



BCCCP Medical Protocol Breast Cancer Screening and Follow-up

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BCCCP Medical Protocol

Purpose - To be used by BCCCP clinicians in identifying:

1. Program protocols relating to provision of breast and cervical cancer screening and follow-up care for BCCCP women
2. Program approved screening and diagnostic services reimbursed by BCCCP.



Protocol Development

- Protocol developed by the MCC Breast Cancer Advisory Committee and the Cervical Cancer Advisory Committee
- Evidenced based guidelines reference national organizations: ACS, ACR, USPSTF, NCCN, ACP, and ASCCP.

** CDC policy restrictions and program funding limits availability of breast and cervical cancer screening and diagnostic services. Not all services recommended by national organizations are reimbursed by BCCCP.*

Medical Protocol: Key Points

1. BCCCP provides the following breast/cervical cancer screening services: CBE, Mammogram, Pap test, Pelvic Exam
2. Women identified with abnormalities are referred in a timely manner for appropriate diagnostic f/u to either CONFIRM or RULE/OUT cancer
3. BCCCP women diagnosed with cancer may be eligible for Medicaid

BCCCP Clinical Care Requirements

CDC Performance Indicators: Timeliness of Care

1. Amount of time* from abnormal screening result to final diagnosis

Indicator: 75%

- Breast timeliness: within 60 days
- Cervical Timeliness: within 90 days*
(effective 10/1/09)

2. Amount of time (within 60 days) from cancer diagnosis to treatment

Indicator: 80% for both breast and cervical

BCCCP Clinical Care Requirements

CDC Performance Indicators: Complete/Appropriate Care

1. Documentation of appropriate follow-up services and a final diagnosis.

Indicator: 90% for both breast and cervical

2. Documentation of a treatment disposition within 100 days from date of cancer diagnoses

Indicator: 100% for both breast and cervical

Mapping CDC Performance Indicators to BCCCP Medical Protocol

1. Identifying Breast/Cervical Abnormalities Requiring **Immediate Follow-up** (an abnormality highly suspicious for cancer – need to confirm or rule/out cancer)
 - Length of time:
Breast (60 days) Cervical (90 days)
 - Timeliness/Completeness Evaluated per CDC Performance Indicators
 - Complete documentation of approved* diagnostic tests/exams

* Based on program reimbursement

Breast/Cervical Abnormalities Requiring Immediate F/U

CBE Results	Mammogram Results	Pap Test Results
<p data-bbox="98 554 581 796">Abnormality: rule/out breast cancer</p> <ol data-bbox="98 829 600 1210" style="list-style-type: none"> 1. Dominant mass, 2. Nipple discharge- no palpable mass, 3. Asymmetric thickening/nodularity, 4. Skin changes 	<p data-bbox="649 554 1222 815">ACR 0: Assessment Incomplete (Additional work-up required)</p> <p data-bbox="649 853 1209 986">ACR 4: Suspicious Abnormality</p> <p data-bbox="649 1025 1141 1229">ACR 5: Highly Suggestive of Malignancy</p>	<p data-bbox="1267 554 1841 625">ASC-US (+ HPV)</p> <p data-bbox="1267 658 1421 725">LSIL</p> <p data-bbox="1267 768 1499 829">ASC-H</p> <p data-bbox="1267 872 1431 939">AGC</p> <p data-bbox="1267 982 1431 1043">HSIL</p> <p data-bbox="1267 1086 1837 1153">Adenocarcinoma</p> <p data-bbox="1267 1196 1779 1258">Squamous Cell</p>

Mapping CDC Performance Indicators to BCCCP Medical Protocol cont.

2. Identifying Breast/Cervical Abnormalities Requiring Short-term Follow-up (benign abnormality – low risk for cancer)

- Length of time: Generally, less than one year – prior to next annual screening cycle
- Timeliness/Completeness Performance Indicators NOT Evaluated

Breast/Cervical Results Requiring Short-term F/U: NO Final Diagnosis Required

CBE Results	Mammogram Results	Pap Test Results
<ul style="list-style-type: none">● Benign Finding or Probably Benign Finding <p>(Symmetrical thickening/thickened tissue/nodularity palpated in the same location in both breasts; irregularity or lumpiness that is <i>not</i> clinically suspicious)</p>	<ul style="list-style-type: none">● ACR 3 – Probably Benign● ACR 0 – Assessment Inc-Film comparison ordered	<ul style="list-style-type: none">● Unsatisfactory Paps● ASC-US (with negative or no HPV test)● LSIL – (women under age 20)* <p>* Not eligible for BCCCP</p>

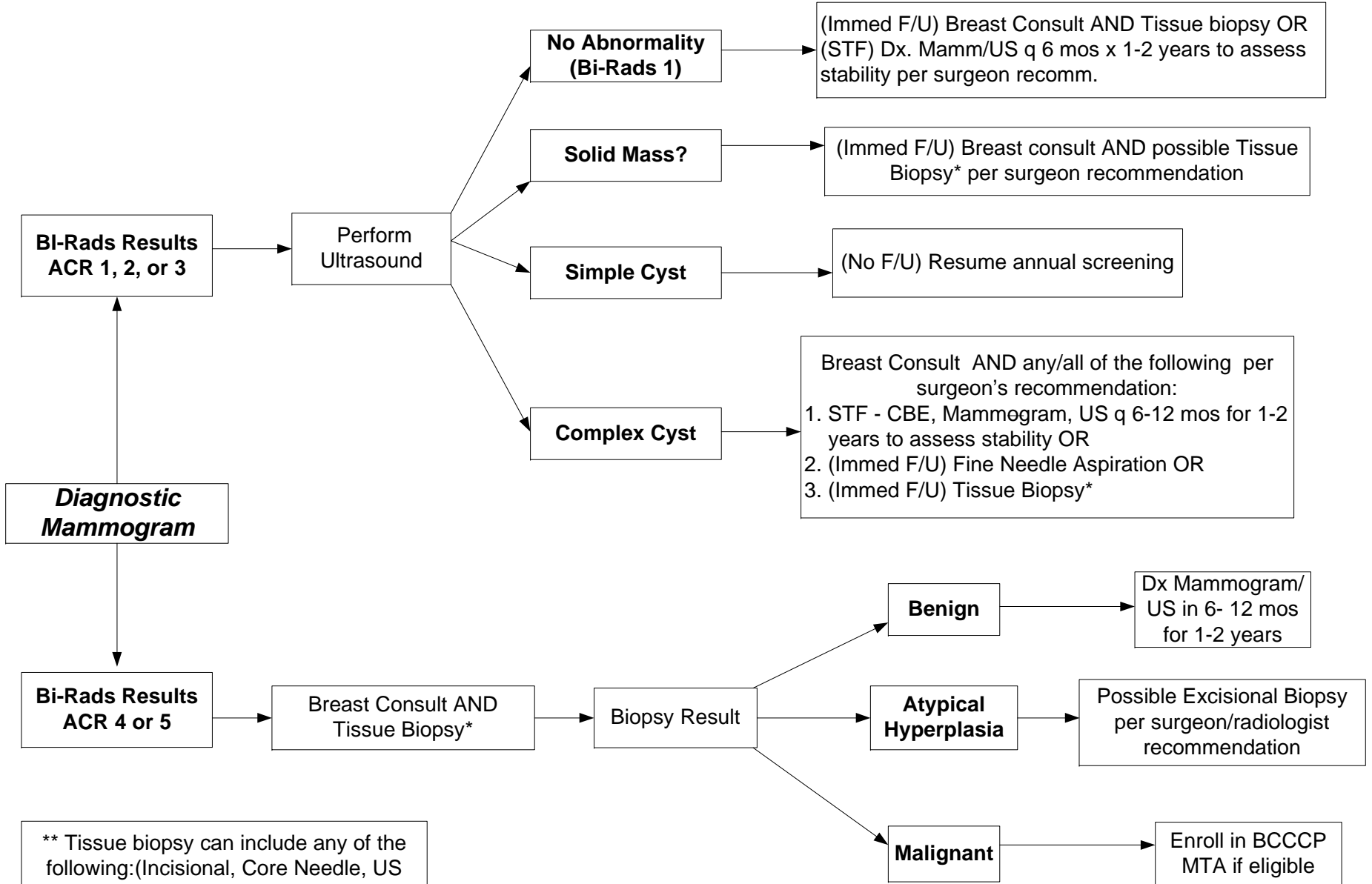
BCCCP Medical Protocol Review

Abnormal CBE Findings

- Dominant Mass (formerly lump/mass)
- Nipple Discharge – no palpable mass
- Asymmetric thickening/nodularity
- Skin changes (Peau d' orange, Erythema, Nipple Excoriation, Scaling/Eczema)

Follow-up of Abnormal CBE Results

DOMINANT MASS (formerly lump/mass)



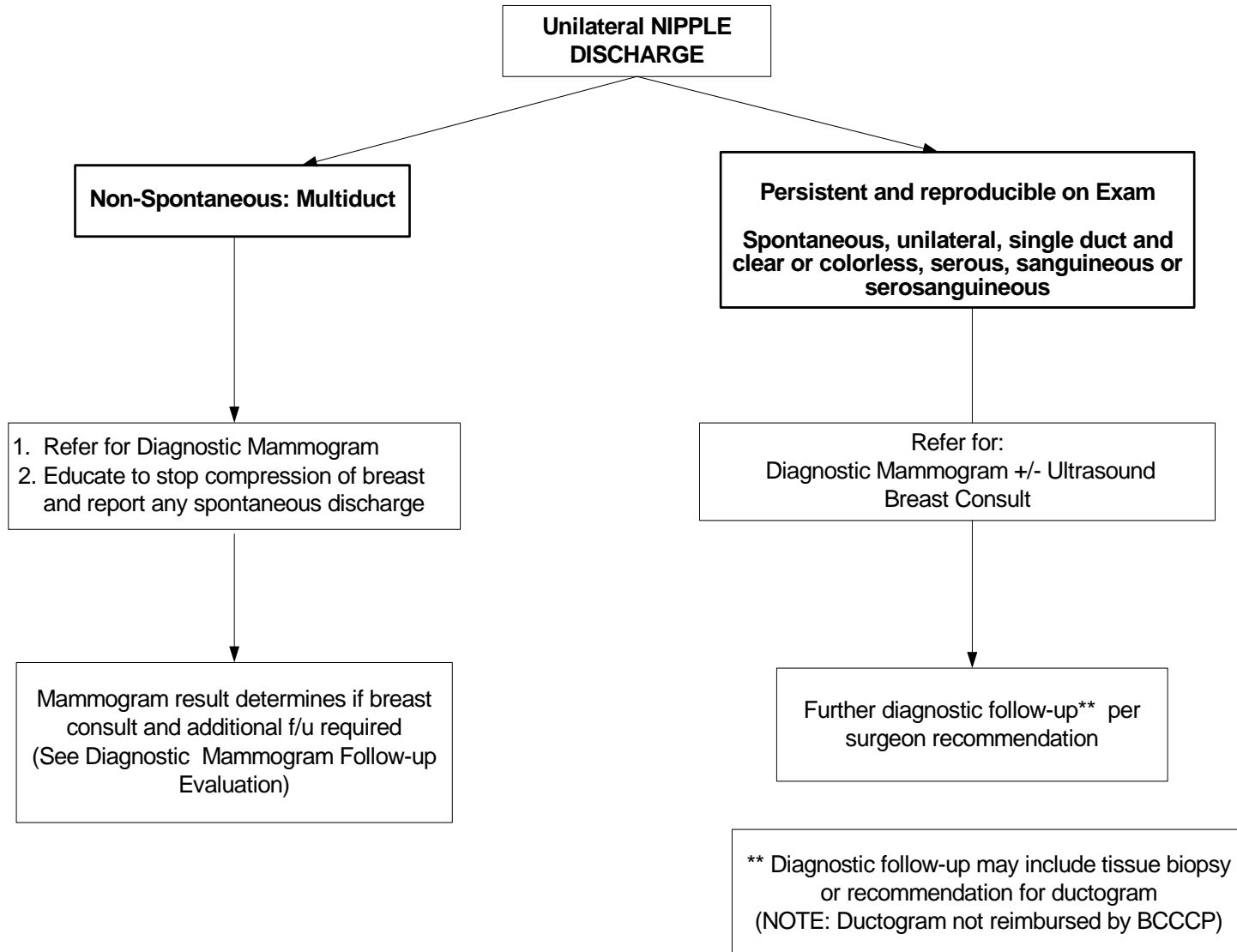
** Tissue biopsy can include any of the following:(Incisional, Core Needle, US Guided, Stereotactic, Excisional)

BCCCP Medical Protocol

Follow-up of Abnormal CBE Results

NIPPLE DISCHARGE

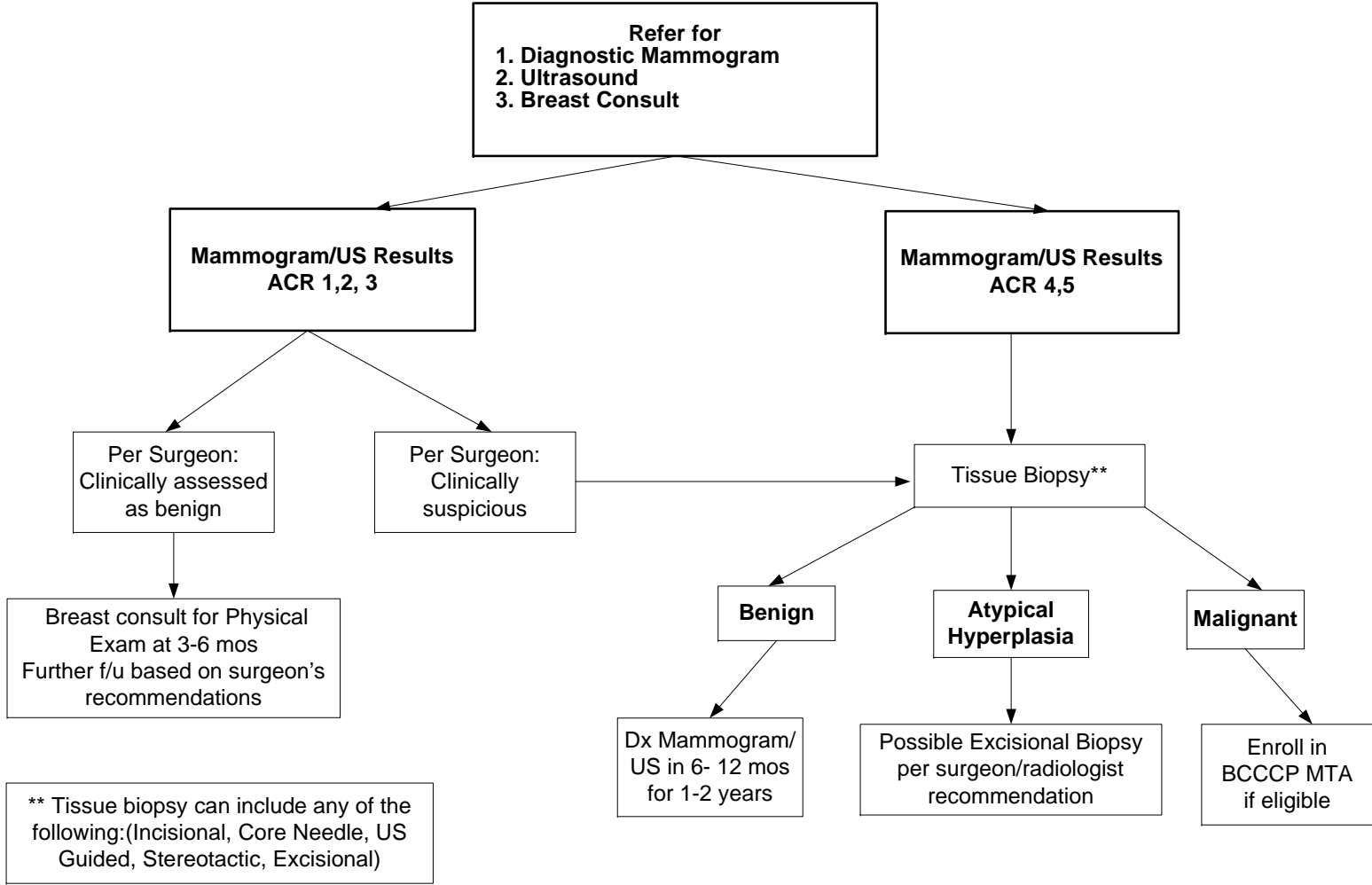
Revised June
2010



BCCCP Medical Protocol

Follow-up of Abnormal CBE Results

ASYMMETRIC THICKENING/NODULARITY

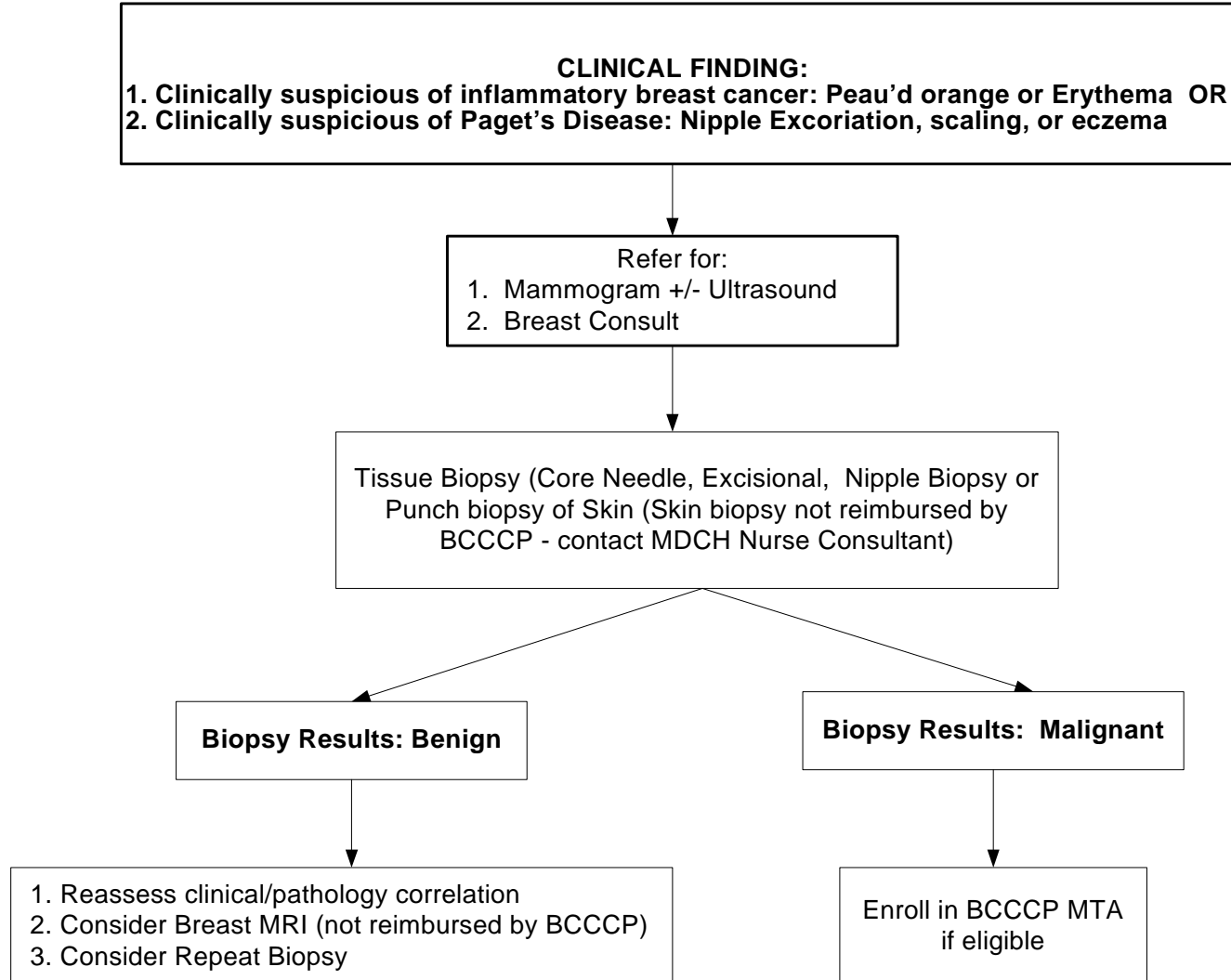


BCCCP Medical Protocol

Follow-up of Abnormal CBE Results

SKIN CHANGES

Revised June
2010



Mammogram BI-Rads: ACR 0: Assessment Incomplete- Need Additional Imaging Evaluation

- Additional imaging evaluation may include: spot compression, magnification, special magnification views, and/or ultrasound
- Further follow-up beyond second imaging depends on final Bi-Rads results



Mammogram BI-Rads

ACR 1: Negative

- There is nothing to comment on.
- Breasts are symmetric, no masses, no architectural distortion or suspicious calcifications are present

Mammogram BI-Rads

ACR 2: Benign Finding

- Normal assessment but the radiologist chooses to describe the benign finding which may include:
 - involuting, calcified fibroadenomas,
 - multiple secretory calcifications
 - fat containing lesions (oil cysts)
 - lipomas
 - galactoceles
 - mixed density hamartomas
- Additional description on intramammary lymph nodes, vascular calcifications, implants, and any architectural distortion related to previous surgery may be included

Mammogram BI-Rads

ACR 3: Probably Benign Finding

- Finding has < 2% risk of malignancy; not expected to change over f/u interval but radiologist wants to establish its stability
- 3 findings classified as probably benign:
 - non-calcified mass
 - focal asymmetry
 - cluster of round calcifications
- Majority of findings can be managed through initial STF (6 mos) up to 2 year
- Biopsy may be performed based on clinician or patient concerns

Mammogram BI-Rads

ACR 4: Suspicious Abnormality

- Reserved for findings that do not have classic appearance of malignancy but have a wide probability of malignancy > than ACR 3 findings
- Follow-up recommended based on appearance/characteristics of findings

Mammogram BI-Rads

ACR 5: Highly Suggestive of Malignancy

- High probability ($\geq 95\%$) of being cancer
- Type of biopsy performed depends on lesion identified
- More than one biopsy may be performed and/or combined with sentinel node imaging or delayed after neoadjuvant chemotherapy

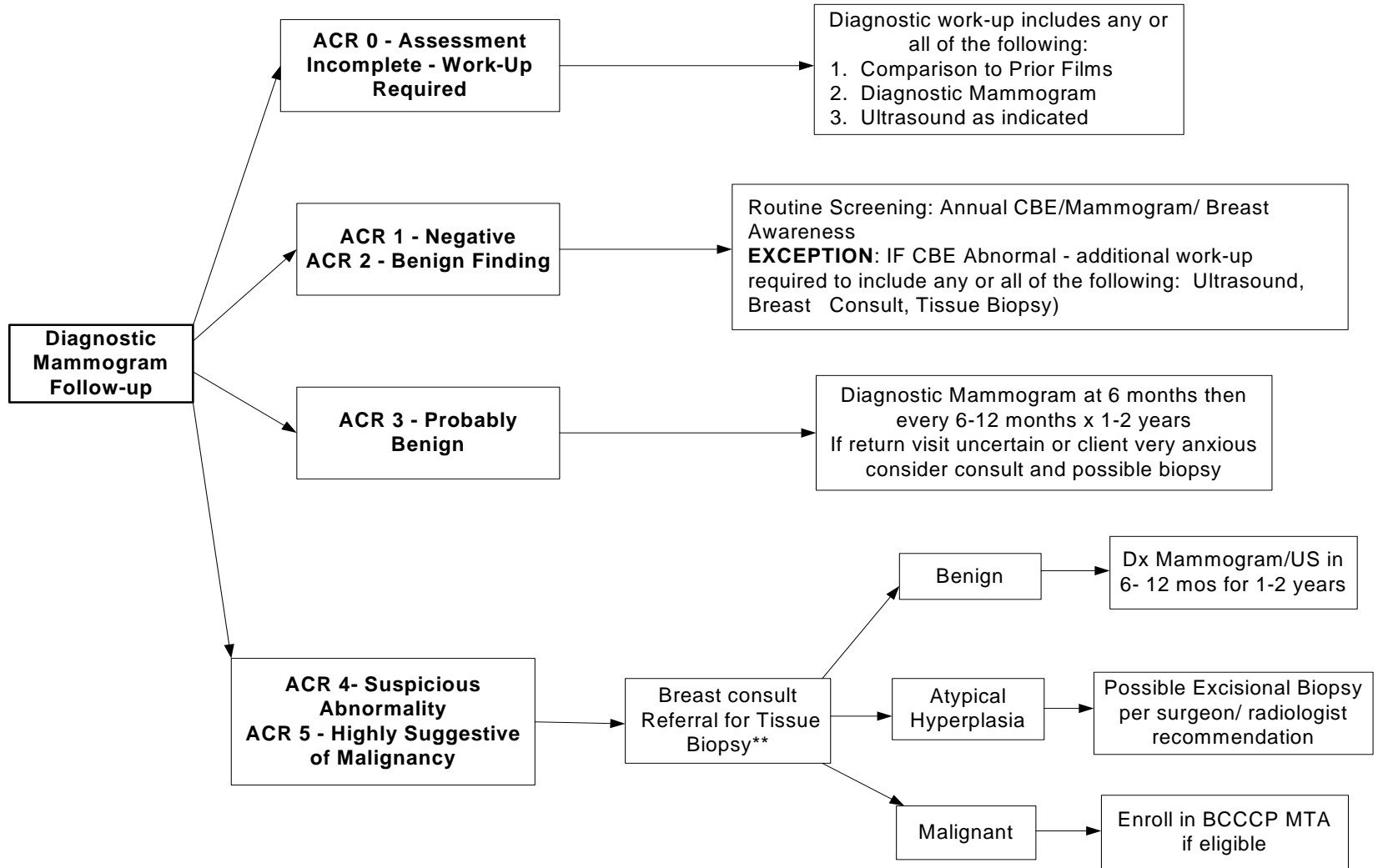
Mammogram BI-Rads

ACR 6: Known Biopsy Proven Malignancy

- Reserved for lesions identified on mammogram after a biopsy has confirmed treatment but cancer treatment has not begun

BCCCP Medical Protocol

Follow-up of DIAGNOSTIC Mammogram Results



QUESTIONS FOR DISCUSSION



??????????

Common Questions asked by Clinicians

- When does short-term follow-up turn into immediate follow-up? Or vice versa?
- How long can the program provide short-term follow-up care for clients?
(# of follow-up mammograms, ultrasounds, consults, pap tests, etc. reimbursed by pgm.)
- How do you approach a provider who is:
 - overusing clinical services (too many office visits, procedures, etc.) ?
 - misusing clinical services (not following medical protocol)?

BCCCP Reimbursement for Breast Cancer Screening and Follow-up Services

1. Amount of funding for direct services and CDC restrictions limit BCCCP reimbursement for some breast screening and diagnostic procedures.
2. Reimbursement guidelines developed to maximize program funding in providing services to all BCCCP women who require them.

Reimbursement of Breast Cancer Screening Services (Program Guidelines)

Service	Time Frame	Reimbursement
Annual Office Visit (to include CBE, Pelvic Exam, Pap test)	≥ 365 days from previous FIRST annual screening office visit	Will reimburse ONE/year (>365 days) CBE only = Partial OV CBE/Pap and or Pelvic = Full OV

Reimbursement of Breast Cancer Screening Services (Program Guidelines) cont.

Service	Time Frame	Reimbursement
Screening Mammogram	> 365 days from previous SCREENING mammogram (NOT Diagnostic f/u mammogram)	Will reimburse ONE/year (>365 days)

Reimbursement of Breast Cancer Screening Services (Program Guidelines) cont.

Service	Time Frame	Reimbursement
Screening Ultrasound	<u>NA</u>	Only reimbursed as follow-up imaging test or in conjunction with screening mammogram NOT in place of mammogram

Reimbursement of Breast Cancer Screening Services (Program Guidelines) cont.

Service	Time Frame	Reimbursement
Breast Consult	<u>Pre-post biopsy (not day of biopsy)</u>	<u>Prior authorization</u> required for consult beyond the 1st post biopsy visit.

Reimbursement of Breast Cancer Screening Services (Program Guidelines) cont.

Service	Time Frame	Reimbursement
Diagnostic Mammogram	ONE/12-months (<365 days) as 6 month follow-up of initial abnormal mammogram	NO prior authorization required for 6 month f/u mammogram AND Ultrasound if indicated

Reimbursement of Breast Cancer Screening Services (Program Guidelines) cont.

Service	Time Frame	Reimbursement
Ultrasounds	ONE/12-months (<365 days) as 6 month follow-up to monitor stability of cyst	<u>Prior authorization</u> required for 2 nd US performed within a 6 month time period or prior to biopsy.

Breast Screening/Diagnostic Services NOT Reimbursed by BCCCP

- Ductogram/galactogram
- Duct Excision
- Ductal lavage
- MRI and MRI guided biopsy
- Computer Assisted Device (CAD)

Breast Diagnostic Services Reimbursed on Case by Case Basis

- Provision of clinical services beyond the scope of the BCCCP protocol limited by program reimbursement guidelines
- **EXCEPTIONS** to the protocol (and reimbursement for select services) are considered on a case by case basis
- These non-reimbursed services, in some instances, can be mapped to a BCCCP approved service
- Nurse Consultant approval is **REQUIRED** prior to the non-approved service being performed



Oncology Nursing: My Career, my Choice, my Passion

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BCCCP Medical Protocol: Cervical Cancer

BCCCP - MI Webinar
June 17, 2010



Background: diagnosing CERVICAL cancer is the program goal

- Policies by and funding from CDC
- Program testing related to cervical cancer (not GC/Chlamydia, ovarian/endometrial cancer, VAIN/VIN, etc.)
- Pap testing frequency: conventional Pap - q year; LBC - q every 2 years.
- Once three sequential, negative Paps in **5** years achieved – Pap every **THREE** years



Process:

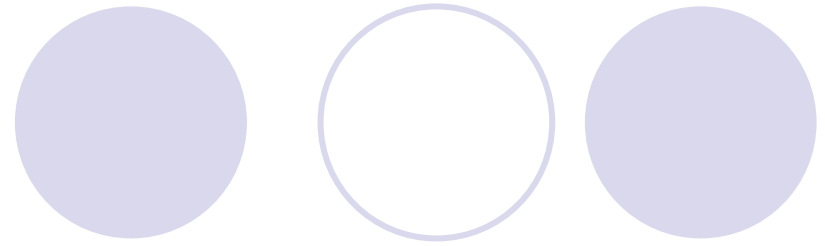
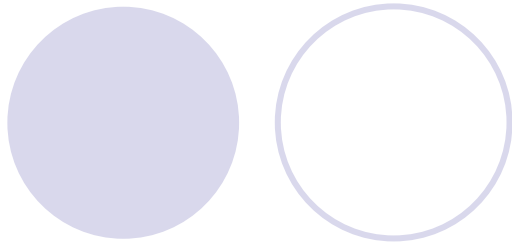
- Will reference BCCCP Medical Protocol (start pg 12) and ASCCP Guidelines www.asccp.org/guidelines
- You may also have ASCCP booklets (green, brown, blue)

Obscured or Unsatisfactory Pap Tests

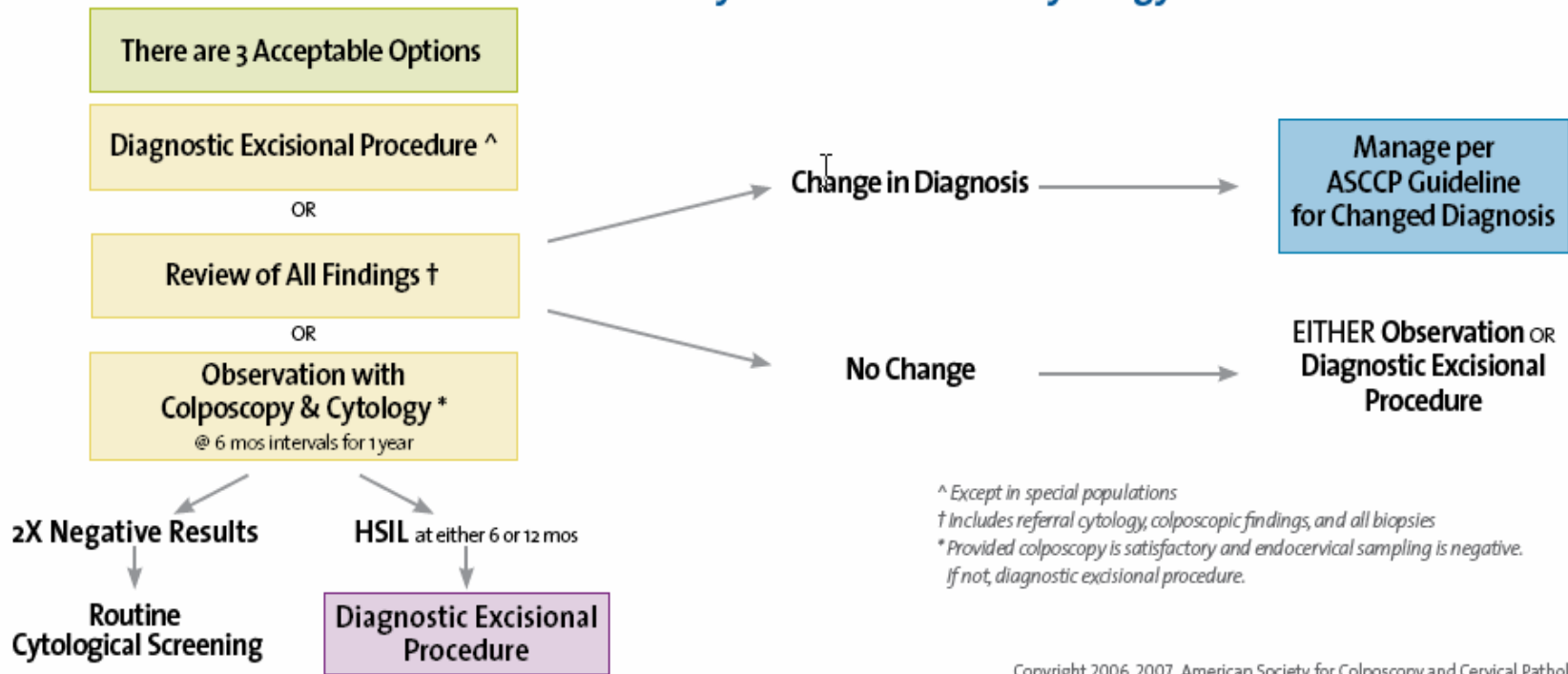
- Pap tests are reported as Satisfactory/Unsatisfactory for Evaluation
- If test is unsatisfactory, repeat Pap in 6-12 weeks. If 2nd Pap is also unsatisfactory, refer for colposcopy (BCCCP will pay)
- If test is negative and satisfactory (but lacks transformation zone cells), Pap is considered NORMAL and will need to be repeated at usual schedule (1/2/3 years)

Diagnostic LEEP and Diagnostic Cone

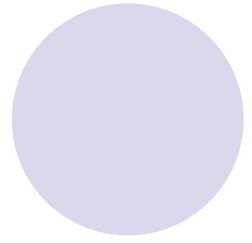
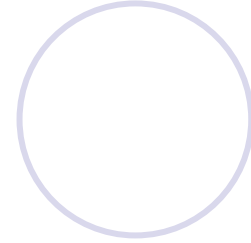
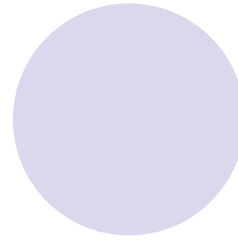
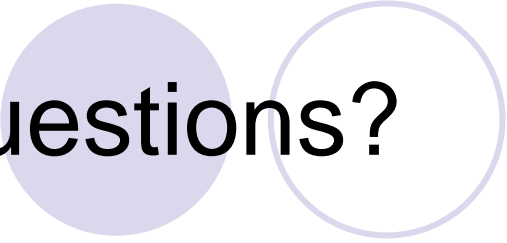
- Pap result of HSIL or AGC only
- Colp result of CIN1, atypia, “not cancer” or unsatisfactory
- Need NC approval for reimbursement and data entry
- Cannot pay anesthesia or facility charges



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



Questions?



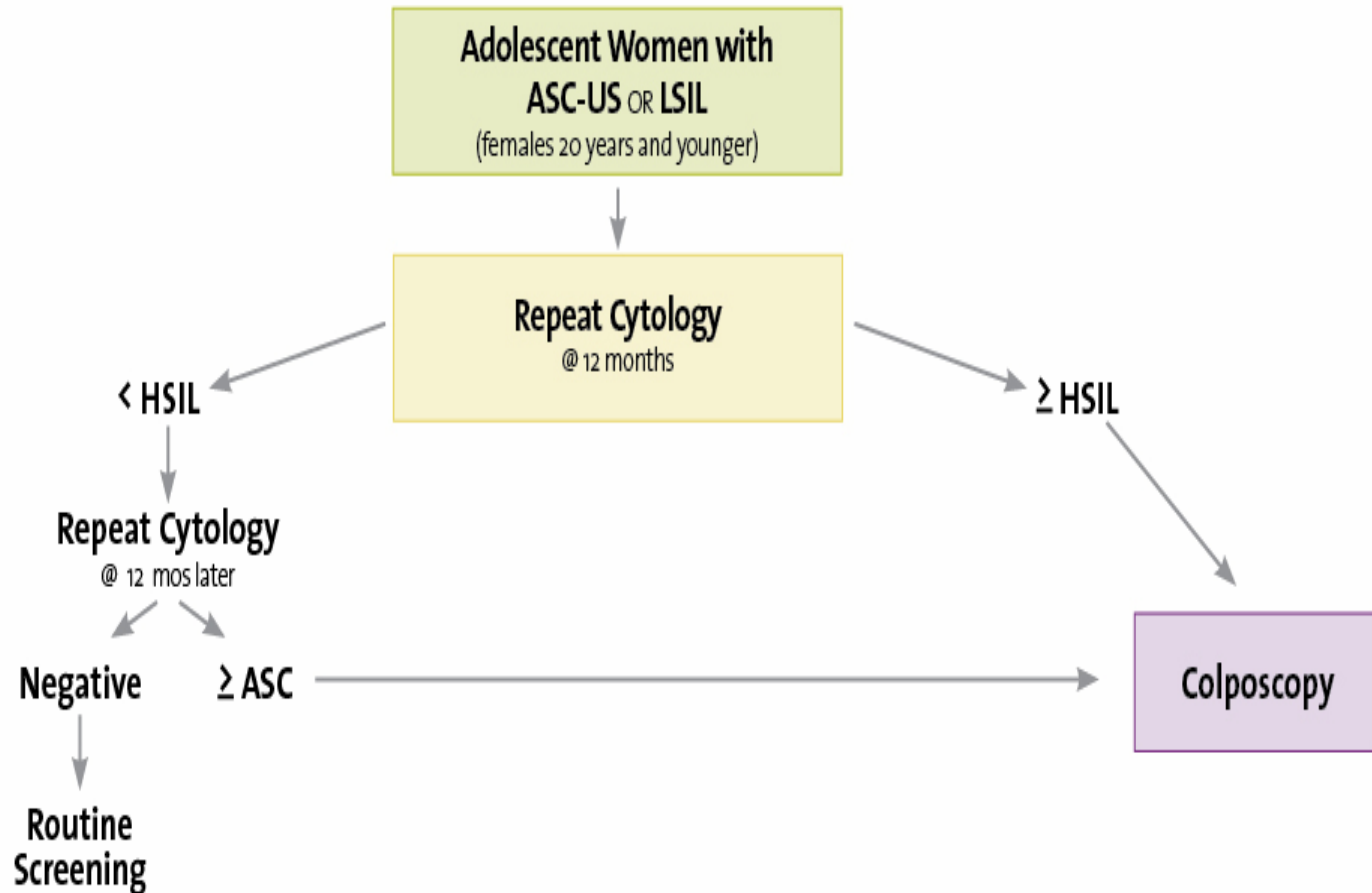
Abnormal Cytology Results

- Adolescent Protocol
- Pap results of ASC-US
- ASC-H
- LSIL
- HSIL
- AGC
- SCC
- Use ASCCP Guidelines for follow-up reference
- Will NOT discuss care of abnormal Paps during pregnancy

Current Cervical Cancer Screening Recommendations

	USPSTF 2003	ACS 2002	ACOG 2008
Age to start	Age 21 or within 3 yrs of sexual activity	Age 21 or within 3 yrs of sexual activity	Age 21
Interval			
<30 yr	Conv: at least every 3 yrs	Conv: 1 yr LBC: 2 yr	2 yrs
≥ 30 yr		2-3 yrs	2-3 yrs

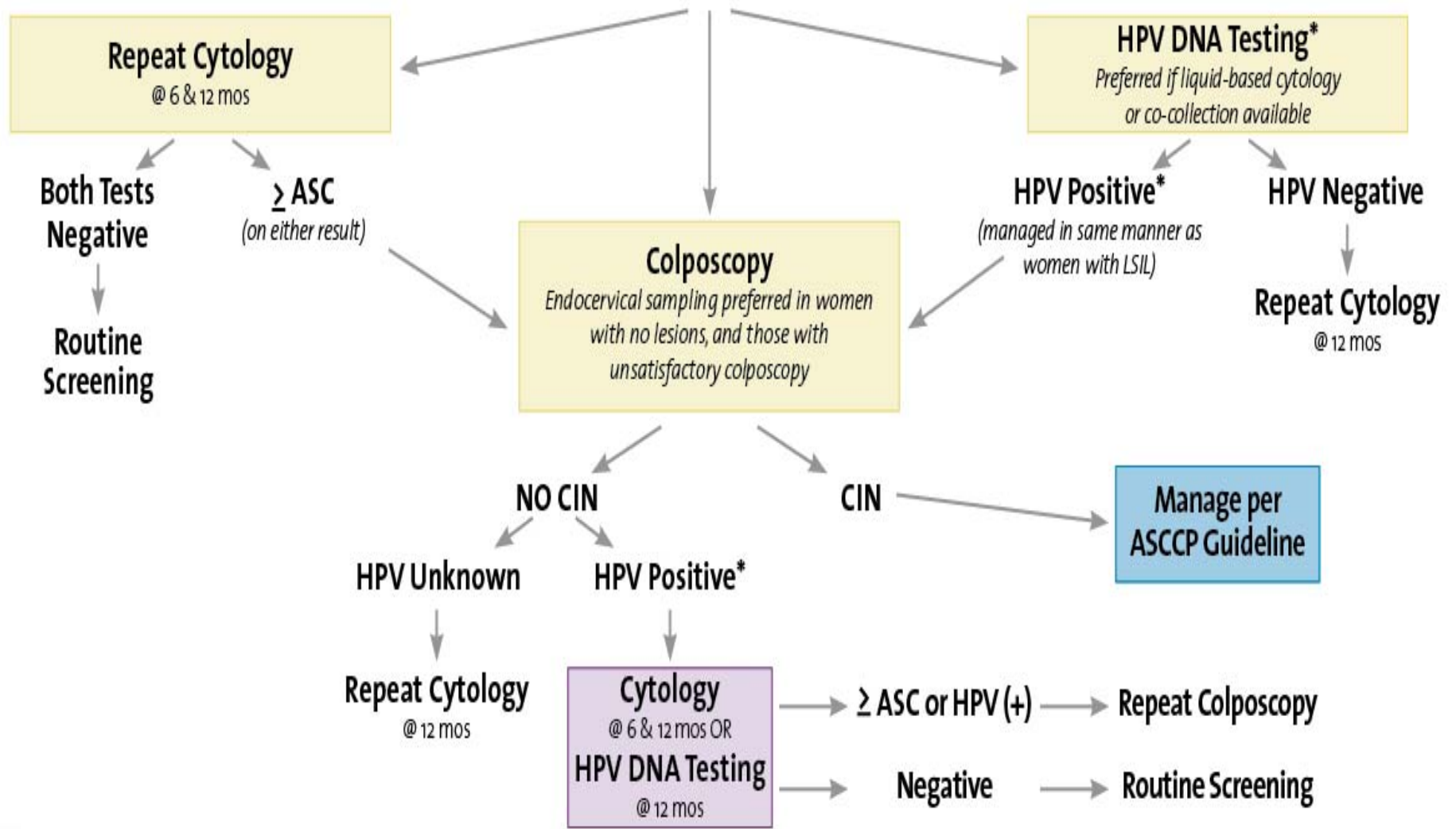
Management of Adolescent Women with Either Atypical Squamous Cells of Undetermined Significance (ASC-US) or Low-grade Squamous Intraepithelial Lesion (LSIL)



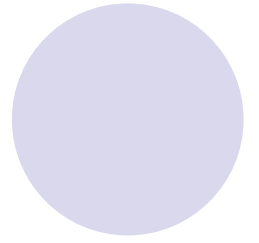
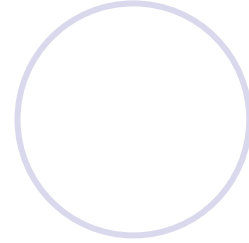
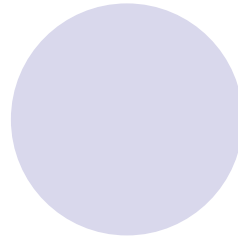
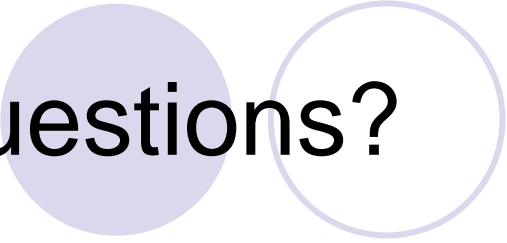
Follow-up for Family Planning Clients

- Patient of Title X, <age 40 w/ abnormal Pap test
- BCCCP cannot pay for triage HPV test (FP) or screening HPV test at same time as Pap (FP and BCCCP)
- For FP clients, refer to BCCCP for colp/ECC, and treatment of CIN2+, as may be indicated
- BCCCP will pay for 1 Pap (only) for 6 month's follow-up
- Return to FP for subsequent care and payment

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



Questions?

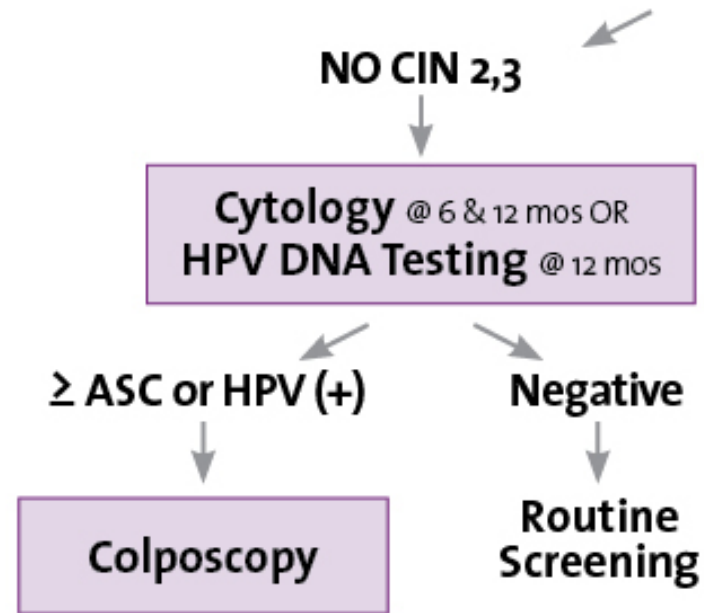


Other results~



- HSIL: refer for colp, regardless of age
- LSIL: refer for colp
- ASC-H: refer for colp
- ASC-H in adolescents: colp is per clinician discretion, due to lack of data for ASCCP to make a recommendation
- Regardless of age, do NOT perform HR-HPV for any of these results!

Follow-up of CIN I/not cancer/atypia on colp





Endometrial Biopsy (EMB)

- Pap result of AGC, only
- Expected in women >34 (if <35, will pay if provider performs), usual performed at same time as colp and ECC.
- HR-HPV testing results are needed to guide follow-up after colp
- Contact NC to be reimbursed for EMB

Initial Workup of Women with Atypical Glandular Cells (AGC)

All Subcategories
(except atypical endometrial cells)



Colposcopy *(with endocervical sampling)*
AND HPV DNA Testing [^]
AND Endometrial Sampling
(if > 35 yrs or at risk for endometrial neoplasia)*

Atypical Endometrial Cells



**Endometrial AND
Endocervical Sampling**



NO Endometrial Pathology

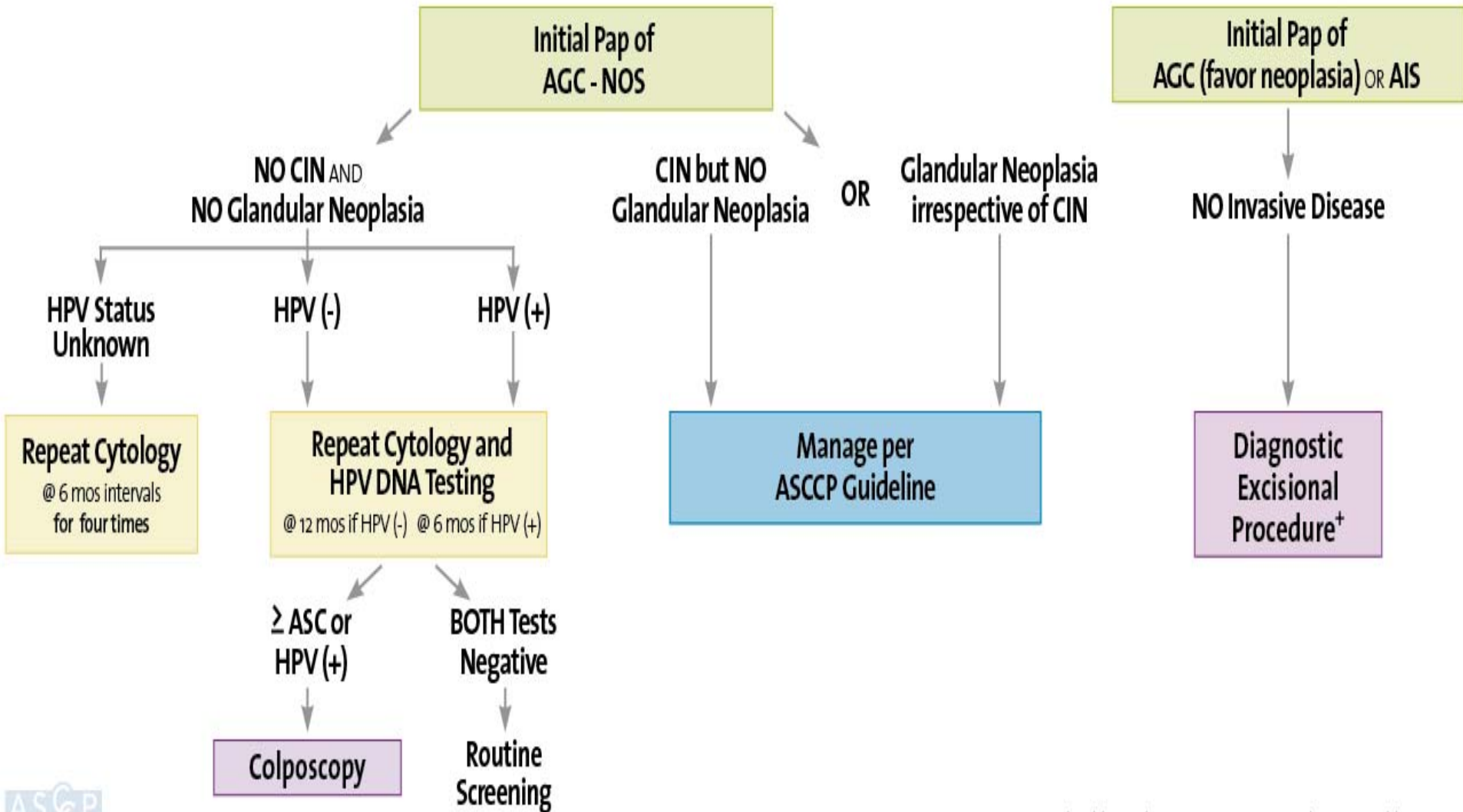


Colposcopy

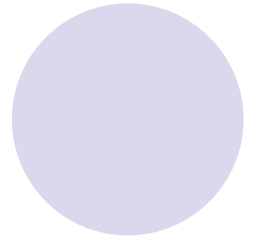
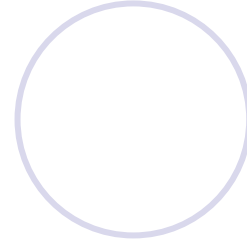
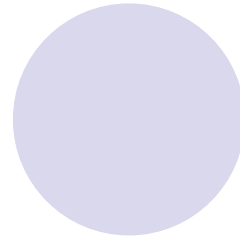
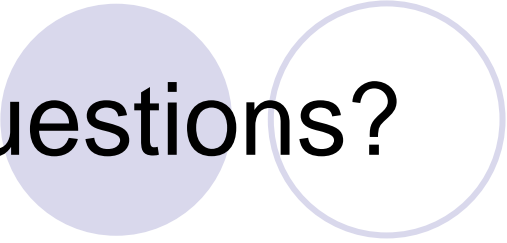
[^] If not already obtained. Test only for high-risk (oncogenic) types.

* Includes unexplained vaginal bleeding or conditions suggesting chronic anovulation.

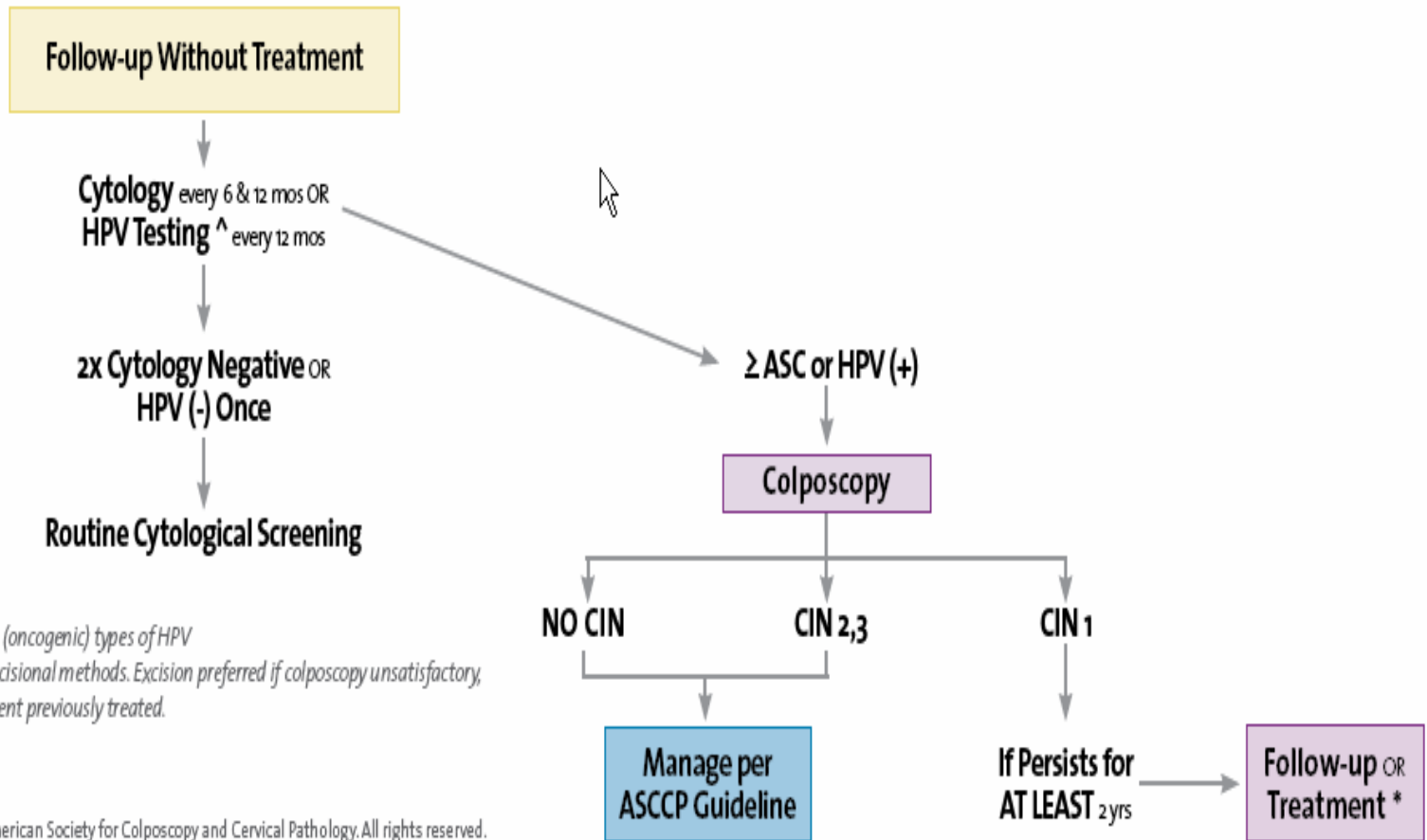
Subsequent Management of Women with Atypical Glandular Cells (AGC)



Questions?



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.



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Reimbursement Considerations

Satisfactory, Negative Pap w/ no endo cells	Pap does NOT need to be repeated	Pay for regular Pap test only
Confirmed HSIL Pap (e.g., dx of CIN2+)	Screen <u>annually</u> for 20 years	Will pay annually, regardless of Pap type
Immuno- compromised? (HIV+)	Screen annually	BCCCP will pay

Reimbursement Considerations

Pap sat but obscured/partially obscured	Repeat in 6 mo If 2 nd abn, refer for colp	Will pay for Pap and colp
<u>Pap unsatisfactory</u>	Repeat in 2-4 months If 2 nd unsat, refer for colp	Will pay for Pap and colp
Hyst for ca/dys (NO cervix)	Screen ann., indefinitely	BCCCP will pay

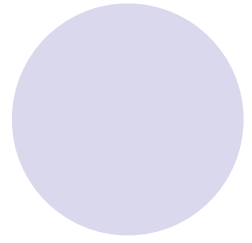
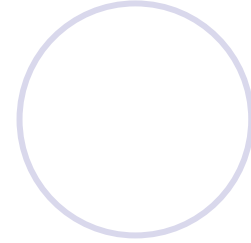
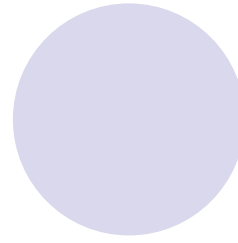
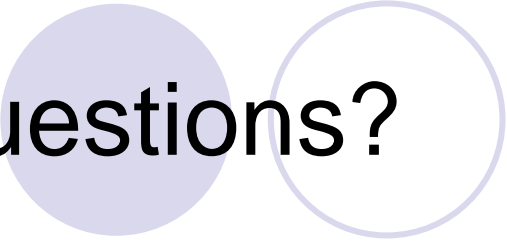
Reimbursement Considerations

Hyst for ca/dys (Cx present)	Cont. testing as indicated by age, type, hx	Will pay
Hyst for benign gyn disease (NO cx)	NO Pap, pelvic indicated	Will NOT pay for Pap
HR - HPV as Pap screening adjunct	Cannot Pay	BCCCP will pay for Pap, not for HPV

Reimbursement Considerations

Abn cervix (r/o cancer)	May do Pap; need NC approval for data	Will pay
Cannot use Pap to r/o endometrial cancer		Will not pay
Endometrial cells in >age 40 woman on Pap	EMB may be indicated but	BCCCP <u>cannot</u> pay if Pap not AGC

Questions?



Case Management List



- Two lists/agency/FY are posted on BCCCP website monthly
- List of who is approved (data complete in MBCIS), may bill for CM reimbursement
- List of pending – will tell you exactly what care is needed (colp) and/or what data we are waiting for (final diagnosis, treatment)
- Questions?: Ann Garvin

Questions?

- Contact Nurse Consultants:
- Ann Garvin garvina@michigan.gov
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- E.J. Siegl sieglej@michigan.gov
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