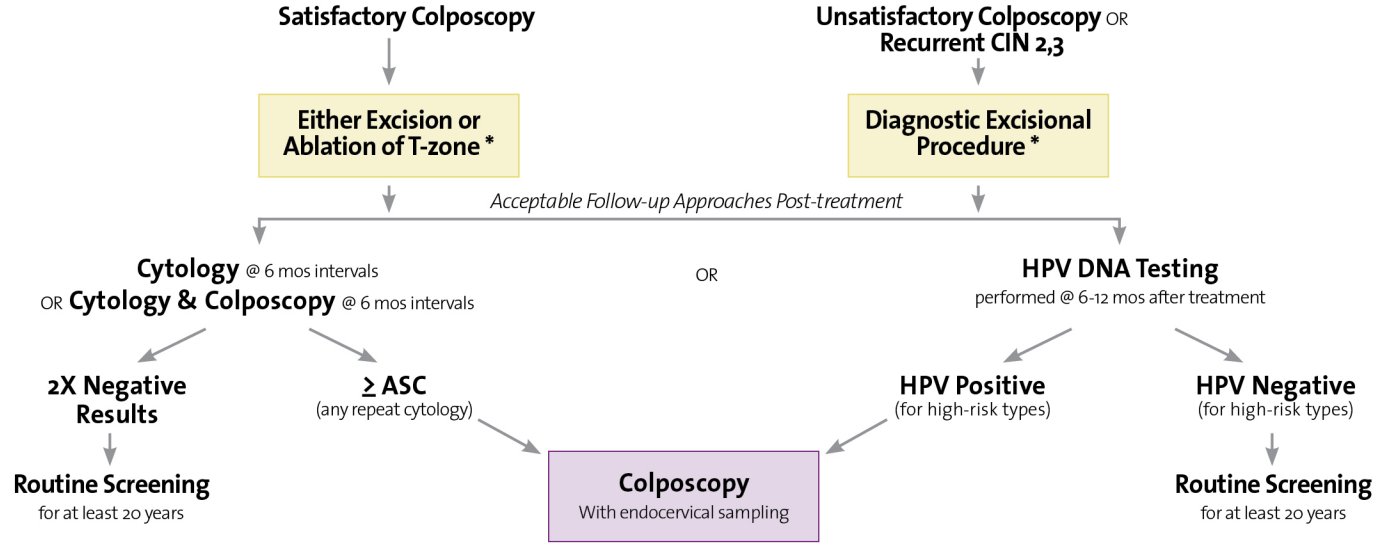
* *Either ablative and excisional methods. Excision preferred if colposcopy unsatisfactory, ECC is positive, or patient previously treated.*

Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia - Grade 1 (CIN 1) Preceded by HSIL or AGC-NOS Cytology



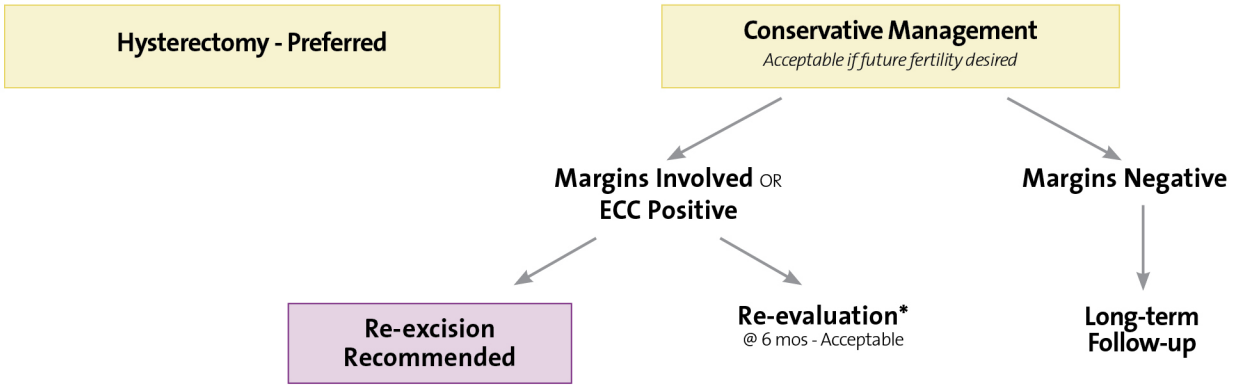
^ *Except in special populations*
† *Includes referral cytology, colposcopic findings, and all biopsies*
* *Provided colposcopy is satisfactory and endocervical sampling is negative. If not, diagnostic excisional procedure.*

Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia - (CIN 2,3) *



*Management options will vary in special circumstances

Management of Women with Adenocarcinoma in-situ (AIS) Diagnosed from a Diagnostic Excisional Procedure



*Using a combination of cytology, HPV testing, and colposcopy with endocervical sampling