

ABNORMAL MENSTRUAL BLEEDING PATTERNS

GYN 3.1

Includes Menorrhagia, Metrorrhagia, Oligomenorhea, and Polymenorrhea.
For Amenorrhea, see "Amenorrhea" Guideline. For Dysmenorrhea, see "Dysmenorrhea" Guideline.

INFORMATION REQUIRED *Any history*

All Applicants:

- Report of Medical Examination to include the following:
 - Description of bleeding pattern
 - Etiology, if known.
 - Complications, if any.
 - Treatment
 - Recommendations for follow-up over the next 3 years.

Applicants with Menorrhagia or Metrorrhagia :

- Evaluation and work-up required (see comments)
- Copy of related diagnostic tests.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Abnormal or irregular menstrual bleeding pattern defined as one of the following: 2. No significant associated complications, e.g., anemia, dysmenorrhea, or amenorrhea.		
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • <u>Polymenorrhea</u> • Resolved, hormonally controlled, or well tolerated, for <i>at least</i> the past 3 months. 	RN	CLEAR
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • <u>Oligomenorhea (Perimenopausal)</u> • <i>Stable</i> menstrual pattern for <i>at least</i> the past 6 months. 	RN	CLEAR
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • <u>Oligomenorhea (Menopausal)</u> 	RN	CLEAR
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • <u>Menorrhagia</u> • Evaluation and work-up complete. • Resolved, hormonally controlled, or well tolerated, for <i>at least</i> the past 3 months. 	RN	CLEAR
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • <u>Metrorrhagia</u> • Evaluation and work-up complete. • Resolved, hormonally controlled, or well tolerated, for <i>at least</i> the past 3 months. 	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • <u>Undefined</u> abnormal or irregular menstrual bleeding pattern. 	RN	_____ See "Dysfunctional Uterine Bleeding" Guideline.

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<p>Does not meet clearance criteria due to one or more of the following:</p> <ul style="list-style-type: none"> • <u>Polymenorrhea</u>: <ul style="list-style-type: none"> - Not resolved, hormonally controlled, or well tolerated for <i>at least</i> the past 3 months. • <u>Oligomenorrhea</u> (Not menopausal): <ul style="list-style-type: none"> - Menstrual pattern not stable for at least the past 6 months. • <u>Menorrhagia</u> or <u>Metrorrhagia</u>: <ul style="list-style-type: none"> - Evaluation and work-up <i>not</i> complete. - Not resolved, hormonally controlled, or well tolerated for <i>at least</i> the past 3 months. • Significant associated complications. 	MED ADVISOR	<p>_____</p> <p>Risk varies - assess based on detailed history.</p>
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DIAGNOSTIC CODES

626.3	Menorrhagia
626.6	Metrorrhagia
626.1	Oligomenorrhea
626.2	Polymenorrhea
Cross Reference ICD.9.CM	

NOTES AND INSTRUCTIONS FOR REVIEWERS**Reviewers to Consider:**

- None

COMMENTS

Background: Any bleeding that is excessive in duration, frequency, or amount is considered abnormal and requires investigation accordingly.

Evaluation: Diagnostic tests to consider as appropriate include prolactin, LH, FSH, DHEA-s, free testosterone, LFTs, thyroid function tests, coagulation profile, CBC, and pregnancy test.

Definitions:

Oligomenorrhea: Infrequently occurring menses at intervals greater than 35 days.

Polymenorrhea: Frequently occurring menses at intervals of 21 days or less.

Metrorrhagia: Irregularly occurring bleeding.

Menorrhagia: Regularly occurring bleeding excessive in duration or flow, usually defined as 8 days in length or greater.

Literature review available.

Includes Absence of Menses.

Amenorrhea Due to Birth Control Pills or Pregnancy; Guideline not Applicable.

INFORMATION REQUIRED *If history within the past 5 years.***Applicants With Absent Menses, i.e., Absent Bleeding Pattern Less Than 6 Months Duration:**

Report of Medical Examination to include the following:

- Etiology
- Specific management recommendations.

Applicants With Amenorrhea, i.e., Absent Bleeding Pattern Greater Than 6 Months Duration:

- Specialist Evaluation (Gynecologist) within the past 6 months to include the following:
 - Etiology
 - Specific management recommendations.
- Copy of related diagnostic tests.

A. Absence of Menses: Absent Bleeding Pattern Less Than 6 Months Duration.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Absence of menses <i>less than</i> 6 months duration, current or by history.		
Meets clearance criteria 1, AND <ul style="list-style-type: none"> • Abnormal bleeding pattern <u>resolved</u>, i.e. normal menses, for <i>at least</i> the past 3 months. 	RN	CLEAR
Meets clearance criteria 1, AND <ul style="list-style-type: none"> • Absence of menses <u>current</u>. • <u>Etiology determined</u>, OR probable benign attributable cause, e.g., strenuous exercise, emotional stress, contraception. • Provider provides specific management recommendations. 	RN	CLEAR PCMO FOLLOW-UP If absence of menses continues for more than 6 months consider evaluation and diagnostic work-up or OMS consult.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Absence of menses <u>current</u>. • <u>Etiology not determined</u>, OR no probable benign attributable cause, e.g., strenuous exercise, emotional stress, contraception. • Gynecologist provides no specific management recommendations. 	RN	DEFER Until evaluation and diagnostic work-up complete, etiology determined, and abnormal bleeding pattern resolved for <i>at least</i> 3 months. Deferral letter requires review by screening manager.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Amenorrhea <i>greater than</i> 6 months duration, current or by history. 	RN	See Table B: "Amenorrhea: Absence of Menses Greater than 6 Months."

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AMENORRHEA

B. Amenorrhea: Absence of Menses Greater Than 6 Months.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Amenorrhea <i>greater</i> than 6 months duration, current or by history. 2. Evaluation and diagnostic work-up complete.		
Meets clearance criteria 1-2, AND • Amenorrhea <u>resolved</u> (with or without hormonal treatment), i.e., normal menses, for <i>at least</i> the past 3 months.	RN	CLEAR
Meets clearance criteria 1-2, AND • <u>Current</u> amenorrhea. • <u>Etiology determined</u> . • Provider provides specific management recommendations.	MED ADVISOR	_____ Risk varies - assess based on detailed history. PCMO FOLLOW-UP Follow-up as recommended by provider.
Does not meet clearance criteria due to one or more of the following: <u>Current</u> amenorrhea, AND • Evaluation and diagnostic work-up <i>not</i> complete. • Etiology <i>not</i> determined. • Gynecologist provides <i>no</i> specific management recommendations.	RN	DEFER Until evaluation and diagnostic work-up complete, etiology determined, and abnormal bleeding pattern resolved for <i>at least</i> the past 3 months. Deferral letter requires review by screening manager.

DIAGNOSTIC CODES
626.0 Amenorrhea
Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:
Reviewers to Consider: <ul style="list-style-type: none"> • Coexisting eating disorder. • Coexisting polycystic ovarian syndrome (stein-leventhal syndrome). • Coexisting congenital disorders.

COMMENTS:
<p>Background: Amenorrhea is one of the most common reasons that women seek medical attention. Frequently there is no underlying cause and the abnormal bleeding pattern resolves spontaneously or with hormones to induce ovulation. Prolonged amenorrhea, however, is a symptom, not a diagnosis and therefore requires a thorough work-up and evaluation.</p> <p>Definitions:</p> <p><i>Ammenorrhea:</i> Absence of menstruation.</p> <p><i>Primary Amenorrhea:</i> The absence of spontaneous vaginal bleeding by the age of 14 years in girls without other signs of secondary sexual characteristics.</p>

AMENORRHEA

Secondary Amenorrhea: Most common type. Defined as the absence of menstruation for at least 6 months in a woman with previously normal and regular menses.

Evaluation and Work-Up of Secondary Amenorrhea: A standard work-up commonly includes the following:

- History and physical exam
- Pregnancy test
- TSH, T4
- Glucose
- Prolactin
- Estrogen status assessment, i.e, progestin challenge or plasma estradiol, FSH, and LH.
- If indicated, testosterone, DHEA-S, 17-hydroxy-progesterone.

Literature review available.

INFORMATION REQUIRED *Any history.***All Applicants:**

Report of Medical Examination to include the following:

- Symptoms
- Treatment
- Recommendations for follow-up over the next 3 years.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. No, or mild, pelvic pain. 2. No, or minimal, interference of symptoms with activities of daily living.		
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • If treated, pain well controlled with NSAIDs or oral contraceptive pills. 	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Moderate to severe pelvic pain. • Symptoms significantly interfere with activities of daily living. • If treated, pain well controlled with <i>narcotics</i>. 	MED ADVISOR	Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

625.3 Dysmenorrhea

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- None

COMMENTS:

Background: Dysmenorrhea is defined as pelvic pain at or around the time of menstruation. There are two types:

- Primary dysmenorrhea - pain without pathological physical findings.
- Secondary dysmenorrhea - pain occurring prior to or during menses, often more severe than primary, having a secondary pathologic (structural) cause.

Symptoms: Symptoms range from mild pelvic discomfort or cramping on the first day of bleeding to severe, intense, cramp-like pain lasting 2-7 days; often associated with gastrointestinal upset, back ache, thigh pain, and headache.

Treatment: Ibuprofen, Naproxen sodium, or Aspirin. [Griffith's 1998]

Literature review available.

For Premenstrual Dysphoric Disorder; See "Mental Health" Guidelines.

INFORMATION REQUIRED *If history within the past 5 years.***All Applicants:**

- Report of Medical Examination to include the following:
 - Symptoms
 - Treatment
 - Recommendations for follow-up over the next 3 years.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
<ol style="list-style-type: none"> 1. No, resolved, or mild symptoms. 2. If symptoms, well controlled with diuretics, NSAIDs, oral contraceptive pills, diet, or exercise. 3. No, or minimal, interference of symptoms with activities of daily living. 		
Meets clearance criteria 1-3, AND <ul style="list-style-type: none"> • If treated, treatment does not include antidepressants, narcotics, or counseling. 	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Current, moderate to severe, symptoms. • Symptoms <i>not</i> well controlled with NSAIDs, oral contraceptive pills, diet, exercise, or diuretics. • Symptoms significantly interfere with activities of daily living. • Treatment includes antidepressants, narcotics, or counseling. 	MED ADVISOR	_____ Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

625.4 Premenstrual Syndrome

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:**Reviewers to Consider:**

- None

COMMENTS:

Background: Premenstrual syndrome is a constellation of symptoms that occur prior to menstruation. Symptoms may be mild or severe enough to interfere significantly with a patient's life.

Symptoms: Depressed mood, mood swings, irritability, difficulty concentrating, fatigue, edema, breast tenderness, headaches, weight gain, depressed mood, and food cravings.

Treatment: No single drug works for all women. Drugs that are used with varying degrees of success include diuretics, ibuprofen or acetaminophen, anti-depressants, alprazolam, Buspirone, magnesium, elemental calcium, Vitamin B6, Vitamin E, and evening primrose oil. Some women obtain relief with diet modification and exercise.

Literature review available.

INFORMATION REQUIRED *Any history.*

All Applicants:

- Specialist Evaluation (General Surgeon or Oncologist) within the past 1 year to include the following:
 - Documentation of recurrences within the past 5 years.
 - Recommendations for follow-up over the next 3 years.

If Applicable:

- Discharge summary for all related hospitalizations.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Treatment complete. 2. No history of recurrences for <i>at least</i> the past 5 years.		
Meets clearance 1-2 criteria, AND • No use of adjuvant therapy.	MED ADVISOR	CLEAR
Does not meet clearance criteria due to one or more of the following: • Treatment not complete. • History of recurrences <i>within</i> the past 5 years.	MED ADVISOR	DEFER Deferral letter requires review by screening manager.
Does not meet clearance criteria due to one or more of the following: • Current use of adjuvant therapy.	MED ADVISOR	_____ Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

183.0 Ovarian Cancer

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- None

COMMENTS:

Prognostic Factors: At the conclusion of a comprehensive laparotomy, the clinical findings and the histology are used to select postoperative therapy. In addition, new prognostic factors are being evaluated that may also be used to identify groups of patients in whom more specific biologic treatments or more aggressive therapy is indicated. Clinicopathologic findings determined to be clinically useful include the following:

- FIGO stage
- Histologic subtype
- Histologic grade
- Factors associated with tumor dissemination
 - Malignant ascites
 - Malignant peritoneal washings
 - Tumor excrescences on ovarian surface

OVARIAN CANCER

Ruptured capsule

Dense ovarian adhesions

Volume of residual disease following cytoreductive surgery

The tumor stage remains the most important prognostic variable. Few trials provide an accurate assessment regarding the long-term survival of patients with early-stage ovarian cancer because earlier studies often included inadequately staged patients. Stage I patients with well- or moderately well-differentiated tumors have a greater than 90% 5-year survival rate. Patients with stage I disease with poor prognostic features are often included in treatment protocols for patients with stage II disease. This group of patients has been termed early-stage disease with unfavorable characteristics. However, there remains limited information regarding the actual survival impact of some of the factors used to characterize patients as having an unfavorable prognosis. Rupture of the capsule increases the stage to IC. However, in a Swedish series, no adverse effect on survival could be established for early-stage patients in whom the capsule was ruptured during surgery. Furthermore, in contrast to the established adverse effect of malignant ascites, there is limited information regarding the prognostic significance of positive peritoneal cytology. Tumor adherence in the presence of dense adhesions has also been considered an adverse prognostic factor and such patients should be considered as having stage II disease even in the absence of pathologic confirmation. Tumor size, bilaterality, and cytologically negative ascites have no prognostic significance. The most reliable long-term survival data on accurately staged early-stage ovarian cancer patients are derived from studies of the Gynecologic Oncology Group (GOG). In these studies, unfavorable prognosis early-stage ovarian cancer patients have a 5-year survival rate of approximately 80%.

Patients with stage III disease have a 5-year survival rate of approximately 15% to 20%, which is dependent in large part on the volume of disease present in the upper abdomen. Patients with stage IV disease have less than a 5% 5-year survival rate.

Volume of residual following cytoreductive surgery for patients with advanced ovarian cancer has a significant impact on survival. Following the administration of postoperative cisplatin-based combination chemotherapy, 5-year survival rates for patients with optimal stage III disease (defined as no residual nodule greater than 1 cm in diameter) are approximately 35%.

The true prognostic impact of histologic subtype and grade in patients with epithelial ovarian cancer remains to be determined. In patients with early-stage ovarian cancer, grade is an accepted determinant of risk and is used to assign postoperative therapy as previously discussed. Studies have also identified an adverse prognostic effect of clear cell histology in early-stage ovarian cancer. In advanced-stage patients, mucinous histology and clear cell histology have also been shown to have an adverse prognostic significance. In a GOG analysis, there were no negative second-look laparotomies in patients with mucinous or clear cell tumors. Some but not all studies have also demonstrated that histologic grade has an impact on survival in patients with advanced-stage disease.

Serum CA125 levels frequently reflect the volume of disease and as such, in multivariate analysis, preoperative levels have failed to exert an independent prognostic effect on survival. However, postoperative CA125 levels were shown to be an independent prognostic variable. Most studies have also demonstrated that serum CA125 levels after three cycles of chemotherapy are accurate predictors for the probability of a patient achieving a complete remission. However, the CA125 level after three cycles of chemotherapy cannot be used as a guide for treatment decisions because of the lack of predictive power.

The prognostic significance of age on survival of patients with ovarian cancer has been recognized. Median survival is at least 2 years longer in women under the age of 65 compared with those over 65.

The prognostic significance of DNA ploidy and S-phase fraction has been examined in ovarian cancer. Investigators in Europe have now included aneuploidy in their selection of high-risk, early-stage ovarian cancer patients for adjuvant therapy. Controversy remains, however, as to the nature of the relationship between histologic grade and degree of aneuploidy. In the GOG, aneuploidy has not been included as a criteria for risk in early-stage disease. [MD Consult, 1998]

Literature review available.

Includes Functional Cysts and Complex Cysts.

For Polycystic Ovarian Syndrome, see Polycystic Ovarian Syndrome Guideline.
For Laparoscopy and Laparotomy, see "Gynecology Surgical Procedures" Guideline.

INFORMATION REQUIRED *Any history*

All Applicants:

- Report of Medical Examination to include the following:
 - Type of cyst.
 - Size, location, and number of cysts.
 - Treatment, e.g., spontaneous resolution, aspiration, hormone therapy, excision.
 - Current status, to include an assessment of cyst(s) progression and/or regression.
 - Recommendations for follow-up over the next 3 years.
- Copy of ultrasound report with interpretation.

If Applicable:

- Copy of laparoscopy report with interpretation.
- Copy of pathology report with interpretation.
- Discharge summary of *all* related hospitalizations and surgeries.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
<ol style="list-style-type: none"> 1. Functional cyst(s), i.e., simple cysts (follicular), or ovulatory cysts (corpus luteum cyst), noted on examination, current or history of. 2. No, or resolved, symptoms. 3. If current cyst, no evidence of cyst progression or enlargement; determined by examining health care provider. 4. No history of complex cyst(s). 		
Meets clearance criteria 1 - 4, AND <ul style="list-style-type: none"> • Cyst resolved; spontaneously, via aspiration, hormone therapy, or excision. 	RN	CLEAR
Meets clearance criteria 1 - 4, AND <ul style="list-style-type: none"> • Current functional cyst, AND • Cyst size < 2 cm. 	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Cyst size > 2 cm. • Current symptoms. • Evidence of cyst progression or enlargement; determined by examining health care provider. • History of complex cyst(s). 	MED ADVISOR	<hr/> Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

620.2 Ovarian Cyst
Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS

Reviewers to Consider:

- None

COMMENTS

Functional Cysts: Most common ovarian cysts. Usually causes no symptoms and resolve in 1-3 menstrual cycles. Birth control pills suppress ovulation and may decrease size and frequency of functional cysts. The type of cyst can easily be distinguished on ultrasound. A small number of women have recurrent cysts that also respond well to birth control pills.

Complex Cysts: Include dermoid cysts, cystadenoma, and endometrioma. These cysts frequently require surgery. Small cysts occasionally require laparoscopy removal. Larger cysts require laparotomy and partial or total oophorectomy. Cysts are considered more serious post menopausal and should be immediately evaluated to rule-out cancer.

Surgery: Surgery is indicated to rule-out ovarian cancer or to relieve pain if:

- The cyst is large (>5 cm) or does not resolve after three menstrual cycles.
- Complex cysts (dermoid cysts, cystadenoma, endometrioma).
- Painful or bleeding cysts.
- Torsion of the cyst has occurred.

Literature review available.

Also called Polycystic Ovarian Disease (PCOD).

INFORMATION REQUIRED *Any history***All Applicants:**

- Specialist Evaluation (Gynecologist) within the past 1 year to include the following:
 - Date of diagnosis
 - Signs and symptoms
 - Treatment
 - Current status
 - Limitations or restrictions of ADLs
 - Recommendations for follow-up over the next 3 years.

If Applicable:

- Copy of most recent ultrasound report with interpretation.
- Copy of laparoscopy report with interpretation.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
<ol style="list-style-type: none"> No, resolved, or mild, symptoms. Sign and symptoms (see comments) <i>do not</i> interfere with activities of daily living. No, or resolved, irregular or dysfunctional uterine bleeding. 		
Meets clearance criteria 1 - 3, AND <ul style="list-style-type: none"> If symptom management requires treatment, symptoms well-controlled with <u>oral contraceptives</u> only. 	RN	CLEAR
Meets clearance criteria 1 - 3, AND <ul style="list-style-type: none"> If on <u>hormone therapy</u>, e.g., aldactone, symptoms well controlled for <i>at least</i> the past 3 months. 	RN	CLEAR
Meets clearance criteria 1 - 3, AND: <ul style="list-style-type: none"> If on an <u>anti-diabetic agent</u>, e.g., glucophage or Thiazolidinedione (actos), symptoms well controlled for <i>at least</i> the past 3 months. 	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> If on hormone therapy, e.g., aldactone,, symptoms <i>not</i> well controlled for <i>at least</i> the past 3 months. If on anti-diabetic agent, e.g., glucophage or Thiazolidinedione (actos), symptoms <i>not</i> well controlled for <i>at least</i> the past 3 months. 	RN	DEFER
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> Current, moderate to severe, symptoms. Signs and symptoms (see comments) interfere with activities of daily living. Current irregular or dysfunctional uterine bleeding. 	MED ADVISOR	_____ Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

256.4 Polycystic Ovarian Syndrome
 Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS**Reviewers to Consider:**

- None

COMMENTS

Background: Polycystic ovarian disease (PCOD) is characterized by a state of chronic oligo-ovulation and/or anovulation culminating in oligomenorrhea and/or amenorrhea. The ovaries are usually enlarged and lined with follicles in all stages of development but most are atretic. No ideal treatment exists although hormones and birth control pills are often used to regulate the menstrual cycle. [Griffith's 1998]

Signs and Symptoms: Amenorrhea, oligomenorrhea, obesity, hirsutism, acne, dysfunctional uterine bleeding, infertility, hypertension, virilism, enlarged ovaries, enlarged clitoris, deep voice.

Literature review available.

Encompasses a Spectrum of Inflammatory Disorders of the Upper Genital Tract Including Any Combination of:

- 1) Endometritis; 2) Salpingitis; 3) Tubo-Ovarian Abscess; and 4) Pelvic Peritonitis.

INFORMATION REQUIRED *Any history.*

All Applicants:

- Specialist Evaluation (Gynecologist) within the past 1 year to include the following:
 - Number of episodes.
 - Dates of episodes.
 - Treatment
 - Treatment complications, if any.
 - Current status
 - Recommendations for follow-up over the next 3 years.

If Applicable:

- Discharge summary for *all* related hospitalizations.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
<ol style="list-style-type: none"> 1. One or two episodes of PID. 2. No, or resolved, symptoms. 3. Treatment complete and infection resolved for <i>at least</i> the past 3 months. 4. No post treatment complications to include chronic pelvic pain. 5. No history of tubo-ovarian abscess. 		
Meets clearance criteria 1-5, AND <ul style="list-style-type: none"> • If hysterectomy for PID, post surgery <i>greater than</i> 3 months. 	RN	CLEAR
Does not meets clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Current symptoms. • Treatment <i>not</i> complete or infection <i>not</i> resolved for <i>at least</i> the past 3 months. • If hysterectomy for PID, post surgery <i>less than</i> 3 months. 	RN	DEFER Deferral letter requires review by the screening manager.
Does not meets clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • More than two episodes of PID, i.e, recurrent infection. • Post treatment complications to include chronic pelvic pain. • History of tubo-ovarian abscess. 	MED ADVISOR	Risk varies - assess based on detailed history. Consider GYN Accommodation.

DIAGNOSTIC CODES

- 614.0 Pelvic Inflammatory Disease, Acute
- 614.1 Pelvic Inflammatory Disease, Chronic
- 614.6 Pelvic Inflammatory Disease, With Adhesions
- 614.2 Salpingitis
- 615.9 Endometritis
- 614.2 Tubo-Ovarian Abscess

Cross Reference ICD.9.CM

PELVIC INFLAMMATORY DISEASE (PID)

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- None

COMMENTS:

Background: PID comprises a spectrum of inflammatory disorders of the upper genital tract among women and may include any combination of: 1) Endometritis; 2) Salpingitis; 3) Tubo-ovarian abscess; and 4) Pelvic peritonitis. PID may recur in 23-42% of women with a previous diagnosis. Twenty percent will have a recurrence within 1 year. Whether or not recurrence is caused by a new infection is not always clear. Frequently, pelvic pain persists after resolution of the infection. In a study of more than 100 women admitted to the hospital for treatment of PID, 24% reported persistent pelvic pain 6 months after discharge. Once damaged, fallopian tubes are believed to be more susceptible to bacterial colonization as a result of depressed host defenses, persistent inflammation, or other mechanisms (Kottman, 1995). Chronic PID needs further treatment to prevent infertility and more adhesions. Patients with a history of PID generally require no extra follow-up but are at risk for ectopic pregnancy and complications from the adhesions.

Literature review available.

INFORMATION REQUIRED *Any history.***All Applicants:**

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

If Applicable:

- Copy of endometrial biopsy with interpretation.
- Discharge summary for *all* related hospitalizations.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Applicant presents with one or more of the following symptoms: <ul style="list-style-type: none"> - Abnormal or irregular uterine bleeding. - Bleeding that is excessive in duration, frequency, or amount. - Bleeding between periods, i.e., spotting, unrelated to ovulation. 		
Meets clearance criteria, AND <ul style="list-style-type: none"> • Evaluation and diagnostic work-up complete. • <u>Etiology determined</u>: benign, or unknown, cause with <i>no</i> underlying pathology. • No, resolved, or well tolerated, symptoms. 	RN	CLEAR PCMO FOLLOW-UP As recommended by provider.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Evaluation and diagnostic work-up <i>not</i> complete. • <u>Etiology not determined</u>. • Symptoms <i>not</i> resolved or well tolerated. 	RN	DEFER Requires evaluation and specific diagnosis for clearance. Correlate with diagnostic guideline.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Etiology determined: Known cause or underlying pathology. 	RN	_____ Correlate with specific diagnostic guideline.

DIAGNOSTIC CODES

626.8 Dysfunctional Uterine Bleeding

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:**Reviewers to Consider:**

- None

DYSFUNCTIONAL UTERINE BLEEDING

COMMENTS:

Background: Dysfunctional Uterine Bleeding (DUB) as defined by the American College of Obstetricians and Gynecologists is 'bleeding from the uterine endometrium unrelated to anatomic lesions of the uterus'. Disruption of normal ovarian function, or anovulation, was considered part the definition, and midcycle staining associated with ovulation, menstrual irregularity associated with corpus luteum defect, and uterine bleeding secondary to 'blood dyscrasias, submucous myomas, endometrial polyps, uterine carcinoma, and accidents of pregnancy' was not to be considered dysfunction. By this definition, the diagnosis of DUB is a diagnosis of exclusion. Implicit is that its anovulatory nature has already been demonstrated." Any bleeding that is excessive in duration, frequency, or amount for a particular patient should be considered abnormal and investigated accordingly. [Novaks Textbook of Gynecology, 11th ed.]

Literature review available.

INFORMATION REQUIRED *Any history.***All Applicants:**

- Specialist Evaluation (General Surgeon or Oncologist) within the past 1 year to include the following:
 - Documentation of recurrences within the past 5 years.
 - Recommendations for follow-up over the next 3 years.

If Applicable:

- Discharge summary for *all* related hospitalizations.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Treatment complete. 2. No history of recurrences for <i>at least</i> the past 5 years.		
Meets clearance criteria 1-2, AND • No use of adjuvant therapy.	MED ADVISOR	CLEAR
Does not meet clearance criteria due to one or more of the following: • Treatment not complete. • History of recurrences within the past 5 years.	MED ADVISOR	DEFER Deferral letter requires review by screening manager.
Does not meet clearance criteria due to one or more of the following: • Current use of adjuvant therapy.	MED ADVISOR	_____ Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

182.0 Endometrial Cander

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:**Reviewers to Consider:**

- None

COMMENTS:

Background: Tumors of the uterine fundus comprise the most common group of gynecologic malignancies. Annual incidence figures for the United States have remained stable at 34,000 to 36,000 cases over the past decade. Deaths from disease occur in 4,000 to 5,000 women per year. Women with high risk or advanced disease have a poor prognosis and account for the most uterine cancer deaths.

Prognosis: Histopathologic risk factors have been extensively evaluated during the past two decades. Major prognostic factors associated with the uterine component of the tumor are grade or cell type, depth of myometrial invasion, and tumor extension to the cervix. Less important are extent of uterine cavity involvement, lymph-vascular space invasion, and tumor vascularity. Obviously, women whose tumors have spread beyond the uterus have a poorer prognosis. The major extrauterine risk factors are adnexal metastases, pelvic or paraaortic lymph node spread, positive peritoneal cytology, peritoneal implant metastases, and distant organ metastases.

ENDOMETRIAL CANCER

A detailed analysis of nearly 1000 patients has been presented by the Gynecologic Oncology Group. The risk for developing recurrent disease was greatest in women whose tumors had metastasized to pelvic or paraaortic lymph nodes, demonstrated gross intraperitoneal spread, or contained unequivocal lymph-vascular space invasion. Not surprisingly, an exceptionally high incidence of recurrence was noted in cases with two or more risk factors. Based on the findings of this and other surgical staging trials, the International Federation of Gynecology and Obstetrics (FIGO) adopted a surgical staging system for uterine fundal cancers in 1988. [DeVita: *Cancer: Principles and Practice of Oncology*, 5th ed., Copyright © 1997 Lippincott-Raven Publishers]

Surgical Staging of Uterine Fundal Tumors:

Stage	Description
Stage I	The tumor is confined to the uterine fundus.
Stage IA	Tumor is limited to the endometrium.
Stage IB	Tumor invades less than one half of the myometrial thickness.
Stage IC	Tumor invades more than one half of the myometrial thickness.
Stage II	The tumor extends to the cervix.
Stage IIA	Cervical extension is limited to the endocervical glands.
Stage IIB	Tumor invades the cervical stroma.
Stage III	There is regional tumor spread.
Stage IIIA	Tumor invades the uterine serosa, adnexa, or positive peritoneal cytology.
Stage IIIB	Vaginal metastases are present.
Stage IIIC	Tumor has spread to pelvic or paraaortic lymph nodes.
Stage IV	There is bulky pelvic disease or distant spread.
Stage IVA	Tumor invades the mucosa of the bladder or rectosigmoid.
Stage IVB	Distant metastases are present [FIGO 1988].

Recurrence in Patients With Positive Risk Factors: (Morrow et al. Relationship between surgical-pathological risk factors and outcome in clinical stage I an II carcinoma of the endometrium: a Gynecologic Oncology Group study. *Gynecol Oncol* 1991;40:60)

Follow-Up:

- Pap smear every 3 months for two years, then every 6 months for 3 years
- Chest x-ray once a year [Griffith's, 1999]

Literature review available.

INFORMATION REQUIRED *If history within the past 5 years.***All Applicants:**

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

If Applicable:

- Copy of ultrasound report with interpretation.
- Copy of biopsy report with interpretation.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. No, or resolved, hyperplasia. 2. No, or resolved, symptoms, i.e, irregular or dysfunctional uterine bleeding. 3. If endometrial biopsy, no adenomatous cells. 4. No history of endometrial or uterine cancer.		
Meets clearance criteria 1-4, AND <ul style="list-style-type: none"> • If treated with progestational agents, post treatment <i>greater than 3 months</i>. • If treated with D&C, post procedure <i>greater than 3 months</i>. • If treated with hysterectomy, post surgery <i>greater than 3 months</i>. 	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Hyperplasia <i>not</i> resolved. • Current progesterone use, or post progesterone treatment <i>less than 3 months</i>. • If treated with D&C, post procedure <i>less than 3 months</i>. • If treated with hysterectomy, post surgery <i>less than 3 months</i>. 	RN	DEFER
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Symptoms, i.e., irregular or dysfunctional uterine bleeding. 	MED ADVISOR	See "Dysfunctional Uterine Bleeding" Guideline.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Adenomatous cells on endometrial biopsy. 	MED ADVISOR	Risk varies - assess based on detailed history.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • History of uterine or endometrial cancer. 	RN	See "Endometrial Cancer" or "Uterine Cancer" Guideline.

DIAGNOSTIC CODES

621.3 Endometrial Hyperplasia

Cross Reference ICD.9.CM

ENDOMETRIAL HYPERPLASIA

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- None

COMMENTS:

Background: Endometrial hyperplasia is a pathologic condition that is usually associated with abnormal uterine bleeding. Hyperplasia of the endometrium results from estrogenic stimulation of the endometrium without the usual cyclic modification of progesterone and, therefore, is almost invariably found in anovulatory women. Women with endometrial hyperplasia have 3 treatment options: 1) hormone therapy with progestational agents; 2) dilation and curettage, or 3) hysterectomy. Patients treated with hormone therapy may be treated for up to one year and require frequent follow-up during treatment.

Literature review available.

Includes Uterine Adenomyosis.

INFORMATION REQUIRED *Any history.***All Applicants:**

- Specialist Evaluation (Gynecologist) within the past 1 year to include the following:
 - Symptoms to include severity
 - Treatment
 - Current status
 - Recommendations for follow-up over the next 3 years.
- If laparoscopy, copy of most recent laparoscopy report with interpretation.

If Applicable:

- Discharge summary for *all* related hospitalizations.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. No, resolved, or mild, symptoms. 2. If symptoms, well controlled with over the counter medication, NSAIDs, or oral contraceptive pills. 3. If laparoscopy diagnosis: <i>mild</i> disease. 4. No, or resolved, irregular or dysfunctional uterine bleeding. 5. If laparotomy, post surgery <i>greater than 3 months</i> . 6. No history of adenomyosis.		
Meets clearance criteria 1-6, AND • Treatment: None.	RN	CLEAR
Meets clearance criteria 1-6, AND • Treatment: Androgenic medication, post treatment <i>greater than 3 months</i> .	RN	CLEAR WITH RESTRICTION GYN Accommodation PCMO FOLLOW-UP Periodic evaluation by a board certified gynecologist or an experienced provider.
Does not meet clearance criteria due to one or more of the following: • Treatment: Androgenic medication; current use, or post treatment <i>less than 3 months</i> . • If laparotomy, post surgery <i>less than 3 months</i> .	RN	DEFER Deferral letter requires review by screening manager.
Does not meet clearance criteria due to one or more of the following: • If laparoscopy, diagnosis of <i>moderate to severe</i> disease. • Current, moderate to severe, symptoms. • If symptoms, controlled with narcotics or pain medication other than over the counter medication, NSAIDs, or oral contraceptive pills. • Current irregular or dysfunctional uterine bleeding. • History of adenomyosis.	MED ADVISOR	Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

617.0 Endometriosis
 617.0 Adenomyosis

Cross Reference ICD.9.CM

ENDOMETRIOSIS

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- None

COMMENTS:

Background: Endometriosis is endometrial growth at distant sites outside of the uterus such as peritoneal surfaces of the bladder, cul-de-sac, pelvic side walls, broad ligaments, uterosacral ligaments, fallopian tubes, lymph nodes, ovaries, and bowel. More distant sites include the vagina, cervix, abdominal wall, arm, leg, pleura, lung, diaphragm, kidneys, spleen, and gallbladder.

Symptoms: Dyspareunia, dysmenorrhea, dyschezia, chronic pelvic pain, premenstrual spotting, spontaneous abortion, infertility, and lutenized unruptured follicle syndrome.

Treatment: May require 6 months of treatment with androgenic medications, with the usual side effect of hot flashes. Patients often need to wait 3 months after treatment to see if symptoms recur before being released by the GYN. Eighty percent of women using hormonal medications have side effects, i.e., weight gain, fluid retention, fatigue, hot flashes, and amenorrhea. Surgical vaporization of implants is the treatment of choice for severe pelvic pain or to preserve fertility.

Adenomyosis: Adenomyosis is characterized by the ectopic presence of endometrial tissue with the myometrium. It is sometimes referred to as endometriosis interna. The uterus is usually diffusely enlarged, but only rarely to a size greater than 12 weeks gestational size. When it becomes symptomatic, it is characterized by either menorrhagia or dysmenorrhea in the late reproductive years. Treatment is based on symptoms and age and include antiinflammatory drugs, LHRH agonists, and hysterectomy.

Literature review available.

INFORMATION REQUIRED *Any history.***All Applicants:**

- Specialist Evaluation (General Surgeon or Oncologist) within the past 1 year to include the following:
 - Documentation of recurrences within the past 5 years.
 - Recommendations for follow-up over the next 3 years.

If Applicable:

- Discharge summary for *all* related hospitalizations.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Treatment complete. 2. No history of recurrences for <i>at least</i> the past 5 years.		
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • No use of adjuvant therapy. 	MED ADVISOR	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Treatment not complete. • History of recurrences <i>within</i> the past 5 years. 	MED ADVISOR	DEFER Deferral letter requires review by screening manager.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Current use of adjuvant therapy. 	MED ADVISOR	Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

182.0 Uterine Cancer

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:**Reviewers to Consider:**

- None

COMMENTS:

Background: Sarcomas may arise from the endometrium, myometrium, cervix, uterine blood vessels, or a leiomyoma. These diseases are most frequently seen in the fifth decade. The incidence of corpus sarcoma is much higher than that of sarcoma of the cervix. Because all elements of the uterus are mesodermal in origin and ectodermal rests may be present, mixed tumors may occur. A wide spectrum of histopathologic types can be found. Rapid uterine enlargement is a prominent sign of uterine sarcoma, and abnormal bleeding may or may not be present. Pain, anemia, and weight loss are late symptoms. Pulmonary metastases frequently occur early. Surgical excision of the uterus, tubes, and ovaries is the recommended treatment for sarcoma of the uterus.

Sarcomas Types:

- Mixed mullerian sarcoma - heterologous element not native to the mullerian systems, such as cartilage or bone; homologous elements native to the mullerian system.

UTERINE CANCER

- Endometrial stromal sarcoma develops from the stromal component of the endometrium.
- Leiomyosarcoma develops in the myometrium or in a myoma (fibroid).

Surgical Staging of Uterine Fundal Tumors:

Stage	Description
Stage I	The tumor is confined to the uterine fundus.
Stage IA	Tumor is limited to the endometrium.
Stage IB	Tumor invades less than one half of the myometrial thickness.
Stage IC	Tumor invades more than one half of the myometrial thickness.
Stage II	The tumor extends to the cervix.
Stage IIA	Cervical extension is limited to the endocervical glands.
Stage IIB	Tumor invades the cervical stroma.
Stage III	There is regional tumor spread.
Stage IIIA	Tumor invades the uterine serosa, adnexa, or positive peritoneal cytology.
Stage IIIB	Vaginal metastases are present.
Stage IIIC	Tumor has spread to pelvic or paraaortic lymph nodes.
Stage IV	There is bulky pelvic disease or distant spread.
Stage IVA	Tumor invades the mucosa of the bladder or rectosigmoid.
Stage IVB	Distant metastases are present [FIGO 1988].

Prognosis for Uterine Sarcomas: Stage is the most significant predictor of outcome for women with uterine sarcomas. Patients whose tumors are confined to the uterus have a survival rate of 60% to 70% following surgical resection. Major sites of failure include the pelvis, upper abdomen, and lung. Few well-conducted prospective adjuvant therapy trials have been accomplished, so a precise role for either adjuvant irradiation or chemotherapy remains undefined.

As has been noted for endometrial carcinoma, adjuvant pelvic irradiation may reduce the rate of pelvic failure without improving survival if more patients succumb to distant failure. Pelvic irradiation and local tumor control may be an important issue in tumors with extension to the cervix. However, so few patients are placed in this category that meaningful treatment data are not available. Very few patients with tumor spread outside of the uterus can be curatively treated. Some women with small-volume regional disease have obtained long-term survival following external-beam irradiation. However, most patients with advanced or recurrent disease ultimately experience disease progression and die. [DeVita: *Cancer: Principles and Practice of Oncology*, 5th ed., Copyright © 1997 Lippincott-Raven Publishers]

Expected Course and Prognosis [Griffith's, 1998]:

Five year survival based on stage and tumor grade:

Grade	5 Year Survival (%)
IAG1	98
IBG2	85
ICG3	60
IIA/B	60
III	40
IV	15

Follow-Up:

- Pap smear every 3 months for two years, then every 6 months for 3 years
- Chest x-ray once a year [Griffith's, 1999]

Literature review available.

INFORMATION REQUIRED *Any history*

All Applicants:

- Report of Medical Examination within the past 1 year to include the following:
 - Symptoms
 - Clinical evidence of GI, GU, or GYN obstruction.
 - Current status, to include comment about *stability* of fibroids over the past 6 months.
 - Treatment history, to include surgery.
 - Assessment of need for medical intervention over the next 3 years.
 - Recommendations for follow-up over the next 3 years.
- Copy of most recent ultrasound report with interpretation to include size, location, and number of fibroids.

If Applicable:

- Discharge summary for *all* related hospitalizations.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Size <i>stable</i> for <i>at least</i> the past 6 months; determined by examining health care provider; may be determined by pelvic exam or ultrasound. 2. No irregular or dysfunctional uterine bleeding. 3. No, or mild, symptoms. 4. If mild symptoms, well controlled non-narcotic medication, e.g., with NSAIDs or birth control pills. 5. No clinical evidence of GI, GU, or GYN obstruction.		
Meets clearance criteria 1 - 5, AND <ul style="list-style-type: none"> • If leiomyectomy or hysterectomy, post surgery <i>greater than</i> 3 months. 	RN	CLEAR
	PCMO FOLLOW-UP Annual pelvic exam.	
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Size <i>not stable</i> for <i>at least</i> the past 6 months. • If leiomyomectomy or hysterectomy, post surgery <i>less than</i> 3 months. 	RN	DEFER
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Irregular or dysfunctional uterine bleeding. • Moderate to severe symptoms. • Symptoms controlled with narcotics or pain medication other than NSAIDs or birth control pills. • Clinical evidence of GI, GU, or GYN obstruction. 	MED ADVISOR	_____ Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

218.0 Uterine Fibroids (Leiomyomas)
 Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS

Reviewers to Consider:

- None

COMMENTS

Background: Uterine leiomyomas are well circumscribed, pseudo-encapsulated benign tumors of the uterus. The majority are asymptomatic and are only suspected from pelvic exam. Approximately 20-40% of all women have uterine fibroids. Fibroids frequently regress after menopause. Approximately 10% recur following myomectomy. [Griffith's, 1998]

Symptoms: The majority are asymptomatic and are only suspected from pelvic examination. The most common symptom is abnormal uterine bleeding. Hypermenorrhea most common. Secondary anemia with associated symptomatology may result. Pressure on the bladder may result in suprapubic discomfort, urinary frequency. Pressure on the rectosigmoid may result in low back pain. Edema and varicosities of the lower extremities may result from large tumors. Pain may result from twisted, pedunculated myomas or degenerating, hemorrhagic or infected myomas. Rapid growth particularly in perimenopausal or postmenopausal may indicate sarcoma (Griffiths, 2003).

Treatment: Treatment must be individualized. Patients with minimal symptoms may be managed with iron preparations and analgesics.

Conservative management: Asymptomatic myomas of less than 14 week's size gestation should be closely observed with pelvic examinations and ultrasonography at 3-6 month intervals, as long as size is stable. Usually regress after menopause.

Nonsurgical therapies:

- Luteinizing hormone releasing hormone (LHRH) agonists induce an abrupt artificial menopause with cessation of bleeding and shrinkage of myomas. Not recommended for more than 6 months. May be useful in perimenopausal patients or as an adjunct to surgery.
- Myolysis by needle cautery or cryotherapy. Long term outcome is unknown.
- Uterine artery embolization average 50% shrinkage; painful.

Surgical Measures:

- Surgical management is indicated in the following situations:
 - Excessive uterine size (> 14 weeks gestation) or excessive rate of growth.
 - Submucous location if associated with hypermenorrhea.
 - Pedunculated myomas may undergo torsion, pain, necrosis and hemorrhage.
 - Symptomatic from pressure on bladder or rectum.
 - If differentiation from ovarian mass is not possible.
 - If there is associated pelvic disease, i.e., endometriosis, pelvic inflammatory disease, etc.

[Griffith's, 2003]

Follow-Up:

- Newly diagnosed uterine myoma, if symptomatic or excessive size, 2-3 months with pelvic exam and ultrasound.
- Consider CA-125 antigen.
- Monitor hemoglobin and hematocrit, if bleeding excessive.
- If uterine size and symptoms are stable, monitor every 6 months. [Griffith's, 2003]

Literature review available.

Includes Infection, Abscesses, and Cysts..

INFORMATION REQUIRED *If history within the past 5 years.***All Applicants:**

- Report of Medical Examination to include the following:
 - Number of episodes
 - Symptoms
 - Treatment
 - Recommendations for follow-up over the next 3 years.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Infection, abscess, or cyst resolved. 2. No, or resolved, symptoms. 3. If treated, treatment complete. 4. If history of incision and drainage or marsupialization, post procedure <i>greater than 6 weeks</i> .		
Meets clearance criteria 1-4, AND <ul style="list-style-type: none"> • Single episode. 	RN	CLEAR
Meets clearance criteria 1-4, AND <ul style="list-style-type: none"> • Multiple episodes, i.e., recurrent. • Definitely treated with marsupialization. 	RN	CLEAR
Meets clearance criteria 1-4, AND <ul style="list-style-type: none"> • Multiple episodes. • No history of marsupialization or failed marsupialization. 	RN	CLEAR WITH RESTRICTION GYN Accommodation.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Infection, abscess, or cyst <i>not</i> resolved. • If treated, treatment <i>not</i> complete. • If history of incision and drainage or marsupialization, post procedure <i>less than 6 weeks</i>. 	RN	DEFER Deferral letter requires review by screening manager.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Current symptoms. 	MED ADVISOR	Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

616.3 Bartholin Gland Abscess
 616.2 Bartholin Gland Cyst

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:**Reviewers to Consider:**

- None

BARTHOLIN GLAND INFECTIONS

COMMENTS:

Background: Many women have a single infection that is easily treated and requires no special follow-up. Recurrent abscesses, however, may require treatment by marsupialization.

Marsupialization: Process of raising the borders of an evacuated tumor or abscess sac to the edges of the wound and stitching them there to form a pouch. The interior sac suppurates and gradually closes by granulation.

Literature review available.

INFORMATION REQUIRED *Any history.***All Applicants:**

- Specialist Evaluation (General Surgeon or Oncologist) within the past 1 year to include the following:
 - Documentation of recurrences within the past 5 years.
 - Recommendations for follow-up over the next 3 years.

If Applicable:

- Discharge summary for *all* related hospitalizations.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Treatment complete. 2. No history of recurrences for <i>at least</i> the past 5 years.		
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • No use of adjuvant therapy. 	MED ADVISOR	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Treatment not complete. • History of recurrences <i>within</i> the past 5 years. 	MED ADVISOR	DEFER Deferral letter requires review by screening manager.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Current use of adjuvant therapy. 	MED ADVISOR	Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

184.0 Vaginal Cancer

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:**Reviewers to Consider:**

- None

COMMENTS:

Background: Vaginal intraepithelial neoplasia is an uncommon pathologic entity. However, in recent decades it has been diagnosed with increased frequency, probably because of more extensive cytologic screening even in women who have undergone hysterectomy. Vaginal intraepithelial neoplasia is considered a premalignant lesion analogous to CIN. However, because of its lower incidence, much less information regarding the magnitude of its premalignant potential, transition times from premalignant to malignant, and factors influencing the transition is available. Once diagnosed, treatment is indicated to prevent progression. Several treatment options exist. The rationale for all modalities is to excise or destroy the dysplastic cells and cause minimal damage to normal epithelium and submucosa.

Primary malignant tumors are rare in the vagina. Only 1% to 2% of genital tract cancers originate in the vaginal tissues; the majority are squamous cell carcinomas. Other primary cancers include melanoma, sarcoma, adenocarcinoma, and endodermal sinus tumors. Most malignant vaginal lesions are secondary. They occur as extensions of cervical or vulvar carcinoma, or as metastatic cancers usually arising in the bladder, rectum, uterus, or ovary.

VAGINA AND VULVA CANCER

International Federation of Gynecology and Obstetrics--Classification of Vaginal Cancer:

Stage 0	Carcinoma in situ
Stage I	Carcinoma limited to the vaginal wall
Stage II	Carcinoma involving the subvaginal tissues but not extending to the pelvic wall
Stage III	Carcinoma extending to the pelvic wall
Stage IV	Carcinoma extending beyond the true pelvis or involving the mucosa of the bladder or rectum.
Stage IVA	Involvement of adjacent organs (bladder, rectum)
Stage IVB	Involvement of distant organs

Prognosis: "The prognosis for patients with vaginal squamous cell carcinoma depends primarily on the extent of disease at the time of diagnosis. Stage I disease treated with radiation therapy results in 5-year survival rates of 80% to 90%. Five-year survival rates for higher stages are 45% to 58% for stage II, 25% to 40% for stage III, and up to 10% for stage IV. The overall 5-year survival rate is approximately 45%." [Ryan: *Kistner's Gynecology: Principles & Practice*, 6th ed., Copyright © 1995 Mosby-Year Book, Inc.]

"The rates of local control, distant metastasis, and survival are all correlated strongly with tumor stage. Tumor size also appears to be an important predictor of outcome. Chyle and colleagues reported a higher rate of local and distant failure for tumors larger than 5 cm in diameter; Kirkbride and colleagues reported a significantly better survival rate for patients with tumors smaller than 4 cm in diameter; and Stock and colleagues reported better survival when disease was limited to one third of the vaginal canal. Most investigators have been unable to find a correlation between tumor site and outcome. However, Chyle and colleagues reported higher rates of local recurrence and overall relapse in patients with posterior wall lesions, and Kucera and Vavra reported a better survival rate for patients whose tumors involved the upper one third of the vagina. Tumors that involve the entire vagina tend to have a poorer prognosis, probably reflecting the larger size of these lesions.

Investigators disagree about the influence of histologic grade and type on outcome. Several investigators have reported a correlation between increasing grade of squamous carcinomas and recurrence, whereas others have found no correlation. Chyle and colleagues reported significantly poorer survival and local control rates for patients with adenocarcinoma, but other investigators found no difference in outcome for patients with squamous carcinomas or adenocarcinomas." [DeVita: *Cancer: Principles and Practice of Oncology*, 5th ed., Copyright © 1997 Lippincott-Raven Publishers]

Recurrence: Recurrences often occur locally and are more common in higher stages. Distant metastases occur later and usually involve the lung and bone. Radical surgery may be attempted in selected cases of isolated, local recurrence. Chemotherapy is being evaluated for a possible role in cases with systemic recurrence. [Ryan: *Kistner's Gynecology: Principles & Practice*, 6th ed., Copyright © 1995 Mosby-Year Book, Inc.]

Literature review available.

INFORMATION REQUIRED — *If history within the past 2 years.***All Applicants:**

- Report of Medical Examination to include the following:
 - Number of episodes within the past 2 years.
 - Etiology
 - Symptoms
 - Treatment
 - Recommendations for follow-up over the next 3 years.
- Copy of related diagnostic tests, i.e., tests to rule out sexually transmitted diseases.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. No, or infrequent, recurrences. 2. No associated complications.		
Meets clearance criteria 1-2, AND <ul style="list-style-type: none"> • Resolved for <i>at least</i> the past 3 months. 	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Not resolved for <i>at least</i> the past 3 months. 	RN	DEFER
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Frequent recurrences. • Associated complications. 	MED ADVISOR	_____ Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

616.1 Vaginitis

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:**Reviewers to Consider:**

- None

COMMENTS:

Background: Vaginitis is characterized by vaginal discharge, and/or ulvar itching, and/or vaginal odor. The most common infectious causes of vaginitis are candidiasis, trichomoniasis, and bacterial vaginosis. Relapses and recurrences are fairly common but can be decreased by increasing the colonization of lactobacilli in the vagina. Complications are uncommon but can include adnexal tenderness, PID, intrauterine infections, and pelvic abscesses.

Literature review available.

Includes Oral Contraception, Barrier Contraception, Intrauterine Devices (IUD), and Long-Acting Progestins.

INFORMATION REQUIRED *Any history***All Applicants:**

- Report of Medical Examination to include the following:
 - Current menstrual pattern
 - Complications

Applicants Using Norplant:

- Insertion date
- If Norplant inserted *greater than* 2 years ago and applicant wishes to keep Norplant in place during PC service: Applicant Personal Statement verifying plan to use barrier method of contraception at 5 years post the insertion date.

Applicants Using an IUD:

- Insertion date
- Type of IUD
- Need for removal or replacement over the next 3 years.

Applicants Using Depo Provera:

- Date injections started
- Date of last injection

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Contraceptive use. 2. No significant complications. 3. Stable amenorrhea, i.e., no, or mild, break through bleeding.		
Meets clearance criteria 1 - 3, AND • Contraceptive method - <u>Oral Contraceptives</u> , includes 91-day regimen (Seasonale).	RN	CLEAR
Meets clearance criteria 1 - 3, AND • Contraceptive method - <u>Contraceptive Patch</u>	RN	CLEAR
Meets clearance criteria 1 - 3, AND • Contraceptive method - <u>Barrier, e.g., Diaphragm, Cervical Cap with Spermicide</u> (see Comments).	RN	CLEAR Peace Corps does not provide the cervical cap (see comments). Alternatives will be offered.
Meets clearance criteria 1 - 3, AND • Contraceptive method - <u>NuvaRing®</u>	RN	CLEAR Peace Corps does not provide the NuvaRing® (see comments). Alternatives will be offered.
Meets clearance criteria 1 - 3, AND • Contraceptive method - <u>IUD</u>	RN	CLEAR WITH RESTRICTION PCMO verification of qualified gynecologist in country required.
PCMO FOLLOW-UP Periodic evaluation, to include pelvic exam, by a qualified gynecologist or an experienced provider.		

(continued on next page)

Meets clearance criteria 1 - 3, AND <ul style="list-style-type: none"> Contraceptive method - <u>Depo Provera</u> Status post first Depo Provera injection <i>greater than 3 months</i>. Documentation of most recent Depo Provera injection. 	RN	CLEAR
Meets clearance criteria 1 - 3, AND <ul style="list-style-type: none"> Contraceptive method - <u>Norplant</u> If Norplant inserted <i>greater than 2 years</i> ago and applicant wishes to keep implants in place during PC service; Applicant Personal Statement verifying plan to use barrier method of contraception at 5 years post the insertion date (see Comments). 	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> Status post first Depo Provera injection <i>less than 3 months</i>. Norplant inserted <i>greater than 2 years</i> ago and applicant wishes to keep implants in place during PC service; <u>No</u> Applicant Personal Statement verifying plans to use barrier method of contraception at 5 years post the insertion date (see Comments). 	RN	DEFER
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> Significant complications. Unstable amenorrhea, i.e., moderate or severe break through bleeding. 	MED ADVISOR	<p>_____</p> <p>Risk varies - assess based on detailed history.</p>

DIAGNOSTIC CODES

V25 Contraception
 Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS**Reviewers to Consider:**

- None

COMMENTS**CONTRACEPTIVE METHODS** (Source: Adapted from the Food and Drug Administration 12/03)**Male Condom**

FDA Approval Date: Latex: use started before premarket approval was required. Polyurethane: cleared in 1989; available starting 1995.

Description: A sheath placed over the erect penis blocking the passage of sperm.

Failure Rate: 11 (a,b)

Some Risks: Irritation and allergic reactions (less likely with polyurethane).

Protection from Sexually Transmitted Diseases (STDs): Except for abstinence, latex condoms are the best protection against STDs, including gonorrhea and AIDs.

Convenience: Applied immediately before intercourse; used only once and discarded. Polyurethane condoms are available for those with latex sensitivity

Availability: Nonprescription

***OMS Policy:** OMS recommends the use of condoms that do not contain the spermicide, nonoxynol-9 (N-9). N-9 may increase the transmission of HIV (see OMS policy memo dated 8/22/2000).

Female Condom

FDA Approval Date: 1993

Description: A lubricated polyurethane sheath shaped similarly to the male condom. The closed end has a flexible ring that is inserted into the vagina.

Failure Rate: (number of pregnancies expected per 100 women per year): 21

Some Risks: Irritation and allergic reactions

Protection from Sexually Transmitted Diseases (STDs): May give some STD protection; not as effective as latex condom

Convenience: Applied immediately before intercourse; used only once and discarded.

Availability: Nonprescription

Diaphragm with Spermicide

FDA Approval Date: Use started before premarket approval was required.

Description: A dome-shaped rubber disk with a flexible rim that covers the cervix so that sperm cannot reach the uterus. A spermicide is applied to the diaphragm before insertion.

Failure Rate: (number of pregnancies expected per 100 women per year): 17 (b, d, e)

Some Risks: Irritation and allergic reactions, urinary tract infection. (c) Risk of toxic shock syndrome, a rare but serious infection, when kept in place longer than recommended.

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Inserted before intercourse and left in place at least six hours after; can be left in place for 24 hours, with additional spermicide for repeated intercourse.

Availability: Prescription

Lea's Shield

FDA Approval Date: 2002

Description: A dome-shaped rubber disk with a valve and a loop that is held in place by the vaginal wall. Covers the upper vagina and cervix so that sperm cannot reach the uterus. Spermicide is applied before insertion.

Failure Rate: (number of pregnancies expected per 100 women per year): 15

Some Risks: Skin irritation, spotting, discomfort (female and male partners), urinary tract infection. Theoretical risk of toxic shock syndrome.

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Inserted before intercourse and left in place at least 8 hours after; can be left in place for up to 48 hours, with additional spermicide for repeated intercourse.

Availability: Prescription

Cervical Cap with Spermicide

FDA Approval Date: Prentiff Cap--1988; FemCap--2003

Description: A soft rubber cup with a round rim, which fits snugly around the cervix.

Failure Rate: (number of pregnancies expected per 100 women per year): Prentiff Cap--17; FemCap--23 (b, d, e)

Some Risks: Irritation and allergic reactions, abnormal Pap test. (c) Risk of toxic shock syndrome, a rare but serious infection, when kept in place longer than recommended.

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: May be difficult to insert; can remain in place for 48 hours without reapplying spermicide for repeated intercourse.

Availability: Prescription

***OMS Policy:** OMS does not supply the cervical cap due to difficulties with proper fitting and use.

Sponge with Spermicide

FDA Approval Date: 1983 (Not currently marketed)

Description: A disk-shaped polyurethane device containing the spermicide nonoxynol-9.

Failure Rate: (number of pregnancies expected per 100 women per year): 14-28 (d, e)

Some Risks: Irritation and allergic reactions, difficulty in removal. (c) Risk of toxic shock syndrome, a rare but serious infection, when kept in place longer than recommended.

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Inserted before intercourse and protects for repeated acts of intercourse for 24 hours without additional spermicide; must be left in place for at least six hours after intercourse; must be removed within 30 hours of insertion. Is discarded after use.

Availability: Nonprescription; not currently marketed

***OMS Policy:** OMS does not supply, nor recommend the use of, the cervical sponge.

Spermicide Alone

FDA Approval Date: Use started before premarket approval was required. Since November 2002, only one active ingredient has been allowed.

Description: A foam, cream, jelly, film, suppository, or tablet that contains nonoxynol-9, a sperm-killing chemical

Failure Rate (number of pregnancies expected per 100 women per year): 20-50 (studies have shown varying effectiveness rates)

Some Risks: Irritation and allergic reactions, urinary tract infections (c)

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Instructions vary; check labeling. Inserted between 5 and 90 minutes before intercourse and usually left in place at least six to eight hours after.

Availability: Nonprescription

Oral Contraceptives – Combines Pill

FDA Approval Date: First in 1960; most recent in 2003

Description: A pill that suppresses ovulation by the combined actions of the hormones estrogen and progestin. A chewable form was approved in November 2003.

Failure Rate (number of pregnancies expected per 100 women per year): 1-2

Some Risks: Dizziness; nausea; changes in menstruation, mood, and weight; rarely, cardiovascular disease, including high blood pressure, blood clots, heart attack, and strokes

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Must be taken on daily schedule, regardless of frequency of intercourse. Women using the chewable tablet must drink 8 oz. of liquid immediately after taking.

Availability: Prescription

Oral Contraceptives – Progestin-Only Minipill

FDA Approval Date: 1973

Description: A pill containing only the hormone progestin that reduces and thickens cervical mucus to prevent the sperm from reaching the egg.

Failure Rate (number of pregnancies expected per 100 women per year): 2

Some Risks: Irregular bleeding, weight gain, breast tenderness, less protection against ectopic pregnancy

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Must be taken on daily schedule, regardless of frequency of intercourse.

Availability: Prescription

Oral Contraceptives – 91-Day Regimen (Seasonale)

FDA Approval Date: 2003

Description: A pill containing estrogen and progestin, taken in 3-month cycles of 12 weeks of active pills followed by one week of inactive pills. Menstrual periods occur during the 13th week of the cycle.

Failure Rate (number of pregnancies expected per 100 women per year): 1-2

Some Risks: Similar to oral contraceptives—combined pill

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Must be taken on daily schedule, regardless of frequency of intercourse. Since users will have fewer periods, they should consider the possibility that they might be pregnant if they miss scheduled periods. May have more unplanned bleeding and spotting between periods than with 28-day oral contraceptives.

Availability: Prescription

Patch (Ortho Evra)

FDA Approval Date: 2001

Description: Skin patch worn on the lower abdomen, buttocks, or upper body that releases the hormones progestin and estrogen into the bloodstream.

Failure Rate (number of pregnancies expected per 100 women per year): 1-2 (Appears to be less effective in women weighing more than 198 pounds.)

Some Risks: Similar to oral contraceptives—combined pill

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: New patch is applied once a week for three weeks. Patch is not worn during the fourth week, and woman has a menstrual period.

Availability: Prescription

Vaginal Contraceptive Ring (Nuva Ring®)

FDA Approval Date: 2001

Description: A flexible ring about 2 inches in diameter that is inserted into the vagina and releases the hormones progestin and estrogen.

Failure Rate (number of pregnancies expected per 100 women per year): 1-2

Some Risks: Vaginal discharge, vaginitis, irritation. Similar to oral contraceptives--combined pill

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Inserted by the woman; remains in the vagina for 3 weeks, then is removed for 1 week. If ring is expelled and remains out for more than 3 hours, another birth control method must be used until ring has been used continuously for 7 days.

Availability: Prescription

Storage: NuvaRing has a shelf life of two years at 2-8 °C in the Pharmacy, followed by a shelf life of 4 months stored below 86°F (30°C) at the users' site. NuvaRing® must be stored at room temperature 77°F, (25°C). Temperatures can range from 59-86°F (15-30°C). Direct sunlight and storing above 86°F (30°C) should be avoided.

OMS Policy: OMS does not supply Nuva Ring® due to overseas procurement and storage difficulties.

Post-Coital Contraceptives (Preven and Plan B)

FDA Approval Date: 1998-1999

Description: Pills containing either progestin alone or progestin plus estrogen

Failure Rate (number of pregnancies expected per 100 women per year): Almost 80 percent reduction in risk of pregnancy for a single act of unprotected sex

Some Risks: Nausea, vomiting, abdominal pain, fatigue, headache

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Must be taken within 72 hours of having unprotected intercourse.

Availability: Prescription

Injection (Depo-Provera)

FDA Approval Date: 1992

Description: An injectable progestin that inhibits ovulation, prevents sperm from reaching the egg, and prevents the fertilized egg from implanting in the uterus.

Failure Rate (number of pregnancies expected per 100 women per year): less than 1

Some Risks (serious medical risks from contraceptives are rare): Irregular bleeding, weight gain, breast tenderness, headaches.

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: One injection every three months.

Availability: Prescription

Additional Information: The most common side effects of Depo Provera include the following: menstrual irregularities (various altered bleeding patterns). As women continue using Depo Provera, fewer experience irregular bleeding and more experience amenorrhea. By one year approximately 55% experience complete amenorrhea. Unusually heavy or continuous bleeding, however, is not a usual side effect of Depo Provera. The recommended dose is 150 mg DMPA every 3 months (13 weeks) by deep, intramuscular injection in the gluteal or deltoid muscle. If Depo Provera is administered under the prescribed schedule, i.e., within 5-7 days from the onset of a normal period, no further contraceptive methods are needed. [Upjohn Drug Information Sheet]

Injection (Lunelle) (Not currently marketed in the US)

FDA Approval Date: 2000

Description: An injectable form of progestin and estrogen

Failure Rate (number of pregnancies expected per 100 women per year): less than 1

Some Risks: Changes in menstrual cycle, weight gain. Similar to oral contraceptives--combined.

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Injection given once a month.

Availability: Prescription

Implant (Norplant)

FDA Approval Date: 1990

Description: Six matchstick-sized rubber rods that are surgically implanted under the skin of the upper arm, where they steadily release the contraceptive steroid levonorgestrel.

Failure Rate (number of pregnancies expected per 100 women per year): less than 1

Some Risks: Irregular bleeding, weight gain, breast tenderness, headaches, difficulty in removal

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Implanted and removed by health-care provider in minor outpatient surgical procedure; effective for up to five years.

Availability: Prescription. In July 2002, Norplant's manufacturer announced that it will no longer distribute the Norplant system. Women using the system should contact their doctors about what their contraceptive options will be after the five-year expiration date of their Norplant systems.

Additional Information: Causes complication in approximately 50% of users. These complications, usually amenorrhea or frequent bleeding, require evaluation by a GYN. The findings are almost always negative. A woman on Norplant with amenorrhea needs access to reliable pregnancy testing. A woman on Norplant with frequent bleeding needs a GYN evaluation to rule out abnormalities that are causing the bleeding. If the exams are negative, she requires no special follow-up. Norplant must be surgically removed or replaced every 5 years.

Removal of Norplant After 5 Years: The manufacturers "strongly recommend the removal of Norplant System after five years. As the Norplant System is a progestin-only contraceptive method, it is presumed that if a pregnancy occurs it may be more likely to be an ectopic pregnancy. In addition, since the extended use of the Norplant System has not been studied, we cannot recommend use beyond five years in patients who are using another method of contraception". [Beamish, 1997]

IUD (Intrauterine Device)

FDA Approval Date: 1976 (f)

Description: A T-shaped device inserted into the uterus by a health professional.

Failure Rate (number of pregnancies expected per 100 women per year): less than 1

Some Risks: Cramps, bleeding, pelvic inflammatory disease, infertility, perforation of uterus

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: After insertion by physician, can remain in place for up to one or 10 years, depending on type.

Availability: Prescription.

Additional Information: Associated with an increased risk of pelvic infection, which may be higher in less hygienic situations abroad.]

Periodic Abstinence

FDA Approval Date: N/A

Description: To deliberately refrain from having sexual intercourse during times when pregnancy is more likely.

Failure Rate (number of pregnancies expected per 100 women per year): 20

Some Risks: None

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Requires frequent monitoring of body functions (for example, body temperature for one method).

Availability: Instructions from health-care provider

Trans-Abdominal Sugical Sterilization – Female (Falope Ring, Hulka Clip, Filshie Clip)

FDA Approval Date: Early 1970s (g)

Description: The woman's fallopian tubes are blocked so the egg and sperm can't meet in the fallopian tube, preventing conception. (h)

Failure Rate (number of pregnancies expected per 100 women per year): less than 1

Some Risks: Pain, bleeding, infection, other post-surgical complications, ectopic (tubal) pregnancy.

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: One-time surgical procedure that requires an abdominal incision.

Availability: Surgery

Sterilization Implant – Female (Essure System)

FDA Approval Date: 2002

Description: Small metallic implant that is placed into the fallopian tubes. The device works by causing scar tissue to form, blocking the fallopian tubes and preventing conception. (h)

Failure Rate (number of pregnancies expected per 100 women per year): less than 1

Some Risks: Mild to moderate pain after insertion, ectopic (tubal) pregnancy.

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: Minor surgical procedure, permanent sterilization. Device is inserted through the vagina using a catheter. Women must rely on another birth control method during the first three months, until placement is confirmed with an X-ray procedure.

Availability: Prescription

Surgical Sterilization - Male

FDA Approval Date: N/A

Description: Sealing, tying, or cutting a man's vas deferens so that the sperm can't travel from the testicles to the penis.
(h)

Failure Rate (number of pregnancies expected per 100 women per year): less than 1

Some Risks (serious medical risks from contraceptives are rare): Pain, bleeding, infection, other minor postsurgical complications

Protection from Sexually Transmitted Diseases (STDs): None

Convenience: One-time surgical procedure.

Availability: Surgery Ld m N P L L L Lkm

Ray Projected from a six-month study and adjusted for use of emergency contraception.

(b) If spermicides are used with barrier methods, be sure that the spermicide is compatible with the condom or diaphragm (won't cause it to weaken or break). Oil-based lubricants (such as petroleum jelly or baby oil) will cause latex to weaken and should not be used with these methods.

(c) Spermicides used alone, with barrier devices, or with condoms can cause irritation to the skin lining the vagina, especially when the spermicide is used frequently. There is a possibility that spermicide might increase the risk of acquiring some sexually transmitted diseases because of disruption of the vaginal skin. Spermicide has not been proven to be effective against bacteria and viruses in people. Therefore, there is no reason to use spermicide during pregnancy.

(d) Medications for vaginal yeast infections may decrease effectiveness of spermicides.

(e) Less effective for women who have had a baby because the birth process stretches the vagina and cervix, making it more difficult to achieve a proper fit.

(f) First approval date of currently marketed IUDs. Some IUDs were sold before premarket approval was required. Those products are no longer on the market.

(g) Sold before premarket approval was required (1976).

(h) A contraceptive option for people who don't want children. Considered permanent because reversal is typically unsuccessful.

Literature review available.

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TERMINATION OF PREGNANCY
Includes Therapeutic and Elective Abortion.

GYN 8.2

INFORMATION REQUIRED *If history within the past 1 year.*

All Applicants:

- Report of Medical Examination to include the following:
 - Report of negative pregnancy test if procedure *within* the past 2 months.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. No, or resolved, medical complications. 2. No, or resolved, emotional complications. 3. Post abortion <i>greater than 2 months</i> .		
Meets clearance criteria 1-3, AND <ul style="list-style-type: none"> • Negative pregnancy test if procedure within the past 2 months. 	RN	CLEAR
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Post abortion <i>less than 2 months</i>. 	RN	DEFER Deferral letter requires review by screening manager.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Unresolved medical complications. 	MED ADVISOR	_____ Risk varies - assess based on detailed history.
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Unresolved emotional complications. 	MHC	_____ Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

69.51 Therapeutic Abortion
69.51 Elective Abortion

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:

Reviewers to Consider:

- Medevac Policy: Following a Medevac for termination of pregnancy, Volunteer may be cleared to return to service as early as 3 weeks following the procedure. Clearance is dependent upon a thorough medical evaluation and counseling clearance.

COMMENTS:

Background: Less than 2% of individuals have medical complications following termination of pregnancy.

Literature review available.

INFORMATION REQUIRED *Any history.***Female Applicants Age 50 or Over:**

- Mammography report with interpretation *within* the past 1 year to include the following:
 - Recommendations for follow-up over the next three years.

If Applicable:

- Comparison films

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. Mammography report includes one of the following findings:		
Meets clearance criteria, AND <ul style="list-style-type: none"> • <u>Negative</u> • Radiologist or examining health care provider recommend routine follow-up, OR no recommendations specified. 	RN	CLEAR WITH RESTRICTION Mammogram Accommodation PCMO FOLLOW-UP Annual mammogram.
Meets clearance criteria , AND <ul style="list-style-type: none"> • <u>Benign Finding</u> (Includes Densities, Irregularities, and Nodularities). • Radiologist or examining health care provider recommend routine follow-up. 	RN	CLEAR WITH RESTRICTION Mammogram Accommodation PCMO FOLLOW-UP Annual mammogram.
Meets clearance criteria , AND <ul style="list-style-type: none"> • <u>Probably Benign Finding</u> (Includes Densities, Irregularities, and Nodularities). • Radiologist or examining health care provider recommend a short interval follow-up to confirm no change in an abnormal finding. 	RN	DEFER Defer until resolved or stable as per radiologist or examining health care provider.
Meets clearance criteria , AND <ul style="list-style-type: none"> • <u>Needs Additional Evaluation</u> • Radiologist or examining health care provider recommend additional views, magnification, ultrasound, or advanced mammographic studies. 	RN	DEFER Defer until resolved as per radiologist or examining health care provider.
Meets clearance criteria , AND <ul style="list-style-type: none"> • <u>Suspicious Finding</u> • Radiologist or health care provider recommend biopsy. 	RN	DEFER Defer until resolved as per radiologist or examining health care provider.
Meets clearance criteria , AND <ul style="list-style-type: none"> • <u>Highly Suspicious Finding</u> • Radiologist or examining health care provider recommend biopsy. 	RN	DEFER Defer until resolved as per radiologist or examining health care provider.

MAMMOGRAPHY

DIAGNOSTIC CODES

87.37 Mammography

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: In addition to regular breast examination, the Public Health Service (and other groups) recommend that women over the age of 50 receive mammography every one to two years. Mammography is expected to detect 2-4 cancers per 1000 women who are regularly screened. The detection rate is expected to be higher for women having their first mammogram.

Literature review available.

Includes Laparoscopy, Laparotomy, Hysterectomy, Salpingectomy, and Oophorectomy.

INFORMATION REQUIRED**All Applicants:**

- Report of Medical Examination to include the following:
 - Date of surgery
 - Type of surgical procedure
 - Reason for surgery
 - Etiology, if known.
 - Post surgical complications, if any.
 - Treatment, if any, e.g., hormone replacement.
 - Recommendations for follow-up over the next 3 years.
- Copy of pathology report if underlying malignant etiology.

If Surgery Within the Past 1 Year:

- Discharge summaries for all related hospitalizations.
- Documentation of release from surgical care.

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
1. History of gynecological surgical procedure within the past 1 year. 2. No post surgical complications. 3. Benign etiology, i.e., no history of malignancy.		
Meets clearance criteria 1 - 3, AND • <u>Laparoscopy (Diagnostic)</u> • Status post surgery <i>greater than 6 weeks</i> .	RN	CLEAR
Meets clearance criteria 1 - 3, AND • <u>Laparoscopy (Therapeutic)</u> • Status post surgery <i>greater than 3 months</i> .	RN	CLEAR
Meets clearance criteria 1 - 3, AND • <u>Laparotomy</u> • Status post surgery <i>greater than 3 months</i> .	RN	CLEAR
Meets clearance criteria 1 - 3, AND • <u>Tubal Ligation (via Laparoscopy)</u> • Status post surgery <i>greater than 3 months</i> .	RN	CLEAR
Meets clearance criteria 1 - 3, AND • <u>Hysterectomy (Vaginal)</u> • Status post surgery <i>greater than 3 months</i> .	RN	CLEAR
Meets clearance criteria 1 - 3, AND • <u>Hysterectomy (Abdominal)</u> • Status post surgery <i>greater than 3 months</i> .	RN	CLEAR

(continued on next page)

Meets clearance criteria 1 - 3, AND <ul style="list-style-type: none"> • <u>Salpingectomy</u> • Status post surgery <i>greater than</i> 3 months. 	MED ADVISOR	<p>_____</p> <p>Risk varies - assess based on detailed history.</p>
Meets clearance criteria 1 - 3, AND <ul style="list-style-type: none"> • <u>Ovarian Cystectomy (via Laparoscopy or Laparotomy)</u> • Status post surgery <i>greater than</i> 3 months. 	MED ADVISOR	<p>_____</p> <p>Risk varies - assess based on detailed history.</p>
Meets clearance criteria 1 - 3, AND <ul style="list-style-type: none"> • <u>Oophorectomy (via laparoscopy or laparotomy)</u> • Status post surgery <i>greater than</i> 3 months. 	MED ADVISOR	<p>_____</p> <p>Risk varies - assess based on detailed history.</p>
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Status post surgery <i>less than</i> the time specified for each procedure. 	RN	DEFER
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Post surgical complications. 	MED ADVISOR	<p>_____</p> <p>Risk varies - assess based on detailed history.</p>
Does not meet clearance criteria due to one or more of the following: <ul style="list-style-type: none"> • Malignant etiology. 	RN	<p>_____</p> <p>See specific cancer guideline.</p>

DIAGNOSTIC CODES

54.21	Laparoscopy
54.19	Laparotomy
66.39	Tubal Ligation
68.4	Hysterectomy
66.6	Salpingectomy
65.5	Oophorectomy, Bilateral
65.3	Oophorectomy, Unilateral
Cross Reference ICD.9.CM	

NOTES AND INSTRUCTIONS FOR REVIEWERS**Reviewers to Consider:**

- Shorter deferral period with adequate documentation and review by Medical Advisor.

COMMENTS

Literature review and abstract available.

Includes Ectopic Pregnancy, Pelvic Mass, and Uterine Prolapse.

INFORMATION REQUIRED Any history.**All Applicants:**

- Report of Medical Examination

If Medical Advisor Requests:

- Specialist Evaluation (Gynecologist)

CLEARANCE CRITERIA	REVIEWER	GUIDANCE
Applicant presents with a history of one or more of the following disorders:		
1. Ectopic Pregnancy	MED ADVISOR	_____ Risk varies - assess based on detailed history.
2. Solid Pelvic Mass or Tumor (includes Ovary).	MED ADVISOR	_____ Requires evaluation and specific diagnosis for clearance. Correlate with diagnostic guideline.
3. Uterine Prolapse	MED ADVISOR	_____ Risk varies - assess based on detailed history.

DIAGNOSTIC CODES

633.0 Ectopic Pregnancy
789.3 Pelvic Mass
618.1 Uterine Prolapse

Cross Reference ICD.9.CM

NOTES AND INSTRUCTIONS FOR REVIEWERS:**Reviewers to Consider:**

- None

COMMENTS:

Ectopic Pregnancy: Extrauterine pregnancy - any pregnancy existing outside the confines of the uterine cavity.

Uterine Prolapse: Occurs when the integrity of supporting structures is lost. This allows the uterus to descend into the vagina. In advanced cases, complete protrusion with inversion of the vagina occurs. Approximately 1 in 10 women experience some degree of prolapse. Signs and symptoms include pelvic pressure and low back pain, dyspareunia, and difficulty with urination and defecation. Treatment includes Kegel exercises, estrogen replacement therapy, and surgery.

Literature review available.