



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

April 30, 2015

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), United States Preventive Services Task Force (USPSTF) and the American Cancer Society (ACS).

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 Breast and Cervical Cancer Program.

In March 2013, The American Society for Colposcopy and Cervical Pathology released Updated Consensus Guidelines on the Management of Women with Abnormal Cervical Cancer Screening Tests and Cancer Precursors. The Medical Advisory Committee revised the Minimal Clinical Elements based on the new Consensus Guidelines.

The changes include:

- A reference to HPV types included in the high risk HPV panel,
- A reference to HPV genotyping, and;
- Replacing *selected* 2006 ASCCP algorithms with *selected* 2013 ASCCP algorithms.

Enclosed are the revised “Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis” and *Selected* ASCCP Consensus Guidelines on the Management of Women with

Abnormal Cervical Cancer Screening Tests and Cancer Precursors © 2013 relevant to the Maryland Breast and Cervical Cancer Program.

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 Ken Lin Tai, M.D., M.P.H., Medical Director for the Center for Cancer Prevention and Control (CCPC) at 410-767-2036 or kenlin.tai@maryland.gov.

Sincerely,



Stanley Watkins, M.D.

Chairman, Medical Advisory Committee

Maryland Breast and Cervical Cancer Program

Enclosure

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**Minimal Clinical Elements for Cervical Cancer Detection and
Diagnosis
Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
April 2015**

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 incorporate into the Minimal Clinical Elements the-2013 American Society for Colposcopy and Cervical Pathology (ASCCP) Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia and Cervical Cytological Abnormalities.
- To inform clinicians of these guidelines.

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, ©2002, 2006, 2013 (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 precancerous 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.

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 $\leq 250\%$ 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. Testing for *the high-risk HPV panel*¹ is reimbursable as a screening test in the Maryland Breast and Cervical Cancer Program (BCCP) if used when co-testing with cytology every 5 years.
 - b. Testing for the high-risk HPV panel is reimbursable if performed as guided by ASCCP Flow Sheets in the management of abnormal cytology/histology.
 - c. Testing for low-risk HPV types is **not** reimbursable in the Maryland BCCP.
 - d. Testing for *HPV genotyping*² (e.g. HPV 16/18) is **not** reimbursable in the Maryland BCCP, therefore the option of genotyping in the ASCCP Flows titled “Cytology NILM but EC/TZ Absent/Insufficient” and “Management of Women ≥ Age 30, Who are Cytology Negative, but HPV Positive” is not a reimbursable option .
7. If the Pap test is read as “unsatisfactory for evaluation,” Follow the ASCCP algorithm titled “*Unsatisfactory Cytology*”
8. If the Pap test is read as “Normal. Satisfactory for evaluation; no endocervical cells present,” Follow the ASCCP algorithm titled “*Cytology NILM but EC/TZ Absent/Insufficient*”
9. If a patient has a history of cervical cancer *without* hysterectomy (e.g., radiation, implant, conization)
 - e. 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).
 - f. 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.

¹ 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.

² Genotyping detects the presence or absence of specific high-risk HPV types (e.g. 16 and 18) only.

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**

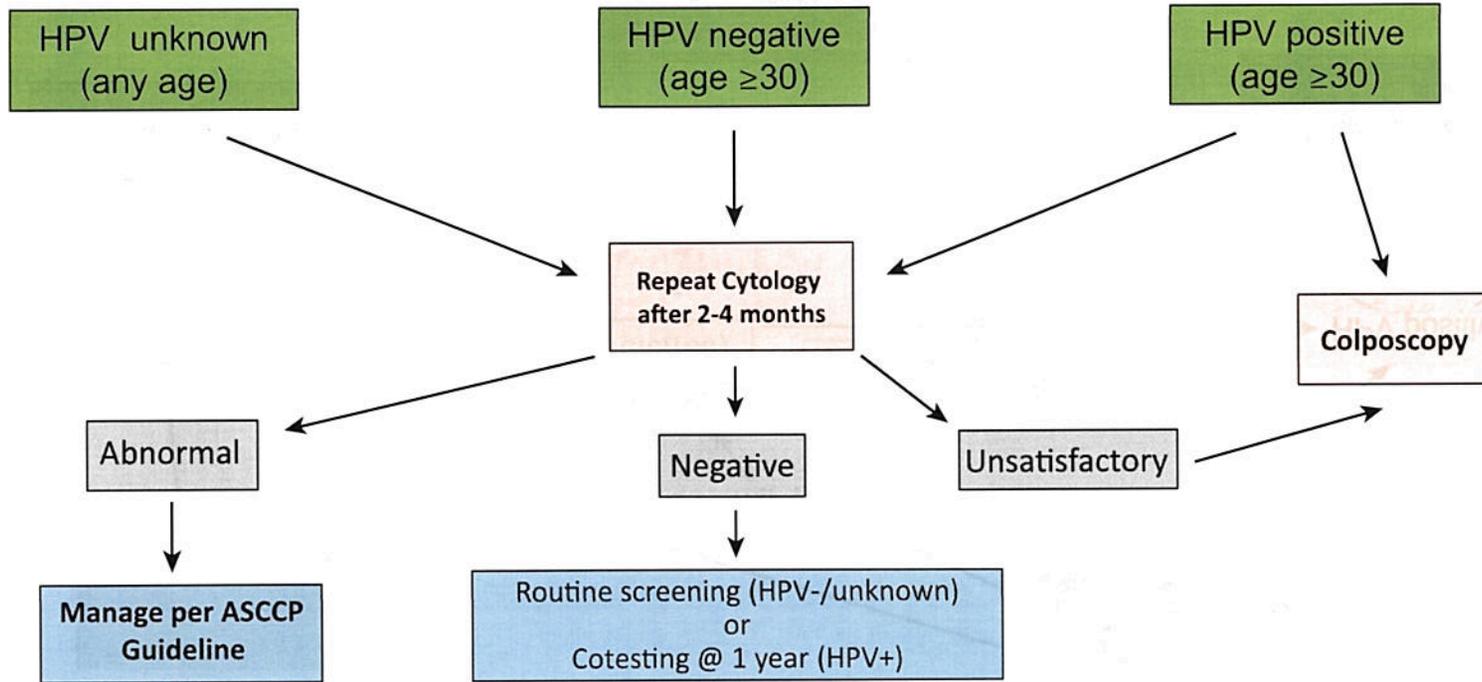
Reprinted from *The Journal of Lower Genital Tract Disease* Volume 17, Number 5, with the permission of ASCCP ©American Society for Colposcopy and Cervical Pathology 2013. No copies of the algorithms may be made without the prior consent of ASCCP.

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:

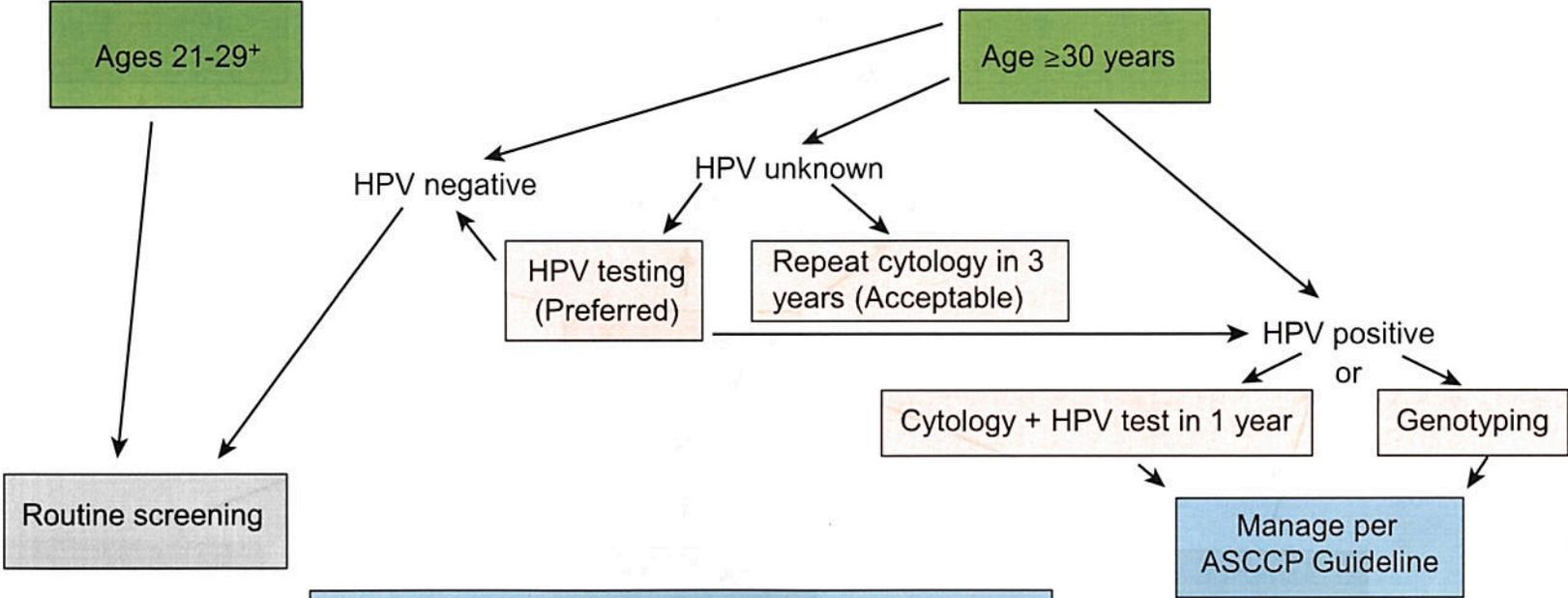
- Management of Adolescent Women with Either ASC-US or LSIL
- Management of Pregnant Women with LSIL
- Management of Women Ages 21-24 years with Atypical Squamous Cells, Cannot Rule Out ASC-H and HSIL
- Management of Women with No lesion or Biopsy-confirmed CIN I in Women Ages 21-24
- Management of Young Women with Biopsy-confirmed CIN 2,3 in Special Circumstances

Unsatisfactory Cytology



Reimbursement for HPV genotyping is **not** allowable in the Maryland Breast and Cervical Cancer Program.

Cytology NILM* but EC/TZ Absent/Insufficient

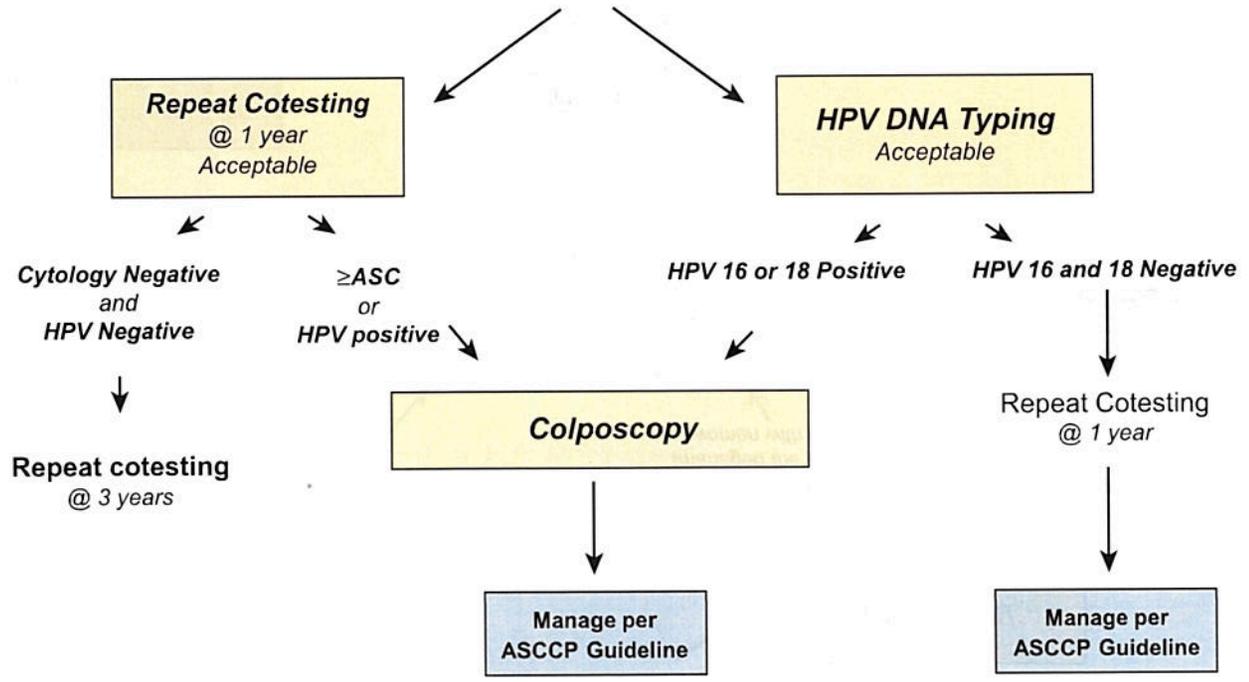


*Negative for intraepithelial lesion or malignancy
 *HPV testing is unacceptable for screening women ages 21-29 years

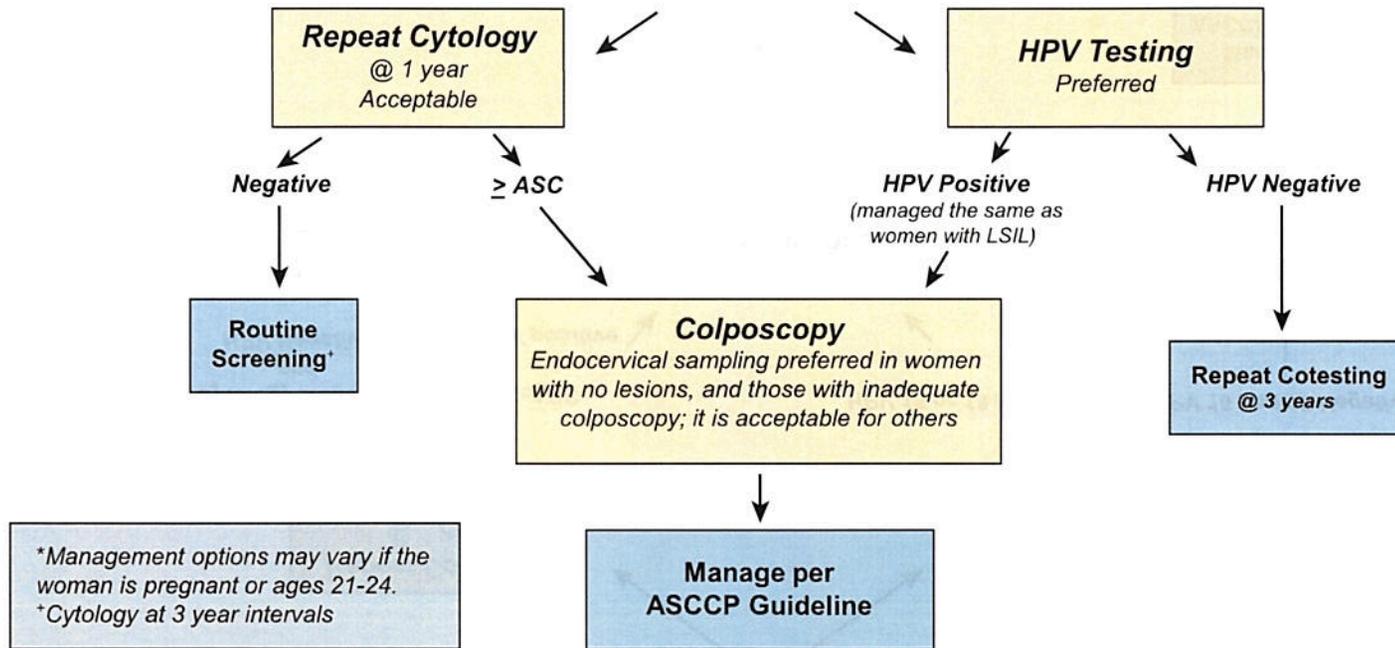
Reimbursement for HPV genotyping is not allowable in the Maryland Breast and Cervical Cancer Program.

Normal Cytology/HPV Positive

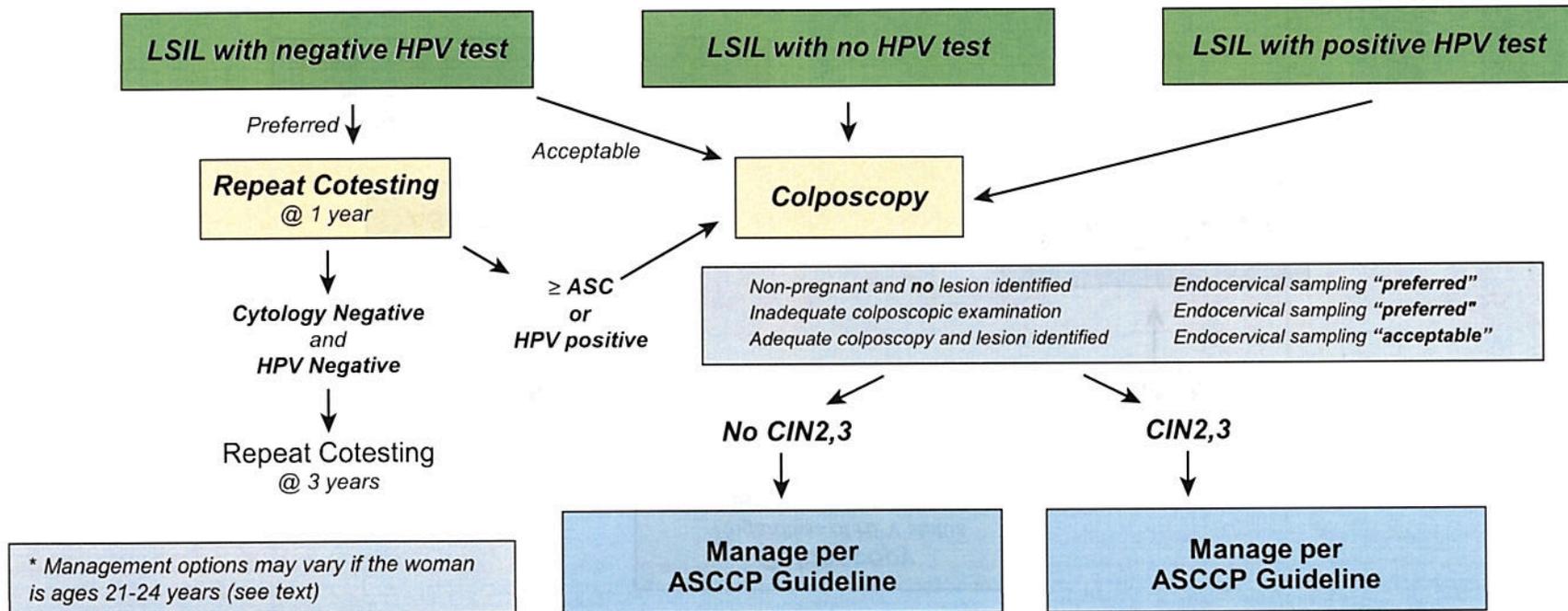
Management of Women \geq Age 30, who are Cytology Negative, but HPV Positive



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

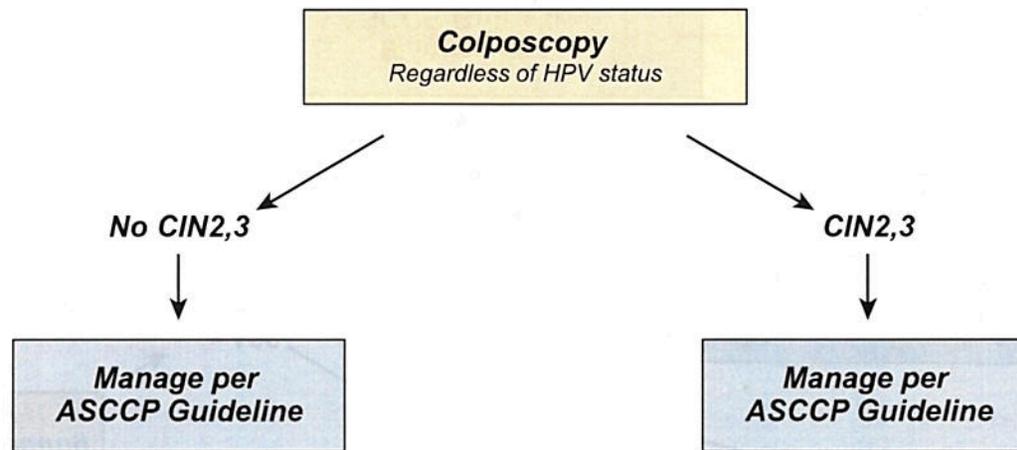


Management of Women with Low-grade Squamous Intraepithelial Lesions (LSIL)*



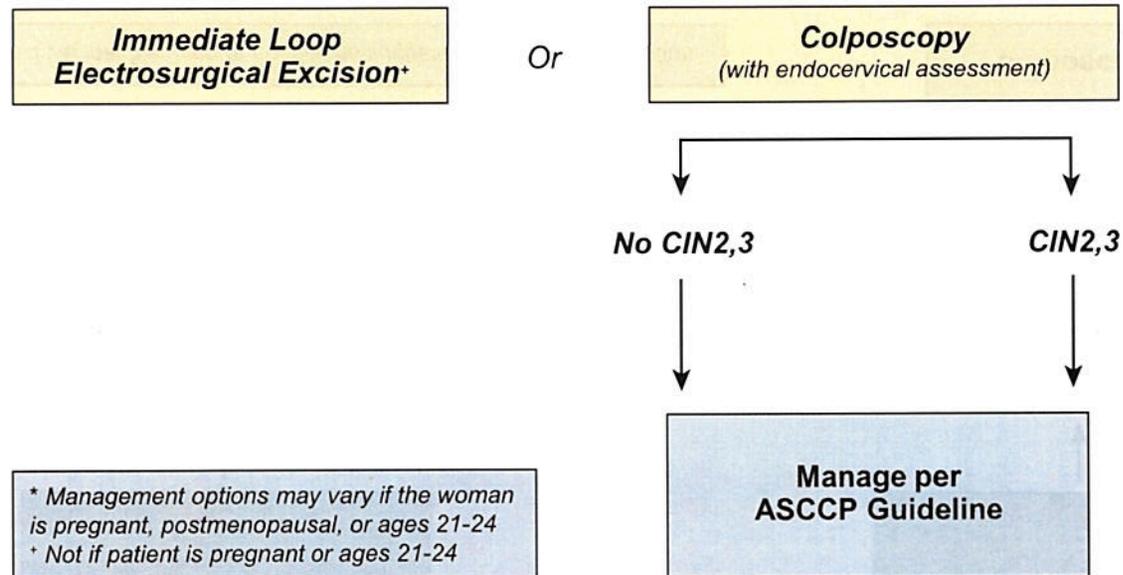
* Management options may vary if the woman is ages 21-24 years (see text)

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



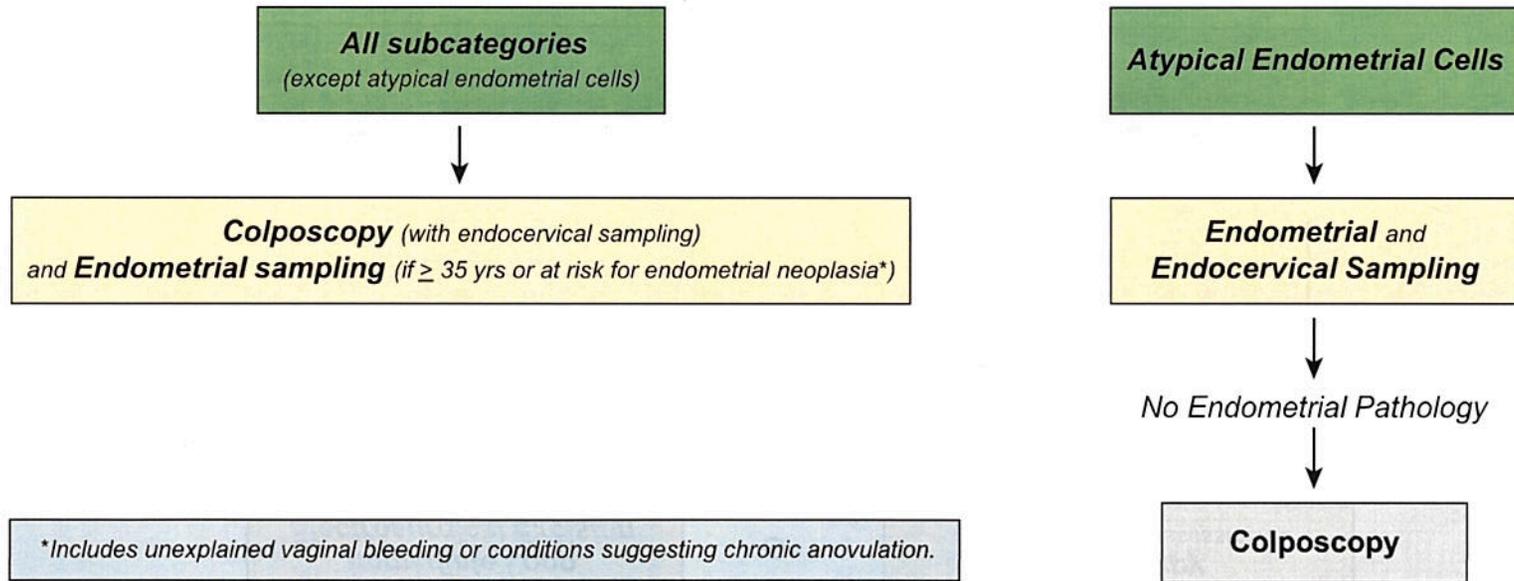
* Management options may vary if the woman is ages 21-24.

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



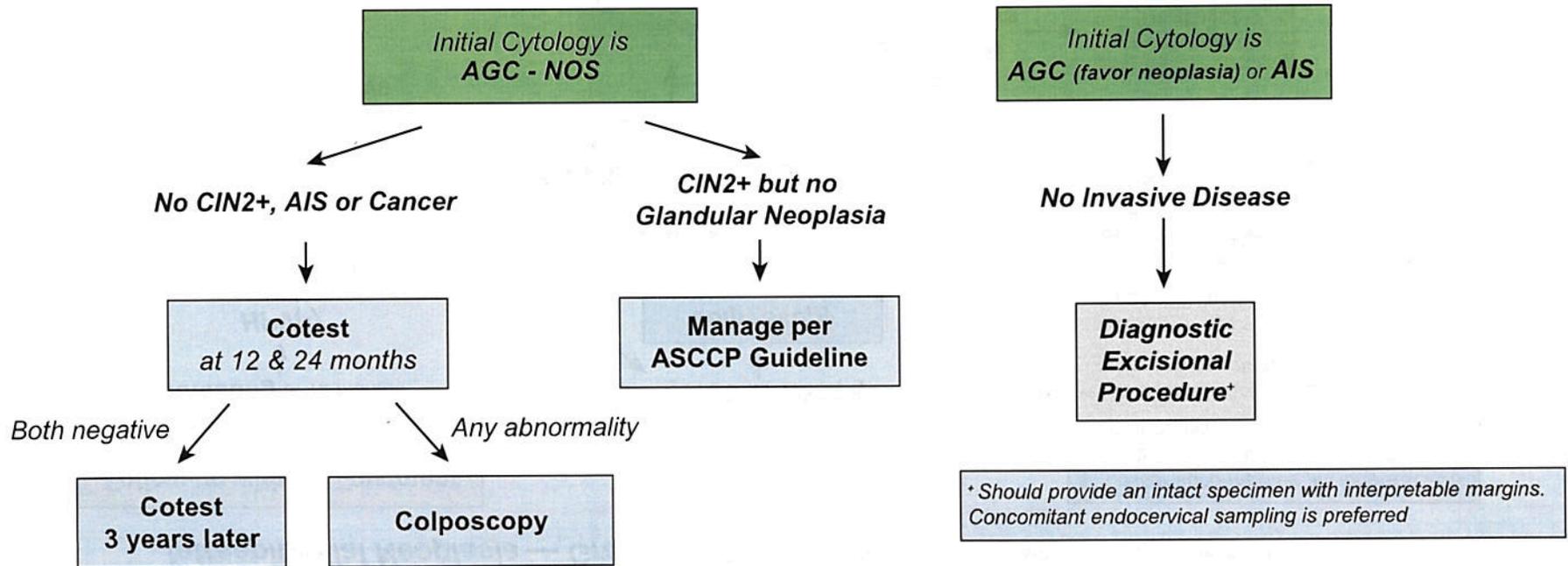
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Initial Workup of Women with Atypical Glandular Cells (AGC)



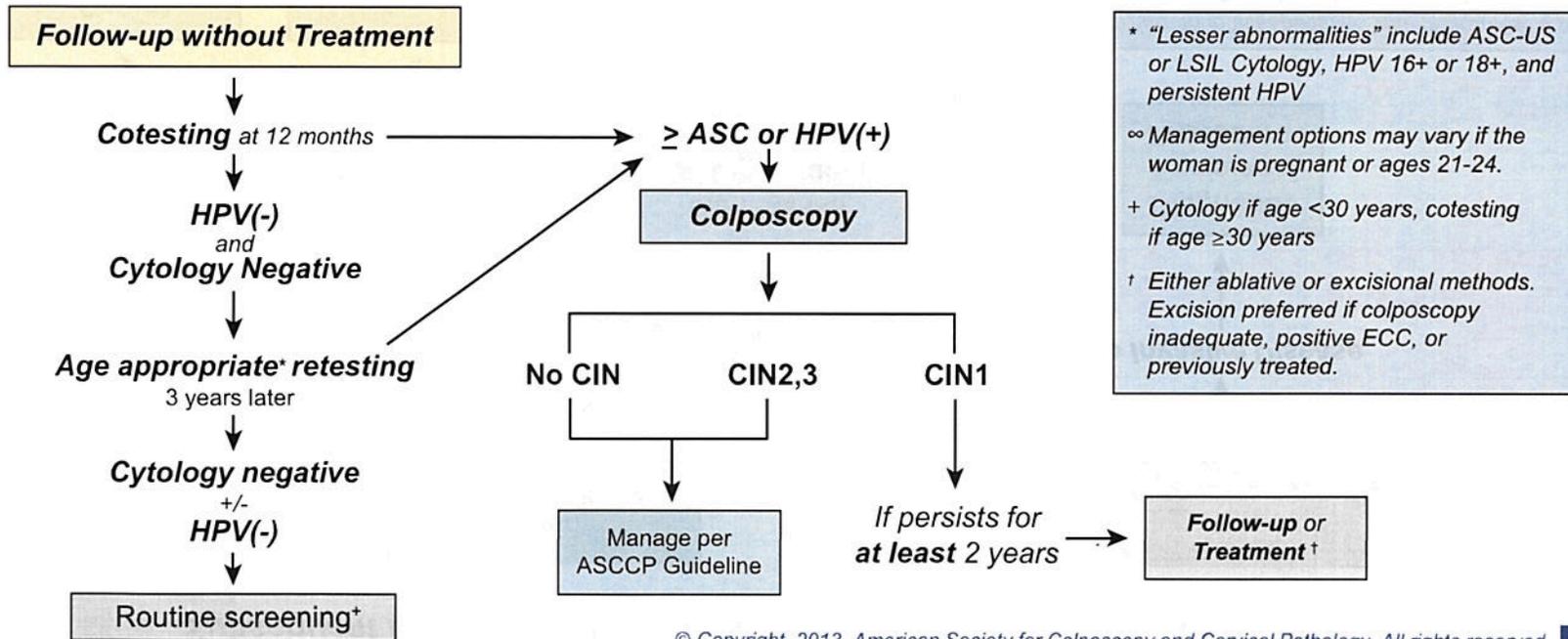
*Includes unexplained vaginal bleeding or conditions suggesting chronic anovulation.

Subsequent Management of Women with Atypical Glandular Cells (AGC)



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Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1) Preceded by “Lesser Abnormalities”^{*∞}



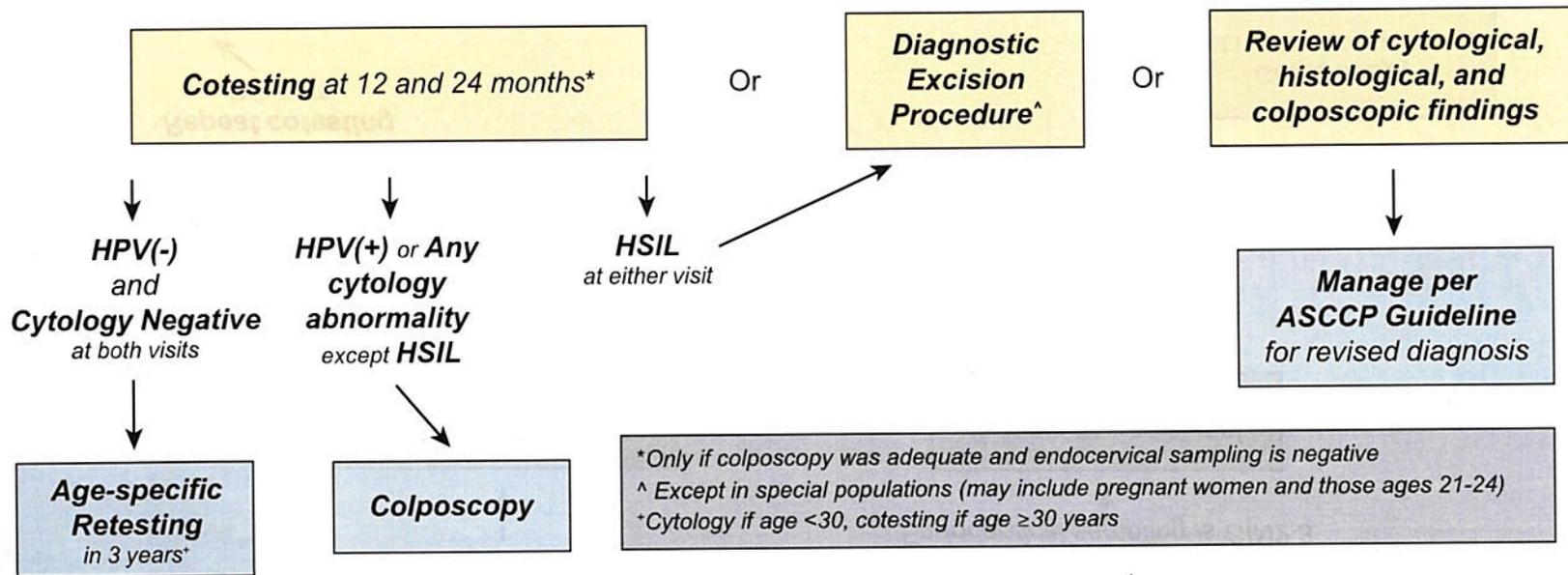
* “Lesser abnormalities” include ASC-US or LSIL Cytology, HPV 16+ or 18+, and persistent HPV

∞ Management options may vary if the woman is pregnant or ages 21-24.

+ Cytology if age <30 years, cotesting if age ≥30 years

† Either ablative or excisional methods. Excision preferred if colposcopy inadequate, positive ECC, or previously treated.

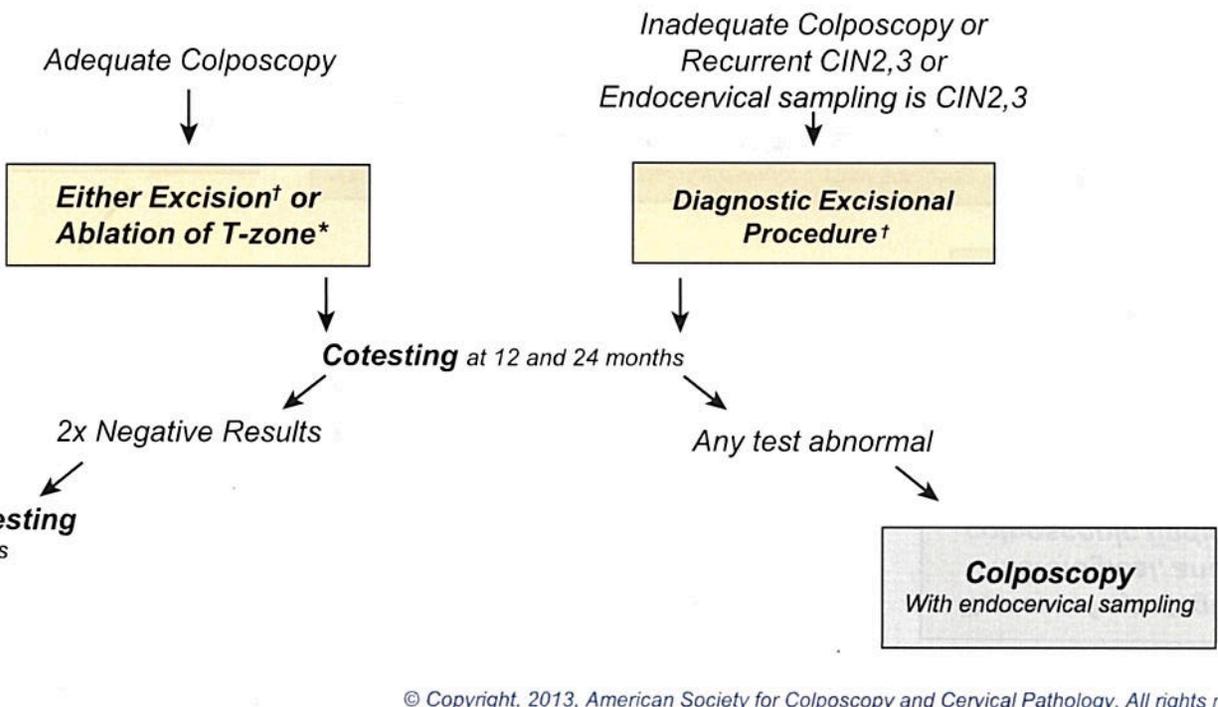
Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1) Preceded by ASC-H or HSIL Cytology



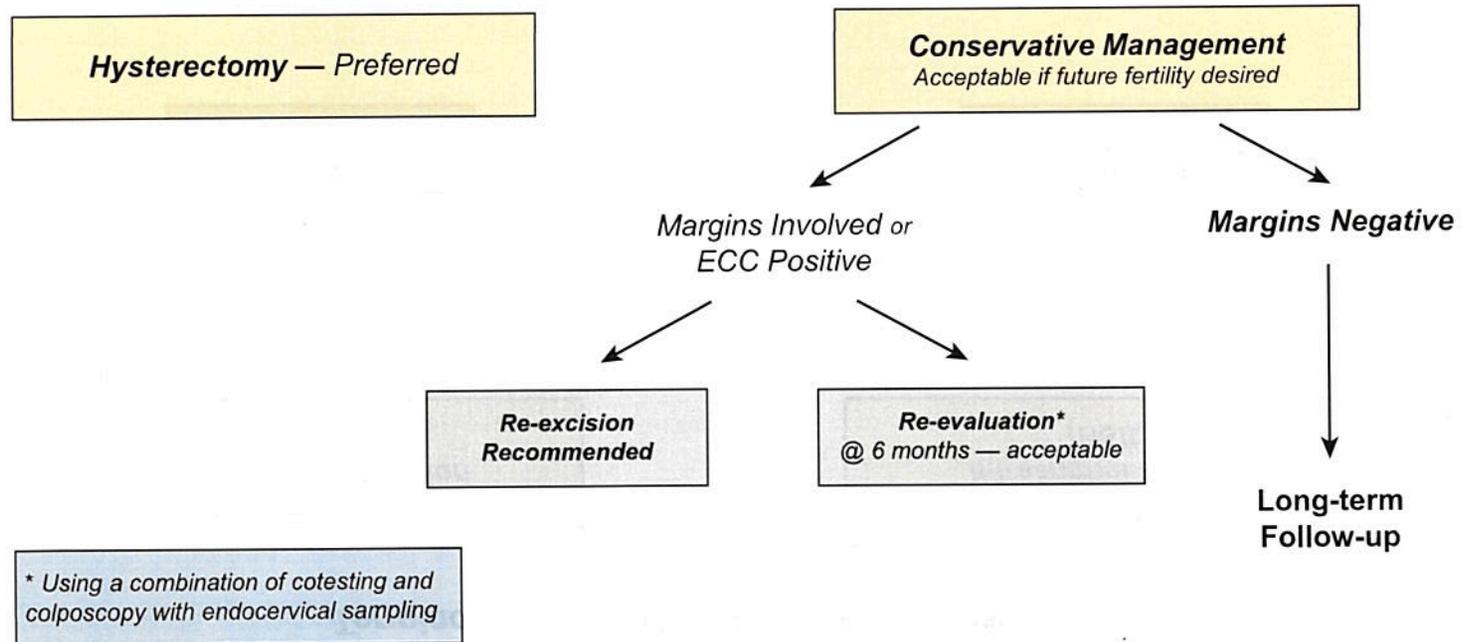
Management of Women with Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 2 and 3 (CIN2,3)*

*Management options will vary in special circumstances or if the woman is pregnant or ages 21-24

†If CIN2,3 is identified at the margins of an excisional procedure or post-procedure ECC, cytology and ECC at 4-6mo is preferred, but repeat excision is acceptable and hysterectomy is acceptable if re-excision is not feasible.

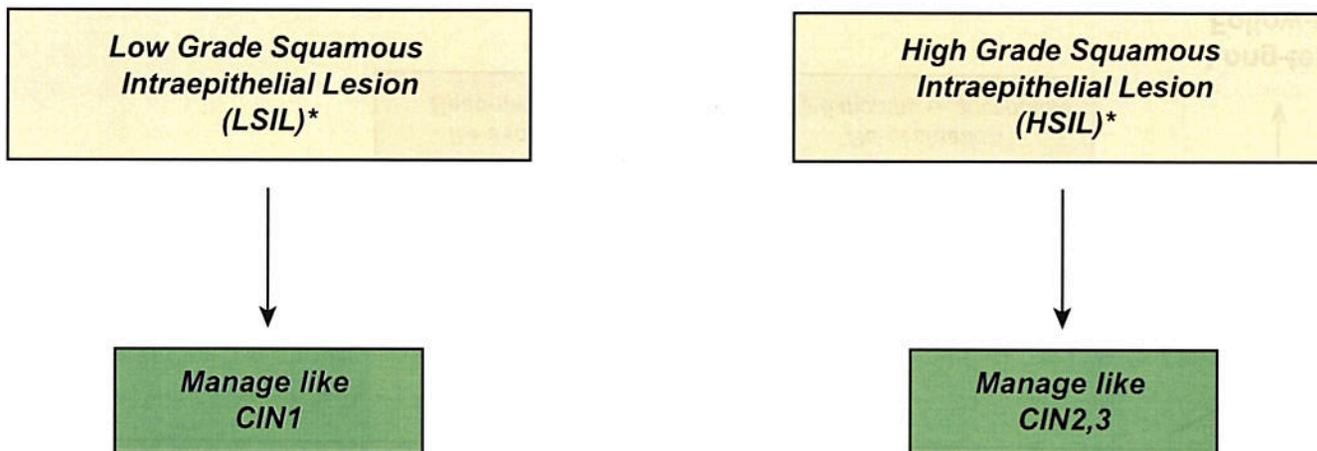


Management of Women Diagnosed with Adenocarcinoma in-situ (AIS) during a Diagnostic Excisional Procedure



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Interim Guidance for Managing Reports using the Lower Anogenital Squamous Terminology (LAST) Histopathology Diagnoses



*Histopathology Results only.