For the Purposes of this Guideline "Solid Breast Mass" is Defined as a Benign Focal Tumor, e.g., Fibroadenoma.

INFORMATION REQUIRED *Any history.*

Applicants Age 30 or Under:

- Specialist Evaluation (General Surgeon) within the past 6 months to include:
  - Diagnosis
  - Size and location of mass.
  - Recommendations for follow-up over the next 3 years.

Applicants Over Age 30:

- Specialist Evaluation (General Surgeon) within the past 6 months to include:
  - Diagnosis
  - Size and location of mass.
  - Recommendations for follow-up over the next 3 years.
- Biopsy (needle or excision) report to confirm diagnosis.

If Applicable:

- Most recent mammogram report.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Solid, discrete, breast mass noted on evaluation. 2. Breast mass *less than* 1.0 cm. 3. No history of breast cancer.		
Meets clearance criteria 1-3, AND • Age 30 or under. • Biopsy (needle or excision) performed.* • Confirmed fibroadenoma or benign focal tumor. • If excision performed, post surgery *greater than* 6 weeks. * *Not required for applicants age 30 or under. Exceeds clearance requirements.*	RN	**CLEAR** If provider recommends annual mammogram; Mammogram Accommodation.
Meets clearance criteria 1-3, AND • Age 30 or under. • No biopsy (needle or excison) performed. • Presumed fibroadenoma or benign focal tumor.	RN	**CLEAR** If provider recommends annual mammogram; Mammogram Accommodation.

Meets clearance criteria 1-3, AND • Over age 30. • Required biopsy performed (Needle). • Confirmed fibroadenoma or benign focal tumor.	**RN**	**CLEAR** PCMO FOLLOW-UP: Periodic (every 3-6 months) breast exam *by a general surgeon or an experienced provider.* Consider OMS consult if mass increases in size or changes in texture.
Does not meets clearance criteria due to one or more of the following: • If excision performed, post surgery/*less than* 6 weeks.	**RN**	**CLEAR** Entry on duty must be *greater than* 6 weeks post surgery.
Does not meet clearance criteria due to one or more of the following: • Over age 30, and breat mass unconfirmed or unresolved. • Breast mass *greater than 1.0 cm.* and breast mass unconfirmed or unresolved.	**MED ADVISOR**	Risk varies - assess based on detailed history.
Does not meet clearance criteria due to one or more of the following: • History of breast cancer.	**RN**	See "Breast Cancer" Guideline.

DIAGNOSTIC CODES

611.72 Solid Breast Mass
217.0 Fibroadenoma

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- Applicants cleared to a mammography country should bring, to their country of assignment, their most recent mammogram films for comparison.

COMMENTS:

Background: All breast masses require a thorough evaluation and diagnostic work-up.

Fibroadenomas: Fibroadenomas are the most common benign solid tumors of the breast and represent the most common breast tumor in women younger than 25 years. Clinically, they are painless, well-circumscribed, freely movable tumors with a rounded, lobulated or discoid configuration. They are hormonally responsive and may increase in size toward the end of each menstrual cycle. Because these tumors will not regress spontaneously and tend to enlarge over time, simple gross excision is the treatment of choice. Very small fibroadenomas - those detected only by mammography - may sometimes be watched rather than excised, depending on the clinical duration. *[Issacs, John H. Benign Tumors of the Breast. "Obstetrics and Gynecology Clinics of North America", Vol.21, No.3, 1994.]*

"Patients who have a solid, benign-appearing mass are presumed to have a fibroadenoma. If this mass is less than 1 cm, old, and is unchanged, it can be observed with repeat examination every 6 months." Fine needle aspiration (FNA) biopsy can be performed to provide additional evidence that this solid mass is benign. Evaluation by a surgeon for possible biopsy is recommended when a woman has a solid mass that does not meet these criteria or when results of FNA are positive. *[Burns, Risa Beth. Evaluation and Management of a Palpable Breast Mass. "The Medical Care of Women", 1995.]*

Evaluation of Breast Masses:

Patients Under 30 Years of Age: The initial evaluation should be with sonogram or an attempt at aspiration rather than mammography. Masses characterized as indeterminate or suspicious by ultrasound should be evaluated with mammography.

Patients 30 Years of Age or Older: The initial evaluation should be with mammographic views of both breasts followed by further diagnostic procedures. *"Evans, Phil W. "Breast Masses: Appropriate Evaluation. "Radiologic Clinics of North America", Vol.33, No.6, 1995.]*

"If the lump is palpable in the patient is over 35 years of age, obtain a mammogram. Even if the mammogram shows no abnormality, further diagnostic procedures should be done. Ultrasonography may be done but biopsy is usually the next step. If a woman is under age 35, the lump will probably not show up on mammogram, so a biopsy should be ordered for any suspicious lump." *[Goldman, Sherry. Evaluation Breast Masses. "Contemporary OB/GYN-NP", June/July, 1994.]*

Literature review available.

INFORMATION REQUIRED *Any history.*

All Applicants:

- Specialist Evaluation (Gynecologist) within the past 1 year to include the following:
  - Current status
  - Recommendations for follow-up over the next 3 years.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. No history of DES related cancer.		
Meets clearance criteria , AND • Normal pap smear.	RN	CLEAR
	PCMO FOLLOW-UP Annual pap smear or as recommended by provider.	
Does not meet clearance criteria due to one or more of the following: • Abnormal pap smear.	RN	—— See "Pap Smear" Guideline.
Does not meet clearance criteria due to one or more of the following: • History of DES related cancer.	MED ADVISOR	—— Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

E932.2 DES Exposure in Utero

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- None

COMMENTS:

Background: The prescribing of DES to pregnant women was stopped in the 1960s. The daughters need yearly pap smears if they have never had an abnormal pap. If an applicant has a history of DES exposure and an abnormal pap smear, she needs treatment and follow-up as indicated by her GYN. The cancer associated with DES exposure is a slowly progressing cancer with a peak incidence in the teen years. The cancer is usually vaginal. Most women exposed to DES in Utero are now older than 30 years old. consequently the number of women at risk for developing DES related cancer is decreasing.

Literature review available.

Includes Cervical Carcinoma-in-Situ and Cervical Carcinoma.

INFORMATION REQUIRED *Any history*

All Female Applicants:

- Report of Medical Examination to include the following:
  - Pap smear (conventional or ThinPrep) within 6 months of the date of Medical Evaluation.

Applicants With Absent Endocervical Cells on Current Pap:

- Pap smear history to include documentation of prior abnormal Pap smears and cervical cancer risk factors.
- If history includes abnormal Pap smears within the past 3 years or patient has cervical cancer risk factors (see comments), repeat Pap smear.

Applicants with ASCUS or ASC-US on Current Pap:

- If conventional Pap smear submitted, copy of *repeat* ThinPrep Pap smear(liquid-based cytology) with reflex HPV DNA testing.
- If ThinPrep Pap smear submitted, copy of HPV DNA test (may normally not be done in conjunction with a ThinPrep Pap smear).

Applicants with ASC-US, HPV(+); ASC-H; or Greater Cytological Abnormality on Current Pap:

- Copy of most recent colposcopy and biopsy report.
- Recommendations for follow-up over the next 3 years.
- If treatment or therapy provided, copy of treatment report.

Applicants with AGS or AIS on Current Pap:

- Specialist Evaluation (Gynecologist)

Applicants Post Hysterectomy for a Benign Gynecological Cause:

- Pap smear not required.

A. Normal, or Minor, Pap Smear Findings.

(Current Pap Smear Reports One of the following Findings)

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Specimen Adequacy: "*satisfactory for interpretation*" or "*less than optimal*". 2. Endocervical Component*: *endocervical cells present*, with or without endocervical mucous or squamous metaplasia. 3. Pathologist or health care provider recommends annual follow-up; or no recommendations specified. ** If endocervical component is absent, OMS recommends that a thorough history be obtained, to include history of abnormal Pap smears and cervical cancer risk factors.*		
Meets clearance criteria 1 - 3, AND • Within Normal Limits.	RN	CLEAR
Meets clearance criteria 1 - 3, AND • Reactive, Reparative, or Benign Cellular Changes.	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: • Absent endocervical cells, AND - no abnormal Pap smears for at least the past 3 years, AND - no cervical cancer risk factors (see comments).	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: • Absent endocervical cells, AND - an abnormal Pap smear *within* the past 3 years, OR - cervical cancer risk factors (see comments).	RN	DEFER Repeat Pap smear.

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Meets clearance criteria 1 - 3, AND • Moderate to Severe Inflammatory Changes. • Evaluation and treatment, if required, complete. * **Evaluation required.*	**RN**	**CLEAR**
	PCMO FOLLOW-UP If no etiology found, repeat Pap smears as recommended by provider; OR repeat every 6 months. *Note: Persistent inflammation may require colposcopy. If finding persists, consider GYN or OMS consult.*	
Meets clearance criteria 1 - 3, AND • Moderate to Severe Inflammatory Changes • Evaluation and/or treatment not complete.	**RN**	**DEFER** Defer until evaluation and treatment are complete.
Meets clearance criteria 1 - 3, AND • Pathogens: Trichomonas. • Treatment complete (verbal report from applicant acceptable). ** Treatment required.*	**RN**	**CLEAR**
Meets clearance criteria 1 - 3, AND • Meets clearance criteria 1-3, AND • Pathogens: Candida, Gardnerella, Actinomyces, and Other. If treated, treatment complete (verbal report from applicant acceptable).	**RN**	**CLEAR**
Meets clearance criteria 1 - 3, AND • Pathogens: Coccobacilli • No, or resolved, symptoms. • If treated, treatment complete (verbal report from applicant acceptable).	**RN**	**CLEAR**
Meets clearance criteria 1 - 3, AND • Hyperkeratosis and Parakeratosis.	**RN**	**CLEAR**
	PCMO FOLLOW-UP Repeat Pap smear for 6 months. *Note: Persistent keratosis may require colposcopy. If finding persists, consider GYN or OMS consult.*	
Meets clearance criteria 1 - 3, AND • Herpes Simplex Virus (I and II).	**RN**	—— See "Herpes Simplex" Guideline.
Does not meet clearance criteria due to one or more of the following: • Pathologist or health care provider recommends follow-up *other than annual* Pap.	**RN**	**CLEAR**
	PCMO FOLLOW-UP Repeat Pap smears as recommended by provider.	

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b. Atypical Squamous Cells - Undetermined Significance (ASC-US)

CLEARANCE CRITERIA	REVIEWER	GUIDANCE

C. Atypical Squamous Cells – Cannot Exclude HGSIL (ASC-H) and Low Grade Squamous Intrapithelial Lesion (LGSIL):

Includes Cellular Changes Associated with HPV and Mild Dyplasia (CINI).

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Atypical Squamous Cells - Cannot Exclude HGSIL (ASC-H) or Low Grade Squamous Intraepithelial Lesion (LGSIL) on *current* Pap smear. 2. Colposcopy and directed biopsy performed (mandatory). *Note: Pap smear may, or may not, be further qualified to include dysplasia and/or HPV changes. These qualifications do not affect the guidance. See comments regarding natural history of LGSIL.*		
Meets clearance criteria 1 - 2, AND • No dyplasia noted on colposcopy and directed biopsy.	**RN**	**CLEAR**
	PCMO FOLLOW-UP Repeat Pap smears as recommended by provider. *Note: In general, repeat ThinPrep Pap smear in 4-6 months and then every 6 months for 2 years. Annual Pap smears may be instituted after 3 consecutive normal smears.*	
Does not meet clearance criteria due to one or more of the following: • Dyplasia noted on colposcopy and directed biopsy.	**RN**	**DEFER** Until resolved as evidenced by: (1) Treatment complete and 1 post treatment Pap smears normal (see Table A); OR (2) If no treatment: three consecutive Pap smears, at least 3-6 months apart, are normal (see Table A).
	PCMO FOLLOW-UP Repeat pap smears as recommended by provider.	
Does not meet clearance criteria due to one or more of the following: • No colposcopy or directed biopsy performed.	**RN** *Note: If provider indicates colposcopy is not necessary, review case with Medical Advisor. Provider must provide justification.*	**DEFER** 1) Until colposcopy and directed biopsy confirm the presence or absence of dysplasia; OR (2) Three consecutive Pap smears, at least 3-6 months apart, are normal (See Table A).
	PCMO FOLLOW-UP Repeat Pap smears as recommended by provider.	

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D. High-Grade Squamous Intraepithelial Lesion (HGSIL):

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. High Grade Squamous Intraepithelial Lesion (HGSIL) on *current* pap.		
Meets clearance criteria, AND • Colposcopy and directed biopsy performed and diagnosis confirmed.	**RN**	**DEFER** Until resolved as evidenced by the following: 1) Treatment complete AND 2 post treatment Pap smears, at 3 and 6 months, are normal (see Table A); OR (2) If no treatment: three consecutive Pap smears, at least 3-6 months apart, are normal (see Table A).
	PCMO FOLLOW-UP Repeat Pap smears as recommended by provider. *Note: In general, after treatment of a preinvasive lesion, repeat Pap smears every 3-4 months for 1 year then annually thereafter. After treatment of an invasive lesion, repeat Pap smears every 3-4 months for 1 year then every 6 months for 2-3 years before resuming annual smears [AGOG].*	

E. Atypical Glandular Cells (AGS) and Adenocarcinoma in Situ (AIS)

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
• Atypical Glandular Cells (AGS) or Adenocarcinoma in Situ (AIS) on *current* Pap smear.	**MED ADVISOR**	**DEFER** Until resolved as evidenced by the following: treatment complete AND 2 post treatment Pap smears, at 3 and 6 months, are normal.
	PCMO FOLLOW-UP Repeat Pap smears as recommended by provider.	

F. Invasive Carcinoma of the Cervix

CLEARANCE CRITERIA	REVIEWER	GUIDANCE

DIAGNOSTIC CODES

/62.2	Pap Smear (Using the Bethesda System)
233.1	Cervical Carcinoma-In-Situ
180	Cervical Carcinoma
	Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS

Reviewers to Consider:

- LSIL, with or without dyplasia, can be managed with consecutive pap smears. Three consecutive pap smears "within normal time limits", at least six months apart, is an adequate way to document resolutions of LSIL.
- Evaluation of abnormal cervical cytology may include HPV DNA testing, colposcopy, directed biopsy, and endocervical curettage.
- Management of postmenopausal women with ASC-US (see comments below): May or may not require HPV DNA testing. Consider review with Medical Advisor.

COMMENTS

Background: Cells of the cervical epithelium, which are sampled in the Pap smear, are stimulated by a wide range of exposures, from infectious agents to the constituents of cigarette smoke. Inflammation from trauma and infections stimulates cell renewal, which increases the probability that dysplastic cells will form. Most such cells revert to normal in a period of months, but some progress, and eventually lead to carcinoma in situ, and may progress to invasive cancer. [*AAFP, 1997*]

Bethesda System Reporting Classifications: Pap smears are classified according to the 2001 modification of the Bethesda System (TBS), which was first developed in 1989. The Bethesda System requires consideration of both the quality of the specimen and a descriptive diagnoses of the sample cells. Because of the relative newness of the system, refinements in management are made as xperience accumulates on the outcomes of each category of abnormal Pap smears.

The most recent *Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities* published in 2001 recommended significant changes in the grading and reporting of ASCUS using the Bethesda System. The Consensus Guidelines simplify the monitoring, follow-up and treatment of women with these cytological abnormalities. ASCUS was subdivided into two distinct subcategories, each subcategory requiring a different management protocol (see OMS Memo on ASCUS Management 9/18/2002). The new categories are:

ASC-US - Atypical Squamous Cells of Undetermined Significance (reactive)
ASC-H - Atypical Squamous Cells (cannot exclude HSIL)

HPV Testing

The *2001 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities* recommended Human Papilloma Virus (HPV) DNA testing for women with ASC-US, *if* HPV DNA testing has not been previously performed. HPV DNA testing is usually done in conjunction with a liquid-based cytology test (ThinPrep Pap Test) or may be done independently. HPV DNA testing cannot be done in conjunction with a conventional Pap "smear" done on a microscope slide.

There are numerous subtypes of HPV, but subtypes 16, 18, 31 and 45 are associated with a higher incidence of cervical dysplasia and invasive carcinoma. *If any of the "high risk" subtypes are identified through HPV DNA testing, the results are reported as "high risk viral types identified".* Individual "high risk" subtypes, i.e., 16, 18, etc., are not reported, nor are any "low risk" subtypes.

Specimen Adequacy - Absent Endocervical Cells: Controversy exists regarding the follow-up of Pap smears with absent endocervical cells. The two viewpoints are summarized below.

- Pap smear without ECC is *not adequate:* Smears without ECC provide no evidence that the at-risk epithelium has been evaluated. Cross sectional studies have shown a higher percentage of abnormalities in smears with ECC than those without ECC.
  Pap smear without ECC *is adequate:* Longitudinal studies that have followed up women whose smears lacked endocervical cells have shown no increased detection of abnormalities on subsequent smears with endocervical cells.

Endocervical cells are not required for an adequate pap smear reading. Endocervical cells are absent in up to 10% of pap smears premenopause and up to 50% post menopausal.

Management

- Test may or may not be repeated based on the *clinical situation as determined by the clinician*. In general, if endocervical cells are absent, OMS recommends that a thorough history be obtained, to include history of abnormal Pap smears and cervical cancer risk factors. In terms of management, OMS follows AGOG recommendations (see below):

- AGOG recommendations:

  No need to repeat Pap smear if:
  - No known risk factors
  - 3 consecutive annual normal pap tests
  - Current pap smear is normal, i.e., no other cellular abnormalities

  Repeat Pap smear if:
  - High risk patient, i.e., presence of cervical cancer risk factors.
  - Previous abnormal pap smears

Cervical Cancer Risk Factors
- Onset of sexual activity < 20 years
- 3 or more sexual partners
- History of HPV or STDs
- Cigarette smoker

Inflammation: Generally mild inflammation on an otherwise normal smear does not need further evaluation. Moderate to severe inflammation, or inflammation with symptoms should be evaluated with a saline preparation, KOH preparation, gonorrhea test, and chlamydia test. If the source of infection is found, treatment should be provided and a repeat pap smear done in 6-12 months. If no etiology is found, a repeat pap smear should be done in 6 months. Infrequently, inflammation may be the only manifestation of HSIL or invasive cancer, therefore, persistent inflammation is an indication for colposcopy

Atypical Squamous Cells - Undetermined Significance (ASC-US): Indicates "reactive" cells with nuclear atypia, i.e., lesions that have cellular abnormalities suggestive of Squamous Intraepithelial Lesions (SIL). About 25% of women with a pap smear diagnosis of ASCUS actually have dysplasia, on further examination. The remaining 75% have no evidence of intraepithelial neoplasia. *[illegible]* Test). According to the 2001 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities, management of ASC-US includes repeat cytology, HPV DNA testing, and colposcopy. Repeat cytology should severe cervical cytologic abnormalities (ThinPrep Pap Test). In general, colposcopy is indicated for those women with HPV or DNA evidence of progressive disease on Pap smear.

ASC-US in Postmenopausal Women: Evaluating a source of intravaginal estrogen followed by a repeat cervical cytology test approximately a week after completing the regimen is an acceptable option for women with ASC-US and have no evidence of atrophy. If the repeat test results in negative or improved cytology, [illegible]

Atypical Glandular Cells (AGS) and Adenocarcinoma in Situ (AIS): The *2001 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities* classifies glandular cell abnormalities *less severe than adenocarcinoma* into 3 categories: (1) atypical glandular cells" (AGS), either endocervical, endometrial, or "glandular cells" not otherwise specified (AGC NOS); (2) atypical glandular cells, either endocervical or " glandular cells" favors neoplasia (AGC "favors neoplasia"); and (3) endocervical adenocarcinoma in situ (AIS).

The AGC category is associated with a substantially greater risk for cervical neoplasia than the ASC-US/ASC-H or LSIL categories. Various studies have found that 9%-54% of women with AGC have biopsy-confirmed CIN 1-3, 0%-8% have biopsy-confirmed AIS, and less than 1%-9% have invasive carcinoma. Biopsy-confirmed high-grade lesions including CIN 2,3, and AIS have been found in 9%-41% of women with AGC NOS compared with 27%-96% of women with AGC "favors neloplasia." The cytological interpretation of AIS is associated with a very high risk of a woman having either AIS (48%-69%) or invasive cervical adenocarcinoma (38%).

Pap Smear Following Hysterectomy: Files show that many groups are silent on the issue of pap smears following hysterectomy. The