STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

Family Health Administration
Russell W. Moy, M.D., M.P.H., Director – Joan H. Salim, Deputy Director

March 31, 2009

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 the BCCP.

In 2007, the American Society for Colposcopy and Cervical Pathology published the "2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening Tests,"[1] and the "2006 Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia or Adenocarcinoma in situ."[1] The Medical Advisory Committee revised the Minimal Clinical Elements based on these new consensus guidelines.

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

Some of the major changes include:

- Discontinues the use of intra-vaginal estrogen therapy for post-menopausal women with atrophy and either LSIL or ASC-US prior to repeating the cervical cytology;
- Allows HPV/DNA test at 12 months for follow-up after specific, designated procedures per the ASCCP guidelines;
- Expands management guidelines for women with biopsy confirmed cervical intraepithelial Neoplasia grades 2/3 (CIN 2/3).

Enclosed are the revised **"Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis."**

We appreciate your cooperation in using these 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 Surveillance and Control (CCSC) at (410) 767-5088 or ddwyer@dhmh.state.md.us.

Sincerely,

Stanley Watkins, M.D.
Chairman, Medical Advisory Committee
Maryland Breast and Cervical Cancer Program

Enclosure

cc: Donna Gugel, M.H.S., Director, CCSC
Diane Dwyer, M.D., Medical Director, CCSC
Courtney Lewis, M.P.H., Program Manager, BCCP
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Local BCCP Coordinators

Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis

Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Surveillance and Control

March 2009

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 results and recommended management
- 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 and Management of Cervical Cytologic Abnormalities in the BCCP

Attachment B. ***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.

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Attachment A

Detection and Management of Cervical Cytologic Abnormalities in the Breast and Cervical Cancer Program

Cervical Cancer Minimal Clinical Elements

A. Maryland Breast and Cervical Cancer Program (BCCP) Program Guidance

1. A woman is eligible for cervical cancer screening (Pap testing) with liquid-based or conventional cervical cytology (See B. and C, below) in the BCCP if she:
    a. Is 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 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 are documented to have required a hysterectomy due to cervical cancer or CIN 2/3.
    a. For other indications (symptoms or vaginal lesion), refer woman to another program for Pap testing or evaluation.

3. The screening interval for average risk women with **negative Pap tests** is
    a. For liquid-based cervical cytology: **every two years** until a woman has 3 consecutive negative cervical cancer screening tests documented within a 60-month period, then provide one test every three years.
    b. For conventional cervical cytology: **every year** until a woman has 3 consecutive negative cervical cancer screening tests documented within a 60-month period, then provide one test every three years.

4. HPV DNA Testing
    a. HPV DNA testing is **not reimbursable as a screening test in the BCCP**.
    b. HPV DNA testing **is reimbursable** if performed as guided by ASCCP Flow Sheets in the management of abnormal cytology/histology, for example:
        1. as a follow-up test to an ASC-US result (See Attachment B, ASCCP Flow, Page 7 of 16); or
        2. for surveillance at 12 months following LSIL without evidence of CIN on colposcopy-directed biopsy (See Attachment B, ASCCP Flow, Page 9 of 16).
    c. Only HPV DNA testing for high-risk genotypes is reimbursable.

5. 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.

6. 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 test in 4 months.

7. If a patient has a history of cervical cancer *without* hysterectomy (e.g., radiation, implant, conization)
    a. If the woman is being released from a gynecologic oncologist to routine screening (e.g., after five 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.

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

9. Only pay for procedures recommended in the ASCCP Flow Sheets based on the Cytologic or Histologic findings. Additional or alternative procedures are usually not paid for by the BCCP. Consultation with the local BCCP public health program is advised before approving procedures for payment.

B. Cervical Cytology

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 A. 1, and 2. above, BCCP Program Guidance)

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 (see A. 1, and 2, above, BCCP Program Guidance)

C. Cervical Cytology Findings Reported (2001 Bethesda System)*

1. **Specimen Type**
    a. Conventional (Pap test)
    b. Liquid Based cytology
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
        ii. consistent with Herpes simplex virus)
        iii. 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 a woman > 40yrs of age)
        ii. Other Malignant Neoplasms (specify)

D. Educational Notes and Suggestions

1. Women who are pregnant or who still desire pregnancy should have additional consultation beyond these guidelines.

Attachment B

Selected ASCCP Flow Charts relevant to the Maryland Breast and Cervical Cancer Program: Cytology and Histology

© American Society for Colposcopy and Cervical Pathology 2006, 2007

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

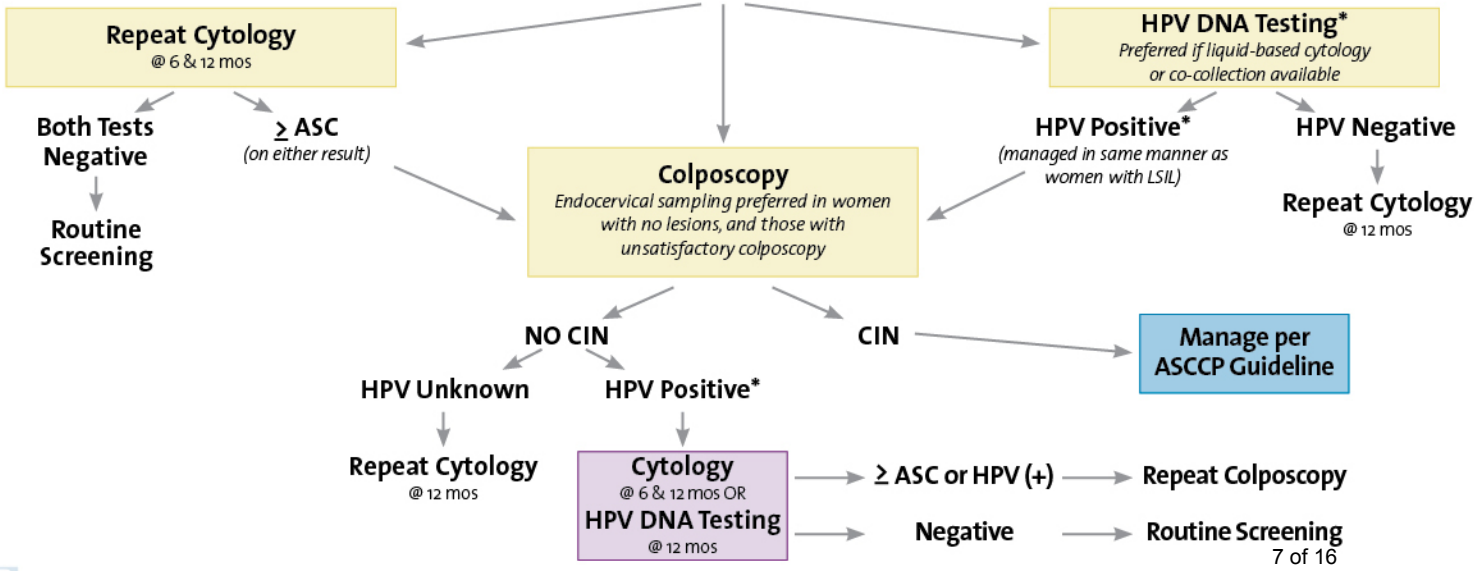
- Thomas C. Wright Jr, MD, L. Stewart Massad, MD, Charles J. Dunton, MD, Mark Spitzer, MD, Edward J. Wilkinson, MD, Diane Solomon, MD for the 2006 American Society for Colposcopy and Cervical Pathology–sponsored Consensus Conference. 2006 consensus guidelines for the management of women with abnormal 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 is available at http://www.asccp.org/consensus.shtml

Charts **not** included here are:

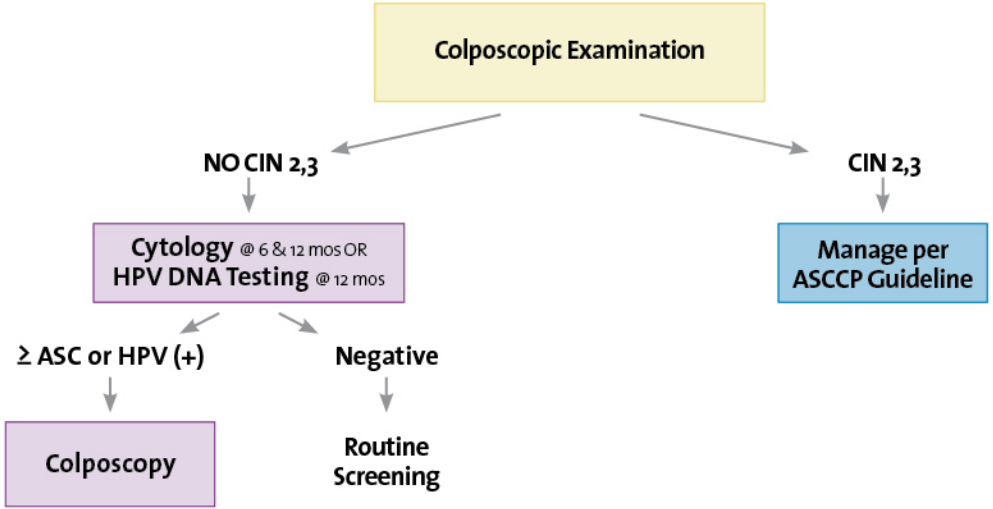
- Management of Adolescent Women with Either ASC-US or LSIL
- Management of Pregnant Women with LSIL
- Management of Adolescent Women (20 Years and Younger) with HSIL
- Use of HPV DNA Testing as an Adjunct to Cytology for Cervical Cancer Screening in Women 30 Years and Older
- Management of Adolescent Women (20 Years and Younger) with CIN-1
- Management of Adolescent and Younger Women with a Histological Diagnosis of CIN 2,3

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

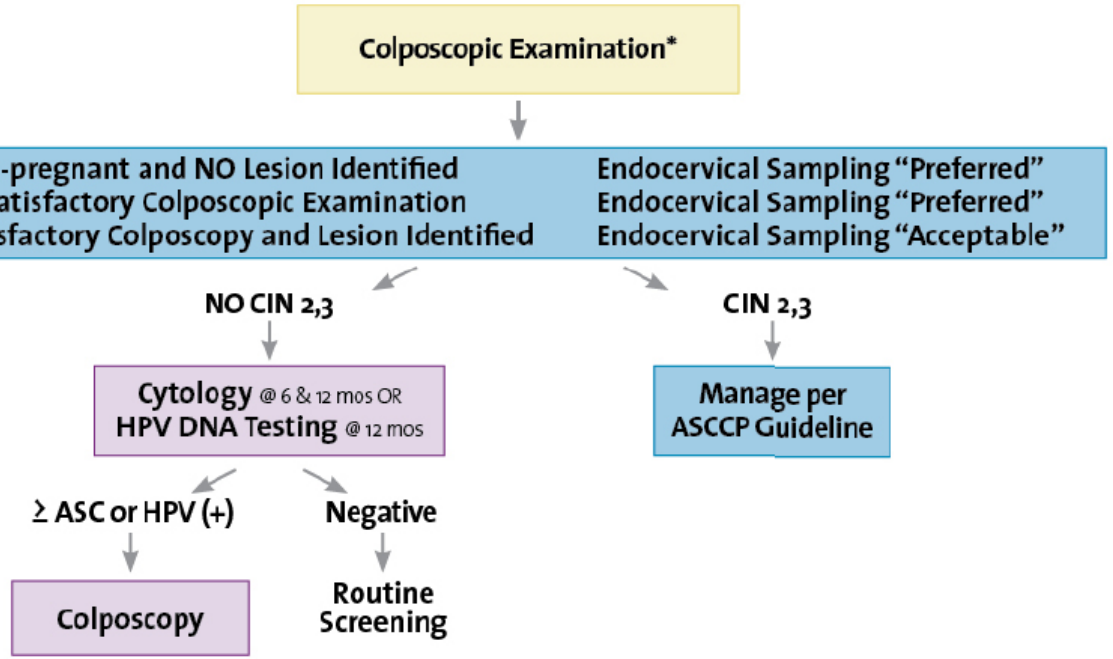


*Test only for high-risk (oncogenic) types of HPV

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



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

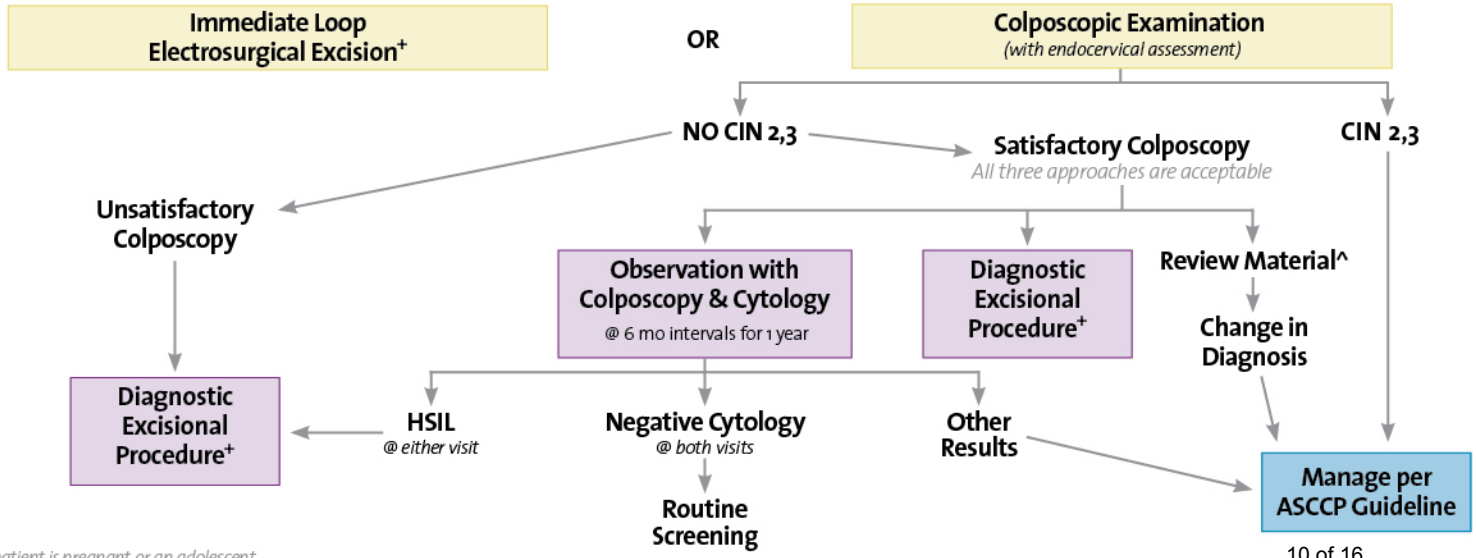


*Management options may vary if the woman is pregnant, postmenopausal or an adolescent - (see text, below)

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) *

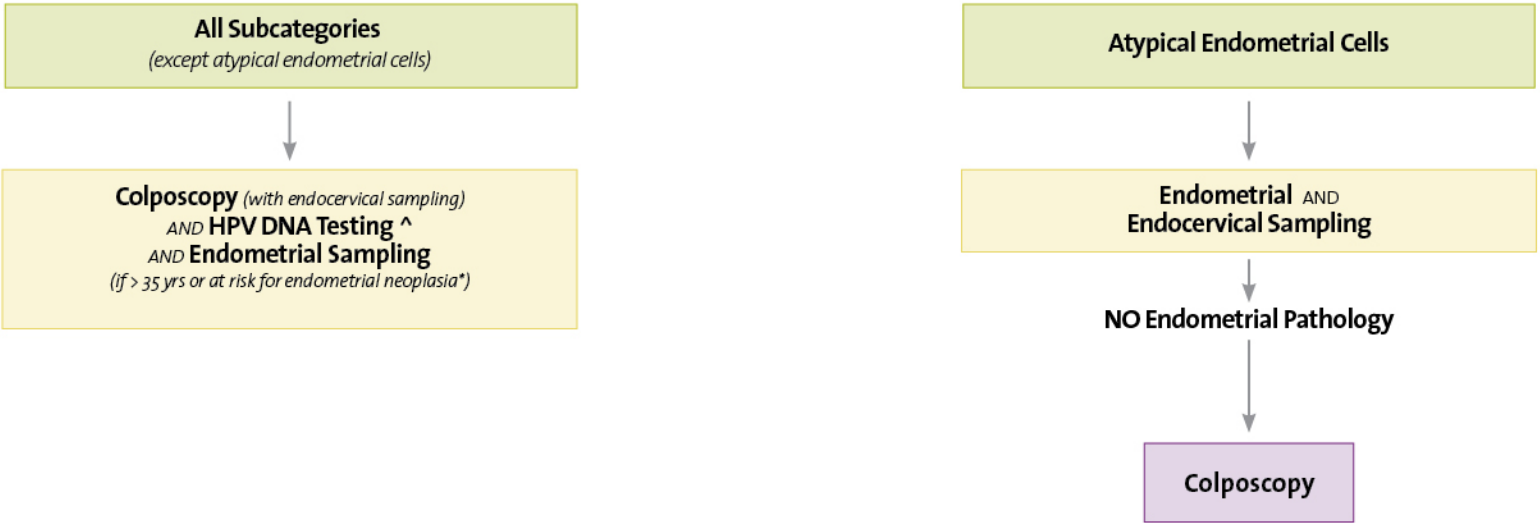


+ Not if patient is pregnant or an adolescent

^ Includes referral cytology, colposcopic findings, and all biopsies

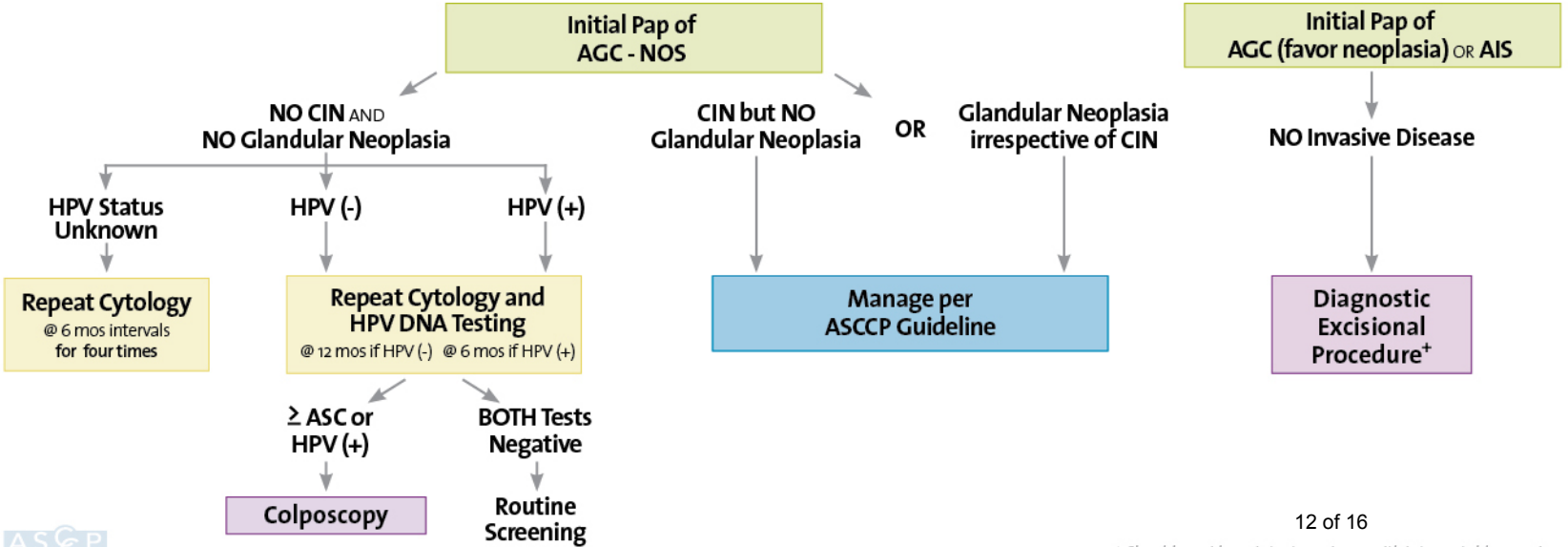
* Management options may vary if the woman is pregnant, postmenopausal, or an adolescent

Initial Workup of Women with Atypical Glandular Cells (AGC)



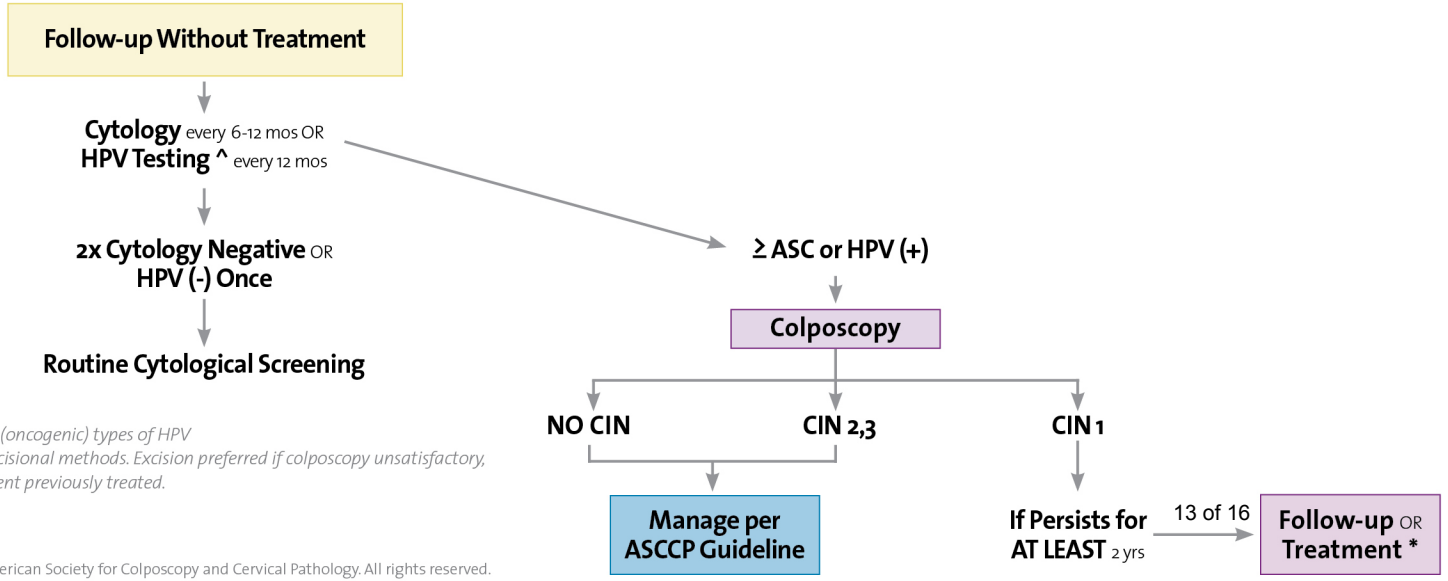
^ If not already obtained. Test only for high-risk (oncogenic) types.
* Includes unexplained vaginal bleeding or conditions suggesting chronic anovulation.

Subsequent Management of Women with Atypical Glandular Cells (AGC)



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

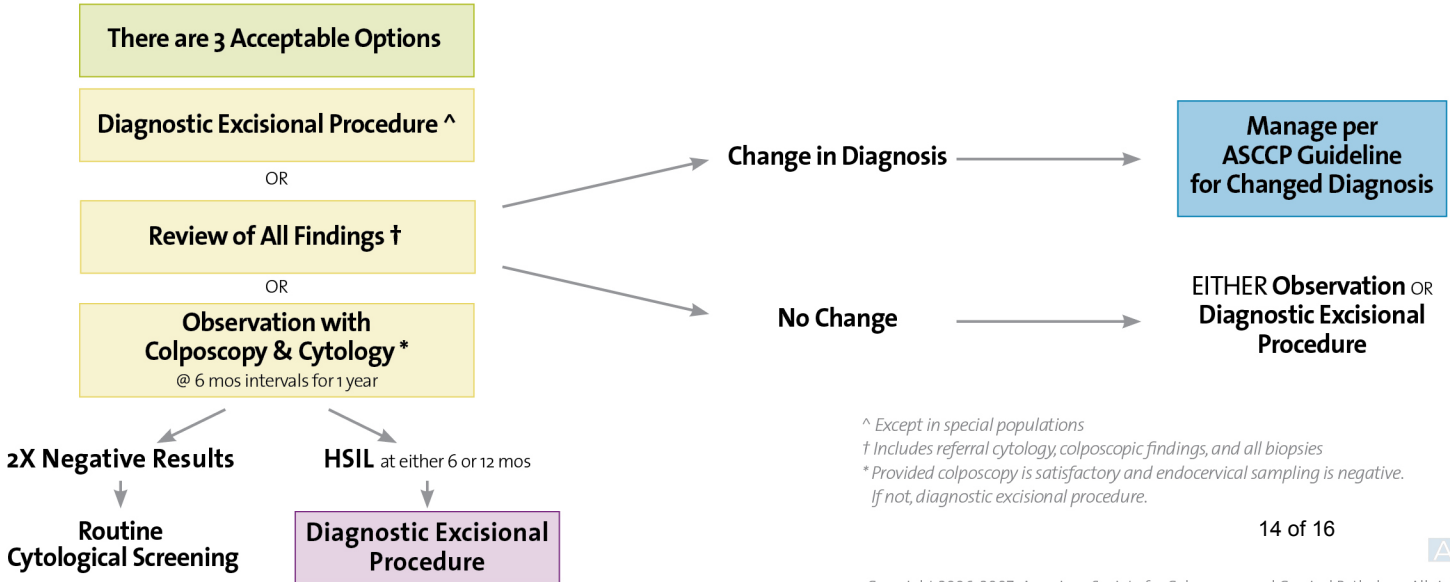
Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia Grade 1 (CIN 1) Preceded by ASC-US, ASC-H or LSIL Cytology



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

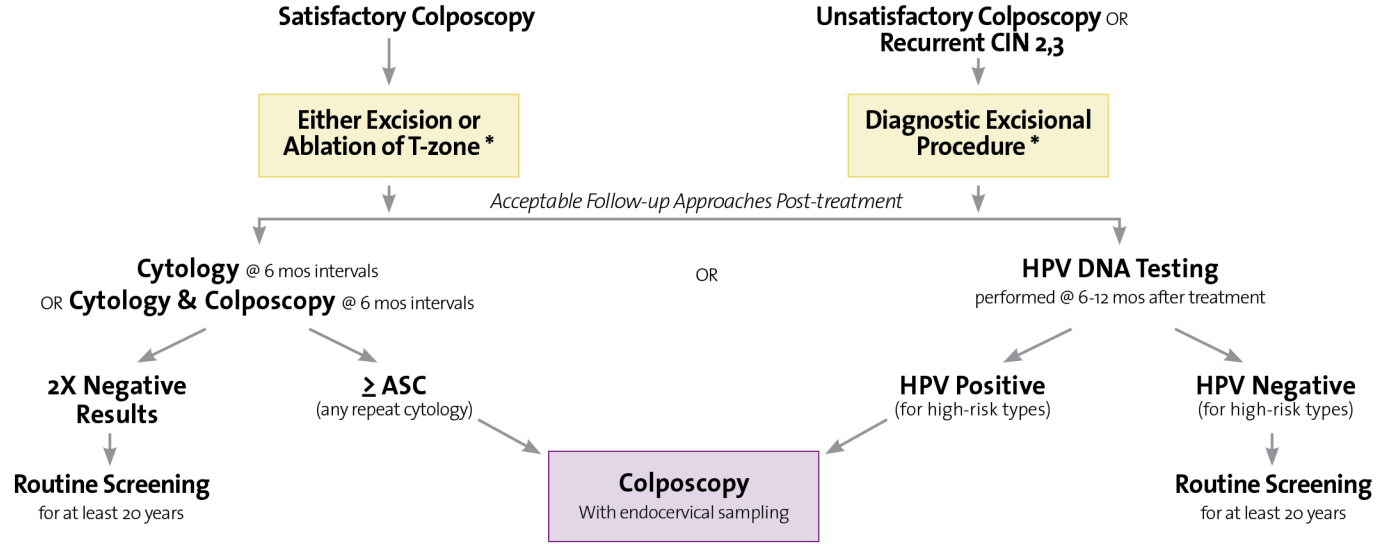
* *Either ablative and excisional methods. Excision preferred if colposcopy unsatisfactory, ECC is positive, or patient previously treated.*

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



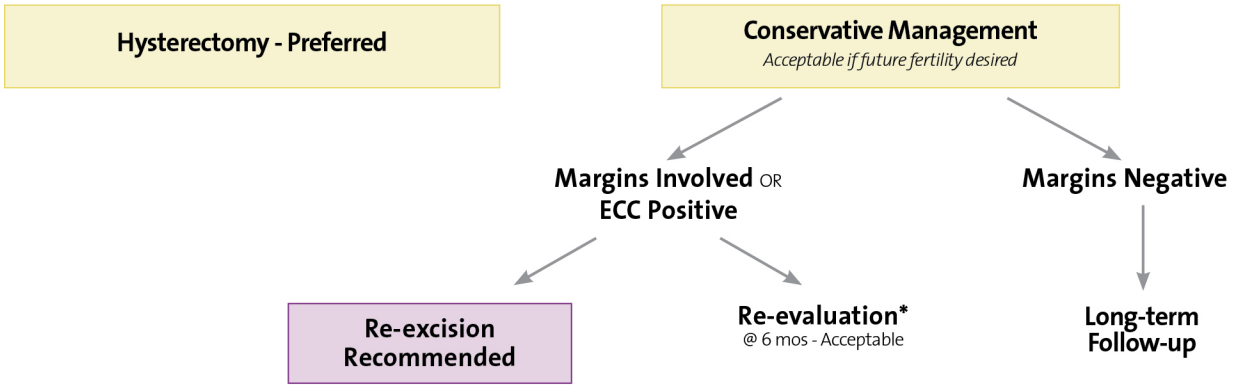
^ *Except in special populations*
† *Includes referral cytology, colposcopic findings, and all biopsies*
* *Provided colposcopy is satisfactory and endocervical sampling is negative. If not, diagnostic excisional procedure.*

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