

UPDATE: MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY

Invasive cervical cancer is a preventable disease in large majority of women, as long as preinvasive cervical lesions are effectively detected and treated. The Family PACT Program has adopted the 2006 Consensus Guidelines of the American Society for Colposcopy and Cervical Pathology (ASCCP), which are included with this *Alert*.

KEY POINTS

- The purpose of cervical cancer screening is the detection and treatment of high-grade squamous epithelial lesions (CIN 2, 3), adenocarcinoma precursors, and cervical cancers.
- Women with biopsy proven CIN 1 should be observed carefully and treated only if the lesion progresses to CIN 2, 3, is persistent for two years or more, or if the woman insists upon early treatment.
- An office-based tracking system should be used to ensure that women with abnormal cytology findings have been notified of their results and that those who are being followed are reminded of the need for return visits, tests, and procedures.
- The tables included in this *Alert* summarize the 2006 ASCCP Guidelines, but more comprehensive versions are listed as references. Since not all recommended interventions are Program benefits, please refer to the *Family PACT Policies, Procedures and Billing Instructions (PPBI)* for more information.

QUESTIONS AND ANSWERS

What is the role of HPV-DNA testing in women under 21 years old?

The new guidelines emphasize that there is *no role* for HPV-DNA testing in women under 21 years old, since incident HPV infections are common and a positive test result would have no impact on client management. HPV infections in young women are likely to be transient and most will resolve quickly.

What is the preferred approach to managing ASC-US?

Adolescents with results of ASC-US or LSIL should have repeat cytology in one year, but not HPV testing or colposcopy. Consequently, in women under 21 years old, “reflex HPV tests for ASC-US” must **not** be ordered when submitting the Pap request to the laboratory. Women 21 years of age and older can be managed by either repeat cytology in six months, reflex HPV-DNA testing, or colposcopy.

Why aren't all women with CIN 1 treated with cryotherapy or LEEP?

Of women with CIN 1 lesions, fewer than 20 percent will develop a high grade lesion, with even lower progression rates in adolescents. For women 21 years and older, observation is recommended, with treatment only if the CIN 1 lesion progresses or persists for at least two years.

Should all women with CIN 2 or 3 be treated?

In general, the treatment for CIN 2 or 3 is cryotherapy or a LEEP procedure. However, the preferred treatment for adolescent and young women with CIN 2 and satisfactory colposcopy is observation, which consists of colposcopy plus cytology every six months for up to 24 months. If the colposcopic pattern worsens or a high grade lesion persists for more than 24 months from diagnosis, treatment is necessary.

What are the indications for colposcopy?

- Cytology result with ASC-H, HSIL, or suspicion of cancer
- Cytology with LSIL in a women ≥ 21 years old (unless pregnant or post-menopausal)
- Cytology with atypical glandular cells (AGC), unless AGC-atypical endometrial cells **and** positive endometrial sampling
- Cytology showing ASC-US in the following circumstances:
 - Women who are unwilling to return for frequent follow-up
 - Repeat cytology test with ASC-US or worse performed during observation period (except adolescents)
 - High-risk HPV-DNA present at initial or subsequent testing (except adolescents)
- Cervical leukoplakia (visible white lesion) or other unexplained cervical lesion regardless of cytology result
- Unexplained or persistent cervical bleeding regardless of cytology result

Why doesn't Family PACT pay for LEEP cone or “cold knife” cone biopsies?

Family PACT is a limited benefit family planning and sexually transmitted infection (STI) program. When a woman requires a medically necessary service and does not have other coverage, the California *Breast and Cervical Cancer Treatment Program (BCCTP)* may provide support. Family PACT providers can easily certify and enroll clients in the BCCTP via an internet application.

PROGRAM POLICY

This Alert provides an interpretation of the Family PACT Standards for management of abnormal Cytology test results. Providers should refer to the Family PACT PPBI for the complete text of the Family PACT Standards, official administrative practices, and billing information. For the purposes of this and other Family PACT Clinical Practice Alerts, the term “shall” indicates a program requirement; the term “should” is advisory and not required.

APPLICATION OF FAMILY PACT STANDARDS

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Family PACT services include family planning methods, STI detection and management, and selected related reproductive health conditions. The detection and management of pre-cancerous and cancerous lesions of the cervix are considered to be part of the later category.

1. Informed Consent

- Clients shall be advised of the availability of cervical cancer screening, diagnostic and limited management services.
- Clients should be informed of the recommended cervical cancer screening interval that applies to her individual circumstance.
- The consent process for cervical cancer screening, diagnostic, and treatment services shall be provided in a language understood by the client and supplemented with written materials.

2. Access to Care

- Cervical cancer screening services shall be provided without cost to Family PACT clients at all clinical service sites.
- Diagnostic and limited treatment services for abnormal cytology are available under Family PACT, although each provider may determine whether these services will be provided on-site or by referral.
- Referral resources for medical and psychosocial services beyond the scope of Family PACT, including treatment for cervical conditions, shall be made available to clients. The BCCTP offers seamless service delivery to clients with high grade lesions and cervical cancer. Services not listed in the Family PACT PPBI are not reimbursable by the program.
- Family PACT providers that have completed a Medi-Cal POS Network/Internet agreement can access the BCCTP Enrollment Application at www.medi-cal.ca.gov and using the BCCTP link and their national provider identifier (NPI) and PIN to certify and enroll clients needing services beyond the scope of Family PACT.

3. Availability of Covered Services

- Family PACT Program benefits include a routine cytologic screening as often as once a year, although clients may choose to have cytology tests less frequently once informed of the guideline.
- Screening for cervical abnormalities as listed in the PPBI shall be made available to clients as a condition of delivering services under Family PACT.
- Clients with cervical abnormalities may receive diagnostic and limited treatment services on-site or through referral as defined in the PPBI.

4. Scope of Clinical and Preventive Services:

- Clinicians delivering services under Family PACT shall have professional knowledge and skills about medical practice standards pertaining to cervical cancer screening, management of abnormal results, and treatment.
- Cervical cancer screening is **NOT** required prior to the provision of contraception.
- The treatment of cervical cytologic abnormalities should be consistent with the *American Society for Colposcopy and Cervical Pathology, Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities*.
- Providers should have an office-based tracking system for all cytology tests, to insure that all results are evaluated, women with cytologic abnormalities are notified, and those who are observed are reminded of their need for follow-up.
- Documentation in medical record shall include clinical findings and justification for services.

5. Education and Counseling Services

- Clients shall receive education on protecting their reproductive health and plans for future pregnancy.
- Individual education and counseling should be provided for all women to inform them of cytology periodicity and the significance and management of abnormal cytology results.

RESOURCES FOR INFORMATION ON CERVICAL ABNORMALITIES

- Breast and Cervical Cancer Treatment Program (BCCTP), at www.medi-cal.ca.gov or call (800) 824-0088
 - Cancer Detection Services: Every Woman Counts (EWC), at www.dhs.ca.gov/cancerdetection or call (800) 511-2300
- * Women not at risk for pregnancy are ineligible for Family PACT but may be eligible for services through BCCTP or EWC.

REFERENCES

1. Wright TC, Massad S, et al. 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ. *Am J Obstet Gynecol* 2007,197(4):340-345. Access at:
 - <http://www.asccp.org/consensus/histological.shtml>
 - <http://ajog.org/article/PIIS0002937807009337/fulltext>
2. Wright TC, Massad S, et al. 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. *Am J Obstet Gynecol* 2007, 197(4):346-355. Access at:
 - <http://www.asccp.org/consensus/cytological.shtml>
 - <http://ajog.org/article/PIIS0002937807009301/fulltext>
3. Davey D, et al. Cervical cytology specimen adequacy: Patient management guidelines and optimizing specimen collections. *J Lower Genital Tract Disease* 2008; 12(2):71-83.

Family PACT Abnormal Cytology Test Guidelines

Cytology Finding	Action
Specimen adequacy	
Unsatisfactory for evaluation ³	<ul style="list-style-type: none"> Repeat cytology in two to four months.
Satisfactory, negative for SIL, but limited by...few (scant) endocervical cells ³	<ul style="list-style-type: none"> Repeat cytology at six months if unable to clearly visualize the cervix or sample the endocervical canal, previous Pap smear with glandular abnormality, similar obscuring factor in last Pap, a previously abnormal Pap without adequate follow up, a positive HPV-DNA test within the past year, or insufficient previous screening. <ul style="list-style-type: none"> Otherwise, repeat cytology in one year. If practice-wide rate is ≥ 15 percent, discuss remediation with cytopathologist.
Organisms	
Trichomonas vaginalis	<ul style="list-style-type: none"> If recently treated, no further evaluation is necessary. <ul style="list-style-type: none"> If not, notify patient and offer <i>either</i> presumptive treatment or confirmatory testing. Finding may indicate presence of other STIs, although long term colonization also is possible. Unless unsatisfactory, repeat cytology at scheduled screening interval.
Fungal organisms morphologically consistent with Candida spp	<ul style="list-style-type: none"> Usually due to asymptomatic Candidal colonization. No action is necessary; patient notification is optional. Unless unsatisfactory, repeat cytology at scheduled screening interval.
Shift in flora suggestive of bacterial vaginosis (BV)	<ul style="list-style-type: none"> Poor correlation with clinical diagnosis of BV. If recently treated, no further evaluation is necessary. <ul style="list-style-type: none"> If not, patient notification is optional. If notified, offer confirmatory evaluation Repeat cytology at scheduled screening interval.
Bacteria consistent with Actinomyces	<ul style="list-style-type: none"> In IUC user, rarely associated with pelvic actinomycosis. To evaluate, perform pelvic exam or refer for gynecologic consultation. <ul style="list-style-type: none"> If negative pelvic exam, IUC removal is not required and there is no evidence of benefit of antibiotic therapy.
Cellular changes consistent with herpes simplex virus	<ul style="list-style-type: none"> Strongly suggestive of herpes simplex viral shedding. If herpes diagnosis is in medical record, patient notification is optional. <ul style="list-style-type: none"> If not, notify patient of result. Direct tests for herpes virus (culture, DFA) are not indicated. If the patient requests confirmation, a positive HSV type-specific serology will confirm prior infection (not a Family PACT benefit). Finding may indicate presence of other STIs, although long standing HSV infection also is possible. Repeat cytology at scheduled screening interval.
Other non-neoplastic findings	
Reactive changes associated with (severe) inflammation ³	<ul style="list-style-type: none"> May be due to GC, Ct, trichomonas, viruses, irritants, (very rarely) cancer. If recent GC, Ct tests were negative, no further STI evaluation is necessary. <ul style="list-style-type: none"> If not recently screened, notify patient and offer GC, Ct testing. Do not presumptively treat with topical or oral antibiotics. If unexplained inflammation, repeat cytology in 6-12 months. If <i>persistent unexplained</i> inflammation, consider colposcopic evaluation.
Reactive changes associated with intrauterine contraception	<ul style="list-style-type: none"> No action is necessary Patient notification is unnecessary Repeat cytology at scheduled screening interval
Atrophy	<ul style="list-style-type: none"> No action is necessary Patient notification is unnecessary Repeat cytology at scheduled screening interval
Benign endometrial cells (including stromal cells or histiocytes)	<ul style="list-style-type: none"> For post-menopausal women, endometrial assessment is recommended (<i>not a Family PACT benefit</i>). For premenopausal women: <ul style="list-style-type: none"> No action is necessary Patient notification is unnecessary Repeat cytology at scheduled screening interval

Family PACT Abnormal Cytology Test Guidelines: Adapted from: ASCCP 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests.

Finding	Initial Intervention	Next step	Following step
ASC-US Women ≥21 years old OR LSIL <i>Post-menopausal</i> Women (not eligible for Family PACT)	<ul style="list-style-type: none"> Repeat cytology @ 6 mos 	<ul style="list-style-type: none"> Negative: repeat cytology @ 6 mos - - → ≥ASC: colposcopy 	<ul style="list-style-type: none"> Negative: routine screening ≥ASC: colposcopy
	OR <ul style="list-style-type: none"> HPV DNA testing (reflex test) 	<ul style="list-style-type: none"> Negative: repeat cytology @ 12 mos - → Positive: colposcopy 	<ul style="list-style-type: none"> Negative: routine screening ≥ASC: colposcopy
	OR <ul style="list-style-type: none"> Colposcopy (with ECS*) 	<ul style="list-style-type: none"> No CIN, HPV pos: cytology @ 6 & 12 mos or HPV testing @ 12 mos - - - → No CIN, HPV unkn: cytology @ 12 mos → CIN: per ASCCP CIN guideline 	<ul style="list-style-type: none"> Negative: routine screening ≥ASC or HPV (+): repeat colposcopy
ASC-US OR LSIL <i>Adolescents</i> Women ≤20 years old	<ul style="list-style-type: none"> Repeat cytology @ 12 mos 	<ul style="list-style-type: none"> <HSIL: repeat cytology @ 12 mos later → ≥HSIL: colposcopy 	<ul style="list-style-type: none"> Negative: routine screening ≥ASC: colposcopy
ASC-H	<ul style="list-style-type: none"> Colposcopy 	<ul style="list-style-type: none"> No CIN 2,3: cytology @ 6 & 12 mos or HPV testing @ 12 mos - - - - → CIN 2,3: per ASCCP CIN guideline 	<ul style="list-style-type: none"> Negative: routine screening ≥ASC or HPV (+): colposcopy
LSIL Women ≥21 years old, not pregnant	<ul style="list-style-type: none"> Colposcopy (with ECS*) 	<ul style="list-style-type: none"> No CIN: cytology @ 6 & 12 mos or HPV testing @ 12 mos - - - - - → CIN/cancer: per ASCCP CIN guideline 	<ul style="list-style-type: none"> Negative: routine screening ≥ASC or HPV (+): colposcopy
LSIL <i>Pregnant women</i> (Not eligible for Family PACT)	<ul style="list-style-type: none"> Colposcopy OR <ul style="list-style-type: none"> Defer colposcopy ≥6 wks post-partum 	<ul style="list-style-type: none"> No CIN 2,3: post-partum follow-up CIN 2,3: per ASCCP CIN guideline 	
HSIL Women ≥21 years old	<ul style="list-style-type: none"> Immediate LEEP (if CIN 2, 3 likely) OR <ul style="list-style-type: none"> Colposcopy with ECS* <p>NOTE: <i>Immediate LEEP is not a Family PACT benefit</i></p>	<ul style="list-style-type: none"> No CIN 2,3 Unsatisfactory: DEP** Satisfactory (either): <ul style="list-style-type: none"> Colposcopy + cytology at 6 mo intervals for 1 yr - - - - - → Pathologist review DEP** CIN 2,3: per ASCCP CIN guideline 	<ul style="list-style-type: none"> Negative cytology x2: routine screening HSIL: DEP** Other results: per ASCCP CIN guideline <p>NOTE:</p> <ul style="list-style-type: none"> If no cervical lesion, evaluate for VaIN with Lugol's solution
HSIL <i>Adolescents</i> Women ≤20 years old	<ul style="list-style-type: none"> Colposcopy <p>Immediate LEEP is unacceptable in this age group</p>	<ul style="list-style-type: none"> CIN 2,3: per ASCCP CIN guideline No CIN 2,3: colposcopy + cytology @ 6 mo intervals for up to 2 yrs - - - → 	<ul style="list-style-type: none"> Two consecutive negative cytologies and no HG colposcopic abnormality: routine screening HSIL cytology persists for 1 yr: biopsy HSIL cytology persists for 2 yrs: DEP** Other: ASCCP CIN guideline
AGC: Atypical endometrial cells	<ul style="list-style-type: none"> Endometrial biopsy + ECS* (in all cases) 	No endometrial pathology: colposcopy	
AGC: All other sub-categories	<ul style="list-style-type: none"> Colposcopy + ECS* <p>AND</p> <ul style="list-style-type: none"> HPV testing <p>AND</p> <ul style="list-style-type: none"> Endometrial sampling (if ≥35 yo or at risk for endometrial neoplasia) 	<ul style="list-style-type: none"> Cytology = AGC-favor neoplasia or AIS: DEP** Cytology = AGC-not specified (NOS): <ul style="list-style-type: none"> Bx = CIN or AIS: per ASCCP guideline No CIN and No AIS: <ul style="list-style-type: none"> HPV neg: cytology+HPV in 12 mos - - - - - → HPV pos: cytology+HPV in 6 mos → HPV status unknown: cytology @ 6 mo intervals 4 times - - - - → 	<ul style="list-style-type: none"> All tests negative: routine screening >ASC or HPV pos: colposcopy

* ECS = endocervical sampling in non-pregnant women, either with endocervical curettage or cervical brush

** DEP = diagnostic excisional procedure, e.g., LEEP cone or cold-knife cone biopsy (*not Family PACT benefits*)

Family PACT Abnormal Cervical Histology Guidelines: Adapted from: ASCCP 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ.

Biopsy Finding	Initial Intervention	Next step	Following step
CIN 1 <i>Preceded by ASC-US, ASC-H, or LSIL cytology</i>	Follow-up without treatment: <ul style="list-style-type: none"> • Cytology every 6 mos twice - - - - - → OR <ul style="list-style-type: none"> • HPV-DNA test @ 1 yr - - - - - → 	<ul style="list-style-type: none"> • Negative: routine screening • ≥ASC: colposcopy - - - - - → <ul style="list-style-type: none"> • Negative: routine screening • Positive: colposcopy 	<ul style="list-style-type: none"> • No CIN or CIN 2,3: per ASCCP guideline • CIN 1 persists <i>for at least 2 yrs</i>: follow-up or treatment
CIN 1 <i>Preceded by HSIL or AGC-NOS cytology</i>	<ul style="list-style-type: none"> • DEP** OR <ul style="list-style-type: none"> • Review findings with pathologist OR <ul style="list-style-type: none"> • Observation with colposcopy + cytology @ 6 mos twice - - - - - → 	<ul style="list-style-type: none"> • 2x negative results: routine screening • HSIL: DEP** 	
CIN 1 <i>Adolescent women ≤20 years old</i>	<ul style="list-style-type: none"> • Repeat cytology @ 12 mos 	<ul style="list-style-type: none"> • <HSIL: repeat cytology @ 12 mos - - - - - → • ≥HSIL: colposcopy 	<ul style="list-style-type: none"> • Negative: routine screening • ≥ASC: colposcopy
CIN 2,3	<ul style="list-style-type: none"> • Unsatisfactory colposcopy or recurrent CIN 2,3: DEP** • Satisfactory colposcopy: ablate or excise T-zone 	<p>Follow up all clients with either:</p> <ul style="list-style-type: none"> • HPV DNA @ 6-12 mos after treatment - - - - - → OR <ul style="list-style-type: none"> • Cytology @ 6 mo intervals → OR <ul style="list-style-type: none"> • Cytology + colposcopy @ 6 mo intervals - - - - - → 	<ul style="list-style-type: none"> • HPV negative: routine screening for ≥20 yrs • HPV positive: colposcopy with ECS* <ul style="list-style-type: none"> • 2x negative results: routine screening for ≥20 yrs • ≥ASC: Colposcopy with ECS*
CIN 2,3 <i>Adolescent and young women</i>	<ul style="list-style-type: none"> • Ablate or excise T-zone (preferred for CIN 3 or unsatisfactory colposcopy) OR <ul style="list-style-type: none"> • Observation with colposcopy + cytology every 6 mos for up to 24 mos (preferred for CIN2) → 	<ul style="list-style-type: none"> • 2x negative results and normal colposcopy: routine screening • Colposcopy worsens or, HG cytology, or CIN 2,3 persists >1 yr: repeat biopsy - - - - - → 	<ul style="list-style-type: none"> • CIN 3 or CIN 2,3 that persists >24 mos since initial diagnosis: treat
Adenocarcinoma-in-situ (AIS)	<ul style="list-style-type: none"> • Hysterectomy preferred OR <ul style="list-style-type: none"> • Conservative management if fertility desired - - - - - → 	<ul style="list-style-type: none"> • Margins involved or ECC positive: re-excision (recommended) OR <ul style="list-style-type: none"> • Re-evaluate at 6 mos (acceptable) • Margins negative: long term follow-up 	

* ECS = endocervical sampling in non-pregnant women, either with endocervical curettage or cervical brush
** DEP = diagnostic excisional procedure, e.g., LEEP cone or cold-knife cone biopsy (*not Family PACT benefits*)